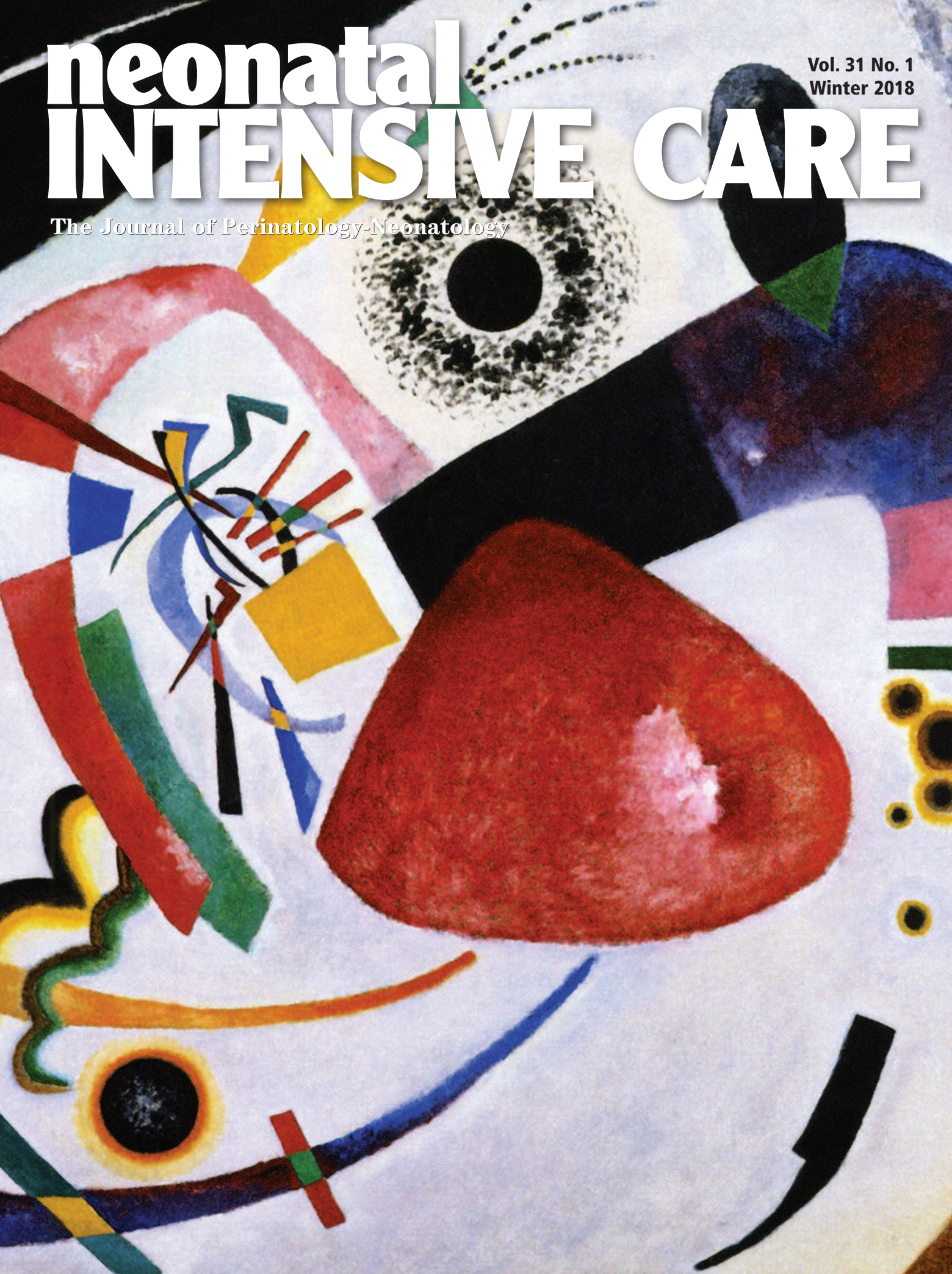


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Vol. 31 No. 1
Winter 2018

The Journal of Perinatology-Neonatology





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Restoring a Baby's Gut Microbiome

Evolve BioSystems, Inc. announced a first-to-market, single-use liquid form of Evivo (activated *B. infantis* EVC001, ActiBif). Evivo with MCT Oil, the first and only probiotic clinically proven to work with breast milk to restore a baby's gut microbiome to its natural state, is now available as single use administration for infants in a hospital setting. Research indicates that *B. infantis* may be both restorative and protective in the infant gut. Administering Evivo with breast milk is clinically proven to allow *B. infantis* to thrive and dominate the infant gut microbiome while also reducing relative populations of potentially harmful bacteria, such as *E. coli*, clostridia, *Staphylococcus* (Staph),

and *Streptococcus* (Strep). A healthy gut microbiome at birth paves the way for lifelong health. Modern medical practices such as C-sections, antibiotic use and formula feeding along with environmental factors in the hospital can impact the development of the infant microbiome. Research has shown that administration of probiotics to infants in the hospital is safe and effective, and may reduce the incidence of many serious, and sometimes devastating conditions. Probiotic administration has also been linked to shorter time to full feeds and may reduce incidence of sepsis. "Safety and consistent high quality are crucial in the NICU environment," said Thomas Young, MD, neonatologist and former NICU director and Mother's Milk Bank medical director at WakeMed in Raleigh, North Carolina. "Evivo with MCT Oil, as a single-use liquid product, will be preferable to probiotics in powder form or multiuse packaging. This formulation allows for administration to term infants in the NICU and is an essential step toward properly designed clinical trials in neonates going forward." In this formulation, Evivo's beneficial bacteria are mixed with medium chain triglyceride oil (MCT oil), providing a safe and streamlined way to deliver the probiotic to infants in a hospital setting. Evivo helps protect the baby's gut microbiome through a variety of actions derived from its ability to consume human milk oligosaccharides (HMOs). The beneficial bacteria in Evivo are able to utilize the HMOs in breast milk in a unique and superior manner compared to other gut bacteria, and convert HMOs into nutrients that nourish both the infant and the gut microbiome. The bacteria in Evivo have been shown to be anti-inflammatory, to decrease intestinal permeability, and increase the production of lactate and acetate,

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which can suppress the growth of potentially harmful bacteria. Furthermore, Evivo given daily to breastfed infants was shown to result in significantly fewer loose and watery stools per day, without an increase in incidence of jaundice or other adverse events. Evolve BioSystems' landmark clinical trial, recently published in the American Society for Microbiology journal *mSphere*, showed that providing dietary *B. infantis* EVC001 resulted in rapid, substantial, and persistent remodeling of the gut microbiome in breastfed infants. This stable colonization of *B. infantis* EVC001 led to significant reduction in the abundance of potentially harmful bacteria. In addition, this improved gut profile persisted for more than 30 days after dietary *B. infantis* was discontinued, as long as infants continued to consume breast milk.

Benefits Found in Probiotic Bacteria

Evolve BioSystems, Inc. announced positive results from their landmark clinical trial in support of Evivo, an activated form of the beneficial bacteria *Bifidobacterium longum* subsp. *Infantis* (*B. infantis* EVC001, ActiBif). The study showed that providing dietary *B. infantis* EVC001 resulted in rapid, substantial, and persistent remodeling of the gut microbiome in breastfed infants. This stable colonization of *B. infantis* EVC001 led to significant reduction in the abundance of potentially harmful bacteria. In addition, this improved gut profile persisted for more than 30 days after dietary *B. infantis* was discontinued, as long as infants continued to consume breast milk. The findings from the IMPRINT (Infant Microbiome Probiotic Intake Trial) clinical trial were published this week in the American Society for Microbiology journal *mSphere*. Historically, bifidobacteria, particularly *B. infantis*, created a protective microbial environment by dominating the infant gut, and continue to do so today in many developing countries. However, modern medical practices such as antibiotic use and C-section deliveries have led to the near-total loss of this keystone gut microbe in infants in developed countries, creating widespread gut dysbiosis. A dysbiotic gut microbiome during infancy has been associated with the growing pandemic of chronic health issues including allergies, asthma, obesity, and type 1 diabetes. To date, no other clinical study has demonstrated a substantial change in the gut microbiome via probiotic use. "These results with *B. infantis* EVC001 demonstrate for the first time that when the appropriate

probiotic bacteria is provided in combination with breast milk, it can rapidly and stably colonize the infant gut microbiome while significantly reducing levels of potentially harmful bacteria linked to long-term disease," said Mark Underwood MAS, MD, Chief of Pediatric Neonatology and Professor of Pediatrics at the University of California Davis and a principle investigator on the study. "This study is extremely important for infant health and nutrition because we may now have the potential to impact many common health issues by simply restoring the microbiome to its natural state. The IMPRINT study showed that breastfed infants who received the probiotic achieved a 79% increase in levels of Bifidobacteria, as measured in stool samples and subsequently confirmed to be *B. infantis* EVC001. Additionally, these infants experienced an 80% reduction of potentially harmful bacteria like *Clostridium* and *E. coli*, which have been linked to chronic diseases later in life. The study also demonstrated that infants colonized at high levels by bifidobacteria, including *B. infantis* EVC001, had significantly lower levels of endotoxin, a known trigger of inflammation. The IMPRINT results further confirmed the unique mechanism of action of *B. infantis* EVC001, showing it maintained its dominant position in the infant microbiome as a result of its unique ability to consume certain components of human milk (human milk oligosaccharides; HMOs) that are otherwise unused by the infant. The IMPRINT trial was a parallel, controlled clinical study in exclusively breastfed infants, that included 68 mother-infant pairs who received either lactation support plus *B. infantis* EVC001 or lactation support alone. Infants randomized to the probiotic group received one daily serving of *B. infantis* EVC001 for 21 consecutive days starting on day seven after birth and continued through day 27. The study design, as well as safety and tolerability results were previously published by Smilowitz et al in *BMC Pediatrics* (2017).

Infant Hearing Screening Device Unveiled

MAICO Diagnostics, MPLS, MN, leading global manufacturer of hearing screening instruments, since 1937, introduces the easyScreen. Continuing our commitment to newborn hearing screening programs, the easyScreen unites AABR and OAE screening capabilities in one device for the first time in MAICO history. Newborn hearing screening has never been so easy. Perfect for the use in hospital well-baby units, the NICU or in the follow-up clinic, easyScreen is designed to lighten your

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Los Angeles CA 90024
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Fax: 310-443-4110
E-mail: s.gold4@verizon.net
Web: www.nicmag.ca

Publisher/Editor in Chief

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Unique Holder Adapts to Neonatal & Small Pediatric Circuits

Respiralogs, a provider of innovative products for hospital, emergency, home and specialty care, has announced its NeoTree Tube Support. NeoTree Tube Support works in conjunction with neonatal and pediatric ventilator circuits. NeoTree Tube Support is reversible in position to accommodate ventilator circuits and tubings. It is constructed of lightweight aluminum with a baked-on power coat finish. The tube holder is reusable, durable and easily cleaned. NeoTree Tube Support provides a stable holder for tubes in all positions. NeoTree Tube Support assists in the reduction of tension on the endotracheal tube or face mask to prevent kinking of the circuit, inadvertent extubations and/or movement of the endotracheal tube or mask in NICU, PICU, Surgery and Clinic settings. More information can be found at www.respiralogs.com.

Hep C in Infants 'Underreported'

Hepatitis C virus (HCV) infection among infants is vastly underreported, suggesting the need for routine testing in pregnant women, a new study from the Centers for Disease Control and Prevention (CDC) has found. "The data from this study may inform ongoing discussions of HCV screening for all pregnant women to protect their health and that of their offspring," the

researchers write. Kathleen N Ly, MPH, from the Division of Viral Hepatitis, Centers for Disease Control and Prevention, Atlanta, Georgia, analyzed data from two of the largest population data sets available in the United States: the National Notifiable Diseases Surveillance System (NNDSS) from 2006 to 2014 and the Quest Diagnostics Health Trends national database from 2011 to 2014. The researchers included 171,801 women of reproductive age (15-44 years) and 1859 children (aged 2-13 years) with HCV infection reported to the NNDSS and 2.1 million reproductive-aged women and 56,684 children who underwent HCV testing by Quest Diagnostics. Between 2006 and 2014, the number of reproductive-aged women with acute HCV infection reported to the NNDSS rose 3.4-fold, from 249 per year to 848. Similarly, the number of past or present cases reported doubled, from 15,301 to 30,191. "[B]y 2012, the total number of cases reported in reproductive-aged women surpassed that of women aged 45 to 64 years," the researchers write. During 2011 to 2014, Quest Diagnostics tested 581,255 pregnant women; of those, 4232 (0.73%; 95% confidence interval [CI], 0.71% to 0.75%) had HCV infection. "Although no HCV treatments have been approved by the US Food and Drug Administration for use in pregnant women, clinical trials of promising drugs are under way. Pregnancy may be the only time a young woman is seen by a clinician, so some clinicians already are screening pregnant women known or suspected to be at risk for HCV infection according to current guidelines," the researchers explain.

Benefits of Using Functional Scoring System

Use of a functional scoring system dramatically reduced morphine treatment and length of stay among infants with neonatal abstinence syndrome (NAS) compared with the widely used Finnegan Neonatal Abstinence Scoring System (FNASS), a new study has shown. Of 50 infants managed with the functional assessment system, called ESC for eating, sleeping, and consolability, only 6 (12%) received pharmacologic treatment compared with 32 (62%) expected if FNASS had been used, Matthew J. Lipshaw, MD, from the Department of Pediatrics at Yale University School of Medicine, New Haven, Connecticut, said during a presentation here at the Pediatric

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Academic Societies (PAS) 2017 Annual Meeting. In addition, the length of stay was dramatically reduced after introduction of the new system, with an average of 5.9 days vs 23 days beforehand. Dr Lipshaw noted that several other changes occurred around the same time as part of a larger quality improvement program, such as having infants room with their mothers and caring for the infants on a regular hospital floor instead of the neonatal intensive care unit. Nonetheless, the reduction in morphine treatment has helped shorten inpatient time for these infants.

Let There Be Light On Patients

Neotech Products has announced the release of their newest product, the NeoGlo Transilluminator. The NeoGlo Transilluminator is a light source that transmits light through tissues to aid in the examination of patients. It is used to find veins, arteries, and other internal structures. This innovative vein finder features LED lights that are cool to the touch for patient safety. It has multiple light settings for user preference including forward facing white lights, upward facing white lights, and upward facing red lights. It's compact size and ergonomic design was engineered with clinician comfort in mind. The NeoGlo is available in five colors, blue, rose, white, silver,

and black. It is powered by a single AA battery and is engineered to shut off before the lights become ineffective. "We like to say 'designed with the clinician in mind,'" said Neotech Products President, Craig McCrary. "The truth is, clinical input was key to the development. A doctor presented his original idea to Neotech two years ago. Respiratory Therapists and Registered Nurses then added their input. They told us what they'd like to see in a transilluminator. Next, our engineers showed us what they could do. And together, we developed the NeoGlo into an exceptional and innovative vein finder. "Our mold makers also offered input," McCrary continues. "Before going to production, we modified

the mold to add the lanyard clip. Which is a simple feature that adds value for the clinicians. No other single device offers the features we do for the price; under \$100. Plus the NeoGlo is made in USA."

Handheld Exam Light Unveiled

Device maker Neoscan has unveiled its LED transilluminator, a handheld exam light that offers a brilliant white light output for excellent contrast between tissues, veins, and organs. With a simple push-button on/off switch and a silicone encased four-foot fiberoptic cable, this transilluminator is designed for easy operation. The all-aluminum body, LED lamp, and rubber switch cover makes this water-resistant, drop resistant, and built to endure the rigorous daily use of the hospital environment. With the brightest light output offered by Sylvan Corporation, the LED transilluminator helps healthcare professionals discover the contrast between muscle tissues, internal organs, and veins in a variety of patients. Made in the US.

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50 mm masks; each nMask is individually packaged and ready for use with resuscitation bag or t-piece resuscitator system. The Babi.Plus nMask can be used in all neonatal critical care units, delivery rooms, pediatric critical care units and special procedure units. Respiralogics specializes in providing tools to meet the unique needs of respiratory patients. We listen to our customers and use that knowledge to assist in development and support of specialty products to benefit patients and clinicians. We have joined with leading specialty respiratory distributors across the USA to provide expert local assistance and the training required for successful implementation.

Benefits of Monitoring Blood Sugar Levels Continuously During Pregnancy: Study

A JDRF-funded study found that monitoring blood sugar levels continuously during pregnancy via a continuous glucose monitor (CGM) led to significantly better health outcomes for mothers with type 1 diabetes (T1D) and their babies. The results of this randomized trial, held across 31 hospitals in Canada, the United Kingdom, Spain, Ireland, Italy, and the United States, prompted the authors to call for physicians to offer CGM devices to all pregnant women with T1D. Currently, one in two babies born to mothers with T1D has complications related to high blood sugars, including premature birth, stillbirth, the need for intensive care after birth, higher than average birth weights, and higher than average rates of pre-eclampsia and Caesarean section for mothers. Despite all the advances in diabetes care over the past 40 years, these birth outcomes have not improved. This trial points to a new way to potentially prevent complications and save lives. "JDRF is proud to have supported this multinational trial that shows that

the use of continuous glucose monitors during pregnancy has positive clinical outcomes for both mother and baby, across all countries where the study took place. This study will serve as a catalyst for improved access to life-saving CGM technology worldwide," said Derek Rapp, JDRF President and CEO. "We hope that these results will help people with type 1 diabetes to be confident in their decision to have children and help them make informed choices with their doctors about care." The study, "CONCEPTT: Continuous Glucose Monitoring in Women with Type 1 Diabetes in Pregnancy Trial", recruited 325 pregnant women with type 1 diabetes aged 18-40 who managed their condition with daily insulin therapy (insulin pumps or multiple daily injections). Half were randomly allocated to use a CGM device, and half to use the traditional monitoring method of testing blood derived from a pricked finger approximately four to eight times a day (as compared to the 288 glucose recordings a day from a CGM device). The device was worn for approximately 24 weeks (from 10-12 weeks until the end of their pregnancy). Continuous glucose monitoring systems track blood sugar levels in real time throughout the day and night, enabling the user to take immediate action when faced with high or low blood sugars. This technology has the potential to transform the day-to-day management of diabetes but had not been previously tested in pregnancy. Women in the CONCEPTT study using a CGM had better blood sugar levels on average, and spent an extra 100 minutes per day with blood sugar levels in the recommended target range in late pregnancy. These improved outcomes for expecting women were accompanied by substantial reductions in newborn complications. The number of babies being born larger than average was reduced (53 percent vs. 69 percent); the number of babies admitted to

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1. Shankaran, Seetha, et al. "Outcomes of Safety & Effectiveness in a Multicenter Randomized, Controlled Trial of Whole-Body Hypothermia for Neonatal Hypoxic-Ischemic Encephalopathy." *Pediatrics* 122 (2008): 790-799.
2. Zanetti, S.A., et al. "Implementation of a 'Hypothermia for HIE' program: 2-year experience in a single NICU." *Journal of Perinatology* 28 (2008): 171-175.

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intensive care for more than 24 hours decreased (27 percent vs. 43 percent); and the number of babies born with low blood sugar levels decreased (15 percent vs. 28 percent). On average, babies whose mothers had used the continuous glucose monitoring device also left hospital one day earlier than babies whose mothers used traditional monitoring (3.1 vs. 4 days). They also had half as many neonatal intensive care unit admissions over 24 hours. Overall, for every six mothers treated, one large birthweight baby and one neonatal intensive care unit admission were prevented.

