Vol. 26 No. 2
March-April 2013

neonatal INTENSIVE CARE

The Journal of Perinatology-Neonatology

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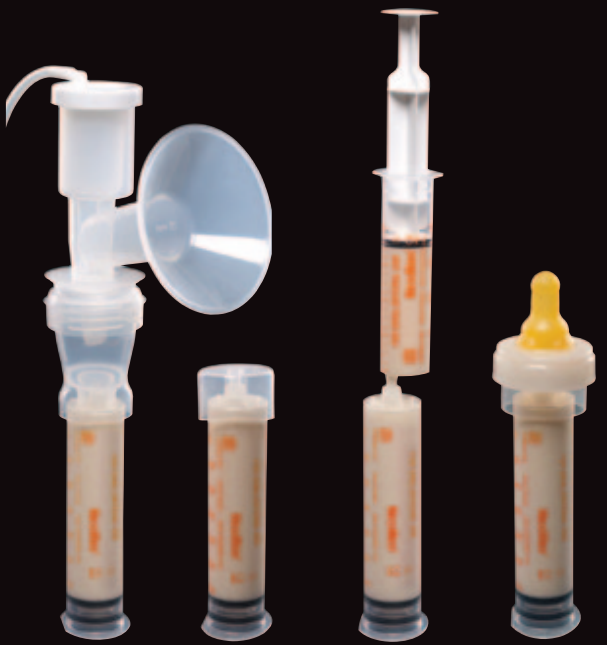

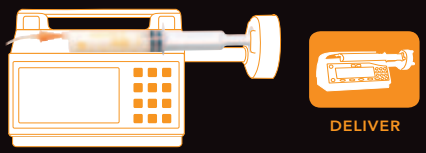

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Editorial

Oximetry And Heart Disease

Recently the e-Journal of Neonatology Research published a paper on the subject of heart disease screening with pulse oximetry [Critical Congenital Heart Disease Screening with Pulse Oximetry in the Neonatal Intensive Care Unit]* According to the abstract: "A case study of an infant with interrupted aortic arch who was discharged from the newborn nursery is presented for root cause analysis and implementation of a modified pulse oximetry screening program at the parent institution where it was described. A rationale for modification of the American Academy of Pediatrics policy statement supporting universal pulse oximetry screening for congenital heart disease in the newborn is made." The authors highlighted the importance of oximetry screening in the NICU.

The authors presented the case of a 38 week gestation infant delivered by a repeat cesarean section. The neonate had respiratory distress that required intubation. A pulse oximeter probe placed on the right upper limb was 95-98% with 21-25% oxygen requirement. This infant's first chest x-ray demonstrated bilateral hazy lung fields. Within 24 hours, the baby was extubated and a subsequent chest X-ray showed marked improvement. She was discharged home in room air with pulse oximeter reading in 98-100% in the right upper limb. Two weeks after discharge, an echocardiogram demonstrated interrupted aortic arch with an aberrant left subclavian artery arising from the patent ductus arteriosus. The right common carotid artery, right subclavian and left common carotid artery came off the proximal part of the aortic arch prior to interruption. The infant underwent corrective surgery and was discharged home at four weeks of life.

The authors noted, "it is likely that SpO2 obtained from the left upper limb or any lower limb would have demonstrated a lower SpO2 compared to the right hand. During her stay in the NICU, all SpO2 readings were obtained from the right hand. The detection of co-arctation of the aorta by pulse oximetry screening is only 53% but the precise detection rate for interrupted aortic arch is not known. The accuracy of this screening is variable with high specificity but low sensitivity. Currently most units do not offer CCHD screenings for all infants admitted to the NICU. There always exists a potential for a positive screen, such as in a patient described above, provided all NICU patients are screened for CCHD. We have developed a modified algorithm, for all patients admitted to the NICU." Some recommendations: "The establishment of a cutoff threshold for an abnormal SpO2 must be associated with high sensitivity and specificity. Setting a high SpO2 cutoff value closer to the normal level will decrease the number of false-negative screening results at the cost of increasing the number of false-positive results. Conversely, a lower SpO2 threshold will lower sensitivity and raise specificity… Neonates requiring oxygen supplementation during their NICU stay [should] be weaned to room air for at least 24 h prior to screening. Infants who are being discharged on home oxygen need to undergo an echocardiogram (if one was not obtained during their neonatal course)." The authors concluded: "We used a root cause analysis to modify the AAP guidelines for pulse oximetry screening in order to improve its specificity and sensitivity for aortic arch abnormality in our NICU. These recommendations are empirical, not evidence-based and need critical evaluation by prospective studies. Collaborative studies among neonatal intensive care units conducting routine pulse oximetry should analyze pooled data and report detection, false positive rates, false negative rates, and cost-effectiveness of these screening measures for CCHD."

By the way, an excellent up to date primer on oximetry and heart disease is the Hospital Guidelines for Implementing Pulse Oximetry Screening, published by the Alabama Department of Public Health. You can find it by typing the above title into a search engine. Another source to look at is the article "It is Time for Routine Neonatal Screening by Pulse Oximetry," by Julien I.E. Hoffman, published in Neonatology (formerly Biology of the Neonate). You can Google it or find it here: www.ncbi.nlm.nih.gov/pubmed/20523077. For nurses, the University of Arkansas for Medical Sciences

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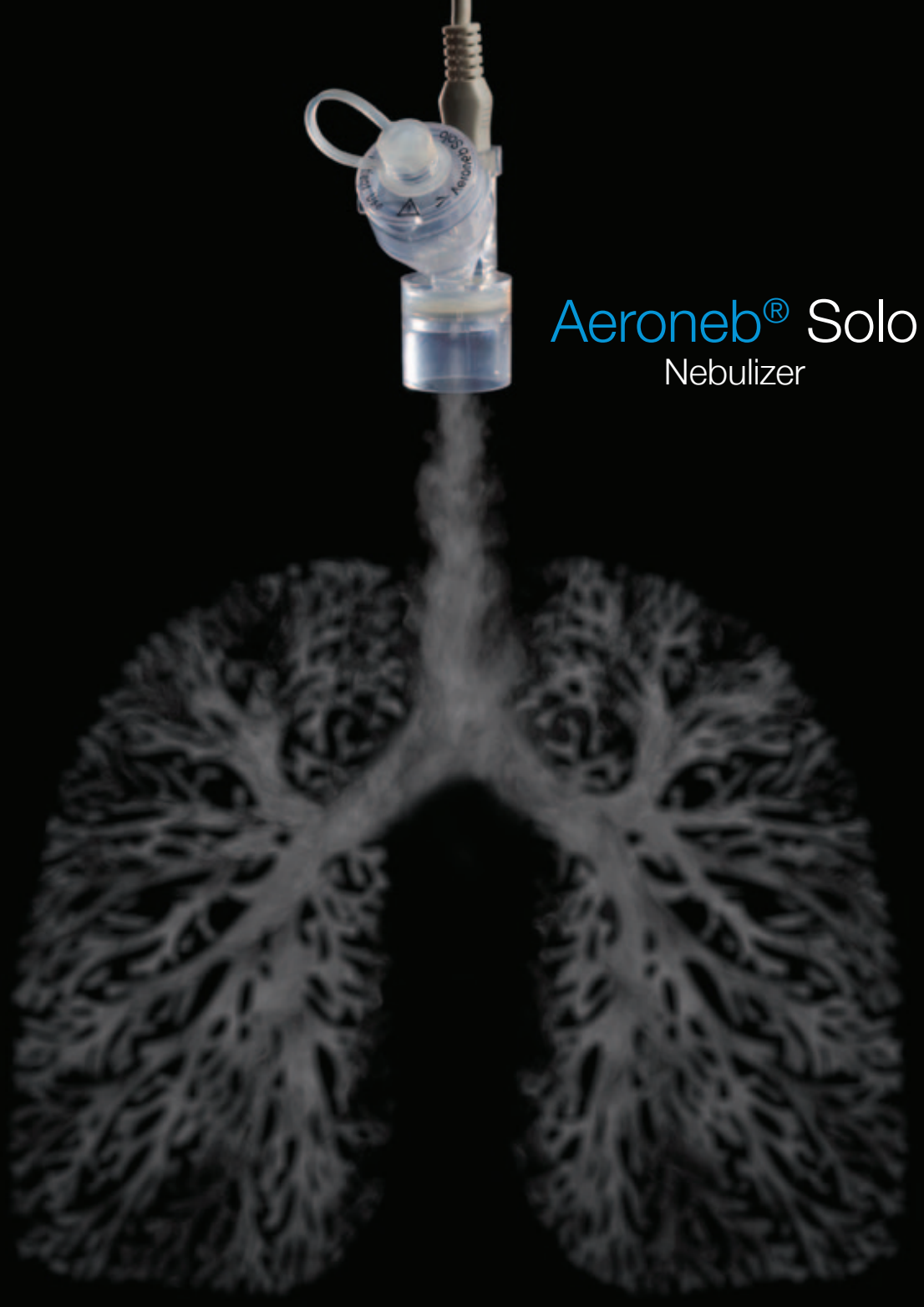

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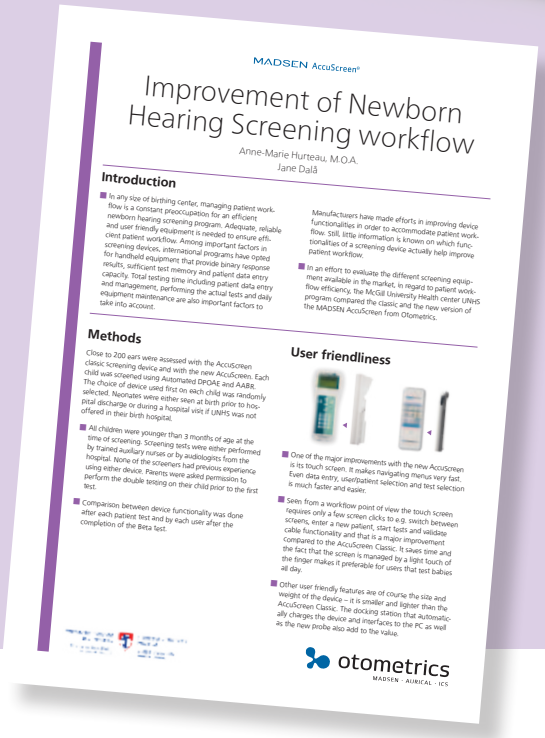

MADSEN AccuScreen®

Improvement of Newborn Hearing Screening workflow

Anne-Marie Hurteau, M.O.A.
Jane Dalâ

Introduction

In any size of birthing center, managing patient workflow is a constant preoccupation for an efficient newborn hearing screening program. Adequate, reliable and user friendly equipment is needed to ensure efficient patient workflow. Among important factors in screening devices, international programs have opted for handheld equipment that provide binary response results, sufficient test memory and patient data entry capacity. Total testing time including patient data entry and management, performing the actual tests and daily equipment maintenance are also important factors to take into account.

Manufacturers have made efforts in improving device functionalities in order to accommodate patient workflow. Still, little information is known on which functionalities of a screening device actually help improve patient workflow.

In an effort to evaluate the different screening equipment available in the market, in regard to patient workflow efficiency, the McGill University Health center UNHS program compared the classic and the new version of the MADSEN AccuScreen from Otometrics.

Methods

Close to 200 ears were assessed with the AccuScreen classic screening device and with the new AccuScreen. Each child was screened using Automated DPOAE and AABR. The choice of device used first on each child was randomly selected. Neonates were either seen at birth prior to hospital discharge or during a hospital visit if UNHS was not offered in their birth hospital.

All children were younger than 3 months of age at the time of screening. Screening tests were either performed by trained auditory nurses or by audiologists from the hospital. None of the screeners had previous experience using either device. Parents were asked permission to perform the double testing on their child prior to the first test.

Comparison between device functionality was done after each patient test and by each user after the completion of the Beta test.

User friendliness

One of the major improvements with the new AccuScreen is its touch screen. It makes navigating menus very fast. Even data entry, user/patient selection and test selection is much faster and easier.

Seen from a workflow point of view the touch screen requires only a few screen clicks to e.g. switch between screens, enter a new patient, start tests and validate cable functionality and that is a major improvement compared to the AccuScreen Classic. It saves time and the fact that the screen is managed by a light touch of the finger makes it preferable for users that test babies all day.

Other user friendly features are of course the size and weight of the device – it is smaller and lighter than the AccuScreen Classic. The docking station that automatically charges the device and interfaces to the PC as well as the new probe also add to the value.

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News

☐ March-April 2013

FAT OR FIT?

A simple assessment can predict at birth a baby's likelihood of becoming obese during childhood, according to researchers at Imperial College of London, who developed the formula using data from a study set up in 1986 following 4,000 children born in Finland. They found that non-genetic information available at the time of birth was enough to predict which children would become obese. The formula proved accurate not just in the Finnish children they studied, but also in further tests using data from studies in Italy and the United States. To see the formula, go to http://files-good.ibl.fr/childhood-obesity. Reported by Reuters, copyright Thomson Reuters 2012.

SURVIVAL

Ireland has among the best rates of survival for premature babies in the world, according to an article by Ronan McGreevy in the Irish Times, which reported that some 83% of babies born under 1.5 kg survive. The international average is 84-90%, with the best rates in the world being in Scandinavian countries. A researcher said the slightly lower survival rates in Ireland had to be seen in the context of the lack of abortion in the country, which means that many malformed babies who may have been aborted in other countries are born in Ireland. Ireland has one of the lowest prematurity rates in the world with an average of six per 100 babies born before 37 weeks. The average in the United States is 12 per 100.

BIRTH RISK

The Wall Street Journal reported that hospitals and public health officials are working to improve safety for mothers in the delivery room following sharp increases in the rate of severe complications from childbirth. Emergencies during delivery, such as cardiac arrest, respiratory distress and kidney failure, increased by 75% in the decade ending in 2009, according to a new study by the Centers for Disease Control and Prevention. In the days immediately following delivery, severe complications for women more than doubled over the same time period. One reason for the increase is the number of pregnant women who are older, obese, or have chronic conditions such as diabetes and kidney disease that put them at higher risk. A nearly 60% increase in the rate of c-sections since 1996 is associated with a sharp increase in placenta accrete.

LED IN INDIA

Light-emitting-diode bulbs have long been used to light homes, computer monitors and televisions. Now, hospitals are increasingly using these energy-efficient lights in nurseries to treat jaundice in babies. To improve the situation in India, several companies are developing phototherapy systems with LED bulbs instead of the compact fluorescent lamps commonly used to treat jaundiced newborns. The new systems use less electricity than conventional lamps and last much longer without a bulb replacement. The LED bulbs can stay on continuously for as long as 50,000 hours, or almost six years, compared with just two to three months for compact fluorescent lamps. More important, LED lamps can help treat jaundice faster than conventional phototherapy lighting. GE Healthcare Pvt Ltd says its phototherapy system cures jaundice in babies in an average of 7.6 hours compared with 10.4 hours using compact fluorescent lamp, or CFL, bulbs. Wipro GE, a joint venture, has sold 1,000 phototherapy units world-wide since an October 2011 launch. Half of these systems are in India at smaller hospitals in remote areas and at big hospital chains.

IT FIGURES

Mississippi has the highest infant mortality rate in the United States, writes Tracie Egan Morrissey on the website slate.com. The state's health office says for every 1000 babies born, 9.4 die before their first birthday, a mortality rate tantamount to those of underdeveloped countries. In 2011, Mississippi had the highest percentage of people living below poverty level in the US. The state also has the highest rate of preterm births, according the March of Dimes. Mississippi also had the highest teen birth rate in 2010, and leads the country in obesity, and 40% of its infants are born to black women, who are 50% more likely to give birth prematurely. Staying healthy during pregnancy is difficult for expectant mothers in Mississippi. Considering the fact that 19% of the state's population is uninsured, many of them aren't getting the proper prenatal care they need. Mississippi, despite being the poorest state in the nation, is perhaps the most vehemently opposed to universal healthcare.

WITHDAWAL

Arian Campo-Flores wrote in the Wall Street Journal that hospitals around the country are seeing a surge in the number of babies born dependent on drugs such as oxycodone. In 2009, more than 13,000 babies in the US were diagnosed with neonatal abstinence syndrome. There is no standard way to treat their withdrawal, so doctors and nurses are improvising to figure out the most effective combination of drugs and dosages. Mean treatment cost is $53,400 and Medicaid covers the tab for 78% of the babies. Hospital charges to care for these babies were at $720 million in 2009. In Florida, where the problem is seen as most acute, Tampa General relies on a system that assigns points for different symptoms, and it initiates drug treatment if the numbers cross a certain threshold. A collaboration of Florida NICUs is relying on morphine and clonidine, experimenting with different dosages. Hospitals are also concerned that they aren't catching all the affected babies, since some moms don't disclose their use of drugs.

FOR BROKEN HEARTS

A painstaking effort to create a biocompatible patch to heal infant hearts is paying off at Rice University and Texas Children's Hospital. Researchers have created a small slab of gelatinous material that beats with the rhythm of a living heart. The material, called a bioscaffold, could be sutured into the hearts of infants suffering from birth defects. The scaffold, seeded with living cardiac cells, is designed to support the growth of healthy new tissue. Over time, it would degrade and leave a repaired heart. Current strategies use synthetic fabrics, are taken from cows, or from the patient's body. However, they only work well until they need to be replaced, and are not incorporated into the heart tissue. While the new patch degrades over time, the researchers noted that it should be stable for long enough that it allows muscular tissue to build up and take over the mechanical process. The researchers hope to find a way to mix stem cell-derived heart cells into the hydrogel and make a patch genetically identical to

the child that could be implanted shortly after birth. A video about the research can be viewed at youtu.be/3ej5rZaeTRU.

PREMATURE RATE

In the last several years, multiple medical advancements have led to a decline in the nation's premature birthrate. On Nov 17, the Society for Maternal-Fetal Medicine (SMFM) celebrated World Prematurity Awareness Day. According to the March of Dimes, worldwide, approximately 15 million babies are born premature each year. Here are recent advancements: In 1996, the New England Journal of Medicine reported that transvaginal cervical length was able to predict preterm birth (PTB). In 2003, 17P, started at 16-20 weeks, was reported to decrease PTB by about a third, with neonatal benefits, in women with a prior spontaneous PTB and a current singleton gestation. In 2011, a meta-analysis of randomized trials, including over 500 women with singleton gestations and prior spontaneous PTB, reported a significant decrease in PTB when ultrasound-indicated cerclage was placed in these women if their CL decreased to less than 25mm before 24 weeks. A second randomized trial confirmed the results of a first randomized trial from 2007, that in women with a singleton gestations and a short CL, vaginal progesterone prevented PTB. Two cost-effectiveness analyses showed that this treatment is not only effective, but also cost-saving. Last year, the SMFM and ACOG publish guidelines for use of CL, progesterone and cerclage for prevention of PTB. Also, in 2012, for the fifth year in a row, the CDC reported that the US PTB rate had decreased, from a maximum of 12.8% in 2006, to 11.99% in 2010, to 11.72% in 2011.

BIG BUCKS

Mana Parast, MD, PhD, an assistant professor of pathology at the University of California, San Diego School of Medicine, has been awarded a $3 million grant to continue her research into new therapies for preeclampsia. Parast's funding is part of an awards program which supports promising young researchers in the early stages of their career. Parast is the fifth researcher from UC San Diego to receive such funding.

RECENT STUDIES

The National Children's Study is the largest research study to investigate environmental influences on the health and development of children. The issues it is studying are presented in the In Focus series in the November/December issue of the JOGGN, published by AWHONN. Maternal Psychosocial Determinants of Fetal and Infant Health and the National Children's Study discusses the maternal psychosocial determinants, such as chronic stress and depression, that may influence the health of fetuses and newborns. The Placenta as a Research Biospecimen examines the role the placenta plays before birth and the subsequent role it plays in infant and child health after birth. Advancing the Science of Environmental Exposures During Pregnancy and the Gene-Environment Through the National Children's Study discusses the possible negative impact toxic environmental exposures, such as pesticides and synthetic hormones, can have on fetal, infant, and childhood development. Research Nurses Collaborate with Clinical Nurses for Success in the National Children's Study highlights the successful implementation of NCS research into clinical practice.

NO SOAP

In our September issue, we reported on false positives for marijuana in babies because of ingredients in soap. Recently Paul Armentano wrote on the website Salon about the likelihood of moms being penalized because of the test's fallibility by having their babies removed from their care. According to a spokesperson for the National Coalition for Child Protection Reform, the emotional damage caused by removing an infant child from its mother, as well as the risk of abuse inherent to foster care, far outweigh any risks to the child that may be caused by maternal marijuana use during pregnancy. Not only that, Armento wrote, studies have shown that there were no significant physical or psychological differences in newborns of heavy marijuana-using mothers at three days old and, in fact, exposed children performed better on a variety of tests than non-exposed infants. Other researchers have found that reported decreases in birthweight of pot-affected babies were statistically insignificant. You can go here to read the full article: www. salon.com/writer/paul_armentano.

GUIDELINES

The National Perinatal Association announced the release of the Multidisciplinary Guidelines for the Care of Late Preterm Infants. Developed in collaboration with more than 20 healthcare professionals and organizations, the guidelines address care from the in-hospital setting immediately after birth, through the transition to home, and beyond. Contact nationalperinatal.org/lptguidelines.php.

LEVEL IV

The American Academy of Pediatrics (AAP) has issued a new policy statement indicating a change in the levels of neonatal care, updating the levels of care from Level I to Level IV. The AAP's updated NICU classifications consist of basic care (level I), specialty care (level II) and subspecialty intensive care (level III, level IV). Subspecialty neonatal intensive care involves providing life support, the ability to care for infants born earlier than 32 weeks gestation and weighing less than 1500 grams, performing advanced imaging including MRI and echocardiography, and providing a full range of respiratory support, among many other criteria. NICUs with a Level IV designation must meet all Level III capabilities, plus: be located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions, maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site, facilitate transport, and provide outreach education. In line with the foregoing, the neonatal intensive care unit (NICU) at Texas Children's Hospital has now been designated as a Level IV NICU.

BAD AT BABIES

Erin Gloria Ryan writes on the website Jezebel: "New data released by the Pew Research Center has shown that the American birth rate dropped 8% between 2007 and 2010, putting the 2010 birth rate at its lowest level since 1920, the first year that we were even keeping track of this sort of thing. Guess this means that my Facebook friends are the last people in this country reproducing successfully. The data shows more than just the fact that American uteruses are taking it easy; some groups of women are scaling back childbearing much more dramatically than others. The survey found that the birth rate for American-born mothers dropped 6%, while foreign-born women's dropped 14%. But the biggest drop in birth rate came among Mexican-born women – in the span of only a few years, their birth rate dropped 23%. So much for the embarrassing myth of the anchor baby… All of this comes in conjunction with new data from the CDC that shows that abortions are at their lowest levels in decades, dropping 5% during the recession. So what gives? Are women – especially non-US-born women – having less sex? Or are they

simply able to access more affordable contraception? Because it appears that it's not just that women aren't having babies; they're not getting pregnant in the first place."

BIG WHOOP

A study in the Journal of the Pediatric Infectious Diseases Society has found that taking early and repeated white blood cell counts (WBC) is critical in determining whether infants have pertussis and which of those children are at highest risk of death from the disease. In 2010, California reported its highest pertussis rates in 60 years. Murray, et al's retrospective study used medical records from five Southern California Pediatric Intensive Care Units between September 2009 and June 2011. Of the 31 infants studied, eight comprised a group considered to have more severe infections, which included suffering from pulmonary hypertension and death from the pertussis. The study showed that infants who had more severe disease had higher WBC counts and were more likely to show at least a 50% increase in WBC. These infants had median peak WBC counts of 74,100 compared to 24,200 among infants with less severe disease. All but one of those with more severe disease had at least a 50% increase in WBC within 48 hours, and none of those infants with less severe disease had more than a 50% increase in WBC. The group of infants with more severe infections had higher maximum heart and respiratory rates and was more likely to develop pneumonia. All of these conditions occurred earlier after illness onset among infants with more severe disease. This group was more likely to have seizures, hypotension/shock, renal failure, and was more likely to be intubated and receive exchange transfusions. Six of the infants received exchange transfusions, and four of those died. Those four were all in shock at the time of their transfusions; the two who survived were not in shock at the time of transfusion.

BMC NEWS

BioMed Central announced its sponsorship of Open Access Week throughout 2013. Open Access Week is a global opportunity for the academic and research community to enhance their knowledge of the potential benefits of open access, to share what they've learned with colleagues, and to inspire wider participation in helping to make open access the norm in scholarship and research. As the pioneer of open access publishing, BioMed Central supports open access in all its forms and is at the cutting edge of ensuring that the results of scientific research are made openly available throughout the international community… BioMed Central congratulates its authors John B. Gurdon of the University of Cambridge, England, and Shinya Yamanaka of Kyoto University, Japan, who were awarded the 2012 Nobel Prize in Medicine. Leading up to this award John Gurdon talked about histone H3 lysine 4 methylation in Epigenetics & Chromatin and, published in BMC Developmental Biology, Shinya Yamanaka looked at the roles of ESG1 and DNA hypermethylation in germ cells… BioMed Central journal websites have been updated so that users on mobile devices, such as smartphones or tablet computers, have an enhanced experience when viewing full text articles, making better use of small screen sizes and touchscreen functionality. Using a "responsive" web design, journal websites automatically respond to the capabilities of the device that is being used, providing a mobile-optimized appearance… A recently published article in BioData Mining introduces "Peer2ref" a new software package which helps to address the challenges of finding suitable referees during the peer-review process. Peer2ref is a fully automated method for helping authors and editors select qualified reviewers… BioMed Central offers registrants to BMC Pregnancy and Childbirth alerts by e-mail about new articles. The journal's open access policy ensures the maximum exposure for submitted papers, and allows for free distribution and re-use, which means contributors can share articles via e-mail or by any other means.

FALLOUT

Sarah Morris writes in The Independent that extremely high rates of miscarriage, lead and mercury contamination and birth defects are plaguing Iraq in the aftermath of the war, especially in Fallujah, where a major battle took place, and where residents changed the name of the city from City of Mosques to "the polluted city." Birth defects there include congenital heart defects, brain dysfunction and malformed limbs. Similar defects were found among kids born in Basra after British troops invaded. When US marines bombarded Fallujah, they used white phosphorous shells and were accused of but didn't admit to leaving behind depleted uranium. In Fallujah, more than half the babies surveyed were born with a birth defect between 2007 and 2010; prior to the siege it was 1 in 10, and the number was less than 2% before 2000. In Basra, more than 20 babies out of a thousand were born with defects, 17 times higher than the previous decade. Researchers said the high rates were due to exposure to metals released by bombs and bullets, and said they found that levels of lead were five times higher in the hair of children with birth defects than other kids. Mercury levels were six times higher. The Defense Department said they know nothing about this, and the UK government denied it, too.

QUICK DNA TEST

We reported previously about DNA testing, in our last issue's editorial and news sections. Gina Kolata, writing in the New York Times, presented a case study about the latest on this front.

When a five week old girl died after numerous seizures, her doctors thought it was because of a genetic disorder. The hospital, Children's Mercy in Kansas City, MO, was conducting a study of a new technique for quick DNA analysis. The method allows for a rapid scan of a baby's entire DNA that pinpoints mutations in a few days. The doctors took a sample of the girl's blood and did an analysis in 50 hours. The baby's gene mutation was so rare there had been only one other case reported. How this method works is, a computer program searches for genes based on the baby's symptoms. Because it only focuses on genes that cause diseases in newborns, the test avoids the ethical dilemma of unearthing too much info. As Kolata noted, "Do parents really want to know that their sick baby has a gene that increases the risk of Alzheimer's disease?" The method currently costs $13,500 and insurance didn't cover it as we went to press.

NO IMPROVEMENT

MedPage Today's Kristina Fiore reported that tight control of blood glucose won't improve outcomes for infant and toddler pediatric heart surgery patients in the cardiac intensive care unit (CICU). A study at Boston Children's Hospital revealed that tightly regulating blood sugar didn't bring down infection rates, mortality rates, or length of stay, though the practice has become common. Researchers assessed 980 children from birth to 36 months of age who were having cardiac surgery with cardiopulmonary bypass. The children were randomized to either tight glycemic control, with a target blood sugar of 80 to 110 mg/dL, or standard care in the CICU. Overall, 91% of the children on tight glycemic control received insulin compared with only 2% of those on standard care (P<0.001). The median insulin dose during the first full day in the CICU was 0.2 units per kg in the tight control group. The tight control group achieved normoglycemia earlier than the standard care group (6 hours vs 16 hours) and maintained it for a greater proportion of the critical illness period (50% vs 33%, P<0.001), but tight control wasn't associated with a significantly lower rate of infections than standard care (8.6 vs 9.9 per 1,000 patient-days). There were no significant differences between the two groups with respect to any of the four types of infections that were tracked, nor were there any differences in secondary outcomes including 30-day or in-hospital mortality, length of stay in the CICU, duration of mechanical ventilation, duration of vasoactive support, or other measures of organ failure. However there were significant differences in the rate of severe hypoglycemia, 3% in the tight control group vs 1% in the standard care group, and in the rate of total hypoglycemia, 19% vs 9%.

DUH

Infant mortality rates increased by 50% for three years after Philadelphia hospitals closed their maternity units in 1997, according to researchers at The Children's Hospital of Philadelphia. The mortality rates subsequently leveled off. Between 1997 and 2007, 9 of 19 obstetric units closed, resulting in 40% fewer obstetric beds. This was the first study to analyze the effects of large-scale urban obstetric service reductions on moms and babies. The before-and-after study analyzed more than 150,000 births over a twelve-year period and compared them to birth records in various suburban and urban communities. A total of 3.1 million births were studied. Compared to the two years before the closures, the difference in neonatal hospital mortality increased by 49% in Philadelphia between 1997 and 1999, and the difference in all perinatal mortality increased by 53%, compared to both control groups. These researchers adjusted for differences in patient characteristics in each county, and found that deaths rose from 5 to 8 per thousand.

SOUNDS FISHY

Low-level prenatal mercury exposure leads to a greater risk of ADHD-like behavior, yet maternal fish consumption can reduce the risk of ADHD. Researchers at Brigham and Women's Hospital and Boston University noted the dilemma this causes for moms. Their study involved 400 children over a five-year period. After the moms gave birth, researchers collected maternal hair samples to check mercury levels and found an increased risk of childhood ADHD-related behaviors. Researchers found a reduced risk of ADHD-related behaviors in children whose mothers reported eating more than two servings of fish per week. Fish that are typically high in mercury are shark, swordfish, king mackerel and fresh tuna. Low-mercury fish are flounder, haddock and salmon.

RADIATED

Few adolescent females undergo pregnancy testing in the hospital emergency department (ED), even when they complain of lower abdominal pain, or before they are exposed to radiation from tests or examinations, according to an abstract presented at the AAP Conference. Researchers reviewed several years of data on female patients aged 14 to 21 who were examined in a hospital ED. Of the 77 million girls who visited an ED, just 14.5 million (18.7%) were tested for pregnancy. Of the patients reporting abdominal pain, 42.3% were tested for pregnancy, and of those receiving radiologic imaging, 21.5% were tested. Of patients exposed to radiation that could cause birth defects, such as a chest radiograph or CT scan, only 27.9% received a pregnancy test. Disparities in testing were noted based on age, race and insurance type.

CONSEQUENCES

High blood pressure in pregnant moms can lead to a deficit in thinking skills in their babies, and the effect doesn't go away, according to researchers at the University of Helsinki, who noted that declines in thinking abilities in old age could have originated in the prenatal period. The researchers analyzed the medical histories of 398 men's mothers' blood pressure. The men had their thinking skills examined and reexamined at age 20 and 69. The men whose moms had high blood pressure received scores that were 4.36 points less on thinking ability tests when they were 69 years than those whose mothers didn't have high blood pressure. The men with high blood pressure moms also scored lower at age 20. The researchers accounted for preemie births and the fathers' profession, but these factors didn't affect the findings. Information is from Medical News Today, written by Christine Kearney, copyright Medical News Today.

EVERYWHERE

Bisphenol A (BPA), an estrogen-like compound, has been linked to changes in thyroid hormone levels in pregnant women and newborn boys, according to researchers at UC Berkeley. BPA is found in hard plastics, linings of canned food, dental sealants, and sales receipts on thermal paper. The FDA had previously banned the chemical in baby bottles and cups. The researchers analyzed BPA levels in the urine samples of 335 women during the second half of pregnancy, and thyroid hormone levels in blood samples taken from the mothers during pregnancy and from the newborns within a few days of birth. For each doubling of BPA levels, there was an associated decrease of 0.13 micrograms per deciliter of total thyroxine (T4) in mothers during pregnancy, which suggests a hypothyroid effect. For newborn boys, each doubling of BPA levels linked to a 9.9 % decrease in thyroid stimulating hormone (TSH), indicating a hyperthyroid effect. The researchers found no changes in newborn girls, and this mirrors studies on rats. Lower thyroid levels lead to delays in cognitive and motor development.

RUPTURE AND BREECH

Breech births increase the risk of complications for the mother and baby when the amniotic sac ruptures early, according to researchers at Loyola University. The study evaluated 569 women who had their water break between 24 to 34 weeks' gestation. Of those, 458 did not have breech babies and 111 did. Both groups had similar characteristics, including age, race, medical and social history. The breech group was significantly more likely to have low amniotic fluid (68% vs 50%), and deliver at a significantly earlier gestational age (30.05 vs 31.52 weeks). Breech pregnancies also were significantly more likely to have an abruption (23% vs 12%). This group was also more likely to have the fetus die in utero (3% vs 0%). Neonatal outcomes were strikingly worse in the breech group, with increased occurrence of RDS (53% vs 31%), NEC (15% vs 6%) and neonatal death (9% vs 3%).

MORE CONSEQUENCES

Being underweight at birth has long-term effects, according to researchers at the University of Melbourne, who found that rats with low birth weight have an increased long-term risk for cardiovascular and kidney disease and diabetes. Older females were found to have a higher risk of developing high blood pressure, which put their offspring at risk for low birth weight. The researchers used female rats that were born small and compared them to rats of normal birth weight. These rats were aged to 12 months (middle to old age in rats) at which time they became pregnant. A number of measurements regarding health were performed on these rats before and during pregnancy including blood pressure, kidney function and tests for diabetes. Researchers also compared these pregnant rats to a group of younger pregnant rats to determine whether older rats have more difficult pregnancies that impact on the growth and development of their babies. Results showed that regardless of the mothers' birth weight, older mothers demonstrated a reduced ability to become pregnant. When they did, they had altered blood sugar levels, poor pregnancy success and carried babies that were smaller or lighter in weight.