Study Finds Prenatal Magnesium Sulfate Protects Fetus

Giving prenatal magnesium sulfate (MgSO₄) to pregnant women at high risk for preterm birth can limit the infant's risk for cerebral palsy (CP) and possibly death, according to a new meta-analysis. "Benefit was seen regardless of the reason for preterm birth, across a range of preterm gestational ages, and with minimal variation in outcomes related to time prior to birth or dosage given," the authors, led by Dr Caroline A. Crowther of the School of Medicine of the University of Adelaide in Australia, wrote. "Widespread adoption of the recommendations to use magnesium sulfate within several national clinical practice guidelines, and now within the recent WHO recommendations on interventions to improve preterm birth outcomes, could lead to significant global health benefits," they add. In the AMICABLE meta-analysis, Dr Crowther and colleagues searched standard medical databases through February 2017 and ultimately analyzed five randomized controlled trials of MgSO₄ involving 5,493 women and 6,131 babies at risk of preterm birth (<37 weeks' gestation). All studies reported infants' neurologic outcomes. Overall, MgSO₄ had no clear

benefit over no treatment for preventing death or CP. However, when the analysis was restricted to the four trials in which fetal neuroprotection was the intent of treatment, MgSO₄ use significantly reduced the rate of CP or death (15.1% vs. 17.4%; relative risk, 0.86). The number needed to treat (NNT) to show benefit was 41 women/babies to prevent one baby from either dying or having CP. For CP among surviving infants, MgSO₄ had a strong protective effect in the overall analysis (RR, 0.68; NNT, 46) and in the neuroprotective intent analysis (RR 0.68; NNT, 42). The authors say their study was strengthened by using individual participant data from all known completed randomized trials of MgSO₄ that reported infants' developmental outcomes. They advise providers to give the smallest effective dose of MgSO₄ for fetal neuroprotection — 4 g with or without a 1-g/hour maintenance dose — close to the time of the planned or expected preterm birth.

RAI-Associated Thyroid Antibodies Link to Neonatal Hyperthyroidism

Elevated maternal thyroid-stimulating hormone (TSH) receptor antibody (TRAb) levels linked to previous radioiodine (RAI) treatment for Graves' disease are associated with an increased risk of neonatal hyperthyroidism, new research shows. "The findings show that fetuses of pregnant Graves' disease patients whose TRAb value is 9.7 IU/L or higher in the third trimester should be carefully followed up by an obstetrician during pregnancy, and the newborns should be carefully followed up by a pediatrician after birth," first author Ai Yoshihara, MD, PhD, of Ito Hospital, in Tokyo, Japan, said. The findings were presented at the 2017 Annual Meeting of the American Thyroid Association. Graves' disease patients who are treated with RAI

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therapy have been shown to have increased levels of TRAb for years after the therapy, with one study showing significantly higher levels over 5 years' post-radioiodine therapy, as well as a significantly lower chance of becoming TRAb-negative, compared with patients treated with antithyroid medication or surgery. Little is known about the effect of those higher TRAb levels on infants born to mothers who conceive after RAI therapy, and this research represents the first time the incidence of neonatal hyperthyroidism has been documented in this group of patients. These new findings should therefore serve as a flag to endocrinologists to follow carefully all women who have a history of Graves' disease and who subsequently become pregnant and to communicate the risks of neonatal hyperthyroidism among these women to obstetricians and pediatricians, said one commentator.

NICU Care Boosted By Genome Sequencing

For patients in the neonatal intensive care unit (NICU), suspected genetic disorders can be diagnosed using whole-genome sequencing in a fraction of the time it takes to arrive at a diagnosis with standard testing methods, and at a lower cost, new research shows. And savings related to care that was eliminated because of sequencing were substantially greater than the cost of the sequencing itself, said Shimul Chowdhury, PhD, from the Rady Children's Institute for Genomic Medicine in San Diego. Sequencing also prevented potential harm for at least one patient, he said during the American Society of Human Genetics 2017 Annual Meeting. The NICU setting is ideal for demonstrating both the clinical utility and cost-effectiveness of on-site, rapid whole-genome sequencing, Dr Chowdhury said. For their study, Dr Chowdhury and his colleagues sequenced infants who presented with signs and symptoms indicating a single-gene disorder or who had a clinical course that did not follow a typical pattern. None of the patients had a known genetic diagnosis at baseline. Of the first 42 infants who underwent whole-genome sequencing, a genetic disorder was diagnosed in 18 (43%), management was changed in 13 (31%), and outcomes changed in 11 (26%). Twelve of the infants had multiple congenital abnormalities. Others had neurologic, hepatic, cardiac, hematologic, gastrointestinal, endocrine, musculoskeletal, or pulmonary abnormalities or symptoms.

New CDC Guidance on Zika

The Centers for Disease Control and Prevention (CDC) has released updated clinical guidance on caring for infants who have or might have congenitally acquired Zika infection. "The updated interim guidance is in response to three main concerns," Margaret Honein, PhD, MPH, chief of the Birth Defects Branch at the CDC National Center on Birth Defects and Developmental Disabilities, said. "In July 2017, CDC updated the Zika guidance for pregnant women, which was intended to reduce the possibility of false-positive results in the setting of lower pretest probability (related to the lower prevalence of reported Zika virus infections). However, there is the possibility that the lack of routine testing might delay identification of some infants, particularly those without clinical findings apparent at birth, but who might have complications from congenital Zika virus infection. Furthermore, optimal tests, types of specimens to test, and timing to test for congenital Zika virus infection are unknown. This update incorporates additional findings associated with congenital Zika virus infection that healthcare providers should be aware of." The new guidance, which incorporates data gathered during the past year, stratifies infants into three risk categories on the basis of



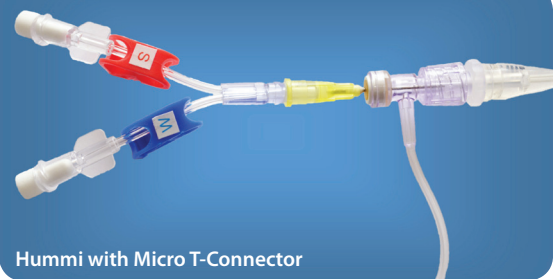
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maternal laboratory test results, presence or absence of birth defects, and laboratory testing for Zika infection in the infant. The recommendations cover diagnosis, evaluation, monitoring, and management approaches for each risk group. The update also cancels some recommendations from the prior version. Thyroid screening and hearing screening at 4 to 6 months of age are no longer recommended because of a lack of data on whether these screenings are needed. Dr Honein said that CDC has received no reports of late-onset hearing loss. “There’s a lot we still don’t know about Zika, so it’s very important for us to keep a close eye on these babies as they develop,” said CDC Director Brenda Fitzgerald, MD. “Learning how best to support them will require a team approach between healthcare providers and families.” Congenital Zika syndrome is associated with a pattern of birth defects that includes brain abnormalities, vision problems, hearing loss, and problems moving limbs. Infants with congenital infection may appear healthy at birth but may already have underlying brain defects or other Zika-related health problems. Therefore, the updated recommendations emphasize the importance of pediatric healthcare providers assessing risk for congenital Zika virus infection, communicating closely with obstetrical providers, and maintaining a high index of suspicion for late-developing problems in infants born to mothers with possible Zika virus exposure during pregnancy, even if none are apparent at birth.

Vaccinations Help Cut Whooping Cough Cases

Vaccinating mothers against whooping cough during pregnancy may prevent 9 out of 10 severe cases of this potentially fatal respiratory infection in their babies, a US study suggests. The bacterium *Bordetella pertussis* causes whooping cough. Pertussis is highly contagious and easily spread when an infected individual coughs or sneezes. About half of babies under age 1 who catch pertussis require hospitalization for serious complications like pneumonia or brain disorders. For the study, researchers examined data on 251 infants who developed whooping cough before 2 months of age and a control group of 537 babies who didn’t catch pertussis as newborns. Overall, researchers estimate that giving pregnant women the Tdap booster vaccine for tetanus, diphtheria and pertussis prevented about 78 cases of whooping cough in their babies for every 100 mothers vaccinated. The vaccine effectiveness rate was 90% when researchers looked only at severe cases requiring hospitalization. “Our evaluation adds to the growing body of evidence that vaccination during pregnancy is effective at protecting infants from whooping cough in the early months of life, a period when infants are more likely to have severe or even deadly whooping cough infections,” said lead study author Tami Skoff of the US Centers for Disease Control and Prevention (CDC) in Atlanta. Health officials in many countries recommend vaccination during pregnancy, as well as a series of three shots for infants starting sometime between ages 6 weeks and 3 months. Some countries also recommend that women get vaccinated during each pregnancy because effectiveness of the shot wanes over time. In early 2013, the CDC recommended that all pregnant women get the Tdap shot, regardless of whether they previously had received this vaccine. The study examined data collected from 2011 through 2014 in California, Connecticut, Minnesota, New Mexico, New York and Oregon. Researchers compared records on babies with whooping cough to records for similar babies who were born at the same hospital but didn’t contract pertussis. Most of the women who got vaccinated received their shots during the third trimester of pregnancy, and the vaccine

was 78% effective at preventing whooping cough for their babies, the study team reports in *Clinical Infectious Diseases*.

Whole-exome Sequencing Urged

A new study provides strong support for whole-exome sequencing of critically ill newborns suspected of having a genetic disorder, researchers say. “Exome sequencing is a powerful tool for the diagnostic evaluation of critically ill infants with suspected monogenic disorders in the neonatal and pediatric intensive care units and its use has a notable effect on clinical decision making,” they report. The team of pediatricians and geneticists from Baylor College of Medicine and Texas Children’s Hospital did a retrospective study to determine the diagnostic yield of exome sequencing and the effect of genetic diagnoses on medical care in 278 infants (mean age, 28.5 days) who had been referred for clinical exome sequencing for a broad range of “medical concerns.” Exome sequencing revealed 106 genetic disorders in 102 infants, an overall detection rate of 36.7%, report Dr. Seema Lalani and colleagues. For 53 infants (52%), the diagnosis affected medical management “and had a substantial effect on informed redirection of care, initiation of new subspecialist care, medication/dietary modifications, and furthering life-saving procedures in select patients,” they note. Whole-exome sequencing also led to genetic diagnoses in 32 of 63 infants (51%) whose parents also underwent sequencing, and clinical care was altered by the diagnosis in 23 of these infants (72%). For 81 infants who died, genetic disorders were molecularly diagnosed in 39 (48%) by exome sequencing, “with implications for recurrence risk counseling,” the researchers write.

Continuous Epidural Impacts Studied

Maintenance of low-concentration epidural anesthesia does not prolong the second stage of labor or adversely affect maternal and neonatal outcomes, according to new study published. Between March 2015 and September 2015, XiaoFeng Shen, MD, from the Nanjing Medical University, Jiangsu, China, and colleagues prospectively enrolled 400 nulliparous women who requested epidural anesthesia at the time of spontaneous labor. All participants received a standard protocol epidural analgesia consisting of an 8- to 10-mL bolus of 0.08% ropivacaine with 0.4 µg/mL sufentanil, followed by an infusion at 8 mL/hour, using a patient-controlled analgesia pump. At full cervical dilation (second stage of labor), participants were randomly assigned (200 in each group) to switch to an epidural saline infusion (placebo) or continuation of the epidural analgesia solution. All those involved were blinded to group assignment. Breakthrough pain was managed with either patient-assisted epidural analgesia or a physician-administered bolus. Using an intention-to-treat analysis, the researchers found no significant difference in the duration of the second stage of labor between the two groups (52 minutes in the intervention group vs 51 minutes in the saline group; $P = .52$). The spontaneous vaginal delivery rate was also similar between the two groups (193/200 for the intervention group vs 198/200 for the saline group; $P = .17$; difference, 3.5%; 95% confidence interval, -0.9% to 5.9%). The authors postulate that the use of a modern low-concentration epidural anesthetic such as the one used in this study may contribute to less motor block, and therefore not hinder maternal expulsive efforts. Secondary outcomes including neonatal Apgar scores, umbilical blood gas results, and fetal position at delivery were similar between the groups. With respect to secondary maternal outcomes, the researchers note that pain scores were not statistically different, but did trend upward during delivery

for women receiving the saline solution. Similarly, patient satisfaction with pain relief was higher among women receiving analgesia throughout the second stage of delivery. The study excluded women who received intravenous or oral analgesics during labor, had a history of opioid use, or were receiving magnesium; those with an American Society of Anesthesiologists physical status 3 or 4; and those with cervical dilation of 6 cm or greater at epidural request.

Soleno Therapeutics Announces Sale of Non-Strategic Assets


Soleno Therapeutics, Inc., a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, announced the sale of one of its non-strategic subsidiaries, NeoForce, Inc., which manufactures and promotes a range of innovative pulmonary resuscitation solutions in the neonatal market, to Flexicare, Inc., a privately-held, leading UK-based manufacturer of airway management, anesthesia and critical care medical devices. "We have recently refocused our business on the development and commercialization of novel therapeutics for the treatment of rare diseases," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "As such, we are pleased to monetize these non-strategic assets, which allows us to focus our resources on our lead product candidate, Diazoxide Choline Controlled-Release (DCCR), currently in clinical development for Prader-Willi syndrome (PWS), a rare and complex genetic neurobehavioral disorder affecting appetite, growth, metabolism, cognitive function, and behavior. We expect to initiate a Phase III clinical trial for DCCR by the end of 2017." "The acquisition of NeoForce advances Flexicare's mission of providing high quality medical devices,

expanding its neonatal portfolio and footprint both in the US and internationally. We will support NeoForce's ambition to become a leading supplier of neonatal resuscitation devices, caring for our most vulnerable of patients. This is a long-term strategic investment in a growing sector that we are actively pursuing and will continue to invest in to realize our full potential within this market segment," said Ghassem Poormand, President Flexicare, Inc. Soleno Therapeutics, Inc. is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company is currently advancing its lead candidate, DCCR, a once-daily oral tablet for the treatment of PWS, into a Phase III clinical development program at the end of 2017. PWS is a rare and complex genetic neurobehavioral/metabolic disorder affecting appetite, growth, metabolism, cognitive function and behavior.

F1 Team Uses Racing Tech to Keep Newborns Safe

A Formula One racing team is employing technology that helps racing drivers survive high-speed crashes to create a new device that keeps newborn babies safe during emergency transportation. The device, known as the Babypod 20, is made from carbon fibre — the same material used in Formula One cars' bodywork. It can withstand a 20 g-force impact and provides newborns with a secure, temperature-controlled environment for ambulance transportation. It was designed and built by Williams Advanced Engineering, an arm of the UK-based Williams F1 team, in collaboration with healthcare firm Advanced Healthcare Technology (AHT). "This challenge of providing a lightweight, strong pod to put infants in to be moved around is absolutely the same challenge, virtually, as we're trying to tackle in the main chassis of a Formula 1 car,"

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Paul McNamara, Technical Director at Williams Advanced Engineering said. “We need it to be strong, light, and crash-proof.” There were 7,938 medical transfers of newborn children in the UK in the 12 months up to June 2017, according to the UK’s Neonatal Transport Group, a medical association specialising in the transporting children. Typically, providing emergency transport to newborn children requires the use of large incubators, which require a power supply and specialist vehicles. The pods are now being used by the UK’s Children’s Acute Transport Service. Eithne Polke, the service’s operational manager, said the design had “made a big difference to our transportation processes”. Williams says it expects to make around 500 of the devices in the first year of production. F1 teams frequently put their engineering know-how to use outside the sport. Williams’ rivals McLaren have applied data management and race simulation expertise to help London’s Heathrow airport improve movements on the ground and reduce the time spent by planes circling overhead. Williams previously developed a device to save money and energy by using aerodynamic technology developed through racing to keep more cold air inside open-fronted refrigerators.

GBS Prophylaxis Urged for Women in Preterm Labor

Updated guidelines on prevention of early-onset neonatal group B streptococcal (GBS) infection were released by the Royal College of Obstetricians and Gynaecologists (RCOG). The authors recommend offering intrapartum antibiotics to all women who go into labor before 37 weeks of pregnancy, whether or not their waters have broken. The recommendations are intended to prevent early-onset GBS infection in newborns. “This guidance provides clear advice to doctors and midwives on which women should be offered antibiotics to avoid passing GBS infection onto their babies,” coauthor Peter Brocklehurst, MBChB, professor, University of Birmingham, Edgbaston, United Kingdom, said in a news release. “The management of women whose babies are at raised risk of developing Group B Strep infection remains a vital part of reducing illness and deaths caused by this infection. Ensuring a consistent approach to care in all maternity units is vital to achieving the best outcomes for both mother and baby,” he added.

Laser Benefits Discovered

Babies with acute-phase retinopathy of prematurity (ROP) who are treated with bevacizumab have more long-term eye problems than babies treated with laser, according to a new randomized controlled trial done in Italy. “Our paper demonstrates long-term ocular effects from using an anti-VEGF (anti-vascular endothelial growth factor) drug such as bevacizumab for the treatment of acute-phase ROP. These effects, including abnormalities of the posterior pole and peripheral retina, are seen much more frequently than they are in laser-treated eyes,” said co-author Dr Graham E. Quinn of the University of Pennsylvania Perelman School of Medicine, in Philadelphia. “The longer-term effects of these structural changes on function have yet to be examined. It is important to provide visual acuity, visual field, and refractive error data, as well as assessment of late detachment and retinal tears, in eyes treated with anti-VEGF,” he said. “Many of these findings are worrisome,” the authors write in their report. “It is incumbent on the medical community caring for the premature infant to determine the optimum treatment regimen for serious ROP, not only from an ocular perspective but also from a systemic perspective.” Dr Quinn and his colleagues studied the structural outcomes, at age 4 years, for all 21 babies born in their clinic (42 eyes) who had type 1 zone 1 ROP and were

treated in the neonatal intensive care unit over roughly 2.5 years. For each infant, they took digital retinal images and performed fluorescein angiography (FA). They randomized one eye to have conventional laser photocoagulation of the peripheral avascular retina and the fellow eye to have 0.5 mg bevacizumab in a 0.02-mL balanced salt solution injected intravitreally through the pars plicata. The babies’ eyes were examined regularly for one year, and they had fluorescein angiography when they were an average of 4 years old. All 20 available 4-year-old bevacizumab-treated eyes showed abnormalities at the periphery — including avascularity, shunts, vessel leakage, abnormal vessel branching and tangles — or at the posterior pole, including hyperfluorescent lesions and foveal avascular zone absence. These lesions were not seen in most of the laser-treated eyes. Among the 19 lasered eyes, the authors found leakage in one eye, shunts and tangles in three eyes, and macular abnormalities in three.

Study Looks at Impact of Farm Pesticides

Women exposed to the highest quantities of agricultural pesticides in California’s San Joaquin Valley while pregnant were at heightened risk of giving birth prematurely and delivering low-weight infants, a new study found. Offspring of expectant mothers who lived near farms that applied the heaviest concentrations of pesticides were most at risk, the research showed. Mothers who lived in close proximity to agricultural operations using the highest percentage of pesticides — the top 1% — had an 11% increased probability of preterm delivery and a 20% increased probability of having a low birth-weight baby. For most women, living near farms growing fruits, nuts and vegetables failed to increase the possibility of low birth weight and preterm delivery, the research found. But an examination of the areas exposed to the heaviest concentrations of pesticides applied showed magnified fetal vulnerability. “There is a smaller subset that seems to be bearing the burden,” said lead author Ashley Larsen, a professor at the Bren School of Environmental Science and Management at the University of California, Santa Barbara. “Hopefully we can pinpoint how to reduce these very high levels,” she said in a phone interview. Larsen and her team coupled birth certificate records for more than 500,000 San Joaquin Valley births between 1997 and 2011 with pesticide-use data to examine how exposure by trimester and pesticide concentration might influence birth weight and gestational length. The San Joaquin Valley is California’s most productive agricultural region. The new study found that women exposed to the top 25% of pesticide loads in the San Joaquin Valley had babies with no detectable effect. But those in the top 5% of exposures had increases in the range of 5% to 9% in adverse outcomes, according to the report.