AFTER ECTOPIC

Women whose first pregnancy is ectopic are likely to have fewer children in the following 20-30 years than women whose first pregnancy ends in a delivery, miscarriage or abortion, according to researchers at Rigshospitalet in Denmark, who studied 3,000 women. Also, these women have a five-fold increased risk of a subsequent ectopic pregnancy. The researchers collected data from four Danish registries covering the period 1977-2009. They found 2,917 women whose first pregnancy was ectopic between 1977-1982 and who, except for those who died or emigrated, were followed to the end of 2009 or for an average of 23 years. These women were matched with other women of the same age whose first pregnancy resulted in a delivery, miscarriage or abortion. They were also compared with a fourth group of women who had no recorded pregnancy in the year of matching. Women who had had an ectopic pregnancy had the lowest long-term rate of subsequent deliveries: 69 per 100 among women, compared with 126 per 100 among women who had a first miscarriage, 77 per 100 among women who had a first abortion, 73 per 100 among women whose first pregnancy ended in a delivery, and 101 per 100 among the women who were not pregnant in the year the women were matched with each other. Compared to women who had a first miscarriage, the number of subsequent deliveries among the women who had a first ectopic pregnancy was reduced by 45%.

The researchers noted that fertility is compromised in women whose first pregnancy is ectopic and even after 30 years they have significantly fewer children compared with other women.

THERE'S A VACCINE FOR THAT?

It might be possible to develop vaccines to prevent premature birth and other pregnancy complications, and if so, such vaccines would be the first intended to stimulate the subset of regulatory CD4 T cells that suppress the immune response. Researchers at Cincinnati Children's Hospital found that the immune system of a pregnant mother stimulates cells that selectively prevent attack and rejection of fetal tissues recognized as being foreign. These pregnancy-induced, immune suppressive regulatory T cells are retained after delivery and rapidly re-accumulate to provide protection in subsequent pregnancy. The researchers showed that immune suppressive regulatory CD4 cells can form immunological memory. The researchers found that their research could be broadly applied to new ways to better control the stringent balance between immune stimulation and suppression for preventing autoimmune diseases. Thus, they posited that they could design vaccines that specifically target immune suppressive T cells. A vaccine that targets the expansion and retention of immune suppressive cells would allow selective silencing of undesired responses and prevent these cells from attacking the body. Thus it might be possible to develop vaccines against autoimmune disorders such as juvenile idiopathic arthritis and type 1 diabetes.

SIDS RISK

The Wall Street Journal reported that subtle abnormalities in the placentas of pregnant women may predispose newborns to an increased risk of SIDS, according to researchers in the UK and Ireland who used 3-D imaging technology to compare placental tissue from 47 full-term babies born to healthy mothers. Of the 47 placentas, 32 came from SIDS victims, including 18 with a normal birth weight and 14 with a low birth weight. Eight placentas from non-SIDS babies with a normal birth weight were used as a control group. The volume of placental villi was significantly greater in normal-birth-weight SIDS babies compared with villi from normal-birth-weight controls. No significant differences were found between villi from low-birth-weight SIDS placentas and the normal-weight controls. The volume of a villous membrane was also greater in SIDS babies. Smoking was more prevalent during the pregnancies of the mothers of SIDS infants whereas all the mothers of non-SIDS infants were non-smokers.

SAME RESULTS

Doctor's Lounge reported that late preterm infants (LPIs), born at 34 to 36 weeks of gestation, who receive intensive care, have similar cognitive, motor, and language skills at age 3 as LPIs who did not receive intensive care, according to a study published online in Pediatrics. Researchers from Queen's University Belfast conducted a cohort study involving 225 children born late preterm in Northern Ireland during 2006. They found that LPI infants who received IC were more often less mature (34 weeks of gestation) than LPI infants who did not receive IC (control group) and had lower birth weight (≤2,500 g) and Apgar scores (<7 at five minutes). LPIs who received IC were more likely than controls to have received resuscitation at birth and to have been born by cesarean delivery. There was no significant difference in measurements of growth between the groups.

AUTISM STUDY

Sutter Neuroscience Institute and CBR (Cord Blood Registry) are launching the first FDA-approved clinical trial to assess the use of a child's own cord blood stem cells to treat select patients with autism. This placebo controlled study will evaluate the ability of an infusion of cord blood stem cells to help improve language and behavior. The study is in conjunction with the Sutter Institute for Medical Research. The study will enroll 30 children between the ages of two and seven with a diagnosis of autism. Enrolled participants will receive two infusions, one of the child's own cord blood stem cells and one of a placebo, over the course of 13 months. For more contact cordblood.com/autism.

NEW MEMBERS

The Children's Hospital of Philadelphia's Center for Fetal Diagnosis and Treatment (CFDT), announced two new members of its team, Maternal-Fetal Medicine Specialist Juan Luis Martinez-Poyer, MD, and General, Thoracic and Fetal Surgeon William Hughes Peranteau, MD. In addition to his attending physician role at The Children's Hospital of Philadelphia (CHOP), Dr Martinez-Poyer also serves as a clinical assistant professor of Obstetrics and Gynecology at the Perelman School of Medicine at the University of Pennsylvania. Prior to joining CHOP, Martinez-Poyer served as a maternal-fetal medicine specialist at Northwest Perinatal Center, a provider of comprehensive medical services for high-risk pregnancies in Portland, Ore. He also served as a visiting physician at the Harris Birthright Research Center for Fetal Medicine in London's King's College Hospital, and chief of Obstetrics and Gynecology at Three Rivers Health, Three Rivers, MI. Dr Peranteau, an attending surgeon in CHOP's Division of Pediatric General, Thoracic and Fetal Surgery, is also serving as an assistant professor of Surgery at the Perelman School of Medicine at the University of Pennsylvania. Prior to joining the CFDT team, he completed his residency in general surgery at Brigham and Women's Hospital, Boston, and a fellowship in pediatric general surgery at CHOP. He served as a research fellow in CHOP's Center for Fetal Research for four years, investigating the role of in utero bone marrow and stem cell transplantation for the management of congenital hematologic disorders such as sickle cell disease.

ASTHMA RESEARCH

The Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center was recently awarded a two-year, $377,220 grant by the National Institutes of Health/National Institute of Child Health & Human Development to conduct a study that could potentially lead to effective treatments and prevention of asthma. The study will focus on maternal smoking as it affects offspring plus the generations to follow, and will investigate if the risk is carried to grandchildren or great-grandchildren.

STAY HOME

A new Cochrane Library review revealed that all countries should think about setting up proper home birth services. Low-risk pregnant women should be provided accurate information to make an informed decision about which type of birth they prefer. In order to have home birth be an appealing and safe option for all women, it should be organized as part of the healthcare system, according to the review. In the case of low-risk pregnant women, previous research has no strong evidence to support or disfavor home birth over hospital birth, according to Cochrane. The review said that women who give birth at home have a higher likelihood of spontaneous labor because hospital schedules and easy access to medical care can cause unnecessary medical interventions. The Cochrane review found that there have been 20-60% fewer interventions, including cesarean sections, augmentation, and epidurals among planned home births. There are also 10-30% fewer complications, such as postpartum bleeding and perineal

tears. Information from an article written by Kelly Fitzgerald for Medical News Today, copyright Medical News Today.

STROKE FOR STRESS

Scientists at the Universities of Liverpool, Manchester, and Kings College have found that mothers who stroke their baby's body in the first few weeks after birth may change the effects that stress during pregnancy can have on an infant's early-life development. It's been held that stress in pregnancy can have an effect on an infant in later life by reducing the activity of genes that play a role in stress response. Studies of early care-giving in rats have found that high levels of mothers' licking and grooming their pups soon after birth can increase the activity of these genes and may reverse the effects of prenatal stress on their offspring. The researchers followed first-time mothers from pregnancy through to the first years of their children's lives and found that links between symptoms of depression in pregnancy and subsequent infant emotions of fear and anger, as well as heart rate response to stress at seven months of age were altered by how often a mother stroked her baby on the head, back, legs and arms in the early weeks of life.

NURSES AND EVIDENCE-BASED PRACTICES

A new national survey of more than 1,000 registered nurses at Ohio State University suggests that serious barriers, including resistance from nursing leaders and nurse managers, prevent nurses from implementing evidence-based practices that improve patient outcomes. Survey respondents said education, access to information and organizational support could overcome these barriers. More than half of respondents reported that evidence-based practice was consistently used in their organization, but only a third said their colleagues consistently used these practices. The survey also revealed that the longer nurses worked in healthcare, the less interested they were in evidence-based care. The researchers based their results on 1,015 members of the American Nurses Association who completed the survey. Respondents ranged from 21 to 79 years of age, 93% were women, 56% held at least a master's degree, 44% had a bachelors or associate degree, the average number of years as a nurse was 24, 47% worked in community hospitals, and 23% in academic medical centers, and a quarter were nurse educators. Forty six percent said findings from research studies were routinely implemented where they worked, but 76% said they needed more education and skills-building in evidence-based practice. Less than a third said mentors for education were available.

PRODUCTS

ZACKY ON TV

Yamile Jackson's story of her preemie and how she came up with the Zaky device as a result was featured on the TODAY show. Here's some excerpts from the broadcast, shown on NBC Latino: "What could she do to increase the odds that would help Zack – a tiny baby, born 12 weeks premature – grow up to become a healthy boy? 'He was born to save my life,' recalls Jackson, who suffered from severe preeclampsia prior to giving birth to Zachary via cesarean section… She thought of what she could do. During the hours spent looking at her baby boy from across the glass in the Intensive Care Unit, Jackson always hesitated when, after an exhausting day spent at the hospital, she was told to leave the premises. 'Who comforted him when I was gone, and how does he know that I am his mother?' she wondered. And recalling the comforting touch of her own mother and wishing to impart that healing power to remove pain, she began to leave a small gardening glove with her baby. Rich with her scent and silky-soft to the touch, it mimicked the tender touch of her hand and imparted that all-important sense of a mother's comfort." When tropical storm Allison left the hospital without electricity, "For nine hours before being evacuated, Jackson clutched her baby skin to skin while her husband Larry and nurses alternated giving Zack manual breaths, because the ventilator and incubator weren't working. She then made a promise to Zachary that his pain and struggle to survive were not going to be in vain. She would not only help Zack, but help all premature babies and would do it on his behalf – not his memory… When nurses called asking about the small gardening glove, Dr Jackson prepared 100 gloves for the NICU hospital." From there Jackson spent three years developing the Zaky. "Since launching Nurtured by Design, Inc in 2001, more than 40,000 Zakys have been produced and are in use in over 300 hospitals in the US and around the world." The broadcast concluded by noting that her boy is now a healthy 11-year old. Contact nurturedbydesign.com.

HOT TOPICS

BabyFirst, a provider of information for healthcare professionals and support for parents of premature babies, has announced it will continue its "Hot Topic" webinar series throughout 2013. After successful Hot Topic webinars in 2012 on the NICU-ization of Labor & Delivery and "Non-Invasive" in Neonatal Care for Neonatal Professionals, the 2013 webinars will continue to provide labor and delivery and NICU practitioners with a rare opportunity to watch and interact with world-renowned professionals in the field of neonatology as they share experiences, philosophies, and best practices. The panelists will be fielding questions through an online forum following the webinar, enabling viewers to participate in "virtual office hours" and discuss approaches, ideas and questions with these key opinion leaders. Once questions are posted, the panelists will respond directly within a week. BabyFirst offers a comprehensive portal with tools and information to support and enhance the practice of neonatal care for clinicians as well as parents. The BabyFirst content and webinars are known for offering unprecedented access to the advice and perspectives of leading neonatal professionals. BabyFirst is an online-resource focused exclusively on providing information, resources and support for the neonatal community, including neonatologists and nurses as well as parents. The website is supported by Dräger, an international leader in the fields of medical and safety technology, and NICUniversity, a Web-based medical education center for clinical professionals. For more, visit www.babyfirst.com.

HEARING SCREENING

A clinical research article in the International Journal of Audiology (2012; 51: 570-575) reports on the validation of a new TEOAE-AABR device, the MADSEN AccuScreen, from GN Otometrics. The abstract states: Because newborn hearing screening (NHS) programs are currently implemented in an increasing number of countries, physiological NHS technologies have to be continuously optimized. This study validates a new TEOAE-AABR screening device. TEOAE and AABR screenings were performed in 299 ears with both the new NHS device and a well-established and validated one. Furthermore, 49 ears, suspected of having a hearing loss, underwent the screenings and an additional diagnostic ABR. One hundred and fifty newborns and infants were included in the study (median age 1.0 months, range 0–54 months; among them 39 babies from neonatal intensive care units). Screening with both devices resulted in a concordance of k=

.98 for TEAOE measurements and .96 for AABR measurements. The mean measurement durations were significantly shorter for the new device than for the established one for both TEOAE (15.4 vs 17.2 s) and AABR (26.6 vs 32.7 s). The study's authors concluded: The algorithm of the new screening device is as valid as that for the established one. The shorter test durations with the new device facilitate hearing screenings and allow for a higher number of valid measurements in restless children than with former comparable procedures. [The article is: Validation of a new TEOAE-AABR device for newborn hearing screening, Katrin Neumann & Alexander Indermark, Department of Phoniatrics and Pediatric Audiology, ENT Clinic, St Elisabeth Hospital, University of Bochum, Germany.]

APPROVED FOR SALE

Airon Corporation announced that its new pNeuton mini, an innovative ventilator designed specifically for neonatal / infant / pediatric life support in hospitals, MRI and transport, has been approved by the FDA for sale in the US. The pNeuton mini is the world's first infant ventilator that gives healthcare professionals the potential to support the smallest of patients, 400 grams to 25 kg, throughout the care continuum. The pNeuton mini is ideal for areas such as L&D, remote hospital locations, surgical procedure support, or the MRI. This ventilator provides full ventilatory support with variable flow rate control, 6-20 L/min or nasal CPAP for spontaneous breathing. It has a full range of oxygen delivery from 21% to 100% and pure pneumatic technology which eliminates the need for any batteries. The pNeuton mini meets airworthiness criteria and is rugged enough for all transport conditions. Contact aironusa.com.

REMOTE MONITORING

Covidien announced that OhioHealth, which owns or is affiliated with 17 hospitals, has converted to Nellcor pulse oximetry and the OxiNet remote respiratory monitoring system. The nationally recognized healthcare organization is further converting to multi-parameter modules with imbedded Nellcor OxiMax digital oximetry technology. The OxiNet remote monitoring system enables continuous monitoring of patients' oxygen saturation levels at a central station. Earlier alerts to adverse events enable clinicians to act faster, greatly enhancing patient safety. OhioHealth joins 400 other hospitals in the United States that have implemented the OxiNet remote monitoring system. There are currently more than 26,000 monitored beds on OxiNet systems in the country. Covidien also announced news about the company's largest capnography installation connected to a centralized remote monitoring system at the Medical Center of Central Georgia (MCCG). MCCG's new 7,583 square foot Logistics Hub incorporates a solution that provides connectivity to Nellcor N-85 pulse oximeters with capnography. This allows MCCG's clinicians to continuously monitor patients' ventilation and oxygen saturation levels, through EtCO2 and SpO2, even when the clinician is not at the bedside. The OxiNet III remote monitoring system and Nellcor N-85 monitors with Oridion Microstream capnography address the recommendations put forth by the American Society of Anesthesiologists, Anesthesia Patient Safety Foundation, the Institute for Safe Medication Practices and The Joint Commission calling for continuous monitoring of ventilation of hospitalized patients receiving opioids postoperatively. The OxiNet III remote respiratory monitoring solution provides customizable systems that effectively monitor any floor in a facility. Relaying data from the bedside to a central station like MCCG's Logistics Hub creates a remote respiratory monitoring system. If a patient's EtCO2 or SpO2 levels dips below the accepted level, clinicians are alerted via visible and audible alarms at the central station. Contact covidien.com.

FORMULAS

Abbott's Similac preterm infant formulas are the first and only preterm infant formulas to have added lutein. Emerging evidence suggests lutein may be important for neonates, especially preterm infants at greater risk for retinopathy and vision loss. In a recent clinical trial, infants fed Similac Special Care followed by Similac Expert Care NeoSure with added lutein were found to have blood plasma lutein levels similar to breastfed infants and greater rod photoreceptor sensitivity, which suggests improved retinal function and maturation. Abbott's Liquid Protein Fortifier is the first and only commercially sterile, extensively hydrolyzed liquid protein for preterm infants who may require additional protein. Because infants in the NICU vary so widely in weight and gestational age, a full range of options is needed to meet their nutritional needs. Until now, no protein fortifier in liquid form was available for these infants. Liquid Protein Fortifier offers many advantages: a) peptides and amino acids for easy digestion and absorption, b) can be used with human milk and formula feedings, and c) eliminates the need for powder mixing, meeting the ADA and CDC recommendations to reduce risk of contamination. Now, whether the infant feeding is human milk fortified with Similac Human Milk Fortifier or Similac Special Care infant formulas, any additional protein needs of infants can be met with ease. Contact abbott.com.

INTEGRATED

Covidien announced the integration of its Nellcor pulse oximetry with OxiMax technology into GE Healthcare Giraffe and Panda infant warmers. Integrating Nellcor SpO2 monitoring, along with the SatSeconds alarm management system, enhances the respiratory support and resuscitation capabilities of GE Giraffe and Panda warmers and helps clinicians safely monitor and screen infants for life-threatening cardiac and respiratory complications, as well as standardize resuscitation protocols across the perinatal care area. The warmers also have incorporated Covidien's innovative SatSeconds alarm management feature and support Nellcor SpO2 sensors that are designed for infant care. SatSeconds technology reduces clinically insignificant alarms by 60% in NICU settings. Nellcor SpO2 adhesive infant and neonatal sensors offer LoSat expanded accuracy, which closely tracks SpO2 values down to 60%. Nellcor preemie and neonatal non-adhesive sensors provide a convenient, gentle sensor designed for young patients with fragile skin and enable monitoring without damage to the epidermis and the skin's protective functions. The announcement recognizes the ongoing, comprehensive partnership between GE Healthcare and Covidien. The GE Giraffe and Panda warmers with integrated Nellcor SpO2 and SatSeconds alarm management system are the latest example of the long-term, global collaboration jointly announced by GE Healthcare and Covidien in May. Contact covidien.com.