‘Kangaroo Care’ a Struggle

Making sure mothers have skin-to-skin contact with newborns is known to benefit babies, especially premature infants, but the practice is slow to catch on in healthcare facilities, researchers say. Known as “Kangaroo Mother Care,” or skin-to-skin, this simple strategy can reduce newborn deaths and sickness, but hospitals often struggle to implement it due to time constraints, lack of staff training, cultural norms and lack of government support, a research review concludes in Health Policy and Planning. “Globally, newborn mortality continues to be very significant. Although the global community has made progress, we have many challenges in the first 28 days of life,” said lead study author Dr Grace Chan of Boston Children’s Hospital in Massachusetts. Preterm birth complications are the leading

cause of death among children under age 5, according to the World Health Organization. Babies born preterm, in particular, face higher susceptibility to infections, lung complications and hypothermia. Studies predict kangaroo mother care can reduce mortality by 40%, Chan added. “Not many of the current interventions we have are cost-effective and scalable,” Chan said. “If we could achieve high coverage of kangaroo mother care across the globe, we could significantly reduce newborn mortality.” Chan and colleagues analyzed 86 studies about kangaroo care and skin-to-skin practices that encourage parents and babies to have as much skin contact as possible in the hours and days following birth. More than half were published since 2010. The research team found six main reasons why healthcare workers and their facilities struggle to implement kangaroo care regularly: buy-in about the benefits, social support, time to train and provide the service, medical concerns such as the stability of the mother or baby after birth, access to training and resources, and cultural norms related to newborn care or facility policies. For example, many healthcare staff said newborn care wasn’t a high priority at their workplace. In some locations, kangaroo mother care was seen as the “poor man’s alternative” to higher-tech postpartum care and was believed to be associated with developing countries, the study authors note. Staff shortages, high turnover and a lack of training in preterm care also slowed buy-in for kangaroo mother care, Chan and colleagues found. If one or two healthcare workers are the main champions for kangaroo care, they are often saddled with the responsibility of training. When they move to a new location, the training and buy-in often leaves with them.

Quality of Care May Be Tied to Race

The quality of care provided to critically ill newborns is linked with multiple factors, including — in some hospitals — the infants’ race, according to a study from California. In some neonatal intensive care units (NICUs), minority newborns received worse care than white children — but the opposite was true at other facilities, Dr Jochen Profit, of the Stanford University School of Medicine in California and colleagues reported. According to the US Centers for Disease Control and Prevention, in 2013 the infant mortality rate per 1,000 live births was about 5 among white and Hispanic mothers, and about 11 among black mothers. NICU care is an understudied area, Profit said. For the new study, the researchers analyzed data from 134 California NICUs on 18,616 infants born from 2010 through 2014 weighing less than 3.3 pounds. To assess the infants’ NICU care, the researchers used a scoring system known as Baby-MONITOR, which takes into account things like steroid use to promote healthy lungs, whether the baby acquired an infection, whether the baby received a timely eye exam and whether the baby was breastfeeding. Other factors like the care mothers received before delivery, their length of pregnancy and the general health of babies in the NICU were taken into account, too. When the researchers looked at all the data together, they found that care did not differ greatly between white, Asian and black infants. Hispanic infants and those in other minority groups did have worse care than whites according to Baby-MONITOR scores, however. Differences between races were larger for individual parts of the score. Black infants were more likely to have chronic lung disease and a collapsed lung, compared to white infants, for example. Black infants grew faster than white infants, however. White infants scored as well or better on all measures than Hispanic infants. Differences in care were also tied to the NICUs’ overall scores, the researchers found.



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App Could Help Assess Neonatal Jaundice

A new smartphone application, BiliCam, might be useful for assessing neonatal jaundice in outpatient settings, according to a study of more than 500 newborns. Current American Academy of Pediatrics guidelines recommend that newborns discharged before 72 hours of age should be seen by a healthcare provider within the ensuing 48 to 72 hours to assess for jaundice, as bilirubin levels typically peak at about 96 hours of life. Studies have shown that healthcare providers often do not accurately estimate the severity of jaundice in this clinical context. Total serum bilirubin (TSB) measurements are more difficult to obtain after discharge, and transcutaneous bilirubin (TcB) meters are not widely available in the outpatient setting given their high cost. BiliCam is designed to obtain images of the skin overlying a newborn's sternum in a standardized manner, using a color calibration card, and to transmit the image via the Internet to a computer server for analysis. Dr James A. Taylor from the University of Washington, Seattle, and colleagues assessed the accuracy of BiliCam assessment, compared with TSB levels, in 530 newborns at seven sites across the United States. The correlation between BiliCam-based bilirubin levels and the paired TSB measurement was 0.91 and was highest among white neonates (0.92) and lowest among Asian American newborns (0.88), the researchers report. Among 331 newborns who also had TcB measurements, the correlation between TcB and TSB was 0.91. BiliCam showed 84.6% sensitivity and 75.1% specificity for identifying newborns with a TSB level in the high-risk zone on the Bhutani nomogram (which predicts the risk of a subsequent bilirubin level in an infant >95th percentile for age) — and 100% sensitivity and 76.4% specificity for identifying neonates with TSB levels of 17.0 mg/dL or higher. BiliCam was

nominally more accurate (AUC, 0.95) than TcB (AUC, 0.92) for detecting a high-risk zone TSB level and for identifying newborns with TSB levels of 17.0 mg/dL or higher (AUC, 0.99 vs. 0.95, respectively), but the differences fell short of statistical significance.



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Finding a Safer Way to Sleep in Hospitals

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Charla Sue Payne, BSN, RNC, IBCLC, Perinatal Nurse Educator Coordinator of Lactation and Childbirth Education, The Christ Hospital Health Network.

Neonatal Intensive Care: What prompted you to initiate the HALO Safer Way to Sleep® program in your hospital?

Charla Sue Payne: The Christ Hospital, located in Hamilton County, Ohio, has an annual birth rate of 3,200 births.

Unfortunately this area has one of the highest rates of infant mortality in the country. Our main focus to decrease this rate is to send a strong message to new parents on how to keep their baby safe through the safe sleep program.

Before utilizing the HALO Safer Way to Sleep program, we were just communicating the ABC's of safe sleep and swaddling in receiving blankets. After the implementation of the program, we brought the ABC's of safe sleep to life by modeling safe sleep in the hospital and by using the HALO® SleepSack® swaddle. We realized that it was difficult to tell parents not to use blankets at home if we were still using them in the hospital, so we adopted a no blanket policy once the HALO Safer Way to Sleep program was in place.

After skin-to-skin contact with parents and other postpartum procedures including the first feeding, all newborns are put in a HALO SleepSack swaddle. In the NICU, we use the HALO SleepSack Swaddle when baby is transferred to an open crib or is transitioning out of the isolette.

There is scientific evidence behind modeling behaviors for new parents as an effective way of teaching, and if we could save just one baby's life, then all these efforts are more than worth it.

The HALO Safer Way to Sleep Program helps hospitals educate parents about sleep safety by providing education materials and promoting safe sleep modeling with the HALO SleepSack Swaddle. To learn more, visit www.halosleep.com/hospital.

NIC: What are the SIDS rates in your part of Ohio?

CSP: We are at 10.8 deaths per 1000 live births, which is about 40 percent higher than the national average. We embrace an education method referred to as "centering care" which allows the expectant mothers to bring family members with them to OB visits, so that family and support persons can all



Photo submitted

attend child care classes together throughout the pregnancy. This allows us to have the dialogue about safe sleep early and often through the prenatal time frame with family members or caregivers present, thus taking the burden off the new parent at home. Even our sibling class which helps older children welcome a baby into the home spreads a safe sleep message.

We find that about 75 percent of first-time parents attend our childbirth classes while second-time parents may participate in part of the program and come for a tour of the hospital. This allows for contact with nearly all of the parents before they give birth.

NIC: What are the hospital's main initiatives with new parents?

CSP: There are three main areas of baby care we focus on: safe sleep, skin-to-skin contact and breastfeeding.

These areas of baby care are emphasized throughout the hospital with posters, videos and educational pamphlets. We utilize our lactation consultants as champions for all three of these areas of care. At many institutions, lactation consultants focus solely on the feeding aspect of the neonate, but at our institution they are intimately involved in the care plan of the newborn. They assist with education of the families, and support not only breastfeeding, but also skin-to-skin contact and safe sleep for baby.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

In addition to the in-person instruction through demonstration, we also have an in-hospital video series. In order to make the

safe sleep message realistic and less clinical, we feature real parents in settings around Cincinnati, sharing how important safe sleep is, how to carry-out safe sleep, and some of them share stories of personal loss. In addition to safe sleep, the video series also covers shaken baby syndrome, breastfeeding, self-care after delivery, basic baby care, pertussis, and for NICU babies, special videos on developmental care and providing breastmilk to NICU infants.

We also send every new baby home with a new HALO SleepSack, so parents can continue to practice safe sleep at home. This is particularly important for those families who may not be able to purchase a HALO SleepSack.

NIC: What parts of your staff are involved in safe sleep and how has that affected their interaction with new parents?

CSP: Nurses, lactation consultants and OB care techs are the three main participants in patient post-partum care. It was a deliberate move to have our lactation consultants become the champions for our initiatives, and they make it a point of seeing all NICU babies daily for the first several days of life if mom is interested in breastfeeding. We have an 88 to 92 percent breastfeeding initiation rate, with less than 1 percent deciding not to breastfeed before discharge. An average length of stay is from five to 30 days, dependent on diagnosis.

We are preparing to open a birthing center with telemetry monitoring in all rooms, so that many NICU/Special Care infants can remain in the mom's room dependent on their medical status and needs.

Rooming in is our standard of care with our infants, but we always have a nursery for babies to go to should staff or parents request for a variety of reasons.

NIC: What tools or materials did you introduce in postpartum baby care that facilitated safe sleep education and practice?

CSP: There are brochures and posters around the hospital focusing on safe sleep for baby, and the in-room videos also cover the topic. In keeping with our safe sleep initiative, a baby is never shown with a blanket in any materials the hospital produces.

NIC: What evidence do you have that the program has become known as part of mom/baby care at your hospital?

CSP: We truly have parents who come in and ask "when will my baby be put in the sleepsack?" and if a child is being treated in another hospital, that staff knows immediately where the baby was born because the parents often pack their HALO SleepSack swaddle for baby to wear in the hospital.

NIC: Have you seen a change in the patient experience at the hospital since the Safer Way to Sleep program was introduced?

CSP: I believe parents appreciate our efforts in safe sleep. They view this program as a way that we are keeping their babies safe, and it demonstrates that their babies' safety is our top concern. We are strict about supporting safe sleep and breastfeeding throughout all our communications, and our amazing PR & marketing department helps us share and model that message by not using photos that send conflicting messaging.

NIC: Is your hospital designated a "Safe Sleep Hospital?"

CSP: Yes. We are Gold Certified Safe National Sleep Champion, the highest level as designated by the Cribs for Kids. The process

included hospital staff training and education; having a hospital safe sleep policy in place; parent education and modeling; a wearable blanket program, and community and media outreach.

NIC: Have you shared your experience with safe sleep with other institutions?

CSP: We created a poster on our safe sleep efforts which we presented at AWOHNN as well as the Cribs for Kids conference, and the information there in was submitted it to Cribs for Kids as part of our certification. We also shared the information with Cradle Cincinnati, a local safe sleep multi-disciplinary collaborative. We are the first institution in our area to utilize the HALO SleepSack swaddle instead of blankets in both the normal newborn nursery and the NICU. As part of our commitment to safe sleep, we have not put babies back in blankets since April 2015, when the HALO Safer Way to Sleep program was initiated. In terms of practicality and effectiveness, I would wholeheartedly recommend this program to other birthing institutions.

Incorporating Cooling for Babies with HIE

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Joanna Beachy MD, PhD, Medical Director, Division of Perinatal Medicine, Cohen Childrens Hospital, New Hyde Park, NY.

Neonatal Intensive Care: In your experience, what is the average occurrence of HIE treatments in a year?

Joanna Beachy: While serving as Associate Director of NICU at University of Utah, we treated approximately 30 babies per year for HIE. Here at Cohen Childrens, we are treating approximately 8 babies per year.

NIC: What factors are contributing to the frequency of treatment?

JB: Smaller to mid-sized facilities now incorporate HIE cooling. Historically, those facilities would have transported babies requiring cooling to Academic Medical Centers for treatment.

NIC: In your experience, what are the differences in treatments across the country and why do you think there may be differences?

JB: People tend to follow standard protocol although there is a possible trend to treat babies with lower gestational age.

NIC: Are the results today from this treatment consistent with what they were 5 years ago? What has changed?

JB: Potentially babies that are a little younger, little smaller. We also can confirm more consistent results due to core temperature measurements as opposed to skin temperature measurements.

NIC: Are you seeing more positive outcomes with this treatment and if so why?

JB: Initiating treatment quicker may lead to better results. Six hours remains the goal but we begin treatment as soon as possible — within a couple hours if possible.

NIC: What are the common follow up procedures for a baby that has been successfully treated and discharged? Is it 1 year, 4 years etc.?

JB: State dependent but follow up to at least 2 years and possibly as much as 6-7 years. Cohen Childrens is currently working on a follow-up Clinic to assist with this research.

NIC: Is there evidence of long term neurological impact for successfully treated patients?

JB: Up to 40% could expect to have some type of deficit but research is ongoing.

NIC: Any thoughts on direction this treatment will take in next 5, 10 years?

JB: Adjunct therapies like EPO and potentially Xenon gas which is already being used in Europe.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Finding the Best Blood Draw System

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Lynn Lingen, BSN, RN, RNC-NIC, NICU Educator at Seattle Children's Hospital, about using the Hummi Micro Draw System.

Neonatal Intensive Care: How long have you used the Hummi Micro Draw System?

Lynn Lingen: I first trialed the Hummi system in 2010 when our unit was experiencing supply and manufacturing issues with the closed blood draw system we were using at the time. After trialing the Hummi, we implemented its use for all arterial blood draws — peripheral and central. In my current unit, we have utilized it for just over 2-1/2 years.

NIC: Why did you decide to use the Hummi system vs. others that were available to you?

LL: Hummi was offered at a reasonable cost compared to other systems and was simplistic in design, as well as easy to use. We really liked that it offered a way to have passive-flow blood draws (and low blood volume moved within the system) vs. aspiration and flushing, typical of most other systems. This minimizes the hemodynamic fluctuations that occur with blood sampling from arterial lines and the variability in aspiration and flushing pressures amongst staff.

NIC: What positive benefits does the Hummi system provide for the premature population vs. other methods of drawing blood?

LL: As mentioned, the passive-flow system and low blood volume necessary to perform the draw minimizes variability in hemodynamic fluctuations, thus reducing the risk for intraventricular hemorrhage for premature patients — particularly in the first week of life when arterial blood sampling is frequently performed. Also, because the Hummi enters the line at one entry point and eliminates the need for excessive, multi-connection tubing set-ups typical of closed blood draw systems, infection risk is also minimized.

NIC: Since the Hummi system is a closed system in use, have you observed any change in your infection (CLABSI) rates since you began using the Hummi system?

LL: Unfortunately, I do not have data on this as I was not involved in tracking line infections.

NIC: What type of blood draws do you use the Hummi system for? Peripheral? Umbilical? PICC?

LL: In my current unit, we utilize the Hummi system for peripheral and umbilical arterial lines, as well as, umbilical venous catheter blood draws.

NIC: Are you aware that the Hummi system can reduce the risk

for IVH development in the premature infant by moving lower volumes of blood and fluid vs. other blood draw methods?

LL: Yes, I have been very involved in advocating for practice changes to reduce the overall incidence and severity of neuro-developmental complications. So, even without considering the other benefits, Hummi was the logical choice for our premature babies.

NIC: Was reduction of IVH risk a determining factor in your adoption of the Hummi system?

LL: Yes, absolutely!

NIC: Have you observed any reduction in the incidence or severity of IVH occurrence in your patient population since you began using the Hummi system?

LL: The first unit in which I used the Hummi system was a delivery hospital with a 47 bed NICU and a high number of premature patients. At the time we brought the Hummi system in, we also implemented other IVH prevention measures. Over the course of one year, we did see a small decline in IVH incidence and severity. In my current facility, we have a lower percentage of premature infants and the majority of these patients are admitted to us after one week of life. So, I am unaware of the impact the Hummi system on IVH occurrence.

NIC: Do you find the training and support material provided by the manufacturer to be of help to you and your staff when learning to use the system?

LL: Yes, definitely. A comprehensive binder of materials and job aids were provided by the manufacturer. A clinical expert was available on sight for several days to provide training and support.

NIC: Would it be of benefit to your patient care from an infection control aspect, if the Hummi was available to you in a fully assembled manner already integrated into your umbilical artery?

LL: Although our unit doesn't have the opportunity to place many umbilical catheters due to the timing of premature patients admission (usually greater than one week of age), I do see tremendous benefit for delivery hospitals to have an integrated UAC/Hummi system. Minimizing extra pieces and connection points not only benefits the patient from an infection prevention standpoint, but having less connections also decreases the concern for inadvertent disconnections.

NIC: How would you rate your overall satisfaction clinically with the Hummi system?

LL: Extremely satisfied.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

The Benefits of Transcutaneous Technology in the NICU

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Marty Sandoval, RRT, NPS, RCP (California), Respiratory Manager, Children's Services at Pomona Valley Hospital Medical Center, a facility he has been with for 35 years, most of them in the NICU.

Pomona Valley Hospital Medical Center is the second-busiest maternity ward in California. It's based in a 437-bed hospital that is a community, stand-alone facility that sees everybody, including underinsured patients. It is a not-for-profit and not attached to other health systems. The NICU has a 53-bed capacity, but can hold up to 62 infants with flex beds. In the NICU, staff members see babies from 23 weeks (gestational age) up to term; they don't have a PICU. Pomona Valley uses transcutaneous monitoring, in which a sensor is gently applied to the body and continuously measures blood gases diffusing through the skin. Transcutaneous monitoring in neonates provides a real-time overview of the patient's often fluctuating oxygenation (tcpO_2) and ventilation (tcpCO_2) status. This not only minimizes blood sampling from the fragile neonate, but the continuous information allows you to intervene immediately should any changes in the ventilation or oxygenation status occur. Pomona Valley uses 13 TCM CombiM Monitors (Radiometer) for the Transcutaneous monitoring and three ABL825 Flex for blood gas (Radiometer).

Neonatal Intensive Care: What makes your facility unique?

Marty Sandoval: One thing that we do that is very unique is that we transfer high-risk moms into our facility from other facilities that have an ICU. The goal is to bring the high-risk in to try to prevent or delay the delivery as much as possible.

NIC: What happens during delivery?

MS: The first hour of a premature baby being delivered is really a make-or-break situation. It's amazing — just temperature regulation. Because those babies can get cold so fast, we need to keep those temperatures up. There are just so many comorbidities related to letting a baby's temperature drop. Places that don't deliver 24-week-old babies are just not used to that. It makes a big difference having those moms come here before delivery. The impact to the baby is just tremendous for their survival. We will even send a team out to pick up the mom; if it's not safe to transport the mom, we'll bring our whole team there to assist in the delivery, so we can best support that first hour of life.

NIC: What happens after the baby is delivered?

MS: Once the baby is delivered, the baby is transferred to the

NICU. We do electrolytes with our blood gases as needed. With transcutaneous monitoring, our blood gas tests go down. We're very cautious of the amount of blood we take out of the baby, so we try to limit blood draws as much as possible. As our transcutaneous values correlate with blood gases, we only do blood gases once or twice a day for the first week. After that, we can go a few days without doing ABGs, provided the babies are stable in the ventilator. Without transcutaneous monitoring, in the past, we would have to do ABGs every two or four hours.

NIC: What was the driver for investing in TC technology?

MS: We've been a TC technology facility since it came out in the '80s. Back then, we weren't monitoring oxygen because there was no pulse oximetry. Transcutaneous monitoring was the only insight into what the pO_2 may be. (Pomona Valley now has 13 monitors in its NICU.) Over the years, we have accumulated a lot of literature on the benefits of using non-invasive CO_2 monitoring. A lot of it is neuro-protective. There's so much evidence that big swings in CO_2 can cause cerebral palsy and other conditions, so it is for their protection. It also helps us wean them off their invasive ventilation. Our goal is to get them off that ventilator as soon as possible — yet make sure that we're not doing it too fast.

NIC: What does TC monitoring tell you?

MS: Doing TC monitoring signals us to look at the baby and do a complete assessment. If the CO_2 goes up, it signals for us to look at the baby and see what's going on. During the high frequency ventilation, we can see the baby's chest movement and that has to do with CO_2 levels. A lot of times the baby's position may stop CO_2 removal. Sometimes they just need to be suctioned. We do an assessment. We may need to do a change in our ventilator settings to get the CO_2 down. With a transcutaneous monitor that we trust, we will make those changes without doing a blood gas.

NIC: Why are more hospitals not using TC technology when there's so much literature out there?