STICK IT

MediPurpose announced the publication of its latest white paper, Reinventing a Better babyLance Infant Heel Incision Device: Defining, Translating and Validating Ergonomic Design Specifications. The new white paper describes how MediPurpose successfully gathered end-users' expectations for an ergonomic neonatal heel incision device, translated those expectations into design specifications, and validated new design ergonomics before launching its all-new babyLance infant heelstick in August 2012. MediPurpose evaluated virtually every component and feature

of its new neonatal heel incision device as it engaged with end-users to better understand their expectations and requirements for the ideal heelstick. Along with end-user performance needs, MediPurpose recognized ergonomics as an equally important design priority. The new babyLance features an ergonomic design to provide a secure and stable grip. It is available in two models, the BLP (Preemie) and BLN (Newborn). Contact medipurpose.com/babylance.

GOOD READ

Professor Nergesh Tejani, MD shares stories of working in the hospitals of Uganda during the 1960s while incorporating personal tales of love and family in her new book, I Hear A Song In My Head: A Memoir in Stories of Love, Fear, Doctoring, and Flight. Dr Tejani was born and raised in India and studied medicine at Jai Hind College and Grant Medical College in Bombay. After falling in love and marrying a medical school colleague, she moved to Uganda to live with her husband's family. The memoir consists of tales of doctoring during a politically turbulent time in Uganda when the country was struggling for independence and finishes in present day New York, where she reflects on her life with her husband and the most event-filled and exciting time of her life, the eleven years they spent in Kampala, Uganda, East Africa. Visit nergeshtejani.com.

ALL SET

Masimo has received FDA 510(k) clearance for Masimo Signal Extraction Technology (SET) pulse oximeters, rainbow SET Pulse CO-Oximeters, and neonatal sensors with labeling for screening newborns for critical congenital heart disease (CCHD). Masimo SET pulse oximeters and sensors have previously been cleared to measure oxygen saturation and pulse rate during motion and low perfusion conditions in newborns, but this is the first time the FDA has cleared specific labeling indicating the use of pulse oximeters, in conjunction with a physical exam, to screen newborns for CCHD. In conjunction with the FDA clearance, Masimo also announced the HEART Program (Help Ensure Access to the Right Technology) for CCHD screening enabling hospitals in countries where Masimo has a presence that want to perform CCHD screening with a Masimo SET pulse oximeter, but do not have one and do not have funds to purchase one, to receive a free Masimo SET pulse oximeter. More details are available at masimo.com/heartprogram. FDA clearance follows HHS's September 2011 action to add pulse oximetry CCHD screening for newborns as part of the Recommended Uniform Screening Panel. HHS took this action based on the published findings of the CCHD Workgroup, which relied on two major independent, published, prospective clinical studies that exclusively used Masimo SET Measure-Through Motion and Low Perfusion pulse oximeters to recommend screening with "motion-tolerant pulse oximeters" that "have been validated in low perfusion conditions." Both of the studies were submitted by Masimo to the FDA to support the new CCHD screening labeling. Dr Anne de-Wahl Granelli, et al, reported on the results of screening 39,821 newborn subjects at five maternity centers in Sweden. Investigators used the Masimo Radical with Masimo SET technology, and found pulse oximetry screening of all well babies in maternity units is practically feasible with a minimum use of nursing time, and that it significantly improves detection of duct dependent heart disease before hospital discharge. The low false positive rate, the fact that other important pathology is unearthed by the screening, and the likely reduced need for preoperative neonatal intensive care suggest that such screening will be cost effective. Dr Andrew Ewer, et al, studied 20,055 newborn subjects at six maternity centers in the UK. Investigators used the Radical-7 with Masimo rainbow SET technology and found pulse oximetry to be a safe, feasible test that adds value to existing screening. It identifies cases of critical congenital heart defects that go undetected with antenatal ultrasonography, and the early detection of other diseases is an additional advantage. The Masimo pulse oximeters that were the subject of this 510(k) clearance are the Radical-7, Rad-57 and Rad-87 Pulse CO-Oximeters with Masimo rainbow SET, and the Rad-5, Rad-5v and Rad-8 Pulse Oximeters with Masimo SET. [Sources: Secretary of Health & Human Services letter to the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC); dated September 21, 2011. Alex R. Kemper, William T. Mahle, Gerard R. Martin, W. Carl Cooley, Praveen Kumar, W. Robert Morrow, Kellie Kelm, Gail D. Pearson, Jill Glidewell, Scott D. Grosse, R. Rodney Howell. "Strategies for Implementing Screening for Critical Congenital Heart Disease." *Pediatrics*; Volume 128, No. 5; November 2011; e1-w10 DOI: 10.1542/peds.2011-1317. De-Wahl Granelli et al, "Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39,821 newborns." British Medical Journal (BMJ) January 2009; 338:a3037. Ewer et al, "Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study." The Lancet 2011: Vol. 378; No. 9793; pp. 785-794. Additional references: De-Wahl, et al. "Screening for duct-dependent congenital heart disease with pulse oximetry: a critical evaluation of strategies to maximize sensitivity." Acta Paediatr 2005;94:1590-6. Wren C, et al. "Presentation of congenital heart disease in infancy: implications for routine examination." Arch Dis Child Fetal Neonatal Ed. 1999;80:F49–F53.]

LISTEN UP

Audiology Systems Inc, the exclusive distributor for GN Otometrics (MADSEN, AURICAL, ICS), Intelligent Hearing Systems and Noise Barriers in more than half of the US, announced that it expanded its national service team with the hiring of Stephen MacDougall as a service technician in the northwest. The company has hired Chris Dean as national service director. Dean will have oversight responsibility for the entire Audiology Systems service team. He joined Audiology Systems from Thermo Fisher Scientific, where he served as manager, supplier network development. Prior to that, Dean was with GE Healthcare for 12 years. Audiology Systems has also added another sales manager to its growing team. Abigail Sweeney, Aud.D, is managing sales in Kentucky, southern Ohio and West Virginia. She was formerly with the Heuser Hearing Institute in Louisville where she worked as a clinical audiologist. Sweeney earned her doctor of audiology degree from the University of Louisville. Contact audiologysystems.com.

FORTIFIED

Mead Johnson Nutrition announced results of a new study published in Pediatrics that shows Enfamil Human Milk Fortifier Acidified Liquid supports significantly higher growth in premature infants than powdered fortifiers and is well-tolerated. Enfamil Human Milk Fortifier Acidified Liquid is the first and only ultra-concentrated liquid human milk fortifier marketed in the US that meets safety guidelines from the Academy of Nutrition and Dietetics and the CDC, as well as new preterm nutrition guidelines from the European Society for Pediatric Gastroenterology, Hepatology and Nutrition. In the third-party blinded, stratified, controlled trial, 146 preterm infants with a gestational age of 23.7 - 30.4 weeks and birth weights between 530 to 1,250 grams received

human milk and were randomized to receive Enfamil powder human milk fortifier (control group; 1.1 g protein/4 sachets) or Enfamil Human Milk Fortifier Acidified Liquid (1.8 g protein/4 vials) for 28 days. Weight and length growth were measured on day 28 and metabolic outcomes and other important outcomes such as necrotizing entercolitis (NEC) and sepsis, were measured on days 14 and 28. Infants who received the Enfamil Human Milk Fortifier Acidified Liquid showed significantly higher linear growth (41.8±0.24 vs 40.0±0.23 cm, p=0.010) and weight growth (1770±35 vs 1670±33, p=0.038) than the control group. Common markers of protein status, such as prealbumin, albumin and blood urea nitrogen (BUN), were also higher in the liquid human milk fortifier group versus the control group. No infants were treated for acidosis. Further, the study showed no statistically significant difference in the incidence of NEC or sepsis versus the control group. The study demonstrates Enfamil Human Milk Fortifier Acidified Liquid is not only clinically proven to provide better growth than Enfamil powdered fortifier, but is also safe and well-tolerated among preterm infants. When mixed with breast milk, Enfamil Human Milk Fortifier Acidified Liquid provides 4 g protein per 100 calories, which was shown to promote significantly higher weight, length, head circumference and linear growth than Enfamil powdered fortifier. Enfamil Liquid Fortifier also has 24 mg of DHA and 38 mg of ARA per 100 calories when combined with breast milk to help support optimal visual and cognitive development in premature infants. Enfamil Human Milk Fortifier Acidified Liquid is the first and only ultra-concentrated human milk fortifier to have DHA and ARA. The CDC, AND and FDA have recommended that sterile liquid products be used instead of powdered products for premature or immune-compromised infants. The AND's amended guidelines suggest using ready-to-feed or concentrated formulas rather than powdered formulas in NICUs. Contact meadjohnson.com.

GROUNDBREAKING

Roche Diagnostics broke ground on the company's new Learning and Development Center. The center is the first element of a $300 million site transformation investment. The city of Indianapolis and the Indiana Economic Development Corporation offered Roche tax abatements, tax credits and training grants to support Roche's investment. The capital investments will support the company's growing diagnostics and diabetes care businesses. The new Learning and Development Center will host the training of more than 1,500 customers from across the nation each year. The center will employ a distinct architectural style consistent with the company's European heritage. Contact roche.com.

COST OF CARE

Beevers Manufacturing recently offered its newsletter, which detailed the way its Cannulaide, by providing a reliable pressure seal, saves money and allows for better care. NICU babies receive consistent, productive air flow to their lungs with the use of the Cannulaide. Using a Cannulaide results in better pressure seal/fewer leaks, consistent air delivery, less risk of "dive response," less risk of apnea/bradycardia, considerably less air flow adjustments, so babies rest undisturbed, and less risk of trauma. Using the Cannulaide leads to productive healing/development, which may lessen the amount of time therapy is needed. The newsletter also referenced studies to reinforce use of the Cannulaide: Covering the Costs of Care in the NICU by Turner et al, Pediatrics and A Critical Review of Cost Reduction in Neonatal Intensive Care, The Structure of Costs, by Richardson et al in the Journal of Perinatology. Contact (503) 472-9055 or beevers.net.

TENDER

Precision Dynamics – St. John announced the release of its new TenderCare Thermal 4-Part Newborn Patient Identification System. The 4-part TenderCare Thermal wristband system identifies and matches newborns to their parents and is seamlessly printed with a thermal printer for on-demand identification and automated patient identification using bar code technology. Ideal for Labor and Delivery departments, TenderCare Thermal helps improve patient safety by using bar coding to reduce misidentification and human errors. TenderCare Thermal is latex-free, phthalate-free, and features ultra-soft material for delicate, newborn skin. Each TenderCare Thermal wristband has a tamper-resistant adhesive closure and is offered in plain white plus nursery style designs including ducks, tiger cubs, and monkeys. The product line includes core sizes ranging from one inch to three inch to accommodate a variety of thermal printers. The 4-part thermal newborn identification wristband set includes two luggage tag style wristbands for newborns that provide high bar code scan rates. TenderCare Thermal features the patented PermaPrint surface which provides a superior imprint quality and maximum resistance to solvents. PermaPrint has also proven in laboratory testing to increase the lifespan of the print head. TenderCare Thermal meets current Joint Commission, AHA, and HIPAA requirements. Contact (800) 772-1122, pdcorp.com, or stjohninc.com.

HAND-HELD

GN Otometrics launched the next generation of newborn hearing screening: the new MADSEN AccuScreen two-step (OAE/ABR) hand-held screening system. The new AccuScreen, which recently received FDA clearance, is an intuitive solution for newborn hearing screening. It features a revolutionary design and interface that improves workflow efficiency and allows the user to focus on the infant. The hand-held device features a completely redesigned housing that is significantly smaller and lighter than its predecessor. It features a large, color touch-screen display with intuitive, vibrant icons that guide the user through the screening process. There are detailed test and results screens, as well as on-screen help menu. The AccuScreen hand-held device has all the capabilities of a cart-based system, without the cart. Test data can be uploaded to the Acculink database software with one click. The new AccuScreen is a combined two step OAE/ABR device that meets all program requirements and interfaces with both the HiTrack and OZ-Systems. It includes multiple OAE protocols and allows for ABR screening at 30, 35, 40 and 45dB. Contact otometrics.com/accuscreen-us.

PATENTED AND CERTIFIED

MediPurpose announced an addition to its expanding portfolio of medical device patents. The medical product company recently received approval of two applications for patent protection of its babyLance infant heel incision device from the Japan Patent Office (JPO) and the Intellectual Property Office of Singapore (IPOS). MediPurpose also holds multiple international medical device patents for its popular SurgiLance safety lancet. The infant heelstick device's patent approval is currently pending in several other countries. MediPurpose launched its all-new babyLance in August 2012. The fully redesigned iteration of its original safe, easy and effective heelstick device was specifically designed to meet end-user requirements for an infant heel incision device that was easy to activate. Combined with a redesigned trigger mechanism, the heelstick device is easy to activate, helping to deliver a consistent incision without damaging the baby's tender nerve fibers. It's available in two models. The babyLance BLP (Preemie), delivers an incision depth of 0.85 mm, and the

babyLance BLN (Newborn) delivers an incision depth of 1.00 mm. The company also announced that its ISO 13485 certification has been renewed. To earn ISO 13485 certification, a medical device company needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. For renewal, a thorough re-certification audit by an independent notified body is performed. The certification also enables the company to use the CE Mark, which permits the company to sell medical products in the European Union. MediPurpose also announced the release of its latest white paper, Reinventing a better babyLance Infant Heel Incision Device: Simulated Use Design Validation Study (see this issue). Contact medipurpose.com.

UPDATED

PDI is issuing an updated label for its Chlorascrub line of skin antiseptics in accordance with the FDA's recent class change in labeling for Chlorhexidine gluconate (CHG) use on neonatal patients. The revised label now reads: "Use with care in premature infants or infants under two months of age. These products may cause irritation or chemical burns." The wording has been moved from the Warnings section to the Directions for use section. Chlorascrub is a pre-operative and pre-injection skin preparation with a 3.15% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol solution, available in four delivery formats: Swab, Swabstick, Maxi Swabstick and Compact Swabstick applications. Contact pdipdi.com.

NEW TESTS

Epocal, Inc announced that the FDA has cleared the company's creatinine and chloride tests, which are performed on the epoc Blood Analysis System, for the US market. Creatinine and chloride will be added to the epoc BGEM Test Card. The test card currently includes in vitro diagnostics for pH, partial pressure of oxygen, partial pressure of carbon dioxide, sodium, potassium, ionized calcium, hematocrit, glucose, and lactate. With the epoc Blood Analysis System, creatinine can be measured at the patient's bedside to screen for and detect early kidney damage as well as monitor kidney status. In conjunction with other parameters, it can also help to inform treatment decisions related to renal function, such as the use of renal replacement therapy or the identification of potentially nephrotoxic agents. Additionally, many critically-ill patients suffer from acid-base imbalances, especially those receiving intravenous treatment. Chloride measurements can help clinicians assess acid-base imbalances and make adjustments where necessary. The epoc Blood Analysis System delivers a full menu of results, including creatinine and chloride, in less than a minute on a PDA. Results can be easily integrated into any Laboratory Information System (LIS), and the system's broad menu will benefit clinical service lines that routinely perform blood analysis, including the emergency department, radiology, cardiac catheterization labs, out-patient centers, and critical care units. The epoc System is marketed Alere. Contact epocal.com or alere.com.

SKIN PROTECTION

Medline Industries, maker of Marathon Skin Protectant, offers several clinical research papers about the use of its product. "Cyanoacrylates in Neonatal and Infants Peristomal Skin Damage" reports: "A cyanoacrylate barrier was applied to infants and neonates with peristomal skin damage in gastrostomy and ostomy patients in an effort to recover denuded skin and, in the case of ostomy patients, increase wear-time of the appliance. Appliance wear-time was increased for neonatal and infant patients with ostomies. Skin condition improved, and none of the patients developed an adverse reaction to the cyanoacrylate during their stay in the hospital. In previous experience this type of skin breakdown has been difficult to manage… We found that the cyanoacrylate protectant dried within about one minute of application and formed a flexible "crust" over the denuded skin. As the skin regenerated naturally underneath the crust, the product sloughed off in course of time without further intervention. Newer layers of the barrier could be applied to the older partially adherent layers with no ill effects. Once in place and dry, the product allowed for wafers to be placed, in order to allow uninterrupted containment of the sometimes corrosive effluent. We found that use of the cyanoacrylate skin protectant provided the needed protection which allowed our patients' highly denuded skin to resolve in a shorter period of time. We saw no adverse effects from the use of the product in infants or children. During application, we noticed no distress on the patients and the parents reported no concerns about the product use. Based on this, it appears to us that the product likely does not sting on skin that is damaged. The application method via the cracking of unit dose vials was easy and the quantity of product quite sufficient for use on our little patients. The absence of solvents was appreciated by us." The paper, "The use of a cyanoacrylate based skin barrier appropriate for both intact and damaged skin to resolve neonatal skin problems" states: "Each patient's skin responded remarkably well to protection with the cyanoacrylate based skin barrier. The product was easy to apply and took less than a minute to cure. Pain was not noticed during application. The longevity of the product on the skin was approximately 3-6 days, and no special measures were required to remove the product from the skin." The paper: "The Use of Cyanoacrylate Skin Prep to Manage Skin Damage in the NICU," concluded, "We believe a product that bonds to skin as strongly as the cyanoacrylate should become the part of a formulary in any neonatal unit such as ours, where we often deal with highly compromised skin that the usual class of skin protectants cannot protect or manage. This is a new class of protectants different from solvent based skin protectants and petrolatum based barrier ointments." Contact medline.com.

HEATED

Fisher & Paykel Healthcare Inc, announced the US release of next generation Infant Evaqua 2 heated breathing circuits and the Optiflow Junior System. The new Infant Evaqua 2 heated breathing circuit uses MicroCell Technology to further minimize expiratory tube mobile condensate, while also withstanding the rigors of the critical care environment. The new Optiflow Junior System combines revolutionary cannula designed for the delicate anatomical features of neonatal to pediatric patients, with new breathing circuit technology that significantly reduces mobile condensate while meeting flow requirements up to 25 L/min. Contact fphcare.com.

CONTRACTIONS

A study on uterine tachysystole, "High Uterine Contraction Rates in Births with Normal and Abnormal Umbilical Artery Gases," published in the June issue of the Journal of Maternal-Fetal and Neonatal Medicine, showed that high contraction rates were common in deliveries with normal blood gases at birth. The study revealed that fetal heart rate decelerations, in response to any level of contractions, and especially during the last two hours of labor, were more closely associated with metabolic acidosis than high contraction rates alone. Many babies were able to tolerate high contractions without

consequence. More than 10% of the 3,636 patients in this study experienced contractions occurring more frequently than 5 in 10 minutes in times near delivery. "This is the first large-scale study to measure how contraction rates evolve during labor, and the results of this study help to clarify the clinical significance of high contraction rates," said Emily Hamilton, MD, one of the authors of the study and Senior Vice President of Clinical Research, PeriGen. Perigen is a national provider of fetal surveillance systems, whose patented fetal monitoring pattern recognition software, PeriCALM Patterns, was used to conduct this research. The software, which is embedded in all of PeriGen's fetal monitoring and perinatal systems, identifies and measures baseline, baseline variability, fetal heart rate decelerations and uterine contractions during labor. In addition to Dr Hamilton, the authors of this study include Daniel O'Keeffe, MD, Executive Vice President of the Society for Maternal-Fetal Medicine, Thomas J. Garite, MD, Professor Emeritus at the University of California at Irvine School of Medicine, G. Eric Knox, MD, founding member of the National Patient Safety Foundation, and Philip Warrick, PhD, Senior Biomedical Research Engineer at PeriGen. Contact perigen.com.

GRANTED

Ikaria, Inc announced that the Center for Devices and Radiological Health (CDRH) branch of the FDA has granted 510(k) clearance for a software upgrade to enable connectivity of the INOMAX DSIR drug delivery system with hospital health information systems. This connectivity allows data regarding INOMAX usage to be transmitted directly to electronic medical records where it can easily be viewed at computer stations to reduce charting time, avoid transcription errors, and improve billing efficiency. This feature, which is aligned with the effort by major health systems to automate and capture patient data, also facilitates reimbursement for INOMAX usage. Additionally, the FDA has cleared three new, non-invasive respiratory care devices for use with the INOMAX DS and DSIR drug-delivery systems, the Fisher & Paykel Healthcare Infant Circuit Nasal Cannula and Optiflow Breathing Circuit and the A-Plus Medical Babi Plus Bubble CPAP. Sixty ventilators, anesthesia systems and other respiratory care devices have now been validated for use with Ikaria's INOMAX DS and DSIR drug-delivery systems. The INOMAX DS and INOMAX DSIR are proprietary drug-delivery systems that deliver INOMAX (nitric oxide) for inhalation, the only drug approved by the FDA to treat hypoxic respiratory failure (HRF) associated with pulmonary hypertension in term and near-term infants greater than 34 weeks gestational age. Contact inomax.com.

LISTEN UP

GN Otometrics announced that the company is expanding its audiology and customer service departments due to sustained growth and a strong product pipeline. The expansion of these key departments will provide additional support to its growing customer base, underscoring Otometrics' commitment to excellent customer care. Other contributors to the company's sustained growth trend include an upgraded distribution network and favorable response to new products like the MADSEN AccuScreen newborn hearing screener, ICS AirCal caloric irrigator and the AURICAL fitting system. A robust Quality Assurance program resulted in Otometrics recent decision to offer a two year warranty on all new purchases. To support this growth, Otometrics is adding to its audiology and customer service staff. The company hired Keeley Moore, MA, CCC/A, as a clinical support audiologist, and Nikki Pierce as an inside sales/customer service representative. Moore will act as client liaison for product support as well as offer clinical education and training. She has more than 15 years of experience as a practicing audiologist. Nikki Pierce is a graduate of Purdue with a BS in psychology. She recently completed the National Association of Medical Sales Representatives medical sales training program. Contact otometrics.com.

REDUCED COSTS

Discovery Laboratories, Inc announced the release of data from a new pharmacoeconomic analysis demonstrating that the previously-reported reduced rate of reintubation in preterm infants treated with SURFAXIN may also result in an average potential hospital cost savings of $389,247 per 100 treated infants by reducing the frequency of BPD when compared with reintubation rates of infants treated with other types of surfactants. It has been previously reported that infants who require reintubation are three times more likely to develop BPD compared with those infants who are not reintubated. This pharmacoeconomic analysis is based on data from a retrospective study, published in the Journal of Neonatal- Perinatal Medicine (Vol 4, No 2, 2011), based on data from Discovery Labs' two large phase 3 trials involving a total of 1,546 patients. Infants who were successfully extubated and did not require reintubation experienced a statistically significantly lower mortality rate across all treatment groups compared with infants who subsequently required reintubation (0.5% vs 18%). Infants who required reintubation had significantly higher rates of BPD, NEC, sepsis, and intraventricular hemorrhage. Nearly half of the infants requiring reintubation developed BPD, whereas only 15% of infants developed BPD if they were not reintubated. Infants treated with SURFAXIN demonstrated a significantly lower reintubation rate compared with those infants treated with animal-derived surfactants. Infants treated with SURFAXIN demonstrated a significantly higher combined outcome of survival without reintubation compared with those infants treated with animal-derived surfactants. Discovery Labs reported results from its first pharmacoeconomic analysis based on this retrospective study, which focused on additional days of mechanical ventilation for reintubated infants. The lower rate of reintubation observed in infants treated with SURFAXIN resulted in a potential decreased costs related to direct hospital expenses associated with the need for extended mechanical ventilation due to reintubation, and hospital cost savings of approximately $160,000 to $252,000 per 100 infants when compared with infants treated with other surfactants. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA. The US commercial introduction of SURFAXIN is anticipated early in the second quarter of this year. Contact surfaxin.com.

TAKE A BREATH

Dräger announced the launch of an innovative new interactive community for respiratory care professionals. Called "A Breath Ahead," the portal provides continuing respiratory care education, along with the ability to interact with peers, academics, researchers and clinicians. Respiratory care professionals can participate in forums, polls, and discussion groups, exchanging information and ideas with peers and experts in the field. Participants can earn complimentary Continuing Respiratory Care Education (CRCE) credits online through the educational component of the portal. Developed in collaboration with leading clinicians and educators, the "A

Breath Ahead" website enables respiratory care professionals to tap into the expertise of clinical experts and opinion leaders to discuss topics such as protective lung strategies, evidence-based best practices, neonatal/pediatric issues, and other relevant topics. Clinicians can earn complimentary CRCE credits online, without the expense and time required to attend classroom educational meetings. Providing a forward-looking approach to clinical education, this unique portal is interactive and provides valuable information and education at the convenience of the clinician's schedule. "A Breath Ahead" includes educational webinars, interviews with key opinion leaders, case studies, and FAQs. The interactive portal also provides a forum for respiratory professionals to interact with peers and opinion leaders. Participants can also take part in polls and surveys on topics of interest and concern for the respiratory care profession. Contact draeger.com/abreathahead.

PRENATAL TEST

PerkinElmer, Inc and Verinata Health, Inc, announced a strategic agreement for expanding access to Verinata's verifi test, the most comprehensive non-invasive prenatal test (NIPT) currently available for high-risk pregnancies. The verifi test, which is performed at Verinata's CLIA-certified, California laboratory, uses a single maternal blood draw at as early as 10 weeks of pregnancy to detect multiple fetal chromosomal aneuploidies. PerkinElmer will serve as an exclusive Verinata Health commercial partner in the joint sales and marketing of the verifi test in the US. The collaboration consolidates and streamlines delivery of prenatal testing options due to the combination of PerkinElmer's extensive prenatal testing menu with Verinata's proprietary technologies for the early, non-invasive identification of specific fetal chromosomal aneuploidies. Highly accurate biochemical screening results can be received as early as 11 weeks gestation, through the current PerkinElmer NTD Labs offering for Down syndrome and other chromosomal abnormalities. The verifi prenatal test can be considered for women who have received high risk first trimester screening results at PerkinElmer's NTD Labs early in the first trimester of pregnancy. Contact perkinelmer.com or verinata.com.

DYNAMIC

The EQUANOX Advance 8004CB Series Sensor with Nonin Medical's patent-pending Dynamic Compensation algorithm is the first and only cerebral/somatic sensor to automatically account for pediatric brain-tissue-development variation when measuring oxygen saturation levels. The sensors are designed for use with Nonin's EQUANOX Advance Model 7600 Oximetry System in cerebral or somatic positions on patients weighing less than 40 kg. EQUANOX is a near infra-red spectroscopy (NIRS)-based monitoring device that noninvasively and continuously detects oxygen saturation status in brain and other tissue. The device allows clinicians to quickly react to reverse harmful tissue ischemia events before they become critical. Previous versions of pediatric cerebral/somatic oximetry sensors have essentially been trimmed versions of adult sensors. Nonin's 8004CB Sensor is designed specifically for pediatric patients. The sensor features adhesive and non-adhesive versions for delicate skin, a small footprint, short light-path spacing for pediatric-appropriate tissue-depth readings, and Nonin's Dynamic Compensation algorithm for calculating accurate, patient-specific values. Contact nonin.com.

COMPANY PROFILE

TIMELESS MEDICAL SYSTEMS

Timeless Medical Systems creates customized barcoding solutions to track and trace the handling and feeding of expressed breast milk, donor human milk, and infant formula in healthcare facilities and human milk banks across the US and Canada. Timeless is the market leader for Infant Feeding Tracking, and Milk Bank Management systems, and takes great pride in having saved thousands of babies from feeding and milk handling errors. We were the first to deliver an advanced Milk Bank Management System for human milk banks, a comprehensive Breast Milk Tracking system, and the industry's only Infant Formula Tracking System. Our patient safety products eliminate errors in the preparation and storage of breast milk and infant formula, eliminates the need for manual verification processes, and stop incorrect or expired feedings from being fed to infants. Our systems interface with ADT, CPOE and EMR systems from all healthcare technology vendors using HL7 messaging technology to eliminate many manual steps in your workflows and ensure data accuracy.

Timeless Medical Women & Infants - Breast Milk Tracking: The Breast Milk Tracking system uses unique barcode identifiers to ensure a correct match for every feeding and that the feeding unit has not expired. The system is able to track and trace expressed breast milk, donor human milk, and additives. Benefits include: • Improves Patient Safety • Increases Nurse Productivity & Satisfaction • Reduces Your Financial Exposure • Improves Patient Satisfaction.

Timeless Medical Women & Infants - Milk Bank Management: The Milk Bank Management System is a software program and barcoding solution that tracks and traces everything from donor to baby. MBMS captures all the key information from screening and collection to the processing and distribution of donor human milk and everything in between. Benefits include: • Improves Patient Safety • Increases Staff Productivity & Satisfaction • Improves Recipient Hospital Satisfaction.

Timeless Medical Women & Infants - FormulaTrak: FormulaTrak is the first of its kind, taking patient safety to a new level for formula fed infants. It tracks and traces infant formula from the time it enters your hospital until the time it is fed, and everywhere in between. Benefits include: • Improves Patient Safety • Increases Nurse Productivity & Satisfaction • Reduces Your Costs.

We have customers throughout the United States and Canada. We have built our market-leading solutions by listening carefully to our customers' needs and customizing our software products to ensure we are exceeding their expectations. Please contact us to learn more about our solutions or to discuss one of your unmet needs. Please contact our sales office at (800) 630-3730 Ext 7025 or visit us online at timelessmedical.com.

AAP Policy Update: Male Circumcision

Muhammad Aslam, MD; Faryal Arif, MD; Benamanahalli K. Rajegowda, MD

Routine neonatal male circumcision has always been a topic of controversy and it continues to remain a controversial topic even after the recent Policy Statement issued by the American Academy of Pediatrics (AAP). In our guest commentary, "Is circumcision medically necessary?" in the May-June 2012 issue of Neonatal Intensive Care, we provided a detailed overview of the available data and then current AAP statement for circumcision which stated, "The decision of circumcision of the male infant should rest with the families and one should always respect religious and non-religious views the family has for the procedure."

The reasons for male infant circumcision vary from "germ phobia" due to the penis being considered dirty, to prevent masturbation, to protect against some sexually transmitted diseases, to treat phimosis, paraphimosis and balanitis, and of course to prevent urinary tract infection. In 1971, the AAP issued a statement stating that there was no valid reason for neonatal circumcision. However, in 1989 the Academy revisited the policy with the revised statement stating that it has some valid "potential benefits" but the academy did not state what possible benefits circumcision could offer. In 1999, the Academy revisited the policy and issued a statement stating that the available data were insufficient to recommend neonatal non-therapeutic circumcision. Following the statement, several organizations around the world adopted the policy. However, the WHO took a different stand, stating that the circumcision has benefits in certain communities and populations (HIV, other sexually transmitted diseases).

In 2012, an AAP multidisciplinary task force on circumcision reevaluated the policy after review of the literature from 1995 to 2010. The current policy states that based on sufficient evidence, the health benefits for newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for families who choose it. The benefits identified were "prevention of urinary tract infection, penile cancer, and transmission of some of the sexually transmitted diseases including HIV." Although the health benefits were not statistically significant to recommend routine circumcision for all male newborns, the benefits identified were sufficient to justify access to this procedure for families choosing it after receiving information in an unbiased and accurate manner, along with the risks associated with it. The AAP also suggested that the procedure should be performed by a trained and competent professional using sterile technique under local analgesia for pain control. They went even further to warrant for third party (insurance agencies) payment for the procedure. This is a step far forward from the prior statements. Again they did not recommend routine circumcision for all male infants, but restated that the procedure should be reserved for those families who choose it for their infants whether it is for personal reasons or religious grounds and that their decision should be respected.

In sum, the recent statement by AAP with a positive view towards male newborn circumcision is welcome to those who wish to have their male infant circumcised. To have third party payment for the procedure is even more reassuring.

Dr Aslam is an Assistant Professor of Pediatrics at Harvard Medical School and an attending neonatologist at Massachusetts General Hospital. Dr Arif is a medical doctor and graduate of King Edward University Lahore, Pakistan. Dr Rajegowda is a Professor of Clinical Pediatrics at Weill Medical College of Cornell University and Chief of Neonatology at Lincoln Medical and Mental Health Center. Drs Aslam and Rajegowda are editorial advisory board members of this journal.

Evelynn

Christopher Boitz

Evelynn was born on September 28, 2012 at Memorial Hospital Central in Colorado Springs, CO. She weighed 2 lbs, 4 oz, and measured 14.5 inches. She was born at 29 weeks and 1 day. My wife, Amanda, was diagnosed with severe IUGR and she was hospitalized for a week before the umbilical cord started to give out. Her placenta ruptured during the C-section, so we were very lucky that my wife and baby survived.

Evelynn spent the next several weeks in the NICU. It was a very stressful situation. She had her ups and downs just like every baby who is delivered early. She had lung problems and they were treating her with surfactant and using an oscillator to help her breathe. She was given 5 doses of surfactant already when she was only one week old. There were some concerns that she would not be able to produce her own surfactant or that she had a lung disease, but only time would tell.

She was very active for being so young and premature. All the nurses and docs agreed that she was very feisty: she pulled her ventilator tube out once and caused a few unnecessary beeps on her machines to go off. She was hanging tough, though, and we hoped that her lung problem would pass and she'd be ok.

October 6

Evelynn became very sick and was listed in critical condition. There were several things being observed, but nothing had been identified as the main cause. She had very poor oxygenation in her blood and her lungs got worse since she was delivered. They believed she may have some sort of lung disease but they hadn't narrowed it down. She was 8 days old and received 5 doses of surfactant; another worry was she may have been surfactant deficient. They had her on nitric oxide for a few days, and they weren't able to completely wean her off of it. It was used as a last ditch effort to save her because she wasn't responding to any of the treatments. She did not have any medical conditions that required the use of nitric oxide (at least that is what we were led to believe). The NICU staff decided to try using steroids to try and improve her condition and get her on a healthy path. We watched her very closely and hoped for her to turn around.

The whole experience was a true roller coaster ride. All the joy and excitement and rush of love that you experience when your child is born is amazing, and it quickly turns to a gut-wrenching and heart-stopping experience when she has all the tubes and wires and medicine going into her.

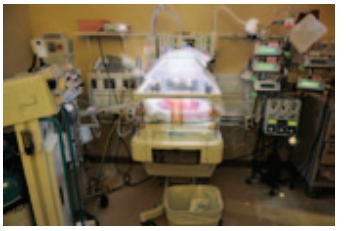
October 28

So Evelynn is now a month old. She has put on some weight, around 3 lbs 7 oz today. On October 6, she was in critical condition due to a severe inflammation cascade. They took her off her regular ventilator and put her on an oscillator to help her breathe. She was on nitric oxide as well among other things like blood pressure medicine, pain medication and TPN. She came to a crossroads where she was unable to make any progress and looked like she might not make it much longer. We spoke to the doctors and decided to try Decadron, a catabolic steroid which helped break the cascade and help her recover.