MS: It's difficult to change old practices. You have clinicians in facilities that have been doing their job for 15-20 years, and they have done it this way and that may be hard to change. And some of it has to do with cost. Our facility has done very well when it comes to cost containment, which gives us the opportunity to explore different technologies and keeping ourselves up-to-date. Other facilities may not be as fortunate as us. Transcutaneous technology we pretty much limit to

Marty Sandoval, RRT, NPS, RCP (California) is the Respiratory Manager, Children's Services at Pomona Valley Hospital Medical Center. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

our intubated patients and some of our smaller patients that are under CPAP and non-invasive ventilation. The reason is that it is an expensive modality; there's a cost related to that. Probably our second most expensive therapy we offer in our department, so we are mindful to not over-utilize it and prioritize to situations where it would benefit patients most.

NIC: What advice do you have for facilities that want to start using TC technology.

MS: Start with one. Once a facility sees how it can change the outcomes of the patients and how that can reduce blood gas testing, I personally don't see how any facility can use high-frequency ventilation on a patient without using transcutaneous monitoring. I think there's a danger in not using it. Unless you have eyes on the baby all the time, you would not know that there are secretions that have built up. And even then, you would have different sets of biases interpreting those physical signals. There are studies that show that high-frequency ventilation had problems in the early days with PVL because it wouldn't monitor CO₂.

NIC: How would you describe your facility's focus.

MS: It's a shift from just surviving to thriving. That's what we are really keen on. That first hour of life is crucial for that survival, and what follows is crucial to their thriving as well. When we deliver a preterm at-risk baby, we send about 5 team members, just for that hour to stabilize the patient. As soon as the baby comes into the unit, the baby is attached to a TC monitor. We may not do a gas for one or two hours. Yet, we have to protect the baby's neural functions by keeping the CO₂ under normal levels. Many years ago, there was a time in our unit that we went away from TC monitoring because of the burns and because of the tape used on the fixation rings. Those used to be rough and upon removal would tear the baby's skin and be a cause of infection. Now, with our current monitors, that is no longer an issue. We currently excel in the outcomes of our extremely small, premature babies. Here in California, I'm not aware of other facilities that would go out and help birth a baby at another facility. We're very unique in the steps we take in trying to protect those very small babies.

Brave Beginnings Grant Assists Neonatal Research

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Dr Anup Katheria, a neonatologist affiliated with the Sharp Healthcare Foundation in San Diego, CA, about the facility receiving a Brave Beginnings grant.

Neonatal Intensive Care: Could you provide a quick history about your hospital and the area it serves?

Dr Anup Katheria: As San Diego, California's only specialty hospital for women and newborns, Sharp Mary Birch Hospital for Women & Newborns is nationally recognized for its quality of care. We operate a 206-bed tertiary-level women's specialty hospital with an 84-bed Level III Neonatal Intensive Care Unit (NICU), a 14-bed women's acute care unit, and a 36-bed perinatal specialty care unit. Sharp Mary Birch is the largest delivery service in California and sixth largest in the nation with over 9,400 deliveries annually. We provide medical, educational, and psychosocial services to promote healthy outcomes at birth to nearly 12,000 women and infants from across Southern California. Sharp Mary Birch serves the increasingly diverse population of San Diego, Riverside, and Imperial counties, many of whom confront disparities in health care by race, ethnicity, and language. Of all babies born at Sharp Mary Birch, approximately 39% are Caucasian, 35% are Hispanic, 16% are Asian, 5% are African American, and 5% are unknown/other. Approximately one-third of NICU newborns are covered by Medi-Cal (CA Medicaid). We provide culturally and linguistically appropriate care to our distinct communities including Hispanic, Somali, East African (Sudanese), Chaldean, Vietnamese, Filipino, and Korean populations. About 60% of women served by the hospital are Women, Infant and Children (WIC) Program eligible participants.

A Hospital Honoring Two Visionaries

Sharp Mary Birch Hospital for Women & Newborns bears the names of two extraordinarily generous families. While Sharp was named by a father in a memorial tribute to his son, our women's hospital was named in honor of Mary Birch, a mother who raised two children during the early 1900's. Though born decades apart, Mary Birch and Donald N Sharp had one thing in common — family members who shared the belief that providing for the health of our community was the greatest gift they could bestow.

NIC: Does your hospital/NICU have any accolades you could share with us?

AK: In California, we deliver more babies than any other hospital; we are the 6th largest delivering hospital in the nation.

We have the largest Level III NICU in Southern California with

84 beds and over 1,600 newborns per year receive advance care in the unit. More than 150 newborns are transferred to us from other hospitals.

Earlier this year, the US Department of Health and Human Services Agency, National Institutes of Health (NIH) awarded the Neonatal Research Institute (NRI) at Sharp Mary Birch a prestigious \$2.9 million award to extend research on umbilical cord milking and delayed cord clamping, which was funded with two prior NIH grants. The cord milking technique has been shown to provide additional cord blood to babies at birth and improve heart, lung and brain function, particularly for premature newborns. The new, larger study aims to show reductions in brain bleeds and improved long-term neurological outcomes in premature babies. Sharp Mary Birch will lead eight other centers participating in this study, which is the largest and most comprehensive of its kind. It is the first private hospital to lead a multicenter international trial. Researchers will follow 1,500 children up to the age of two to analyze the outcomes resulting from using the cord blood milking and delayed clamping methods. If these results are positive, it could improve how preterm babies are cared for worldwide.

We have received the International Board Certified Lactation Consultant (IBCLC) Care Award for employing board-certified lactation consultants and providing educational programs and processes that support patients and their breastfeeding needs.

The hospital is part of Sharp HealthCare, the largest integrated not-for-profit health care delivery system in San Diego County and recipient of the Malcolm Baldrige National Quality Award, the nation's highest honor for organizational performance excellence.

In July 2013, Sharp Mary Birch was recognized as a Minimally Invasive Center of Excellence Center for Gynecologic Surgery; the first of its kind in San Diego.

In 2011, we were recognized for our "Outstanding Patient Experience Award" which recognizes hospitals that scored in the top 10% nationally in the Hospital Consumer Assessment of Healthcare Providers and Systems patient survey database.

In 2009, we received a "Best Place to Practice" award from Press Ganey, a leading national health care consulting group that partners with more than 10,000 hospitals.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

We are one of 13 members of the Council of Women's and Infants' Specialty Hospitals (CWISH), a prestigious, invitation-only organization of nonprofit leading hospitals in providing services to women and infants.

Our hospital was named in Fit Pregnancy magazine as one of the "10 best hospitals in America to have a baby."

NIC: How has the equipment purchased with the (help of) Brave Beginnings grant impacted your NICU/Hospital?

AK: The generously provided LifeStart equipment has been integral to a number of our recent neonatal research studies. Because of this critically important equipment, our newborns receive placental blood while they also receive resuscitation. Studies have shown that newborns that need resuscitation have poorer outcomes compared to healthy newborns. However, prior to the development of the LifeStart equipment, it was impossible to allow newborns to receive placental blood since they had to be disconnected from the placenta to be moved to an adjacent space for resuscitation. This vital equipment has allowed us to positively impact the lives of many of the most vulnerable newborns born at Sharp Mary Birch.

NIC: Explain how this equipment provided a better level of care for your neonate patients.

AK: On average, a baby is born every hour at Sharp Mary Birch. Resuscitation systems such as provided on the LifeStart bed, dramatically improve the level of care for our neonatal patients and their families. The bed, when placed together with our current resuscitator and adjacent to the mother for both cesarean and vaginal births, allows the newborn to receive immediate resuscitation without being separated from the mother and placenta. This connection promotes both mother/baby bonding and permits continued blood perfusion to the infant.

NIC: What does your NICU hospital do to stay current with research and best neonate practices?

AK: Our hospital prides itself on creating new and best practices for others to follow and emulate. We have provided evidence for a number of delivery room interventions such as the use of an electrocardiogram during resuscitation, umbilical cord milking and now resuscitation with an intact cord.

NIC: Was the Brave Beginnings grant able to ease any financial burdens pertaining to the purchasing of equipment? Explain how.

AK: We are so grateful to Brave Beginnings for the wonderful grant that allowed our NICU to purchase a new LifeStart bed. Without this important funding, purchase of this bed would not be possible this fiscal year. As a not-for-profit health system and hospital, Sharp HealthCare and Sharp Mary Birch Hospital for Women & Newborns depend upon the generosity of grantors, individuals and donors to help support these critical needs.

NIC: Is there a NICU success story that stands out in your mind that you could tell us about?

AK: We would be honored to share the success story of Leona:

Leona's Story

"When we were given the choice to participate in the research study, we really didn't think twice. Our only question was, how will this affect our baby? We quickly prayed, gave it to God then gave our consent. I can't imagine if Leona didn't receive the stem cells and blood that day. Her brain bleeds may have been much

worse, or her fragile lungs may not have been able to finally rebound and begin to heal. What Dr. Katheria and all the amazing staff at Sharp Mary Birch are continually doing makes me so happy and grateful." — Heidi B., Leona's Mom.

For more of Leona's story, please see the following video link: <https://www.youtube.com/watch?v=adeTfKXrazs>

Meconium in the Amniotic Fluid: An Algorithm Has Changed: A Brief Clinical Update

B Petrikovsky, MD, PhD

An old story

Meconium in amniotic fluid is present in 9-14% of all pregnancies.^{1,2} While meconium aspiration syndrome (MAS) occurs in only 2.1% of these cases, it results in a 40% mortality.³ An aggressive oral and naso-pharyngeal toileting should theoretically minimize and/or eliminate such an occurrence. Regrettably, however, this had not been the case. Despite vigorous suctioning before delivery of the shoulders, meconium was still present below the vocal cords in 5-7% of cases; 10-33% of these neonates subsequently developed MAS.

Amnioinfusion has been advocated as a technique to reduce the incidence of meconium aspiration and to improve neonatal outcome. Known complications of amnioinfusion include uterine hypertonus, uterine rupture, placental abruption, and chorioamnionitis.

A large randomized trial was conducted recently, which included 1,998 women in labor at term either subjected to amnioinfusion or no intervention at all.⁴⁻⁶ The authors found that amnioinfusion did not reduce perinatal death (0.5% in both groups) or meconium aspiration (4.4% versus 3.1% in controls).



Figure 1. An amnioscope to detect the color of the amniotic fluid through intact membrane. The device had been inserted very close to the cervix to detect meconium presence. It is no longer in use. From the author's collection of antique obstetrical instruments.

B Petrikovsky is a Professor of Obstetrics & Gynecology and Editorial Board Member.



Figure 2. The drawing was done by HR Bogart, an artist and a medical illustrator.

In-utero intervention: (author's experience)

Intrauterine meconium suctioning from the fetal mouth and pharynx was successfully performed in 11 fetuses through the operational channel of a fibroscope (Olympus, Japan).

Suctioning was performed using a modified DeLee suction device at -100 mm Hg. Each procedure lasted 15 minutes or less. Technically, the procedure of inserting the endoscopic device is similar to that of introducing an intrauterine pressure catheter (fig. 1).⁷

A new story

The management algorithm of MAS had changed at around the year 2000. Ghidini et al. among others⁸ postulated that MAS

is not caused by meconium aspiration in labor, but rather, by chronic hypoxia and infection. Proper understanding of the causative processes underlying fetal or neonatal compromise in these cases was essential to direct future research into preventive or therapeutic treatment modalities.⁸

Before the 2005 guidelines, management of a newborn with meconium-stained amniotic fluid included suctioning of the oropharynx and nasopharynx on the perineum after the delivery of the head but before the delivery of the shoulders. The 2005 guidelines did not support this practice anymore. However, these 2005 guidelines did support intubation of the trachea and suctioning of meconium or other aspirated material from beneath the glottis in nonvigorous newborns. In 2017, these guidelines were updated. Routine intubation and tracheal suctioning are no longer required. Infants with meconium-stained amniotic fluid should no longer receive intrapartum suctioning, whether they are vigorous or not. Resuscitation should follow the same principles for infants with meconium-stained fluid as for those with clear fluid.⁵

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Marijuana Use in Pregnancy and Lactation: Sure it's Natural, But is it Safe?

Lori Wood, MSN, CNS, RNC-NIC, IBCLC

Human milk is always placed as a priority for both term and preterm infants whenever possible as the multiple health and immunity benefits are undisputed (Wood, 2013). Even in cases of maternal medication use, infection exposure, or health issues, the properties of breast milk are often favored and a risk versus benefit appraisal must be considered (Mourh & Rowe, 2017). Policies and statements have long existed to provide guidance and a stance on maternal drug use during pregnancy and lactation. With the continued legalization of marijuana in 29 current states plus the District of Columbia, increasing use among women of child bearing age, and a general consensus that natural is good, many healthcare providers are left wondering what is best (Metz & Stickwrath, 2015).

As the legalization of marijuana both medical and recreational continues, usage among women of childbearing ages rises. Current percentages of reported use are varied, largely attributed to self-reporting. Marijuana user's honesty regarding use may be influenced by their comfort and trust with those collecting data, as well as the laws in their state of residence. In a report from the American College of Obstetricians and Gynecologists (ACOG), marijuana is the most commonly used illicit drug. 2-5% of pregnant women self-report using marijuana during their pregnancy, but these numbers increase to 15-28% among young women with socioeconomic issues or those who live in urban settings (ACOG, 2017). Of interest is the growing number of highly educated women with steady employment and an annual income of \$75,000 or more. These people are turning toward marijuana as a natural cure and treatment for a number of medical maladies. In a recent survey of 10,000 California commercial marijuana customers, 57% were millennials (birthdates between 1983-1996), 21% Generation X (birthdates between 1965-1982) and 15% Generation Z (birthdates between 1996 to now). Almost 93% of this survey includes people of general child bearing years; 32% are women, and 20% are parents. The common desire of these marijuana consumers is to reduce the use of alcohol and pharmaceuticals and enjoy the healing of marijuana (Merwin, 2017).

As society's increasing approval of marijuana continues, more pregnant and breastfeeding women are turning to marijuana for relief of symptoms such as nausea, anxiety, and to replace

medications known to be harmful to the fetus (Merwin, 2017). Women who use marijuana in pregnancy report a higher usage in the first trimester when nausea is highest with decreasing usage often reported by the third trimester (Mourh & Rowe, 2017). Women suffering from bipolar disease often look for replacement medication when pregnant and/or breastfeeding. A Google search of treating bipolar disease with marijuana results in numerous remedial blogs and suggestions for healing in a natural fashion. Many bipolar medications often have detrimental effects to the fetus (Epstein, et al, 2014). For this reason, marijuana is often considered by this population of patients to be a safer, more natural way to treat a serious condition. Because opinions are so varied and research is not plentiful, supportive information for either side of the marijuana issue is readily available (Wilcox, 2016). Use of marijuana during lactation continues after the symptoms of pregnancy are gone in many moms who used during this time. Continued use of marijuana during breastfeeding to treat symptoms and issues could often be replaced with alternative therapies considered safer and more studied (Mourh & Rowe, 2017). A 2014 survey highlighted the most commonly reported reasons for marijuana use in pregnant or breastfeeding moms as: depression, stress relief, anxiety, pain, and nausea and vomiting (Saint Louis, 2014). Many women have incorporated marijuana into their daily lifestyle well before becoming pregnant and wish to continue its use. ACOG reports that 34-60% of marijuana users consider it safe to use during pregnancy and lactation (ACOG, 2017). Because marijuana use is not directly linked to congenital abnormalities, many healthcare providers and people in general, feel it is a safe alternative to medications and support its use. Withdrawals from marijuana in infants is also not noted, lending to the notion that marijuana is safe to use in pregnancy and while breastfeeding. Absence of major anomalies and withdrawal does not allude to safety, especially in the developing neonatal brain (Saint Louis, 2017)!

Another loosely associated support for the use of marijuana in pregnancy and lactation is tied to the endocannabinoid system. The endocannabinoid system (ECS) is present in the developing fetus from approximately week 16 of gestation and is extremely important in the development of the neuronal brain circuit (Volkow, et al, 2016). This system is responsible for the differentiation of stem cells into neurons and axons, guiding the migration of axons and creating the matrix for neurons to plant and establish synapses. The proper development of this circuitry is essential to the continued ability of the fetus to grow and develop a brain ready for higher development and eventual

Lori Wood is a Clinical Nurse Specialist at Desert Regional Medical Center, Palm Springs, CA. Lori is certified as a RNC-NIC in Neonatal Intensive Care Nursing and is an International Board Certified Lactation Consultant. She is also a consultant for Medela, LLC.

learning. Cognition, suckling, and motor development are all controlled by this system (Fantasia, 2017; Mourh & Rowe, 2017). Cannabinoid receptors, CB1 and CB2, also develop in the brain and peripheral tissue. These receptors are responsive to both natural endocannabinoids which are produced and available in human breast milk as well as phytocannabinoids present in marijuana (Onaivi, 2011). Exposure prenatally to an excess of cannabinoids present in marijuana is thought to oversaturate these receptors. Tetrahydrocannabinol (THC), the main cannabinoid in marijuana is much stronger than those naturally occurring. As THC is passed from the mother to the fetus, it is stored in the fat cells of both (Fantasia, 2017). THC crosses both the placental and blood-brain barrier exposing the fetus and newborn to potentially high levels (Mourh & Rowe, 2017). This THC can be released over time causing increased exposure of the cannabinoid receptors to these substances resulting in changes to normal neural development (Fantasia, 2017). Exposure to these phycannabinoids has been demonstrated to influence the expression of genes, causing epigenetic changes to cell proliferation, migration of the neurons, and elongation of the axons during fetal brain development (Fernandez-Ruiz, et al, 2004). Disruption of fetal position and axon differentiation can lead to changes in postsynaptic selectivity. Physical, cognitive, emotional, social, and motor function changes have been reported by some; these issues were demonstrated into adult life (Day, et al, 2011)! Proponents of marijuana use in pregnancy and lactation will cite the necessity of these cannabinoids and their natural occurrence in breast milk and the body as a positive reason for marijuana use. At this time with limited randomized controlled trials and true evidence, exposure to phytocannabinoids, in any amount, cannot be deemed safe (Johnson, 2016).

Stronger concentrations of THC can be passed on through the breast milk of moms who use marijuana. While exact levels of marijuana metabolites in breast milk are hard to determine, researches have completed studies which give a generalization. Because THC is stored in fat cells, the breastmilk of moms with chronic and moderate to heavy use of marijuana is found to contain eight times more THC than mom has in her plasma. THC continues to concentrate and remain in human milk resulting in too much for baby. Infants ingest approximately 0.8% of the maternal dose from one marijuana cigarette during each feeding (Djulius, et al, 2005). Because THC is extremely lipophilic and breast milk contains high amounts of fat, THC concentrates in the milk. The THC from that one cigarette will continue to stream into mother's milk as the average half-life for excretion is 20-57 hours depending on mother's metabolism. As baby continues to nurse 8-12 times a day, the infant has the potential exposure of about 10% of mom's intake of THC. If mom consumes more THC edibles or smokes more than one marijuana cigarette, the amount of exposure increases. Multiple studies show that infants born to mothers who use marijuana occasionally, test positive for THC in their urine days after exposure. Positive infant results can continue longer, from 5-13 days following exposure, in babies whose moms use marijuana heavily/chronically (Huestis, 2007; Paramore & Paramore, 2017). Perinatal cannabinoid exposure via mother's milk has also been shown to change both dopaminergic and opioid receptors in the brain of animals post birth. Rat models were exposed to levels of THC via mother's milk and these changes were noted (Fernandez-Ruiz, et al, 2004). One study compared postmortem fetal brains of infants exposed to marijuana against those who had not.

Similar changes to dopamine and opioid receptors were seen (Metz & Stickwrath, 2016). Changes in these receptors can be responsible for motor changes and drug seeking behavior, thus a theoretical concern is established (Fernandez-Ruiz, 2004).

Because the concentration of THC in the average marijuana cigarette has increased from approximately 3.4% per cigarette to 12-13% with new genetically modified and commercially grown marijuana, the marijuana smoked or consumed now is not the same that past generations have been exposed to (ElSohly, et al, 2017; Volkow, et al, 2014)! Early studies of the effects of marijuana on the fetus and in breastfeeding are no longer applicable today! A study by Dreher and Associates in 1994 looked at infants in Jamaica. This study compared infants of moms who used marijuana to those whose mothers did not. Comparison of the results of the Brazelton Neonatal Assessment Scale showed no differences at three days and one month of life (Dreher, et al, 1994). Fried reported similar findings in 1982 as well as Tennes and associates in 1985 (Paramore & Paramore, 2017). Higher concentration levels noted in today's marijuana, however, are exhibiting different effects. Marijuana is changing the critical circuits of the developing fetal and post-birth neonatal brain (Fernandez-Ruiz, et al, 2004; Saint Louis, 2017).

Most research on the effects of marijuana in breast milk in baby surround the area of infant development. As discussed, considerable exposure to THC in utero can have negative effects on the development of the fetal brain. Elevated concentrations of THC in breast milk consumed by the infant can have the same effects. Since the endocannabinoid system is responsible for the normal development of brain circuitry controlling motor development, suckling, memory, and cognitive function, all of these areas can suffer. Multiple studies have been conducted to follow motor development and the achievement of developmental milestones by using the Baley Scale of Infant Development. Infants exposed to marijuana in the first months following birth were noted to have lower psychomotor scores at one year. Results were difficult to isolate however as 84% of the mothers consenting to the study had used during the pregnancy as well as breastfeeding. Slow weight gain has been noted in several studies (Metz & Stickwrath, 2015).

Route of marijuana intake has no difference on maternal plasma levels or infant exposure, therefore all forms of marijuana use, smoking, vaping, and ingestion via candies, cookies, and other edible sources are potentially harmful to infants. Edibles in particular are difficult to judge for novice users. Adults exposed to approximately 10-30 mg of THC will experience the psychotropic effects of marijuana. Edible sources such as cookies usually contain 100 mg of THC. Eating 1/10th of a cookie isn't a very realistic expectation for most people, making over consumption and true marijuana poisoning a possible reality. Adult users also underestimate the timing of clinical effects with ingestion as compared to inhalation. The effects of marijuana are usually felt within 10 minutes of smoking, while edibles must be digested, resulting in about 30 minutes time for the effects to be felt. This time difference is often not understood, resulting in consuming much more than was needed. Emergency Departments in Colorado report increasing numbers of visits due to marijuana edible dosing errors. In addition, pediatric visits are reported due to unintentional intake of marijuana edibles. With such a wide availability of types of marijuana for commercial use, mothers may be more enticed to try marijuana

and potentially exposed to high dosing with negative outcomes that can be passed to their baby (Monte. et al, 2015).

ACOG and The American Academy of Pediatrics (AAP) both recommend screening for maternal marijuana use at the onset of obstetrical visits. Verbal questioning is the usual form of screening and is acceptable to most patients, although truth in answers may vary (AAP & ACOG, 2012). A study in Pennsylvania where marijuana is legal, unveiled that only 36% of moms who tested positive for marijuana were truthful in disclosure. Self-reporting is often limited by the mother's perception of trust, communication style of the provider, feelings of guilt or worry regarding judgement, punishment, stigma, or custody issues following birth (Chang, et al, 2017). A non-judgmental and open style of communication both during prenatal visits and following birth at the pediatrician's office or with healthcare staff including nurses in the neonatal intensive care and maternal units will foster truth and better outcomes. At this time it is suggested that women who use marijuana should be counseled about the possible effects on both the fetus and the developing newborn and assisted with options to discontinue use (ACOG, 2017). Some mothers may be unwilling to do so and upon education and discussion, a plan to reduce use may be created. Assistance with treatment programs may be an option for some. Above all honesty, integrity, and support should be conveyed. Nurses and staff in prenatal counseling positions should consider their own personal biases and be aware of the legal implications in the state of practice to be able to work effectively with women who need guidance.

For staff practicing in hospitals, perinatal units or the NICU, the subject of marijuana use in breastfeeding mothers should be considered, researched, and a unit policy or guidelines developed. If the state of practice has legalized medical and recreational marijuana laws, hospital providers may not be able to force a mom to discontinue the use of breastmilk for her baby. Education sheets and a standard team of people to speak to and counsel mothers should be created. By establishing a team, all members will be able to provide uniform and consistent information. Educating mothers and families about the use of marijuana during breastfeeding can be approached in the same manner as anti-vaccination requests, or refusal of Vitamin K and Erythromycin at birth. The opportunity to present information and assist with a risk versus benefit discussion can be created. After education and discussion, if the mother and/or family still decide to continue using breast milk while mom uses marijuana, an against medical advice or waiver form can be presented and signed.

While current evidence and science points to marijuana being unsafe to use in pregnancy or breastfeeding, not enough research has been established to make a definitive call. The benefits of human milk in the newborn diet are a concrete given; yet marijuana and its effects are not well studied. Current research has a stronger emphasis on the use of marijuana during pregnancy. Use during the postpartum period and during lactation is often confounded by pregnancy use as well; more research on marijuana use during breastfeeding is needed. As societal norms change, and the stigma surrounding marijuana use in general dissipates, women of child bearing years are likely to turn to marijuana for alleviation of medical symptoms. With the message of marijuana and its safety conflicting depending on the source, healthcare providers, nurses, and staff working with the pregnant and breastfeeding


woman must do their best to research, understand, and reduce personal bias. Working together with our patients to educate and collaborate, we can provide the best outcomes that our evidence at this time can support.

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Cytomegalovirus placentitis

Surasak Puvabanditsin, MD, Lauren Walzer, MD, Melissa February, MD, Suja Vinod, MD, Francisco Zaldana, DO, and Sumi Thomas, MD

Case Report

A 25-year-old Gravida 2, Para 1 Indian female was seen for abnormal fetal ultrasound at 29 weeks of gestation. Ultrasound showed intrauterine growth restriction and the biophysical profile score was 4/10. Infant was delivered by cesarean delivery after failed induction of labor because of fetal distress at 29 weeks of gestation. The birth weight was 740 gm (<5%), the length was 34 cm (<5%), and head circumference was 23 cm (<5%). There were no other associated anomalies. Initial blood counts showed white blood cell 1,900/cubic mm, hemoglobin 13 g/dL and platelets 17,000. Neurosonogram was unremarkable. Pathologic study of the placenta showed diagnostic changes of CMV infected cells on routine histologic examination and immunochemical study (Figures 1, 2, 3). Cytomegalovirus (CMV) DNA was detected in the urine by Polymerase chain reaction (PCR); viral load was 6085. A 6-week-course of Gancyclovir was begun at 2 weeks of age. She was discharged home at 83 days; at 12 months of age her weight was 7000 grams (<3%) and she had mild developmental delay. Her brainstem auditory evoked response (BAER) was normal.

Discussion

Human CMV is a DNA virus of the herpesvirus group. CMV infection was described first in the early 1900s in pathologic specimens from an infant who died of presumed congenital syphilis. The virus initially was named salivary gland virus due to the characteristic pathologic changes seen in the salivary glands. It was isolated in tissue culture in 1956, and in the early 1960s, the more descriptive name cytomegalovirus was adopted. CMV infection of host cells results in a characteristic massive enlargement of the affected cells that contain intranuclear and cytoplasmic inclusions.¹ Congenital cytomegalovirus (CMV) is the most common cause of congenital infection in the United States. This occurs in approximately 1% of all live births. While 85% to 90% will have asymptomatic or “silent” congenital infection, 10% of infected infants have symptoms at birth.² CMV remains under-diagnosed because of low index of suspicion,

Surasak Puvabanditsin, MD - Associate Professor of Pediatrics, Department of Pediatrics, Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey. Lauren Walzer, MD - Department of Pediatrics, Rutgers RWJ Medical School. Melissa February, MD - Assistant Professor of Pediatrics, Department of Pediatrics, Wayne State University School of Medicine. Suja Vinod, MD - Department of Pediatrics, Rutgers RWJ Medical School. Francisco Zaldana, DO - Department of Pathology, Rutgers-RWJ Medical School. Sumi Thomas, MD - Department of Pathology, Rutgers RWJ Medical School.

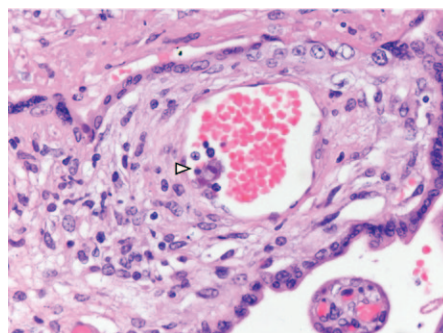


Figure 1a. Placenta: cytomegalic cells (arrow) in the endothelium

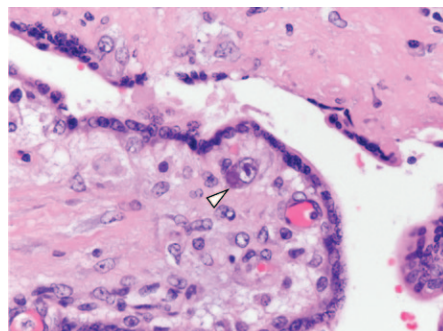


Figure 1b. Placenta: cytomegalic cells (arrow) with intracytoplasmic and intranuclear inclusions

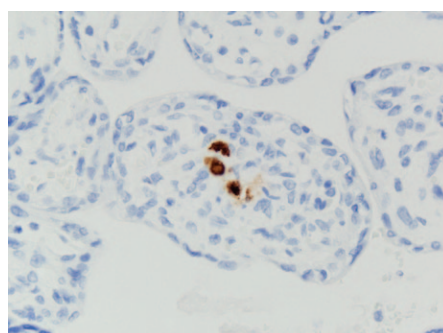


Figure 2. Immunocytochemistry stain for CMV in the placenta, brown nuclei indicate CMV-infected cells

lack of public awareness, no publicly funded programs, lack of laboratory diagnostic facilities and high cost of work-up. Manifestations of symptomatic congenital CMV include intra-uterine growth restriction, periventricular intracranial calcifications, microcephaly, thrombocytopenia, hepatosplenomegaly, petechiae/purpura, chorioretinitis and deafness.^{3,4} 60-80% of infants are seropositive by adulthood making CMV the leading nongenetic cause of sensorineural hearing loss in US children (21% of all hearing loss at birth).

A diagnosis of congenital CMV infection includes standard serologic tests, such as detection of cytomegalovirus IgG and

IgM antibodies, polymerase chain reaction(PCR) analysis of CMV DNA, or viral culture. Prenatal diagnosis may be made by viral culture or DNA detection of the virus in amniotic fluid or by CMV IgM antibody determination of fetal blood of a symptomatic fetus.

False-positive and false-negative serologic results occur, and confirmatory viral culture must be performed.⁵ PCR CMV-DNA is rapidly replacing viral culture as the most sensitive and efficient method for detection of CMV (urine, saliva, serum, liver tissue). Saliva PCR is now considered the investigation of choice to detect CMV.⁶ Amniocentesis may be the most valuable single antenatal diagnostic test, and viral culture or PCR test of amniotic fluid are equally specific and sensitive.⁷

CMV infection of host cells results in a characteristic massive enlargement of the affected cells that contain intranuclear and cytoplasmic inclusions. Section of placenta demonstrates villitis and typical inclusion cells due to infection with CMV.¹ CMV-positive cells in the placenta are mainly found in the stromal component of the villi such as fibroblasts and endothelial cells. Interestingly, the different degrees of placental inflammatory response is often correlated with the severity of brain inflammatory infiltrate. Severe placentitis is associated with severe cerebral damage.⁸

Placental CMV infection documented by pathognomonic viral inclusions is a rare finding. In cases of proven intrauterine CMV infection, the placenta usually shows only nonspecific villitis or appear normal on routine histologic examination.⁹ Immunocytochemistry is now available for the demonstration of CMV in infected tissue. It is also more sensitive and specific method than conventional histology.⁹ The importance of placental histopathology as an aid in the diagnosis of congenital infection cannot be overemphasized in our case.

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Head Ahead: Nutritional Consideration Among Extremely Low Birth Weight Infants

Shabih Manzar, MD, FAAP and Liaqat Hayat Khan, MD

Head growth is important in postnatal phase. Infants born prematurely are at increased risk for growth delays. We present a case of an extremely low birth weight (ELBW) infant that despite the adequate nutrition failed to grow appropriately. The magnetic resonance imaging (MRI) of the brain showed delayed frontal lobe growth. We suggest MRI brain should be routinely followed in ELBW infants as following head circumference could be deceptive.

Case

Infant was the second of the twins, born to a 21-year-old gravida 2, para 1. All antenatal labs including HIV, Hepatitis B, and rapid plasma reagin were negative. There was no history of sexually transmitted diseases. Pregnancy was complicated by preterm labor and she delivered twins at 24 weeks of gestation. Mother received two doses of betamethasone prior to delivery. Apgar scores were 4 and 7 at one and five minutes respectively. Infant's birth weight was 543 Grams (3%), head circumference 22 centimeters (3%) and length of 32 centimeters (50%), using Fenton chart.

Infant was intubated in the delivery room for poor respiratory effort and placed on ventilator in NICU. Physical examination was normal for gestational age. A septic work up was done including complete blood count and blood culture and infant was started on antibiotics.

Chest X-ray was compatible with respiratory distress syndrome. Surfactant was given via endotracheal tube. Blood gas on admission was pH of 7.44 pCO₂ of 34 PO₂ of 61 and HCO₃ of 24 on 60% FiO₂. Infant was started on total parental nutrition with 3.5 to 4 gram/kg/day. Lipids were started on day 2 and gradually increased to 3.5 g/kg/day. Feeds were started on second day of life and were gradually advanced. By day 24, infant was on full enteral feeds. Donor breast milk was used, fortified with Prolacta +10 to provide maximum calories per feed. Total fluid volume was restricted to 140 ml/kg/day in view of severe lung disease. Infant had multiple head ultrasounds over the first month of life, and all showed no signs of bleed or periventricular leukomalacia. An echocardiogram done at day of life 7 showed a small patent ductus arteriosus, which was managed conservatively. Follow up serial echocardiogram performed to screen for pulmonary

Shabih Manzar and Liaqat Hayat Khan are with Rapides Women's and Children's Hospital, Neonatal Intensive Care Unit, 211 Fourth Street Alexandria, LA 71301. Telephone: 318-769-7160/7791. Fax: 318-769-7473 shabihman@hotmail.com.

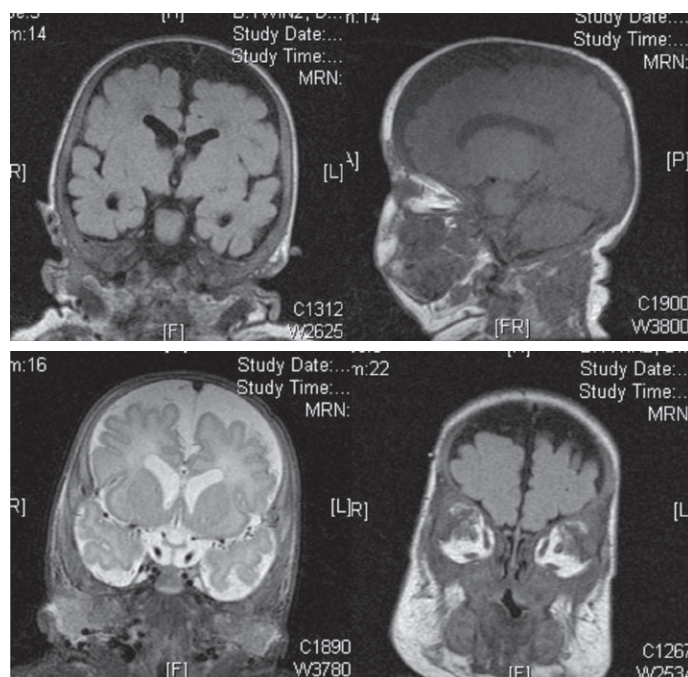


Figure 1-4. MRI brain taken at 120 day of life, note the underdevelopment of frontal lobe

hypertension, showed trivial tricuspid regurgitation with gradient range of 23-33 mm Hg, normal sized right atrium and normal right ventricular function. Infant's respiratory status continued to deteriorate and he failed several extubation attempts.

At 120-days of life, the infant remained on very high ventilatory settings (On Oscillator; Fraction Inspired Oxygen 100%, Mean Airway Pressure = 24, Amplitude = 60 and Frequency = 5) and was unable to wean. Infant was transferred to Level 4 NICU for tracheostomy. MRI of the brain did not show any congenital anomalies but showed significant underdevelopment of frontal lobe (See Figure 1-4). On growth chart head circumference was plotted between 10-50%, see Figure 5.

Discussion

Extra uterine growth restriction (EUGR) is a common occurrence in VLBW infants. Traditionally changes in weights, and weight to length ratios are used as the main parameters to assess postnatal growth and used as yard sticks for EUGR. However, head growth is an important landmark that should be followed closely, as described by Padilla et al.¹ They concluded that premature exposure to extrauterine environment affects

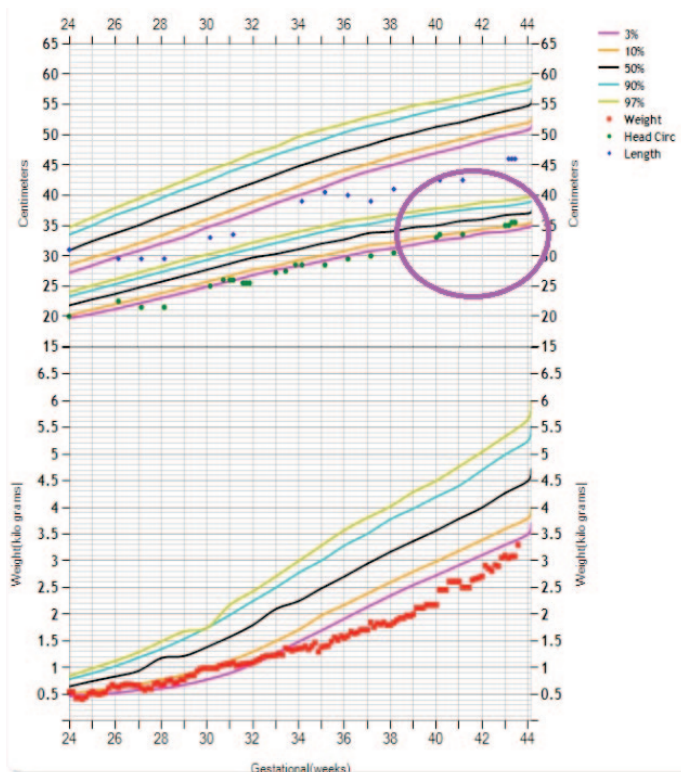


Figure 5. Growth chart (note the purple circle, Head Circumference plots at 10-50%)

the brain growth negatively. NICU environment is stressful and not developmentally friendly. Efforts have been taken to change the extrauterine environment by reducing noise, exposure to unnecessary bright light, offering single rooms, etc. But by far, adequate nutrition is the key to post-natal neurodevelopment.²

Following head circumference weekly and plotting it on growth chart is routine in most NICUs but MRI brain is not routinely followed. As noted in the case presented, that serial head ultrasounds were normal. Also the head circumference, when plotted on growth chart, was following along the 10-50% curve giving a false sense of security and brain growth. However, when MRI brain was performed it clearly showed delayed frontal lobe structural growth.

The potential implication of the findings of MRI in the infant presented will be delayed cognitive functions. The infant is scheduled to be followed up in the developmental clinic after his return from the level 4 unit. We plan to obtain follow up MRI brain to see the progress of frontal brain.

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Feeding Dilemma During Non-Invasive Ventilation in Extremely Low Birth Weight Infant

Shabih Manzar, MD, FAAP and Liaqat Hayat Khan, MD

Feeding the extremely low birth weight (ELBW) infant is a challenging endeavor in neonatal intensive care (NICU). Nasogastric tube (NGT) is commonly used in ELBW infants to provide nutrition. Bolus feeds are provided as standard but in certain circumstances continuous feeding is used as an alternative, e.g. to combat frequent reflux. Gastroesophageal reflux (GER) is commonly seen in NICU. The lower resting tone of lower esophageal sphincter (LES) is a potential reason for reflux. When an NGT is inserted across LES it potentiates GER. The dilemma happens when infants need to be fed continuous feeds and is on Non invasive/Nasal intermittent positive pressure ventilation (NIPPV) or Nasal continuous positive airway pressure (NCPAP).

During non-invasive ventilation, external air is pumped into nasopharynx, thereby pushing extra air in stomach causing its distension. This extra air needs to be vented out. Therefore during continuous feedings two NGTs are used one to feed while the other to vent the stomach (Figure 1). We have noticed that this practice leads to increase in clinical reflux as noticed by increase bradycardia and desaturation episodes observed during feeds.