After a few more weeks on the ventilator, they were able to move her off it and put her on SiPAP. She has been doing great with it.

1: Evelynn Boitz glances at her doctor after being removed from her mother during a C-section at Memorial Hospital Central, Sept 28, 2012, Colorado Springs, CO. Evelynn was born at 29 weeks, 1 day. Her early delivery was caused by Intrauterine Growth Restriction (IUGR).

2: A doctor wipes ink from Evelynn's foot after being stamped on a card.



3: Evelynn receives care through an oscillator, receiving nitric oxide and several medications in her pod.

4: Tubes and wires surround Evelynn as she rests under photo lights.

5. An eye doctor inspects Evelynn's eye development.

6: Evelynn receives attention from her CARES team.

7: This was the first time Amanda was able to give Evelynn a bath since birth.

8: November 2. All is going well…

9: Amanda and Evelynn, home for New Year's.

Christopher Boitz, Evelynn's dad, is a photographer for the United States Air Force. All photos are by Christopher Boitz.

Medical Course of Evelynn Boitz

Susan F. Townsend, MD, FAAP

Dr. Townsend, Evelynn's doctor, is Neonatologist, Pediatrix Medical Group; Associate Clinical Professor of Pediatrics, University of Colorado Denver, Children's Hospital of Colorado at Memorial Hospital Central.

Evelynn Boitz, birth weight 1025 grams, was delivered by cesarean section at 29 weeks gestation due to severe maternal preeclampsia. Her mother had received 2 doses of betamethasone a week prior to delivery. Evelynn was intubated due to respiratory distress at birth, and received surfactant shortly after delivery. She weaned on ventilator support and was extubated to nasal CPAP by 24 hours of life. However, she was reintubated shortly thereafter when she developed severe hypoxemic respiratory failure complicated by hypotension and a patent ductus arteriosus (PDA), which was treated with indomethacin. Her condition deteriorated, and she required maximal doses of dopamine and dobutamine, and 100% oxygen delivered by high-frequency oscillation on the third and fourth days of life. She received multiple doses of surfactant due to radiographic evidence of atelectasis consistent with surfactant deficiency and ongoing need for maximum ventilator and oxygen support. There was not evidence for infection. She was started on "rescue" inhaled nitric oxide on day 5 of life, due to development of pulmonary hypertension documented by echocardiogram. She remained critically ill and unstable on maximal support until a week of life when a brief course of systemic dexamethasone was given. She was then able to be weaned on ventilator and pressor support. However, she remained ventilator-dependent until one month of life when she was successfully extubated to nasal CPAP and subsequently weaned to supplemental oxygen by nasal cannula. During her early hospital course, she had ongoing need for blood transfusions, parenteral nutrition, and intermittent evaluations for infection with brief courses of antibiotics. Screening head ultrasounds were normal, as were her eye exams. Once she was extubated and tolerating full enteral feeds, her growth was steady, although head circumference lagged behind improvements in weight and length. By the time she approached her corrected post menstrual age of 40 weeks, she was not eating well, so a feeding gastrostomy was placed. She was discharged home at 91 days of life, weighing 3330 grams, with a head circumference of 33 cm and length of 48 cm. Her neurological exam and developmental assessments were normal at the time of hospital discharge, and she was still requiring ¼ lpm oxygen by cannula.

We are going to watch her progress closely and determine if she will be able to make it to CPAP within the next few days. Since coming off the ventilator, her respiratory rate has cut in half and is now comfortably breathing at 30-40 breaths a minute.

We've been able to start holding her recently. She does extremely well with skin-to-skin contact; her saturation levels go to 100% and her oxygen requirements go down dramatically. Evelynn becomes very relaxed and enjoys each time we get to hold her.

She is no longer getting TPN, but getting a steady stream of breast milk with extra calories to help her gain weight and grow. She is still very active and is very strong for her age. She also has started rooting and taking pacifiers. Once she is able to control her breathing and sucking, she will be able to enjoy it more. But the nurses and the rest of the NICU staff are very impressed with her; apparently, it is uncommon for premature babies to start rooting at such an early age. If things keep going well, we are on track to have her home by her due date of December 13. She has come an awfully long way and had a bumpy road, much like every premature baby.

It really is amazing what can happen in the NICU. I would have never thought my wife and I would have to go through something this stressful, but we have learned a lot and have a real appreciation for the entire medical staff. They've made all the difference in our lives, and a lot of other people's lives too. They're definitely a pillar of strength for my wife and I.

December 20

Evelynn has been progressing nicely. She made the transition from CPAP to high flow oxygen and now is on low flow oxygen. The docs and nurses expect her to be on low flow oxygen for quite some time. She has been gaining weight steadily. Her current weight is over 6 lbs 7 oz and she is receiving additional calories through breast milk. She turns 12 weeks old on Friday, the 21st. She is still having trouble eating food from the bottle though and she gets tired due to her chronic lung disease. She has passed her hearing and eye tests; the doctors say she is exactly where she needs to be. Tomorrow [the 21st] she will go in for a G-Tube surgery to help feedings. We are hoping that without a tube running through her nasal passage to her stomach and being able to have her at home, she will be able to eat better from the bottle. She is a great candidate for this surgery, and we're hoping that she will start taking from the bottle more regularly. Since she will be getting this surgery, we will be able to bring her home sooner than we thought, so we are very excited. We will have to stay a night or two at the hospital before she comes home to learn how to feed her through the G-Tube during periods where she cannot eat from the bottle and during the night.

Our stay at the NICU has been pretty wonderful. And by that I mean that Evelynn has done some incredible things. She hasn't gotten sick while she's been at the hospital; from what I understand, pneumonia is almost a given when being in the hospital while on a ventilator and lying in bed. She doesn't show signs of being in distress like other infants with lung disease. She has incredible tone and is considered very strong for her age. No brain bleeds, no infections, no colds or RSV. Simply amazing considering the amount of babies who have these while they're in the NICU. She truly is amazing. Amanda and I are very fortunate; the staff at Memorial Central Hospital is top notch. If everything goes well, we are hoping that Evelynn will be released from the NICU on Christmas day or the day after. We are very excited!

December 29

Evelynn was released on the 27th. She is doing great and adjusting to a new surrounding and a new schedule. She's still on oxygen and is learning to eat by bottle a little bit better every day.

The Preemie Parent Perspective: RSV Season

Deb Discenza

It doesn't matter if you are the parent of a 23-weeker or a 30-weeker or even a 35-weeker preemie. Respiratory Syncytial Virus (RSV) season is one that is equally dreaded by all parents of preemies.

With hand sanitizers and hand soap at the ready and a mental list of questions for interrogating well-meaning but potentially germ-ridden visitors to the home, parents arm themselves to fight off illness and protect their newborn. But even they realize that they need help during this season; that it is unrealistic to expect that they can truly protect that infant from invisible germs 100% of the time.

Yet the general public is largely unaware of RSV and so parents must spend a huge amount of time educating family and friends on this topic. Sadly the parents' desperate attempts to inform come off more as pure drama to the average person. They have not seen the inside of an NICU. They have not walked the halls where babies are hooked up to every machine imaginable. Nor have they witnessed a family saying their goodbyes to an infant born too soon and too sick to survive. The NICU to many families is a true battleground for life.

So discharge day is a bittersweet moment of celebration and total fear for these families. They see going home as a chance to be a real family. Yet they are also weighed down with more responsibility than the average family of a full-term newborn.

PREEMIE NEWS PARENTS CAN USE

Preemie Organization: Preemie Parent Alliance
The Preemie Parent Alliance, preemieparentalliance.com, is the brainchild of Keira and Richard Sorrells, parents of surviving triplets born at 25 weeks and 5 days, and the founders of the Zoe Rose Memorial Foundation (zoerose.org). PPA's mission is to represent organizations that provide support to parents of preemies by helping it's members provide quality information, resources, and support efficiently and effectively for the families they serve. The organization hosts a summit each autumn. For more information on a membership, please contact Keira Sorrells at keira@zoerose.org.

Preemie Events
March 10, 2013, Parents of Preemies Day, Graham's Foundation, www.parentsofpreemiesday.org.

Deb Discenza is the mother of a 30-weeker preemie, now 9 years old, and the author of The Preemie Parent's Survival Guide to the NICU, available at preemieworld.com.

Germs are everywhere in the mind of a parent of a preemie and so life becomes almost OCD-like in terms of compulsive hand-washing, hand-sanitizing and practically jumping at any sneeze or cough within a mile of the baby.

Local newspapers love to put out warm stories about preemies and the "warrior" mentality of their ability to fight against all odds to survive and thrive. But they do little to warn of the lasting effects of prematurity, especially that of the concerns of re-hospitalization within the first year. It would be a public service if they could tell the story but also raise awareness about RSV on behalf of the families. Doing so could make preemie parents less fearful each winter season.

Resources

www.Inspire.com Preemie Support Forum: Boasting over 12,000 members worldwide, this forum seeks to support families in the NICU, at home and through the school years as well as through another pregnancy post-preemie. Specialty forums include "School Years, " "Preemies with CP," "Preemie Dads," "Preemie Angels" and more.

GUIDE FOR PARENTS

Following their previous successes, the multi-award winning writer/director of the movie, little man, Nicole Conn, and Preemie Magazine's Founder and Publisher Deb Discenza have teamed up to create a must-have survival guide for parents in the Neonatal Intensive Care Unit.

The Preemie Parent's Survival Guide, (How to Maintain Your Sanity & Create a New Normal) "should be handed out to every preemie parent in the NICU," remarks renowned neonatologist Alan Spitzer, MD, the medical expert for Conn's and Discenza's unique and heartfelt guide.

Both Conn and Discenza know all too well the different life that occurs with a baby born prematurely. As parents of preemies born at 1 pound and just under 3 pounds respectively, their stories cross the spectrum of the challenges that arise early on and even continue well into the school years.

"Collectively our business, community and personal knowledge allows us to provide materials to this community that are unique and most importantly, useful," comments Discenza.

PreemieWorld, LLC is the entity behind the book The Preemie Parent's Survival Guide to the NICU: How to Maintain Your Sanity & Create a New Normal. The book is available for purchase at preemieworld.com.

Guiding Change in the NICU

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

A passion for promoting health, restoring function, and nurturing patients and their families are often the altruistic roots of individuals seeking a career in healthcare. Neonatal Intensive Care Units (NICUs) serve the smallest of patients and their families through a difficult time when expectations for a full-term, healthy baby, are shattered and growth and healing must be optimized.

Healthcare teams are more than protective of their tiny babies; new practice must be thoroughly researched and carefully implemented to ensure that outcomes will be positive and every baby will be safe. With these considerations in mind, our NICU began a journey to research, plan, and initiate the provision of oral care with mother's own, fresh colostrum (Wood, L. 2012).

Reviewing the literature and making a decision driven by evidence-based research can be the easiest part of creating something new. Successful change is planned, charted, and carefully cultivated by an interdisciplinary team. Thought must be given to every aspect of the change — workflow, attitudes, and outcomes. Input from all disciplines ensures a carefully laid path to success. Excluding recommendations from any group involved in the change demotes their importance and reduces "buy in."

Major change is always hard. People cling to methods and outcomes which are familiar. If current practice delivers acceptable outcomes, then why change what is already known? The concepts and understanding of how a change in practice will improve results, which may be acceptable but could be outstanding, becomes a critical point in guiding that change.

Educating the staff, the people responsible for the change, becomes a main priority in the successful implementation of any new process. Open collaboration and participation in the planning stages promotes understanding, acceptance, and trust — key elements to the promotion and adoption of something new. People drive change; without support, a change in practice will never occur (Suran, S. 2002).

To create the needed change in our unit along with participation and acceptance from all staff, our leadership team looked for a conceptual model to guide us in the implementation of new practice. Transformational Leadership is the direction that we chose to move our change forward while creating a culture of ethical and moral responsibility to provide oral care to our babies. The new oral care practice would promote health and improve outcomes for our tiniest of patients.

This article was provided by Medela.

Today's healthcare system demands cost-effective quality outcomes as well as mandates efficient, evidence-based care. Leaders must transform the values, beliefs, and behaviors at every level from organizational to unit based populations (ANCC, 2012). Through Transformational Leadership, multifaceted committees consisting of "layers" of disciplines, management, clinical leaders, and other support staff can influence change, provide direction, and motivate groups to achieve greatness.

Transformational Leadership provides passionate leaders who are actively engaged and provide enthusiasm by "walking the talk" and sharing their vision and knowledge with other members of the team. These leaders are often described as charismatic people driven by ethical mores to do what is ultimately the right thing for patients and their families. Transformational leaders do not lead by wielding power, authority, or titles. Instead they lead by enthusiastically guiding others to follow the practice, educate staff, and one by one influence other staff to adopt the set practice.

With so many factors to weave into the matrix of our project, our leadership team set out to create a patient care team focusing on:

- The policy and procedure of providing oral care with fresh colostrum
- The purchase and use of the Medela Symphony Breastpumps with Preemie + Technology
- Education on the use of the pumps for both mothers and staff
- Staff competencies on the use of our new pumps
- Education on the evidence behind the change
- Education on the need for change to improve outcomes and reduce ventilator associated pneumonia in our neonatal population

Our patient care team followed the principles of change management and Transformational Leadership throughout the planning of this project. Members of our teams were empowered to use our researched evidence to guide them during the creation of policies and procedures. Members of our team included:

- NICU Leadership
- Advanced Clinical Nurses (our nursing ladder)
- Staff Nurses
- NICU Lactation Consultants
- Respiratory Therapists
- Occupational Therapy
- Baby Friendly Team
- Neonatologist support

Transformational Leadership and the Magnet Model were used as our conceptual model to give momentum to our project (ANCC, 2012). Transformational Leadership empowers leaders by:

- Using a multidisciplinary approach
- Using nurses at all levels from administration to bedside care
- Allowing clinicians at any level to be viewed as colleagues not superiors or subordinates
- Promoting influence not authority as the mechanism for change

Teachings empower and encourage instead of direct. Values entice "buy in" from the group encouraging adoption and support of the new practice. Leaders become mentors and champions for change, resulting in staff satisfaction and confidence.

Our current policies and procedures were reviewed and changes made to include use of the Symphony Preemie+ Breastpumps and ensure consistency throughout our mother/baby units. VAP bundles including oral care with fresh colostrum were created.

Education was a key element in the success of our program; the new changes, policies, and bundles needed to be conveyed and buy-in secured. Nurses, therapists, and staff needed to understand the science behind the pump and the need to encourage mothers and support pumping. NICU staff needed to understand why the provision of breastmilk was so very important and key to improving the outcomes of our vulnerable infants.

Education was layered and included individual initial education and hands on practice, attendance at group education in a competency fair setting, competency demonstration by each staff member on setting up the pump, and rounding by our champions. Our message, that oral care with breastmilk was the gold standard in preventing VAP and a necessary component in quality care, reached the staff. Moms were pumping and milk yields were increased. Our leaders were successful in communicating their message.

Continued efforts that help create a dedicated team committed to providing the highest quality of care to our infants include educating new, incoming staff nurses, providing evidence to support the practice, and reaching out to each staff member one by one. Conflicting ideas and resistant staff members are always part of any change, but with careful planning and a model such as Transformational Leadership, motivated teams can create a positive environment for growth, change, and success.

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Lori Wood is a Neonatal Clinical Nurse Specialist at Desert Regional Medical Center in Palm Springs, CA. Lori has been a neonatal nurse for 27 years and began her career as a bedside neonatal nurse before moving into a clinical manager position and then into the arena of clinical staff education. Lori has been certified through the National Certification Corporation in Neonatal Intensive Care Nursing since 1990 and is also an International Board Certified Lactation Consultant. Awarded the honor of being named Nurse of the Year at her hospital in 2008 as well as twice being awarded the title of Notable Nurse from California by Senator John Benoit in 2007 and 2009, Lori shares her passion for mentoring, nursing as a profession, and restoring health to mothers, babies and families with hospital disciplines and the community. Lori is the Versant Nurse Residency manager at DRMC and enjoys guiding new nurses through creative, student immersed learning. She has presented on the topics of Transformational Leadership and the use of case studies, scenarios, and games in educating nurses to foster critical thinking. Lori participates in numerous community based groups promoting breastfeeding and the use of human milk, neonatal nursing, and nursing education and professionalism. She is a member of the National Association of Neonatal Nurses, Inland County Association of Neonatal Nurses, Sigma Theta Tau – Xi Theta Chapter, National Association of Clinical Nurse Specialists, and the International Lactation Consultant Association.

Safety Assessment of a Novel Neonatal Ventilator Circuit Patient Interface Connector for the Delivery of Aerosolized Medication to Mechanically Ventilated Infants

Christopher Henderson; Timothy J. Gregory, PhD; Jan Mazela, MD, PhD; Russell G. Clayton, DO.

Abstract

Background: Aerosolized medications are frequently used as part of the treatment regimen for patients requiring positive pressure ventilatory support. Recently, a novel ventilator circuit (VC)/patient interface connector has been developed to simplify the introduction of aerosolized medications into neonatal positive pressure circuits. This connector includes an internal channel that is intended to direct the aerosol flow towards the infant while shielding the aerosol from the bias flow in the positive pressure circuit. As part of a safety assessment of the connector, studies were conducted to determine the dead space volume and the resistance to gas flow through the VC connector relative to a standard wye connector. In addition, the interaction between the ventilator circuit gas and the aerosol carrier gas was studied using both configurations.

Methods: Mechanical dead space was measured volumetrically. The resistive pressures of a standard wye connector and the VC connector were assessed using a testing system at various ventilator settings within a range appropriate for neonatal positive pressure ventilator support. A second test system was assembled to assess the dilution effect of aerosol carrier gas using both connectors. One end of the inspiratory limb of the circuit was connected to a source of 21% oxygen. 100% oxygen was delivered to the aerosol port of the VC connector or a tee connector in the inspiratory limb. Oxygen was measured at the tip of an endotracheal tube.

Results: Dead space volume of the VC connector was within the range of typical standard neonatal wye connectors. Resistive pressures were similar between comparably-sized connectors at all ventilator settings tested. Ventilator circuit gas was minimally affected by the aerosol carrier gas when delivered at the tee connector, but dilution of the ventilator circuit gas by the aerosol carrier gas was profoundly changed when the aerosol carrier gas was delivered through the VC connector.

Conclusions: When used correctly, the novel VC connector is comparably safe relative to standard wye connectors and aerosol delivery configurations. Further studies are needed to determine the impact of use of the VC connector relating to delivery of aerosolized medications to mechanically ventilated infants.

The authors are with Discovery Laboratories, Inc. Mazela is also with the Department of Neonatology, Poznan University of Medical Sciences, Poznan, Poland. This article was provided by Discovery Laboratories, Inc. Christopher Henderson, Timothy Gregory, and Russell Clayton are employees of Discovery Laboratories, Inc. Jan Mazela is a consultant to Discovery Laboratories, Inc. Christopher Henderson and Jan Mazela are inventors of the VC connector. Discovery Laboratories, Inc holds the patent on the VC connector.

Background

Aerosolized medications are frequently used as part of the treatment regimen for patients requiring positive pressure ventilator support.[1] Recently, a novel ventilator circuit/patient interface connector (Afectair, Discovery Laboratories, Inc, Warrington, PA) has been developed to simplify the introduction of aerosolized medications into the ventilator circuit. This novel connector includes an internal channel that is intended to direct the aerosol flow towards the patient while shielding the aerosol from the bias flow in the positive pressure circuit. As part of a safety assessment, this study assessed the dead space volume of the novel neonatal connector and the resistance to gas flow through the connector relative to a standard wye connector, as well as the interaction between the positive pressure circuit flow and the aerosol carrier gas introduced through the connector compared with a standard of care (SoC) configuration for introducing aerosolized medication into a positive pressure ventilator circuit.

Methods

Equipment

The novel connector is a disposable, single-patient use ventilator circuit connector. It has five dedicated-use ports for connection with the inspiratory and expiratory positive pressure circuit limbs, the aerosol source, a proximal pressure port, and a patient interface such as a mask or endotracheal tube. The novel connector also has an internal aerosol channel that extends just beyond the inlet of the inspiratory limb port (Figure 1). The neonatal connector is intended for use with 10 mm neonatal positive pressure circuits. The novel connector replaces the standard patient wye connector and has a capped port for aerosol introduction. This allows for simplified introduction of aerosol into the ventilator circuit and reduces the need to disconnect parts of the circuit to initiate aerosol therapy.

Mechanical dead space was calculated for four standard wye connectors typically used with neonatal ventilator circuits: Intersurgical (Intersurgical Ltd, Workingham, Berkshire, UK), Neo2-Safe (B&B Medical Technologies, Carlsbad, CA), Fisher & Paykel RT-131 (Fisher & Paykel, Irvine, CA), and Hudson 780-12 (Hudson RCI, Research Triangle Park, NC). The Hudson wye connector was for all standard of care (SoC) testing.

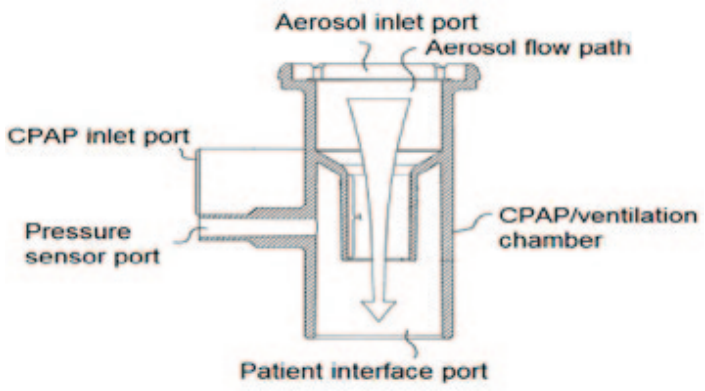

Figure 1. Schematic of the novel connector.

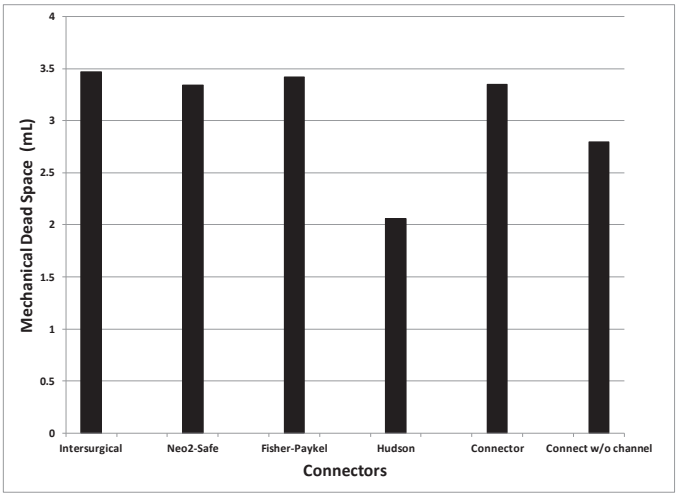

Figure 2. Mechanical dead space of four typical standard wye connectors: Intersurgical (Intersurgical Ltd, Workingham, Berkshire, UK), Neo2-Safe (B&B Medical Technologies, Carlsbad, CA), Fisher-Paykel RT-131 (Cardinal Health, Dublin, OH), and Hudson 780-12 (Hudson RCI, Research Triangle Park, NC). Mechanical dead space of the novel neonatal connector with (Connector) and without (Connector w/o channel) compensation for the volume of the internal channel is also shown.

The SoC aerosol delivery circuit consisted of a 10 mm neonatal positive pressure breathing circuit (Hudson RCI, Research Triangle Park, NC and Fisher & Paykel, Irvine, CA) and a standard wye connector (Hudson RCI, Research Triangle Park, NC). The aerosol delivery SoC was simulated by placing a tee connector (Hudson RCI, Research Triangle Park) into the inspiratory limb of the circuit approximately 18 cm from the standard wye connector.[2]

Resistance was determined using utilizing a Sechrist Millennium ventilator (Anaheim, CA) and a Biopac MP150 with AcqKnowledge v 4.1 (BioPac Systems, Inc, Goleta, CA). A pressure port was inserted into the circuit proximal to the connector for measurement of pressure. A pneumotachometer (Hans Rudolph, Kansas City, MO) was placed between the patient interface port of each connector and a NVM-1 Neonatal Volume Monitor test lung (BC Biomedical, St Charles, MO) for measurement of flow.

Gas dilution was determined by measuring oxygen concentration using an OxyCheq Expedition O_2 analyzer (OxyCheq, Marianna, FL) connected to the tip of a 3.5 mm ID endotracheal tube (Vygon Corporation, Montgomeryville, PA). When 21% oxygen/balance nitrogen positive pressure gas flow through the circuit was required, an air compressor (Maquet, Inc, Wayne, NJ) was used to introduce the gas into the ventilator circuit. When 100% oxygen was introduced into the ventilator circuit, the gas flow was provided from a gas tank containing 100% oxygen. Flows were regulated with rotometers (Precision Medical, Northhampton, PA) and measured using a mass flow meter (Sierrra Instruments, Inc, Monterey, CA).

Connector Dead Space
The mechanical dead space of the novel neonatal connector and four typical standard wye connectors was determined by calculating the internal volume from the patient interface port to the insertion of the inspiratory/expiratory ports. In the case of the novel neonatal connector, the volume of the internal channel was subtracted because this volume was not considered to be re-breathable volume. During aerosolization aerosol flows from the internal channel, eliminating the potential of it contributing to re-breathable volume. When aerosol is not being delivered, the aerosol port is capped, creating a column of air that is not expected to mix with exhaled air. Therefore, it should not contribute to re-breathable volume.

Resistance Testing
Resistance testing was conducted on the novel neonatal connector and the SoC circuits using the settings noted in Table 1. All test conditions were conducted in triplicate (n=3). Resistance was calculated as $R = \Delta P/\Delta F$, where R is resistance, ΔP is the change in pressure, and ΔF is the change in flow.

Dilution Testing
Dilution testing was conducted on both the novel neonatal connector and the SoC circuits. Positive pressure gas flow through the ventilator circuit was first set at 6 L/min for the neonatal connector and the corresponding SoC circuit. Aerosol carrier gas flows through the novel connector and the tee connector in the SoC circuit were tested at 0, 1, 2, 3, 4, 5, and 6 L; single readings were captured 5 times (n=5), separated by at least 15 seconds. The first reading was not made until at least 60 seconds from initiation of each run to allow for stabilization. The positive pressure gas flow through the ventilator circuit was then set at 12 L/min for the novel neonatal connector and the corresponding SoC circuit, and the testing was repeated. All tests were conducted with ventilator circuit gas of 21% oxygen/balance nitrogen and aerosol carrier gas of 100% oxygen, and then conversely with ventilator circuit gas of 100% oxygen and aerosol carrier gas of 21% oxygen/balance nitrogen.

Results
Mechanical Dead Space Determinations
The total volume of the novel neonatal connector was 3.35 mL. After subtracting the volume of the internal channel that is not expected to contribute to re-breathable dead space, the mechanical dead space volume was 2.80 mL (Figure 2). For the four standard wye connectors used the mean (SD) dead space was 3.07 (0.68) mL with a range of 2.06 to 3.47 mL.

Resistance Determinations
Resistance to gas flow at all settings tested was similar between the novel neonatal connector and the standard wye connector (Figure 3). The average resistance ranged from 2.01 (0.29) cmH_2O/L/min to 3.57 (0.03) cmH_2O/L/min for the novel neonatal connector, and from 1.87 (0.24) cmH_2O/L/min to 3.57 (0.14) cmH_2O/L/min for the standard wye connector.

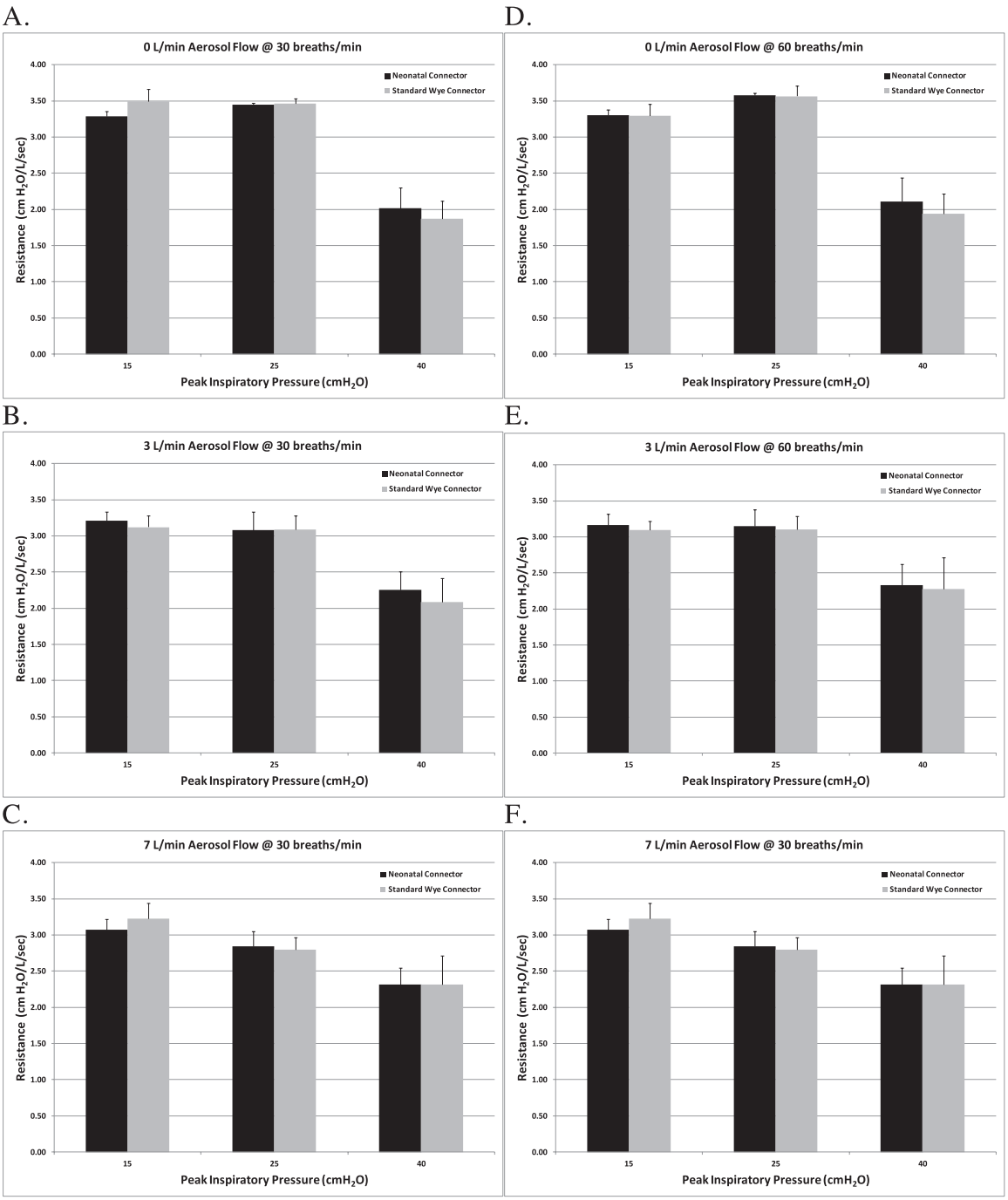

Figure 3. Neonatal resistance testing: Dynamic resistance was measured at peak inspiratory pressures (PIP) of 15, 25, and 40 cmH2O and a respiratory rates (RR) of 30 (Fig 2A-C) and 60 (Fig 2D-F) bpm for the novel neonatal connector and standard wye connector. Aerosol carrier gas was introduced into the aerosol port of the novel neonatal connector at flow rates of 0, 3, and 7 L/min. For the standard wye connector, aerosol carrier gas was introduced at a flow rates of 0, 3, and 7 L/min using a tee connector placed in inspiratory limb of the circuit approximately 18 cm proximal to the connector.

Dilution Studies

At all aerosol carrier gas flows greater than 1 L/min, the aerosol carrier gas delivered through the novel neonatal connector completely diluted the 6 L/min positive pressure circuit gas (Figure 4). When 100% oxygen was used as the aerosol gas, the concentration of oxygen that was measured at the tip of the endotracheal tube was 97.4% at an aerosol carrier gas flow of 1 L/min and a ventilator circuit gas flow of 6 L/min. When the aerosol carrier gas flow was at least 2 L/min, the measured oxygen concentration was 100%. When the ventilator circuit gas flow was increased to 12 L/min, the oxygen concentration was 67.7, 85.3, 98.0, and 100% at aerosol carrier gas flows of 1, 2, 3, and 4-6 L/min, respectively. In contrast, the aerosol carrier gas delivered through the tee connector in the corresponding SoC circuits only partially diluted the positive pressure circuit gas, even at aerosol carrier gas flows up to 6 L/min (Figure 4).

Discussion

A novel connector has been developed to simplify the introduction of aerosolized medications into the ventilator circuit. These studies were conducted to evaluate the safety of use of the novel neonatal connector, specifically the dead

	Neonatal Connectors		
RR (bpm)	30		60
PIP (cmH_2O)	15	25	40
Aerosol Flow (L/min)	0	3	7

Table 1. Ventilator parameters for resistance studies

space volume, the resistance to gas flow through the connector and the potential for aerosol carrier gas introduced through the connector to dilute the ventilation gas.

The mechanical dead space volume is the volume within the connector between the ventilator gas flow channels and the patient interface where potential re-breathing occurs.[3] The mechanical dead space volume becomes particularly important when ventilating a patient with small tidal volumes. The mechanical dead space volume of the novel neonatal connector was 2.80 mL and was within the range of the dead space volumes of typically used standard wye connectors. The 1.41 mL difference between the smallest and largest dead space measurements is trivial relative to the continuous bias flow in the ventilatory circuit and therefore is not likely to be clinically relevant. Therefore, during clinical use of the novel neonatal connector, dead space should not be a safety consideration unless very low bias flows are utilized during ventilation.

All parts of the ventilator circuit add resistance to the patient's respiratory efforts during mechanical ventilation, with the endotracheal tube contributing the most to resistance.[4] Increased resistance in the ventilator circuit can add to work of breathing and affect the ability to decrease ventilator support or provide synchronized ventilation to the patient. Therefore, it is important to determine whether the internal aerosol channel adds to the resistance of the ventilator circuit. Resistance to gas flow at all settings tested was similar and within error measurements between the novel neonatal connector and the standard wye connector. Therefore, when compared with a standard wye connector, the novel neonatal connector does not add additional resistance to the ventilator circuit.