The esophagus is a flattened muscular tube that is collapsed and the lumen opens only during a swallowed bolus.¹ This function is compromised when a NGT is present in the lumen. The relationship between the circumference and diameter of a tube is depicted in Figure 2. Imagine two French 6 size tube passing through the esophagus in ELBW infants. This will take up to 4 mm of esophagus lumen (Figure 3). The lower sphincter is open all the time, which is a potential risk for reflux.

In the advent of recent changes, the management of GER in ELBW is to avoid using medications. The use of prokinetics and reflux medication are viewed critically. The use of double NGT is overlooked in NICU. We suggest changing this practice to avoid increase risk of GER in ELBW infants. The goal could be achieved by inserting a single smallest tube and avoiding continuous feeds or feeding for 2 hours and venting for 1 hour.

Shabih Manzar and Liaqat Hayat Khan are with Rapides Women's and Children's Hospital, Neonatal Intensive Care Unit, 211 Fourth Street Alexandria, LA 71301. Telephone: 318-769-7160/7791. Fax: 318-769-7473 shabihman@hotmail.com.

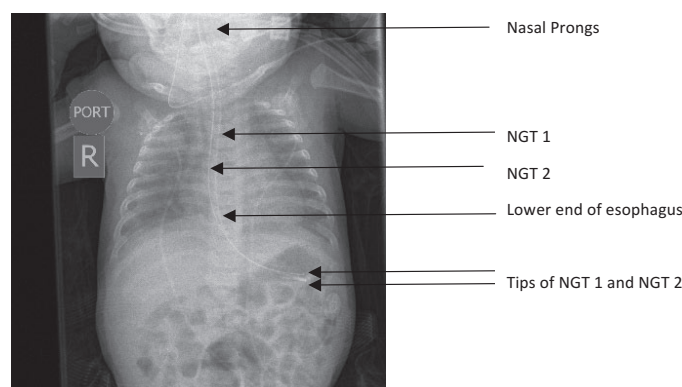


Figure 1. Chest x-ray of ELBW infant showing two NGTs

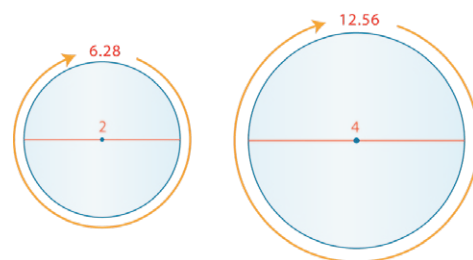






























Figure 2. Difference between circumference and diameter

in	.223	.21	.197	.184	.17	.158	.144	.131	.118	.105	.092	.079	.066	.053	.039
mm	5.7	5.3	5.0	4.7	4.3	4.0	3.7	3.3	3.0	2.7	2.3	2.0	1.67	1.35	1
Fr	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3
															
															
Fr	18	19	20	22	24	26	28	30	32	34					
mm	6.0	6.3	6.7	7.3	8.0	8.7	9.3	10.0	10.7	11.3					
in	.236	.249	.263	.288	.315	.341	.367	.393	.419	.445					

CREGANNA MEDICAL DEVICES French Catheter Scale

Figure 3. Catheter scale: French to millimeter

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Fetal Intubation in Management of Nearly Fatal Shoulder Dystocia

BM Petrikovsky, MD, PhD

By definition, the diagnosis of shoulder dystocia requires a time delay (60 seconds or more) between the delivery of the baby's head and shoulders.¹ The American College of Obstetricians and Gynecologists (ACOG) defines shoulder dystocia as a condition requiring special maneuvers to deliver the shoulders. Traditionally, brachial plexus palsies injuries have been attributed to the impaction of the shoulder behind the symphysis and to excessive force applied to the fetal head in an attempt to release the shoulder. Whether or not they are the result of a "difficult" delivery, brachial palsies are a major source of obstetrical litigation.² Nearly 30% of infants with brachial plexus palsy have no identifiable risk factors.^{1,2} As a result, the prediction and prevention of shoulder dystocia remains difficult. Macrosomia, one of the major risk factors for shoulder dystocia, remains hard to predict with either Leopold maneuvers or ultrasound examination. ACOG guidelines recommend a cesarean section delivery for fetuses having an estimated weight greater than 5,000 g in non-diabetic mothers, and over 4,500 g for mothers with diabetes. Despite an increase in cesarean section deliveries, the incidence of brachial plexus injury has not decreased.^{1,2}

Case report

A 16-year-old primigravida with poorly controlled type I diabetes was diagnosed with shoulder dystocia. Initial management included the McRoberts maneuver combined with simultaneously applied suprapubic pressure. Both took approximately 1 minute and failed. Next rotational maneuvers were applied, then "Wood's corkscrew", followed by attempts to deliver a posterior arm. This took approximately 4 minutes and also were unsuccessful. At this point, the fetal head turned blue and became very edematous. Maternal soft tissue was very swollen as well, effectively ruling out Zavanelli maneuver. At this point, the decision was made to intubate the fetus once the head and upper portion of the neck had been delivered. After the first attempt of orotracheal intubation failed, a transoral intubation was performed successfully using a rigid bronchoscope. Improvement of fetal head and face color was noted within 60 seconds. The additional time allowed the team to resume the efforts and finally resolve the condition successfully. The newborn was finally born weighing 4,250 g and Apgar score of 3 at 1 minute, 8 at 5 minutes. The newborn was diagnosed with mild brachial palsy and was discharged home on day 9. Symptoms of brachial palsy resolved by 6 months of age.

BM Petrikovsky, MD, PhD is a Professor of Obstetrics and Gynecology and an Editorial Board Member.

Discussion

Over 90% of cases of shoulder dystocia can be resolved within minutes by the sequential use of the McRoberts maneuver and suprapubic pressure, rotational maneuvers, and finally the delivery of the posterior arm. The greatest efficacy was seen with delivery of the posterior arm, which decreased anterior nerve stretch by 71% and showed an 80% decrease in delivery force.² However, severe shoulder dystocia may become a perilous complication for the fetus causing severe asphyxia. Hope et al.³ reviewed autopsy results on 56 cases of fatal shoulder dystocia. Maternal obesity and large babies were overrepresented in labors complicated by fatal shoulder dystocia. Fetal distress was recorded in 26% of cases. Animal studies would suggest that a healthy fetus could withstand at least 5-10 minutes of hypoxia and still respond to resuscitation. Mechanisms of fetal demise in severe cases of shoulder dystocia may be different from the mechanisms seen in cerebral hypoxia due to umbilical cord prolapse or placental abruption.³ In cases of shoulder dystocia, compression of the neck causes cerebral venous obstruction, further aggravated by excessive vagal stimulation and fetal bradycardia. From the clinical standpoint, when all the efforts to resolve shoulder dystocia appear fruitless, the Zavanelli maneuver remains the last hope. The Zavanelli maneuver consists of cephalic replacement with subsequent delivery by cesarean section.⁵ However, the Zavanelli maneuver is not always doable and in the best scenario, requires additional time. In our case, significant maternal soft tissue and fetal neck edema ruled out the Zavanelli maneuver. At this point, the decision was made to perform fetal head intubation to allow more time for the resolution of shoulder dystocia while maintaining fetal oxygenation. Intubation of the fetus before severing the umbilical cord has previously been reported and named the EXIT procedure.⁶⁻⁸ The EXIT procedure offers the advantage of insuring uteroplacental gas exchange while on placental support.^{6,7} Skarsgard et al.⁸ first described EXIT procedure for management of fetuses with in-utero airways obstruction. The EXIT procedure is now used for a variety of entities, including teratomas and laryngeal atresia, among others.⁹⁻¹² The EXIT procedure is based on a multidisciplinary approach, looking for maintaining airway patency in extrauterine life. It uses the nasotracheal intubation, laryngeal mask, or tracheostomy, while uteroplacental circulation is maintained. So in this way, you can avoid asphyxia due to tumor compressive effect, and in a second time, you will treat the obstruction. The EXIT surgery gives to you a 45-60 minutes working time, to ensure the control of the neonatal airway, while the fetus has uteroplacental perfusion. This technique involves many risks. You must maintain

an adequate uteroplacental perfusion with a good uterine relaxation, a mean arterial pressure above a 65 mmHg with CVP around 10 cmH₂O is recommended.¹⁴ So, you get an excellent fetal blood perfusion, but it is frequent with a poor uterine relaxation, the appearance of arterial desaturation, bradycardia, placental abruption, or umbilical cord compression.^{16,17}

Our previous experience with in-utero excess to fetal oropharynx^{13,14} lead us to consider intubation of the fetal head as a temporary measure to maintain fetal oxygenation, which allows more time to resolve shoulder dystocia. Details of measurement of severe shoulder dystocia is beyond the scope of the report. Our goal was to present head intubation as a step to allow extra time for further measures while sustaining fetal oxygenation.

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Probiotics for Hospital Use: Choosing the Right Strain, Right Food and Right Form

Tracy Shafizadeh, PhD

The Origins of the Infant Gut Microbiome

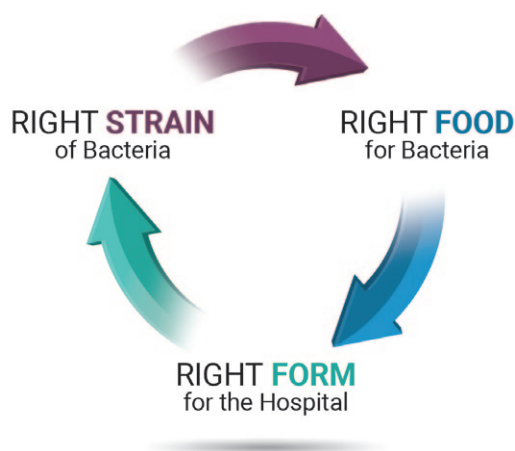
Considerable attention and research funding have recently been put toward understanding the role of the gut microbiome in human health, and its therapeutic potential for both infectious and chronic disease. Despite this increased effort, we are only beginning to understand how the infant gut microbiome is first established, how the microbial community is shaped, and the effect this critical period has on infant health.^{1,2} The organisms that comprise the gut microbiome are initially acquired at birth, and are largely dependent on delivery mode: vaginal vs C-section.³ Shortly following delivery, an infant's community of gut microbes is strongly shaped by diet, with human milk fostering the growth of a distinctly unique gut microbiome compared to formula fed infants. Finally, gut physiology and environmental exposure, such as the use of antibiotics, can further impact each individual gut microbiome. It is now increasingly recognized that this early composition of the newborn gut microbiome plays a major role in lifelong disease risk, as well as the acute risk of infection by opportunistic or overt pathogens.^{1,2} For health care providers, this becomes a unique opportunity to influence acute drivers of dysbiosis as well as the trajectory of an infant's lifelong health through careful consideration of each of these factors.

Historically, it has been observed that the gut of breast-fed infants was uniformly colonized by *Bifidobacterium*, the keystone gut symbiont of infants.⁴ Early *Bifidobacterium* colonization has potentially profound and beneficial effects for the infant, including a role in important immunological and metabolic programming events in the first few months of life.² *Bifidobacterium longum* subsp. *infantis* (*B. infantis*) is a particular type of bifidobacteria that is well adapted to the infant gut, in part due to its ability to consume complex carbohydrates found in human milk.⁵ This diverse set of carbohydrates, called human milk oligosaccharides (HMO), naturally make up about 15% of nutrients in human breast milk. Remarkably, these complex carbohydrates are not digestible by the newborn. Instead, HMOs are consumed by bacteria in the infant large intestine, or otherwise excreted in the infant stool.

Dysbiosis – an Emerging Issue in Healthcare

Recent research in the area of the infant gut microbiome has shown that HMOs are preferentially consumed by certain strains of bacteria, such as *B. infantis*, which can convert these

carbohydrates to short chain fatty acids in the infant intestine. In the scientific literature, intestinal short chain fatty acids have been shown to lower intestinal pH, improve gut barrier function and serve as energy signaling molecules during growth and development.



An infant gut microbiome colonized by *B. infantis* and fed by human breast milk will flourish and minimize the growth of pathogenic bacteria.⁶ However, if beneficial bacteria such as *B. infantis* are not present, other potentially harmful bacteria can partially utilize these milk oligosaccharides for growth, such as *Streptococcaceae*, *Staphylococcaceae*, *Clostridiaceae*, and *Enterobacteriaceae* often found in the dysbiotic infant gut. High populations of *Enterobacteriaceae* are increasingly recognized as having a negative impact on long term health and represent gut community dysbiosis.^{2,7} Recent work has indicated that blooms of gut microbial populations associated with gut dysbiosis play a role in everything from colic to Type 1 Diabetes. Although probiotics are hypothesized to alleviate this dysbiosis, the reported results are not consistent across probiotic organisms. Notably, a recent publication reported for the first time that significant modification of the infant gut microbiome, and complete resolution of dysbiosis, is possible through probiotic feeding of *B. infantis* in breastfed infants.⁸

Safely Building a Healthy Infant Microbiome in a Hospital Environment

With new data emerging that supports the use and efficacy of probiotics in infants, special consideration must be used for use in a hospital setting. First, as discussed above, the selection of an infant-adapted bacterium along with the appropriate fuel source

Tracy Shafizadeh, PhD is a nutritional scientist and Director of Scientific Communications for Evolve BioSystems, Inc.

to promote growth of these beneficial bacteria is key to seeding and feeding a protective gut microbiome. Human milk has many well-known benefits for the newborn infant, and it now appears that human milk has an equally important role in shaping the infant gut microbiome. Additionally, the method of delivery is particularly important in a hospital setting, where quality, ease of use and adaptability to existing feeding protocols (ie. enteral feeding tubes) will play a role in both safety and efficacy of probiotic administration. As powdered formulations of dietary products are often not allowed in hospitals nurseries, a single use, liquid formulation probiotic would be not only preferred but required.

While considerable work is yet to be done to validate the efficacy of probiotics in reducing risk of disease, there must be a thoughtful rationale to choosing the appropriate beneficial bacteria, paired with the appropriate food source, and administered in the right form for maximum benefit.

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Reference: 1. Frese SA et al.
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Implementing Researched-Based Best Bathing Practice in the NICU and Well-Baby Nursery: Swaddle Bathing

Dana Denton, MPT and Susan Bowles, DNP, CNS, RNC-NIC, CBC

Stressful experiences can alter the structure and function of the preterm infant brain.^{1,2,3} “Routine” interventions in the NICU, while medically necessary, can result in undue stress to the newborn infant. The practice of developmental care strives to decrease infant exposure to stress and provide an environment for optimal development.⁴ Swaddle bathing an infant integrates the concepts of developmental care into the routine practice of bathing and enables the parents to be involved in infant care.^{5,6,7,8,9,10} Swaddle bathing is also recommended by the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) for preterm and newborn infants.¹¹

Bridging the gap between recommended practice and routine hospital care can be daunting. In an effort to help hospitals implement swaddle bathing, the Swaddle Bathing Clinical Guideline (Figure 1) was created. Our guideline is proposed based on scientific literature and current clinical practice. Changes and improvements to the guideline will occur based on further use and research.

Bathing has historically been a routine activity done in a quick fashion and without the necessary equipment to bathe the infant in a developmentally supportive manner. But with newly available products, immersion swaddle bathing is easily done in the hospital. Immersion swaddle bathing integrates four of the petals of the Neonatal Integrative Developmental Care model⁴ including: partnering with families, positioning and handling, minimizing stress and pain, and protecting the skin. In addition, by providing this calming activity, immersion swaddle bathing prepares the infant for comfortable sleep and more organized feeding.

In swaddle bathing, the infant is well supported, swaddled in a blanket, and immersed in warm water. The infant is calm. After swaddle bathing, the infant is able to participate in skin-to-skin holding, breastfeeding, bottle feeding, or the infant can sleep. Bathing without respect for stress cues and physiologic stability exhausts the infant both during and after bathing.^{5,6,9,12,13} A quick,

stressful bath can have long lasting instability and create more work for the caregiver. In addition, an exhausting intervention can cause an infant to lose an opportunity to practice eating.

“Family involvement is a key to realize the potential for long-lasting positive effects on their baby’s physical, cognitive and psychosocial development.”¹⁴ The family is an integral part of developmental care. The stress associated from having an infant in the NICU can lead to Acute Stress Disorder (ASD)¹⁵ and or symptoms similar to Post Traumatic Stress.¹⁶ Infants in the NICU are whisked away from their parents and placed in a medical environment where the parent is not the primary caregiver. Guilt, loss of control, fear, stress and uncertainty are all common emotions felt by parents in the NICU. Involving parents in infant caregiving improves confidence.¹⁷ Involving fathers specifically helps prevent disengagement and promote interactions.¹⁸ Swaddle bathing is one of the few “typical” parenting activities in the NICU. Pictures of the first bath are positive, tender memories from a difficult period of parenting. Learning a calm bathing skill also transfers to caregiving at home.

Swaddle bathing is beneficial to not only preterm infants, but also to full-term infants with Neonatal Abstinence Syndrome (NAS) and to healthy full-term infants.

Swaddle Bathing for the Well-Newborn Infant

Delayed bathing practices have been endorsed by AWHONN and the World Health Organization (WHO)^{11,19} to enhance parent/infant bonding, enhance breastfeeding, and physiologically stabilize the newborn infant. The AWHONN Neonatal Skin Care Guideline recommends bathing newborn infants between 2-4 hours after birth and the WHO recommends bathing at 24 hours if possible, but at least 6 hours after birth. Delayed bathing practice also gives the family time to recover from delivery and participate in caring for their newborn. This is a perfect opportunity to educate parents on the researched-based bathing method of swaddle bathing. The protective vernix covering can remain intact during the bath when vigorous scrubbing is avoided. With swaddle bathing the first bath moves from a cringe-worthy activity with an infant crying and flailing, to a calm, nurturing activity that families can continue at home. The authors believe that this experience will likely influence patient satisfaction.

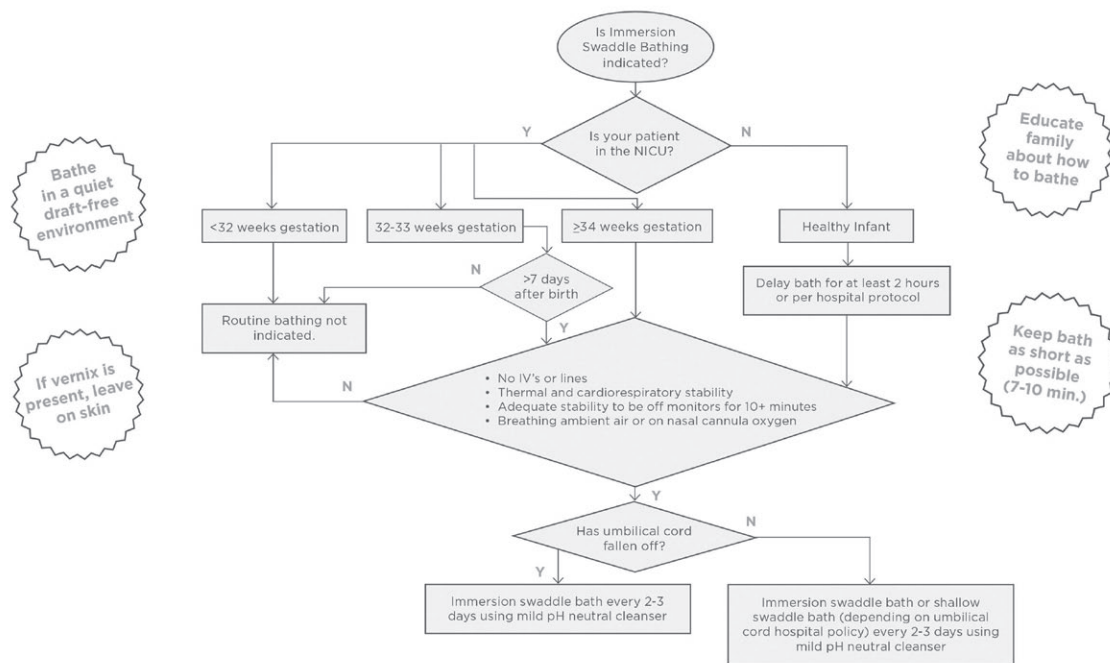
Swaddle Bathing for the Infant with Neonatal Abstinence Syndrome

From 1999-2013 the overall incidence of NAS has increased

Dana Denton, MPT is a Pediatric Physical Therapist with over 20 years of clinical experience. The last 10 years she has worked in the NICU at Intermountain Medical Center. Her mission is to improve the long term functional outcomes of infants. She is a co-founder and Clinical Specialist for Catapult Products, LLC. Susan Bowles, DNP, CNS, RNC-NIC, CBC is a doctorally prepared Clinical Nurse Specialist with 30+ years of experience in Neonatal Care. Sue is an advocate for the development and use of evidence based practices with babies and their families.

Figure 1

Swaddle Bathing Clinical Practice Guideline*



*This guideline was compiled from available literature and is for educational reference only. Although every effort has been made to report faithfully the information, the editors and publisher cannot be held responsible for the correctness. Catapult Products LLC and their editors disclaim any liability arising directly or indirectly from the use of this guideline.

300% from 1.5 per 1,000 hospital births to 6.0 per 1,000 hospital births.²⁰ The aggregate hospital cost for NAS increased to \$1.5 billion in 2012.²¹ Some of the common symptoms of NAS include: irritability, GI disturbance, high-pitched cry, hypertonia, sweating, congestion and tremors. Infants with NAS are currently treated in the hospital with pharmacological interventions, although with the epidemic numbers of infants exposed to NAS, alternative ways of treatment are developing such as Lily's Place in West Virginia where parents and infant live together as they work through withdrawal.

Strong research in non-pharmacologic treatment for NAS is sparse.²² Breastfeeding, rooming-in and prone positioning are shown to be effective treatments for NAS.²² Clinically, comfort measures for infants with NAS include swaddling, dim lighting, quiet environment, and a pacifier.²³ Hydrotherapy has long been used as treatment for hypertonicity, and anecdotally, swaddle bathing has a calming effect on infants with NAS. It is a typical activity for the parents to do with their infant that can be transferred to home. Specific research on swaddle bathing and NAS is warranted.

Our Guideline

Our guideline is proposed as a starting point to help hospitals implement research-based swaddle bathing. It is an evidence based intervention that translates easily into clinical practice. Key features of the guideline include the importance of including the family during bathing and keeping bath time between 7-10 minutes. Additionally, environmental stressors such as drafts and noise need to be controlled.

Assessment for whether an infant is ready for immersion swaddle bathing starts at age of 32 weeks gestation. The

AWHONN Neonatal Skin Care Guideline recommends using warm water, soft materials and no rubbing prior to 32 weeks. The protective stratum corneum skin layer develops at this time. At 32 weeks the infant is entering the phase of development where they can tolerate a little more stimulation and are more physiologically stable.²⁴

Waiting 7 days after birth to bathe the preterm infant from 32-34 weeks gestation optimizes stability in this more fragile group of infants. For skin-to-skin holding, WHO, suggests that low birthweight infants from 1200-1799g (gestational age of 28-32 weeks) may need to wait a week or more before having the medical stability for skin-to-skin holding.²⁵ Edrika's study on swaddle bathing in preterm infants, the babies were at least 7 days old. Bathing can be a more taxing activity than skin-to-skin holding so the criteria of 7 days was added to the guideline for infants between 32 and 33 weeks gestation. The medical stability is the most important criteria for bathing regardless of gestational age or days of life. Clinical judgement must always be made on the ability of the infant to tolerate a bath, even the most developmentally supportive bath.

Physiologic stability must be assessed prior to starting an immersion swaddle bath, since bathing requires the infant to be off the monitor to safely perform. If the infant is not determined to be safe without monitoring for 10 minutes, then the infant should not be immersion swaddle bathed. Basic health parameters including thermal and cardiorespiratory stability and no central lines should be established prior to bathing. Infants can be immersion swaddle bathed with nasal cannula oxygen and nasogastric and orogastric feeding tubes. Tube placement should be checked after the bath since the tape can loosen with moisture.

Choosing A Tub

Hospitals should consider providing a new bathtub to each family for several reasons. The family will become familiar with how to successfully give a bath in the hospital, and the technique can then easily be transferred to home. One bathtub per infant will reduce risk of cross-contamination. Studies have shown that hospital wash basins (even after cleaning) are frequently contaminated with pathogens.^{26,27} In addition, the authors believe that providing a bathtub to a family can positively impact patient satisfaction scores. Multi-use bathtubs can also be used, but they must have a disposable liner to reduce the risk of cross-contamination (Figure 2). Cleaning protocols need to be in place for both single-patient-use tubs and multi-patient-use tubs, and the tub should be free of tight corners and small spaces in order to be cleaned thoroughly between uses. The tub should also be void of foam due to the inability to clean foam adequately.

Figure 2



Additional features to be considered: Does the tub adequately support the infant without using ancillary towels? Can the tub be used to bathe preterm and full-term infants? Does the size of the tub fit on a workspace, a warmer bed or cart? Is it easy to lift and carry when filled with water? Does the tub have a water temperature measurement feature? And, is the water easy to pour out to avoid spills? The TurtleTub swaddle bathing system (Figure 2) satisfies these criteria. The swaddling blanket material should also be considered. Fleece stays warmer than cotton when wet and it dries faster than cotton. When swaddling an infant for bathing, a fleece blanket will sustain the water temperature better than a cotton blanket. The fleece can be laundered according to the hospital protocol for infant clothing and reused on more than one infant.

Conclusion

Swaddle bathing an infant provides a developmentally supportive bathing method for preterm infants, infants with Neonatal Abstinence Syndrome and full-term infants. When a family is taught how to swaddle bathe their infant, they participate in a typical parent activity that transfers to home care. As a starting point in defining infants for bathing, our Swaddle Bathing Clinical Guideline gives direction on how to implement swaddle bathing based on current research and clinical use. The TurtleTub swaddle bathing system bridges the gap between recommended practice and routine infant bathing. Hospitals now have the tools to use swaddle bathing as a routine bathing method to decrease stress, maintain temperature and involve families in infant caregiving.

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Beta Lactamase Negative Haemophilus Influenzae Sepsis in a Premature Infant Associated with Chorioamnionitis and Funisitis

Shabih Manzar, MD, and Liaqat H Khan, MD

Case

Infant was born at 32 weeks of gestation to a 27-year old gravida 4, para 3 mother. All antenatal labs including HIV, Hepatitis B, and rapid plasma reagin test were negative. There was no history of sexually transmitted diseases. Pregnancy was complicated by premature rupture of membrane (PROM) for > 24 hours and preterm labor. Mother received two doses of betamethasone prior to delivery. Apgar scores were 6 and 8 at one and five minutes respectively. Infant's birth weight was 1970 grams, head circumference 29.5 centimeters and length 43 centimeters.

On admission to the Neonatal Intensive Care Unit (NICU), physical examination was normal for gestational age. The vital signs showed a temperature of 101.1° F, heart rate of 179 beats per minute, respiratory rate of 38 per minute and blood pressure of 77/37 mmHg. A septic work up was done including complete blood count and blood culture and infant was started on ampicillin and gentamicin. For respiratory support, infant was placed on Bubble CPAP. Chest X-ray (Figure 1) was not suggestive of pneumonia or hyaline membrane disease. Blood gas on admission was pH of 7.20, pCO₂ of 74, PO₂ of 41, and HCO₃ of 22 on 26% FiO₂. Follow up blood gas at 8 hours of life showed improvement with pH of 7.35, pCO₂ of 38, PO₂ of 124, and HCO₃ of 21 on 21% FiO₂.

Table 1. Laboratory indices

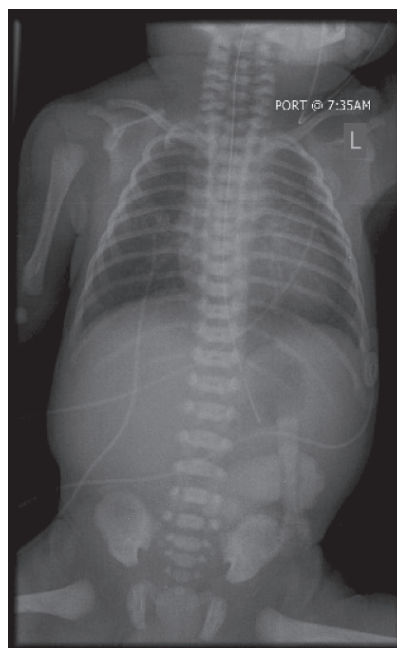
Laboratory Test	Day 1	Day 3	Day 4	Day 5
Hs-CRP (mg/L)	60.5	34.5	7.2	—
Procalcitonin (Ng/ml)	>100	47.9	1.31	0.46
White blood cell (K/mm ³)	3.7	4.3	6.9	10.3
Segmented	6%	61%	64%	44%
Bands	2%	12%	4%	none

Hs-CRP – High sensitivity C-reactive protein

Infant was started on intravenous fluids. Feeds were started on day of life two and gradually advanced to full feeds. Infant's respiratory status continued to improve and infant was in room air by day 3. The admission labs were suggestive of sepsis, see Table 1. The blood culture drawn at admission was positive for *Haemophilus Influenzae* (HI), which was sensitive to Ampicillin. The repeat blood culture in 24 hours was negative. A spinal tap was performed.

Both authors are with the Neonatal Intensive Care Unit in Rapides Regional Medical Center, 211 Fourth Street, Alexandria, LA 71301. Telephone: 318-769-7160/7791. Fax: 318-769-7473. shabihman@hotmail.com.

Figure 1. Chest X-Ray obtain soon after birth



Results showed sterile Cerebrospinal fluid. Placental pathology showed chorioamnionitis and funisitis. Infant received a 7-day course of Ampicillin and was discharged home in stable condition with follow up with Pediatrician.

Discussion

Bacteria involved in early neonatal sepsis are mainly *group B streptococcus* and *Escherichia coli*. HI infection is not very common in early neonatal period. One of the important risk factors for the early onset HI neonatal sepsis is PROM > 24 hrs, as observed in the case.

The role of PROM in HI infection has been reported earlier¹. On admission, the clues to infection were high temperature, low white blood cell count and elevated acute phase reactants, viz. C-Reactive Protein and procalcitonin. The placental pathology report showed chorioamnionitis and funisitis. The association of chorioamnionitis with nontypeable HI (NTHi) has been described in literature.^{2,3}

HI are classified into HI a, b, c, d and NTHi.⁴ The infection noted in the neonate was beta lactamase negative HI sensitive to ampicillin. HI used to be common infection in infants and young

children but with the advent of global HiB vaccine, the disease spectrum has changed in children. The case presented pose an important question regarding maternal HiB vaccine status and early onset HI neonatal infection.

In summary, high suspicion and early treatment remains the mainstay of management of early onset neonatal sepsis secondary to HI to decrease the associated mortality and morbidity.

The question arises from the case on the possible association of maternal HiB vaccine status and risk of HI infection in neonates, needs further evaluation.

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Carinal Capnography in High Frequency Percussive Ventilation (HFPV)

Curt Partain RCP, RRT-NPS,¹ Stephen J Elliott MD,²
Hank Perry RCP, RRT,³ Michelle Eichbrecht MBA, RRT⁴

Background

Capnography or end tidal carbon dioxide (EtCO₂) monitoring has not been broadly adopted in the Neonatal Intensive Care Unit (NICU) due to technical problems such as leakage around an uncuffed endotracheal tube (ETT), dead-space in the airway adapter, and its perceived inaccuracy in conditions of ventilation-perfusion mismatch.^{1,2} However, the NICU at Community Regional Medical Center (CRMC; Fresno, CA, USA) evaluated the utility of an FDA-cleared, but not yet commercially available product (Carinal Vitaline™ sampling line, Medtronic, Boulder, CO, USA), allowing the option to monitor EtCO₂ during both conventional and high-frequency ventilation (HFV) by means of sampling the breath from the distal end of a special ETT (near the carina) to obtain a distal end-tidal carbon dioxide (dEtCO₂). The configuration is shown in Figure 1.

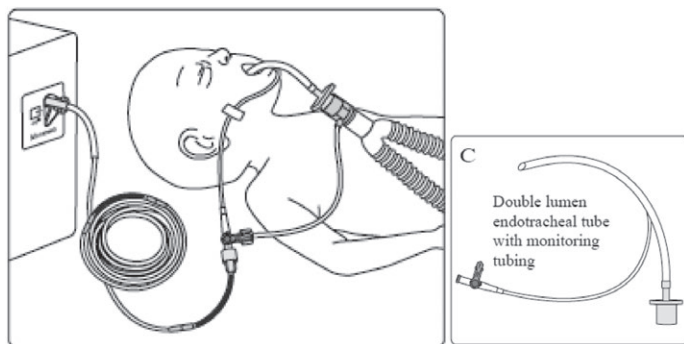


Figure 1. At right, the dual lumen ETT contains a sampling lumen that runs the length of the tube from the distal (carinal) end of the tube to a 3-way stopcock. At left, the sampling lumen is connected to the 3-way stopcock. The side-port of the 3-way stopcock connects to an airway adapter, similar to the traditional airway adapter that is attached to the ETT. The third port of the 3-way stopcock is connected to the monitor via a FilterLine™ sampling line. The stopcock can then be positioned to sample from the airway or from the sampling lumen at the carinal tip of the ETT.

Carbon dioxide is an important vasoactive agent, especially in cerebral circulation. Stable cerebral blood flow in the developing premature brain depends in part on the prevention of wide swings in arterial pCO₂ and avoidance of over-ventilation with concomitant severe hypocarbia. Furthermore, there is an imperative in the NICU to decrease phlebotomy and so reduce the need for replacement transfusions. Current non-invasive technology includes transcutaneous monitoring (TCM) which

can be highly problematic in very premature infants with fragile skin. Thus, continuous non-invasive monitoring of ventilation, especially from alternative modalities, might help accomplish these objectives.³

At CRMC, High Frequency Percussive Ventilation (HFPV) or more descriptively, High Frequency Pulsatile Flow Ventilation (HFPPV), is achieved using a Volumetric Diffusive Respirator (VDR; Percussionaire Corp., Sandpoint, ID, USA). The VDR4 model provides a hybrid form of ventilation that creates convective-type tidal breaths and positive end expiratory pressure (PEEP) using high frequency pulses of flow.

HFPPV is delivered via the Phasitron® system. Gas is pulsed through a jet orifice while a venturi body slides back and forth on a millisecond basis and serves as the inhalation and exhalation valve. Humidified and blended gases are entrained through a dedicated entertainment port. A series of rapid high-frequency pulses of flow (200 to 900 per minute) at sub-tidal volumes are stacked in a successive stepwise pattern that result in the formation of both PEEP and low-frequency convective pressure control type breaths. Lung volume is progressively increased during inspiration with sub-tidal volume delivery until an oscillatory plateau is reached and maintained at end-inspiration. Passive exhalation occurs during an oscillating end-expiratory pressure.⁴

The clinical case below describes the first time the Capnostream™ 20p bedside capnography monitor with HiFi software and the Carinal Vitaline sampling line has been used with HFPPV and specifically with the VDR4. The Capnostream 20p bedside capnography monitor and VDR4 are shown in Figure 2. Waveforms and numeric readouts of pCO₂ are displayed on the Capnostream 20p monitor (Figure 3). During HFPPV via the VDR4, the Capnostream20p tracked end-tidal CO₂.

Case Report

This 24 week, 705 gram male infant was born to a 35 year old gravida 3 para 0 mother after a pregnancy complicated by preterm labor and by short cervix requiring cerclage. Because of the high risk of preterm delivery, the mother received betamethasone at 23 weeks. She presented to the hospital in advanced labor and was taken for urgent cesarean section.

At delivery, Apgar scores were 1, 5, and 5. The infant was intubated and given surfactant (Curosurf, Chiesi USA, Cary, NC, USA) and umbilical arterial and venous lines were placed. He

The authors are with the Community Regional Medical Center, Fresno, California, USA (1,2,3) and University of California San Francisco, Fresno, California, USA (2) and Medtronic, Boulder, CO, USA (4).

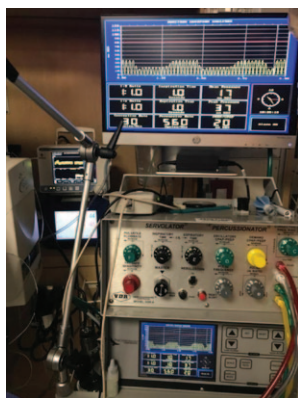


Figure 2. The VDR4 with Capnostream 20p bedside capnography monitor in the background on the left.

remained intubated on mechanical ventilation for 48 hours using a Drager VN500 ventilator (Drager, Telford PA, USA) in pressure control mode with volume guarantee. The infant was extubated to bubble continuous positive airway pressure (BCPAP) but required re-intubation at age 8 days and was then ventilated with the VDR4.

He had a stormy neonatal course due to intercurrent episodes of sepsis and at age 31 days developed fulminant necrotizing enterocolitis necessitating aggressive resuscitation. At age

64 days, post-menstrual age 33 weeks and 2 days, and weight of 2150-grams, the infant was on HFPV but required elective re-intubation. He was intubated with the dual lumen ETT size 3.0. Serial blood gas determinations and transcutaneous CO₂ readings were obtained as part of his routine care. In addition, EtCO₂ and dEtCO₂ measurements were recorded (Figures 2 and 3).

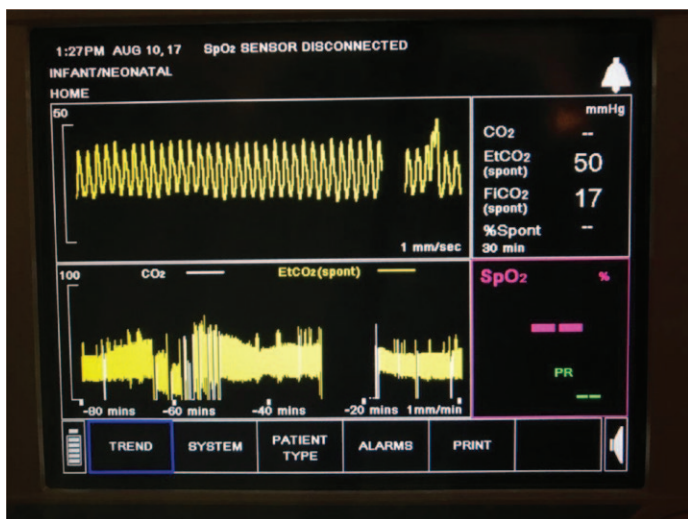


Figure 3. The waveform on the Capnostream 20p bedside capnography monitor during use with the VDR4 ventilator. In the upper right panel, pCO₂ is displayed in 3 fields; the field labeled “CO₂” displays mixed end tidal pCO₂, the field labeled “EtCO₂ (spont)” displays measured pCO₂ from either the carina or the ET adaptor, and the field labeled “FICO₂” displays the value of rebreathed pCO₂. Typically, when used in conjunction with high frequency oscillator ventilation (HFOV), the Capnostream 20p bedside capnography monitor displays measured pCO₂ in the CO₂ (mixed end tidal) field because it cannot discriminate inhalation/exhalation. By contrast, while monitoring the current patient on HFPV via the VDR4 ventilator, EtCO₂ (spont) and FICO₂ (spont) values were displayed, indicating that the Capnostream 20p bedside capnography monitor was able to discriminate between inhalation and exhalation, as it would during conventional ventilation. Left upper panel shows EtCO₂ signal at 1 mm/sec; left lower panel shows same signal on a trend function at 1 mm/min.

Comparison between measurement modalities

Carinal measurements were compared to pCO₂ values obtained by capillary blood gas (CBG), TCM and EtCO₂ at the airway adapter. Whereas CBG and TCM values reflect systemic measurement of pCO₂, EtCO₂ and dEtCO₂ are pulmonary measurements. Figure 4 (left) shows the correlation of 16 CBG values versus dEtCO₂ sampled from the carina using the Carinal

Vitaline sampling line solution. Figure 4 (right) shows the correlation of pCO₂ obtained via TCM versus dEtCO₂ sampled from the carina. The correlation coefficient between dEtCO₂ and CBG was 0.655, and between dEtCO₂ and TCM was 0.755. Figure 5 shows simultaneous TCM and Capnostream 20p bedside monitoring with representative pCO₂ values. Figure 6 shows pCO₂ values obtained from TCM and the Capnostream 20p monitor trended over a 2-day time period.

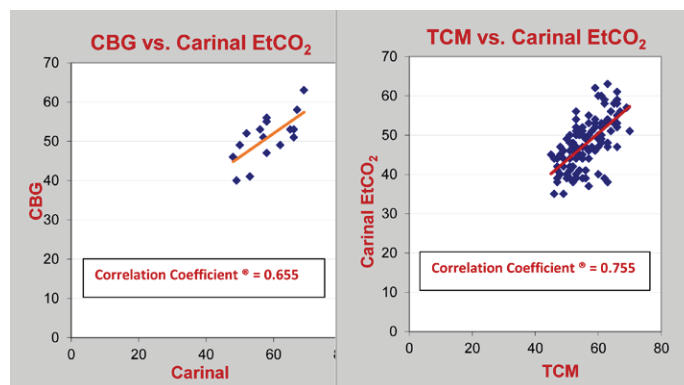


Figure 4. Left: Comparison of carinal pCO₂ (dEtCO₂) versus pCO₂ obtained via capillary blood gases (CBG; n = 16). Right: Comparison of dEtCO₂ versus pCO₂ obtained via TCM (n = 117).



Figure 5. Capnostream 20p bedside capnography monitor pictured with a value of 49 on the top and TCM monitor with a value of 51 on the bottom during real-time monitoring of the presented patient.

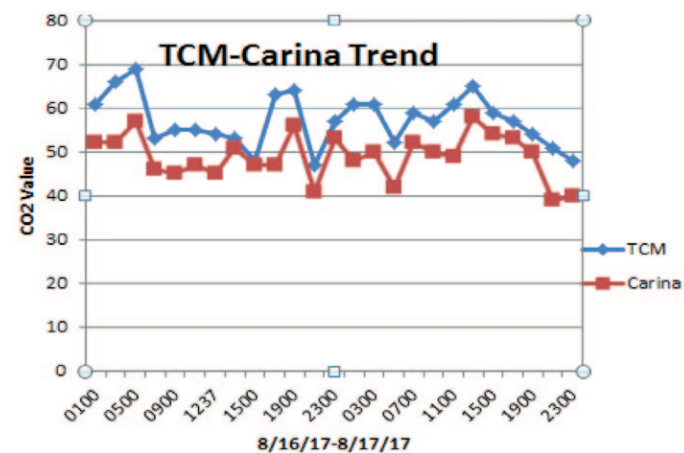


Figure 6. Shown are pCO₂ values obtained from the presented patient. Values for dEtCO₂ (red) versus pCO₂ measured via TCM (blue) are trended over a 2-day period.

Summary and Conclusion

In summary, dEtCO₂ values indicated that the Capnostream 20p bedside capnography monitor dual lumen ETT system was able to detect tidal changes in pCO₂ during HFPV via the VDR4 ventilator in an NICU patient. The correlation coefficient between dEtCO₂ and pCO₂ measured by TCM was 0.755 and when trended over a 2-day period, values appeared to move in synchrony. This case report suggests that use of dEtCO₂ may decrease the need for TCM monitoring, decrease trauma to fragile skin, and further decrease the need for phlebotomy and blood gas analysis.

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Of Social Justice and Nursing Theory: Two Rationales for Treating Pain and Stress for Infant Endotracheal Intubation

Curtis Caldwell, PhD, NNP-BC

Endotracheal intubation is a common procedure in Newborn Intensive Care Units (NICU). It is a procedure that is considered to be both stressful and painful, yet many infants are not sedated or offered pain medication for this procedure.¹ In 2010, the American Academy of Pediatrics recommended that all locations that intubate infants develop a written protocol for premedication for this procedure.² We conducted an observational study in our NICU to determine what medications were being used to premedicate for intubation and the effects of those medications on the pain and stress reaction to the procedure.³ We found that less mature infants were less likely to be premedicated for intubation than infants closer to term adjusted gestational age. Imbedded in that study was an evaluation of the effect of swaddling as an adjunct method for the control of pain and stress during endotracheal intubation. This article addresses the outcome of the use of adjuvant pain control methods and encourages their liberal use by nursing staff for those infants premedicated and not premedicated for endotracheal intubation.

Background and Significance

Guiding principles for equal pain treatment across gestational ages are Carper's "fundamental patterns of knowing"⁴ with the addition of Chinn and Kramer's emancipatory knowing.⁵ Emancipatory knowing places social justice in the forefront of care and emphasizes the need for the ethical treatment of pain and stress in preverbal individuals who are dependent upon their caregivers for the interpretation of their pain and its management. Carper identified four fundamental patterns of knowing from an analysis of the conceptual and syntactical structure of nursing knowledge; 1) empirical, 2) personal, 3) ethical and 4) aesthetic. These basic concepts formed a foundation for understanding this research.

Chinn and Kramer expanded on these fundamentals of knowing with the addition of emancipatory knowing. Emancipatory knowing, also referred to as "critical theory" research, has as its end goal as the liberation from oppression that lead to inequities in health care and health disparities.^{5,6} Such disparities exist in a population such as infants who do not have the ability to advocate for themselves, and must rely on their healthcare providers to ensure equitable and humane treatment. Emancipatory knowing in nursing is expressed by "understanding that the social context in which care is given

determines the nature of care provided and affects the health and well-being of individuals and groups."^{5,p2} Their concept of emancipatory knowing is based on historical nursing action regarding the social and political context of nursing and health care disparities.⁵ Emancipatory knowing examines existing social, cultural, and political systems in an effort to determine how injustices arose. Infants have long suffered from misconceptions regarding their ability to experience pain and what the consequences of those painful experiences may be. In the instance of adequate sedation for endotracheal intubation, infants have been denied adequate pain control due to fears of side effects of the medication or the belief that infant pain has no long-term consequences.

Critical inquiry is committed to social justice and advocacy and was derived from the evolution of critical social theories such as those developed by Karl Marx, Max Weber, members of the Frankfurt School, including Jurgen Habermas, and other theorists such as Paulo Freire and Foucault. Nursing's commitment to emancipatory knowing dates back to such historical figures as Florence Nightingale and Lillian Dock, and more recently to the influence of the women's movement on a growing number of nurse scholars in the latter half of the 20th century.⁵ The expansion of nursing doctoral programs in the last 20 years has resulted in a reexamination of the philosophical foundations of nursing science. Through this expansion, nursing has become directly involved in changing health care policies, health care disparities, and other social injustices. Nurses are taking seriously the dual role of questioning the status quo and imagining an equitable society.^{7,8} Our study was undertaken in the spirit of this emancipatory philosophy directed towards one voiceless and powerless population, infants.

The debate regarding the reality of infant pain and its potential consequences has been long standing. Hippocrates believed that having had a history of a painful experiences prepared one to be able to endure it: "those who are used to endure pain, even if weaker and older, cope with it better than the young and strong ones, who are not used to it."^{9,p154} Luis de Granada, 16th century theologian, viewed infants as "a lower animal in human form" which implied infants were not accepted as real people with real feelings having real experiences. The first article on the use of anesthesia was published in 1848.¹⁰ Its use quickly became commonplace, but not for everyone. Physicians were taught to consider sex, race, age, ethnicity, economic class, personal habits, and temperament before using anesthesia, suggesting that infants did not require its use. Dr. Bigelow, a surgeon, wrote for

Curtis Caldwell is a Neonatal Nurse Practitioner, Newborn Intensive Care Unit at the University of New Mexico.

the American Medical Association in 1848 that anesthesia was not necessary for infants because they lacked the anticipation and remembrance of suffering and the very young lacked the mental capacity to suffer.¹¹

In contrast, Surgeons Samuel Gross and Eliza Thomas stated: "The young are innocents, unconscious of the motive for the surgery, and they should be saved from suffering."¹⁰ Felix Wurtz, a Physician, wrote in 1656,

"If a new skin in old people be tender, what is it you think in a newborn Babe? Doth a small thing pain you so much on a finger, how painful is it then to a Child, which is tormented all the body over, which hath but tender grown flesh? If such a perfect Child is tormented so soon, what shall we think of a Child, which stayed not in the womb its full time? Surely it is twice worse with him."¹²

Literature Review

Good and Moore have developed a middle-range theory that proposes a balance between pharmacological and non-pharmacological pain management. This combined management approach stresses an interaction between the nurse and patient in which feedback and collaboration minimizes the use of pharmacologic agents and their accompanying side effects while effectively controlling post-operative or procedural pain.

Their theory focuses on the interventions and general nursing actions that reduce pain and the side effects of pain medications. This theory was developed because research shows that intense pain is unnecessary, unethical, and related to complications. Pain control is achieved by using an attentive goal directed process, multiple strategies for relief including pharmacologic and non-pharmacologic adjuvants, and patient participation¹³. The theory is summarized as a prescription. To achieve a balance between analgesia and side effects in patients with moderate to severe acute pain, the nurse should administer analgesics plus pharmacologic and nonpharmacologic adjuvants. The nurse further assesses pain and side effects regularly, and teaches patients to participate in their pain control. If an unacceptable degree of pain persists or excessive side effects occur, the nurse should intervene, reassess, and re-intervenes as needed to meet the relief goal¹³.

Neonates in a neonatal intensive care unit are exposed to a large number of painful procedures. Since repeated and sustained pain can have consequences for the neurological and behavior-oriented development of the newborn, attention needs to be paid to systematic pain management in Neonatology.^{14,15} Non-pharmacological treatment methods are being increasingly incorporated into pain prevention and relief, either alone, or in combination with pharmacological treatment.^{16,17}

A number of randomized controlled studies have considered the question of nursing practice regarding non-pharmacological pain management methods in infants. The most common interventions used were "non-nutritive sucking," "music," "swaddling," "positioning," "olfactory and multi-sensorial stimulation," "kangaroo care (skin-to-skin contact)" and "maternal touch." There is evidence that the methods of non-nutritive sucking, swaddling and facilitated tucking do have pain-alleviating effects on neonates.¹⁸ Some of the non-pharmacological interventions show evidence of favorable effects on pulse rate, respiration and oxygen saturation, the

reduction of motor activity, and the excitation state after invasive measures. Further research should emphasize the use of validated pain assessment instruments for evaluation of pain-alleviating effects of non-pharmacological interventions.¹⁸

Infants are dependent on their caregivers for receiving compassionate treatment. Often the victims of unjust treatment, they need a voice to counter the social and institutional wrongs they suffer such as inadequate pain and stress relief. Nurses have a history of recognizing that infants experience pain and have advocated for the use of pain control in this vulnerable population. Adults no longer tolerate their pain being ignored, having become emancipated in their own medical treatment. There has also been recognition of the social as well as medical value of pain control in pediatrics. Children are now receiving conscious sedation for procedures such as lumbar punctures, MRI scans, and placement of central lines. They are also given nerve blocks for the insertion of central lines.¹⁹ Pain issues are beginning to be a dominant aspect of patient care and nurses have been at the forefront of this advocacy for infants, children and adults. Virginia A. Henderson said it best; "The nurse is temporarily the consciousness of the unconscious, the love of life for the suicidal, the leg of the amputee, the eyes of the newly blind, a means of locomotion for the infant, the knowledge and confidence of the young mother, and a voice for those too weak to speak."²⁰

The theory of acute pain management developed because research demonstrated that intense pain was unnecessary, unethical, and related to complications.²¹ It focuses on the general nursing actions that decrease pain and simultaneously reduce the use of narcotics and the risk of their side effects.

A variety of non-pharmacological treatments have been studied for pain and stress control in infants. These interventions include both environmental and behavioral strategies. These strategies reduce neonatal pain both directly, by blocking nociceptive transduction or transmission or by activating descending inhibitory pathways, and indirectly by reducing the total amount of noxious stimuli to which infants are exposed.²² Non-pharmacological interventions have short-term efficacy, good tolerability, and are widely recommended for preventing and managing pain.²³ They can be readily implemented by nurses, rarely require a medical order, and should be used systematically before painful or stressful procedures to preserve the well being of the neonate.¹⁸ These interventions are not substitutes or alternatives; instead they are complementary to pharmacologic interventions that must be used if needed.¹⁸

This middle-range theory of balance between analgesia and side effects contains three propositions that predict the outcome of the balance between narcotics and side effects. These propositions predict that multimodal intervention, attentive pain management, and patient participation contribute to the balance between analgesia and side effects. The balance is vital in infants because opioid use carries the risks of apnea, hypoventilation, hypotension, bradycardia, and cyanosis.²⁴ These side effects should be countered by the careful and judicious use of narcotic agents. Controlling potential analgesic related side effects while maintaining an adequate degree of pain attenuation is important for ethical, humanitarian, and economic reasons.²⁵

In formulating the theory of acute pain management, Moore and Good used statement synthesis procedures to formulate their

three propositions, two of which are applicable to neonates.²⁶ The first proposition, multimodal intervention, was based on randomized controlled trials that have shown the effectiveness of pharmacologic and nonpharmacologic modalities for treatment of pain. The second proposition, attentive care, was determined by 20 years of research that showed patients with acute pain suffer needlessly due to the failure of physicians and nurses to routinely assess and intervene with pain symptoms until the pain is controlled. The third proposition, patient participation, uses patient teaching and patient goal setting for pain relief, contributing to the achievement of a balance between analgesia and side effects.

The two propositions of the theory of acute pain management, as applied to infants are multimodal intervention and attentive care. Multimodal intervention refers to giving pain medication along with pharmacologic and nonpharmacologic adjuvants, which together contribute to achieving a balance between analgesia and their side effects. Nonpharmacologic measures to control pain in infants include swaddling, pacifiers, noise control, and light control.²⁷ Attentive care involves regular and reoccurring pain assessment, assessment of side effects, identification of unrelieved pain and unwanted side effects, and a process of intervention, reassessment, and re-intervention, all of which contribute to a balancing of pain relief and side effects. As a component of our study the nursing staff were observed during intubation to determine if swaddling was used as an adjuvant pain control measure during endotracheal intubation and what the effect that had on the pain and stress reaction.³

Methods

Our study examined the effect of premedication for intubation on the pain and stress response to the procedure.³ The Institutional Review Board with waiver of informed consent approved this study. Additional data collected in that study examined whether there was a significant difference in pain score and change in blood glucose level during intubation when infants were swaddled, after removing the effects of premedication. There were multiple dependent variables for this question; therefore, the statistical tool employed was MANCOVA.

The measurements for the dependent variables are interval and ratio. Analysis of this data was done using MANCOVA with swaddling as the independent variable and mean difference DAN score, mean difference glucose level, mean number of intubation attempts and mean laryngoscope dwell time as the dependent variables. The covariate was whether premedication was used. After controlling for the effect of premedication, swaddling remains significant for blood glucose change and DAN score. There was a statistically significant difference in change in blood glucose and DAN score in neonates who had been swaddled compared to those who had not ($p=0.001$; $p=0.047$), but no difference on total number of attempts ($p = .898$) or on the total time required for intubation ($p = 0.781$). Infants of all gestations exhibited a lower pain score and a small change in their blood glucose when swaddled as opposed to not swaddled. This was true whether they were premedicated for the intubation or not.

Results

Less mature infants were less likely to receive premedication or swaddling for intubation. Sedation for intubation is recommended by the AAP for all infants undergoing this procedure. The neurological developmental progress by which even the most premature infants experience pain has been

Summary of Recommendations Table

What we know	<ul style="list-style-type: none"> Intubation is a common procedure in the NICU Intubation is a painful and stressful procedure, even for newborns Infants deserve the same consideration for sedation and pain control during intubation as other populations
What needs to be studied	<ul style="list-style-type: none"> Stress levels of infants during intubation Ideal medication(s) for premedication for intubation Alternatives to intubation
What can we do today	<ul style="list-style-type: none"> Encourage sedation for endotracheal intubation Swaddle infants for endotracheal intubation Advocate for non-invasive respiratory support
Implications for Practice	<ul style="list-style-type: none"> Swaddling is a simple and effective measure that nurses can use to reduce the pain and stress reaction of infants to endotracheal intubation
Implications for Research	<ul style="list-style-type: none"> Future research should focus on additional non-pharmacologic adjunctive practices that may reduce the pain and stress of infant intubation
What This Study Adds	<ul style="list-style-type: none"> Swaddling is a safe and effective non-pharmacologic adjunct to pain and stress control during neonatal endotracheal intubation. It is a technique that can easily be employed by nurses and has shown to be effective regardless of whether pain and or sedation premedication is used

well documented^{28,29} and is now generally accepted by infant caregivers. Those that care for these patients no longer accept the fallacy that infants in general, and the most premature infants in particular, cannot feel pain. The smallest of infants can easily be intubated without premedicating. It is a simple matter to hold them down while the intubation occurs. However, infants as young as 24 weeks gestation are noted to cry, wave their arms and kick their feet during non-medicated intubation. The tenants of critical social theory demand equal treatment across social, cultural and racial groups. Emancipatory knowing is based on historical nursing action and a literature concerned with the social and political context of nursing and health care, and the social injustices that were witnessed⁵. Infants continue to be inadequately treated for endotracheal intubation and those with the least strength to fight the procedure are the least likely to be treated.

Use of Adjuvant Pain Control Techniques

Of the non-pharmacological techniques available, the one most appropriate for intubation is swaddling. Infants show a decrease in response to external stimuli when placed in a tucked position with their hands positioned near their face and with boundaries.¹⁸ Swaddling infants in the tucked position with their hands near their face accomplishes both the proper position and the establishment of boundaries. Swaddling reduced the pain response to intubation in our study as shown by a statistical difference in the change in blood glucose and lower DAN scores. However, infants ≤ 30 weeks adjusted gestational age were less likely to be swaddled or medicated for intubation. A total of 74 (44.6%) infants were swaddled. Of the 99 infants (59.6% of total) that were greater than 30 weeks adjusted gestational age, 61 (62.3%) were swaddled, while only 13 (17.6%) of the 67 (40.4% of total) infants who were less than or equal to 30 weeks gestational age were swaddled. Swaddling older, larger infants accomplishes two goals; they are more likely to be calm for the procedure in this position, and those that are not sedated should

be easier to intubate with their activity contained by the restraint of swaddling. Fair and equal treatment of all infants regardless of gestational age requires equal application of adjuvant pain control techniques.

Discussion

Social and structural change is one of the responsibilities of nursing. Nurses recognize social and political instances of injustice and inequality, and are obligated to intervene when a problem is recognized and its rectification could improve the quality of a life. Within the context of emancipatory knowing, the theory of acute pain management can be applied to the neonate through the nurse who recognizes injustices, examines why the injustice is allowed to persist, and identifies social and structural changes needed to correct the social and institutional wrongs.³⁰ The goal in emancipatory knowing is freedom from institutional and institutionalized social and political contexts that confirm their sustenance. Change occurs when the current situation becomes intolerable and the status quo is questioned. When the acknowledged situation or condition is identified as unjust and the accepted treatment is challenged, the emancipatory process is set in motion. Once in motion, it can take on a life of its own, but current practices can be very difficult to change. Nursing can effect change in practices by advocating for adequate pain and stress treatment in infants. Swaddling does not require a written order; it can be done at the nurse's discretion and whether or not premedication is used.

If the belief is that infants should be treated as humanely as older patients, and that they deserve the consideration of premedication for intubation, then all infants deserve such consideration. Those of younger gestational ages should receive the same treatment as the larger, more advanced gestational age infants. The same holds true for adjuvant methods of pain control. The comfort measure of swaddling should not be reserved for the more active and stronger infants, but should instead be provided to infants of all gestational ages.

Of the non-pharmacologic interventions available for pain and stress reduction in infants, swaddling is the most practical for use during endotracheal intubation. Swaddling should occur at the beginning of the procedure, while equipment and medications are being prepared, and continued through the course of the procedure. It is a simple yet effective measure that can be taken to reduce pain and stress. Swaddling was noted to reduce the stress reaction to intubation by attenuating the change in blood glucose and the DAN score given during the procedure. Swaddling should routinely be used for endotracheal intubation in all gestational ages.

We have the opportunity to improve our treatment of infants in the NICU during endotracheal intubation based on the results of this study. It is in the best interest of our small patients to treat them with the same considerations provided to older patients.

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