The delivery of aerosolized medications can alter the concentration of oxygen in the gas delivered to the patient if a matched blended gas source is not used to drive the aerosol device. This potential problem is recognized by the American Association of Respiratory Care and listed as a caution in the policy of delivering aerosolized medication to patients on mechanical ventilation.[5] Nevertheless, in the hospital setting, wall source air and oxygen provide a convenient source for aerosol carrier gas, and practitioners may elect to use either 21% or 100% oxygen to deliver the aerosol rather than match the blend of gas in the positive pressure circuit. This study demonstrates that, regardless of the method used to introduce the aerosol into the positive pressure circuit, the aerosol carrier gas can alter the gas mixture delivered to the patient when the aerosol carrier gas mixture is not matched to the gas mixture in the ventilator circuit. However, when delivered through the novel connector, the aerosol carrier gas can dramatically change the ventilator circuit gas mixture, even when introduced at relatively low flows. Thus, when delivering aerosol through the novel neonatal connector, the aerosol carrier gas mixture should be equivalent to the gas mixture in the ventilator

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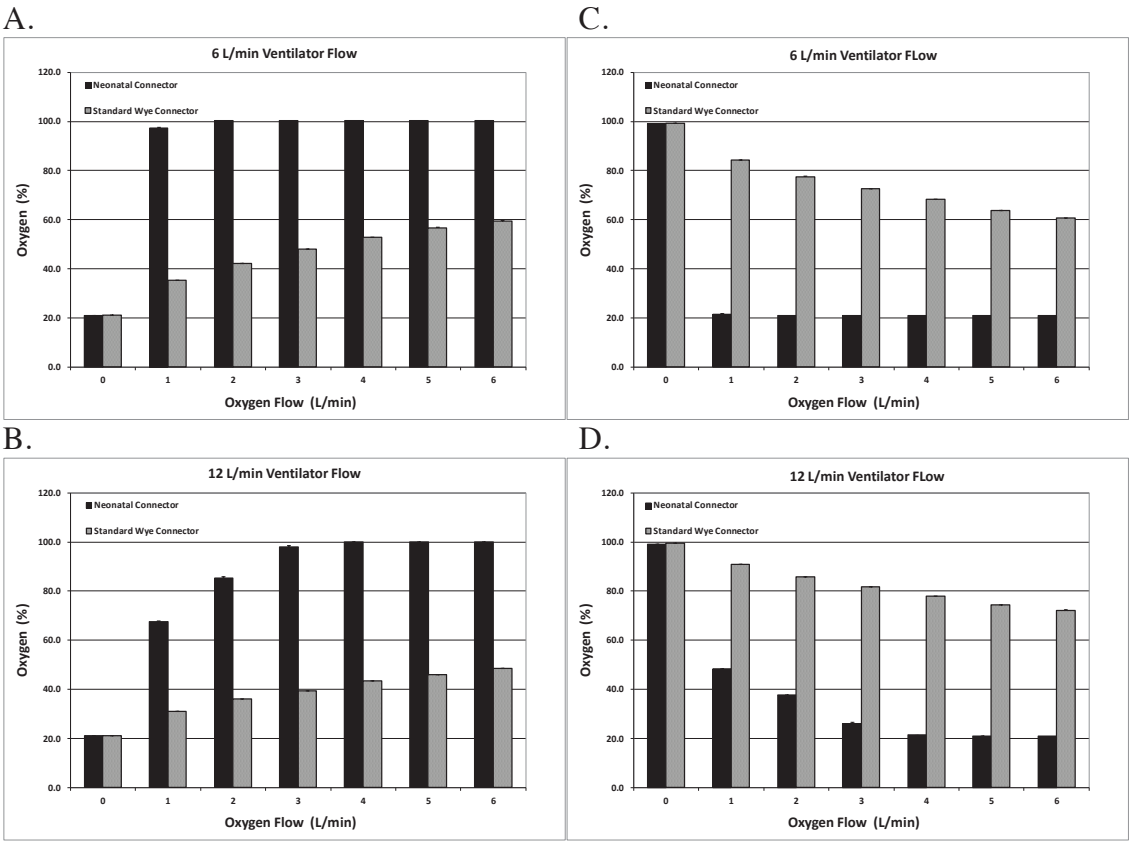

Figure 4. Neonatal dilution testing: The oxygen concentration was measured at the tip of the endotracheal tube for the novel neonatal connector and standard wye connector at aerosol flows ranging from 0 to 6 L/min of 100% oxygen and ventilator circuit gas flows of 6 and 12 L/min of 21% oxygen (Fig 3A-B). Oxygen concentration was also measured at aerosol flows ranging from 0 to 6 L/min of 21% oxygen and ventilator circuit gas flows of 6 and 12 L/min of 100% oxygen (Fig 3C-D).

Croup and the Precision Flow Heliox: A Product Case Study Based on Clinical Experience

Thomas L. Miller, PhD; Jenna Flores, MS, RRT

The concept of reducing work of breathing by ventilating with helium-oxygen gas mixtures (heliox) has been in practice for more than 80 years. Because helium has a much lower density than nitrogen, breathing heliox results in an immediate and dramatic reduction in airway resistance, and therefore work of breathing, compared to conventional air-oxygen blends.[1] However, a limitation of heliox use has been accessibility, whereby configuring blenders, tanks and patient interface components limit the speed at which the therapy can be applied. In this regard, other therapeutic options for the treatment of acute incidences of airway obstruction have been implemented ahead of heliox, despite the potential for heliox to limit the need for more invasive ventilation strategies and ultimately lower treatment costs while improving patient experience. Recently, the availability of products designed and approved for use with heliox can simplify administration, improve reaction times and reduce length of stay and associated healthcare costs.

This article presents a patient case scenario we experienced first-hand in 2012. This scenario is associated with the release of the Precision Flow Heliox, a high flow nasal cannula system designed for the delivery of heliox therapy. Now, imagine an infant aged 3 months presented in the ED with suspected croup. The physician orders heliox…

Lets imagine a typical scenario. You have a cylinder, but can't find a regulator or wrench, or a humidifier to connect to a blender with an adapter for heliox. Timely patient care hangs in the balance as you scramble to cobble everything together. As we understand, reduced work of breathing is associated with increased respiratory muscle stamina, which can help avoid potential respiratory failure. The success of a therapy, including heliox, can be dramatically impacted by the methods and devices used. The all too common practice of modifying commercially available devices to function outside of the range of their intended design creates risks for the patient, clinicians and the institution. In the interest of patient safety, one of the best ways to minimize these risks is to use devices that are cleared by the Food and Drug Administration (FDA) and designed specifically for use with heliox.[2]

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Let's consider some important aspects of heliox delivery

Heliox typically comes in pre-mixed cylinders; common mixtures are 80% helium / 20% oxygen or 70% helium / 30% oxygen. In the past, it was common to deliver the gas straight from the cylinder, through a regulator and flow meter to a non-rebreather mask. There are several problems delivering heliox in this manner. First, if not using heliox calibrated equipment, the set flow and the flow actually delivered will differ. This can cause confusion among the care team. Second, non-rebreather masks can lead to dilution with room air. In fact, a study done in 2008 by Standley and associates showed an average of only 37.2% tracheal helium in patients breathing 80/20 heliox through a non-rebreather mask.[3] In addition, patient compliance with a mask interface can be a significant challenge. Finally, lack of proper gas conditioning can be an issue with respect to both patient comfort and failure to mitigate potentially worsening disease processes. In this regard, some asthmatics will react to cold gas with bronchospasm.

The Precision Flow Heliox is the first FDA approved high flow nasal cannula system specifically designed for heliox delivery. Coupling this unit with a practical and convenient tank management system and integrated regulators designed for use with heliox makes for a complete therapy platform that can be set up rapidly for immediate use at the bedside. The device is pre-calibrated for heliox delivery, so no calculations are necessary to determine delivery flow rates; setup does not require wrenches or special tools to make connections; the device has an internal blender to allow delivery of any helium-oxygen mixture necessary (FiO2 ranges from 21-100%). And lastly, the Precision Flow Heliox has the capabilities to properly condition heliox with heat and humidity, making the gas more comfortable for patients to breath and soothing to a reactive airway.

Now, let's revisit our patient with croup in the ED

Croup (laryngotracheal bronchitis), as we know, causes obstruction in patient's airways due to swelling around the vocal cords. It can lead to increased work of breathing and features a "barking" cough. The most common cause of croup is a viral infection; however, it can also be caused by bacterial infections, allergies or acid reflux. Croup typically occurs in children 5 months to 6 years of age.[1,4]

With viral croup, treatment is typically palliative in nature. Anti-inflammatory agents are often prescribed in an effort to reduce the swelling, and pain medication is given to alleviate fevers and

pain. There is no cure. Occasionally, if the inflammation persists, work of breathing gradually increases, and additional support is necessary. Support can range from less invasive options, such as heliox therapy if respiratory muscle fatigue occurs, to more invasive measures such as intubation if respiratory failure occurs. (Respiratory failure can occur in as high as 6% of patients admitted for croup if muscle fatigue persists).[1,4,5,6]

In fact, our 3 month old patient was suffering from severe croup, and was successfully treated with the Precision Flow Heliox in the ED/ICU. He arrived with signs of increased work of breathing and a "barking cough." His WOB continued to increase and croup scores averaged 5-7. The decision was made to start heliox therapy and the Precision Flow Heliox was initiated. He started on a 5 LPM flowrate, but subsequently required an increase to 8 LPM. With that increase in flow, the oxygen concentration was able to be decreased from the initial 35% to 25%, (proportionally raising the helium concentration). His croup scores improved after therapy was initiated and averaged 3-5. All other clinical indicators improved over the next 15 hours, when the physician discontinued therapy. During heliox therapy the patient did receive five in-line racemic epinephrine aerosol treatments. Altogether, the patient was discharged home within 24 hours of being admitted and was able to stay on a non-invasive support method throughout his stay.

With the ease of use and precise control of the Precision Flow Heliox, more patients may be able to be maintained on a non-invasive support method. With an average length of stay for patients admitted with croup being two days, early discharge and the avoidance of invasive therapies saves time and money for staff and hospitals and more importantly, helps patients.[7]

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Cord Around the Neck Syndrome

Morarji Peesay

A nuchal cord (or Cord-Around-the Neck (CAN)) occurs when the umbilical cord becomes wrapped around the fetal neck 360 degrees. Nuchal cords are very common; the incidence of nuchal cord increases with advancing gestation from 12% at 24 to 26 weeks to 37% at term.[1] Most are not associated with perinatal morbidity and mortality. In some fetuses and newborns, CAN may cause problems, especially when the cord is tightly wrapped around the neck. The cluster of cardiorespiratory and neurological signs and symptoms associated with unique physical features that occur secondary to tight cord-round-the-neck has been referred to as "tCAN syndrome" (tight Cord Around the Neck Syndrome).[2] A small number of studies have shown that nuchal cord and or tCAN can affect the outcome of delivery and may have long-term effects on the infant[3] but as a causative factor for stillbirth it is debatable.[4,5] However, some case reports of postmortem findings on stillbirths show negative pathology reports and tight cord around the neck being the only cause of death.[6]

It is the unique physical features of tCAN syndrome that distinguishes it from birth asphyxia even though there are many similarities between these two conditions. Umbilical cord abnormalities are considered as one of the causative factor for birth asphyxia. The manifestation of tCAN symptomatology seems to happen both in the presence of normal and depressed AGPAR scores.[7] Umbilical cord compression due to tCAN may cause obstruction of blood flow first in thin walled umbilical vein, while infant's blood continues to be pumped out of baby through the thicker walled umbilical arteries thus causing hypovolemia and hypotension resulting in acidosis.[8] Anemia[9] and mild respiratory distress may occur. Some of these infants may also have facial and conjuctival petechiae[10] and rarely petechiae of the neck and upper part of the chest and skin abrasion of neck[11] where the cord was tightly wrapped, and facial suffusion,[12] all of which can also be seen in some post-mortem findings of stillbirth infants who had tCAN [Archana Bargaje, personal communication]. If born alive, some of these infants may also be somewhat obtunded with a low tone and have transient feeding difficulties. These findings raise the possibility of transient encephalopathy, which may lead to long-term complications.

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A stillbirth attributed to a cord problem should have evidence of cord obstruction or circulatory compromise. Other potential causes of stillbirth need to be excluded prior to labeling cord abnormalities as the causative factor, since cord abnormalities seen in more than a third of all normal live births.

The tCAN Syndrome may conceptually be similar to strangulation which may result in non lethal problems or death. The pathophysiological mechanisms of strangulation injuries (lethal and non lethal) involves venous, arterial obstruction (arterial spasm due to carotid pressure) in the neck and vagal collapse (increased parasympathetic tone).[13] This can lead to cerebral stagnation, hypoxia, and unconsciousness, which, in turn, produces loss of muscle tone. The same pathophysiology of strangulation may possibly be applicable to tCAN syndrome in neonates. A study on potentially asphyxiating conditions and spastic cerebral palsy in infants of normal birth weight showed evidence of association of tCAN in children with quadriplegia.[14]

Intermittent umbilical cord occlusion in preterm and near term sheep caused a decline in pO2 and pH, and higher PCO2 and altered brain protein synthesis/degradation.[6] Whether human fetal intermittent strangulation by tCAN have similar brain protein alterations and thus long-term effects remains to be seen. Using specific placental histologic criteria for umbilical blood flow restriction in unexplained stillbirth, Parast et al[4] showed significant correlation of placental changes of "minimal histologic criteria" with cord accidents (as tCAN is part of cord accidents). Nuchal cords showed highest rates of thrombosis-related placental histopathology and fetal thrombotic vasculopathy and thrombosis seems to be highly specific for cord related stillbirths.[4,5]

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Safety Assessment…continued from page 31
circuit in order to maintain the prescribed gas mixture.

The lack of dilution effect when the aerosol carrier gas is introduced through the novel neonatal connector suggests that the delivery of an aerosolized medication to a patient may increase when administered through the novel neonatal connector, relative to the current SoC. Clinicians who employ non-standard dosing regimens when delivering aerosolized medications to patients receiving mechanical ventilation should be aware that more medication may be delivered to the patient if the novel neonatal connector is used. Further study is necessary to verify this observation and quantify the relative difference in the delivery of aerosolized medication between the novel neonatal connector and the SoC.

Conclusion

The novel connector is comparably safe when compared to the typically-employed standard wye connectors. The use of the novel neonatal connector appears to allow for an increased delivery of the aerosol carrier gas relative to the current SoC. Therefore, when using the novel neonatal connector, the aerosol carrier gas mixture must be equivalent to the gas mixture of the ventilator circuit to maintain the gas mixture delivered to the patient. Further studies are needed to determine whether the use of the novel neonatal connector results in an increased delivery of aerosolized medications and therapeutic medical gases.

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Controlling the Health Risks Associated with DEHP Exposure

Jeri E. Eiserman, MBA, RRT, FAARC; James Lorek, Eric Halsey

Abstract

DEHP is one of the most commonly used plasticizers in the world and is utilized in many medical devices. Both the FDA and the European Chemicals Agency (ECHA) have issued advisories or statements regarding DEHP and its potential risks to patients.[1,2] This paper discusses DEHP; why it is used; its potential risks, particularly in medical devices; the patient populations at risk; and a new non-DEHP product option for oxygen delivery to patients in the hospital and the home.

Introduction

Medical devices are commonly made from polyvinyl chloride (PVC) because it is durable, cost effective and easily manufactured. However, PVC is inherently rigid and is made tougher and more flexible through the addition of plasticizers.[3,4] DEHP (di(2-ethylhexyl)phthalate) is the most common plasticizer in PVC products and is part of a family of chemicals called phthalates. Many PVC medical products typically contain approximately 30% DEHP.[3] When PVC is formulated using DEHP, no bonds form between the DEHP and PVC chemicals, allowing DEHP to exist as free molecules between polymer fibers. These molecules can leave the plastic and migrate to the surrounding environment. This process is referred to as "leaching," and is of greater concern from soft plastic components, such as tubing, when exposed to liquids or moisture.[1,3]

The amount of DEHP that will leach depends on the temperature, the lipid content of the liquid, the duration of contact with the plastic, and the percent of DEHP in the product.[2] It has been known for a long time that DEHP can leach out of PVC, resulting in exposure to body tissues and fluids.[1] Medical products such as IV bags and tubing, blood bags and infusion tubing, enteral nutrition feeding bags, nasogastric tubes, peritoneal dialysis bags and tubing, tubing used in cardiopulmonary bypass procedures, extracorporeal membrane oxygenation (ECMO) and hemodialysis, and tubing used for oxygen delivery typically contain DEHP as a softening agent in the PVC.[5]

Studies with laboratory animals have shown that exposure to DEHP may produce a range of adverse effects. Thus, the subject of DEHP and its potential health risks is being debated worldwide based on the possibility of plasticizers leaching from PVC.[5]

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Risks Associated with DEHP

Although there have been no documented reports of adverse events in humans, the FDA reported that exposure to DEHP has produced a range of adverse effects in laboratory animals, with the effects on the development of the male reproductive system and production of normal sperm in young animals being of greatest concern. The FDA issued a public health notification that provides steps to reduce the risk of exposure to DEHP in certain patient populations and released an advisory recommending that precautions should be taken to limit exposure of the developing male to DEHP.[2] The FDA also issued a safety assessment that reported that DEHP is released from a wide variety of medical devices, including nasal cannula tubing.

The European Chemicals Agency (ECHA) has identified DEHP as a substance of very high concern (SVHC), as it is classified as toxic to reproduction, category 2. As such, it was included on the organization's Registration, Evaluation, Authorization, and Restriction of Chemical Substances (REACH) candidate list in October, 2008. ECHA has called for the progressive substitution of the chemicals on this list when suitable alternatives have been identified.[1,6]

Populations at Risk

The amount of DEHP that a patient might be exposed to is largely determined by the patient's sensitivity to DEHP,[2,5] the type of procedure performed,[5] and the frequency and duration of these procedures.[2] Based on evidence that the FDA, ECHA and other credible studies have found, the male fetus (through exposure to his mother), male neonate, and peripubertal male would appear to be high-risk groups, as they have a higher sensitivity.[2,6,7] The National Toxicology Program, a component of the National Institutes of Health, has recently reached a similar conclusion.[8] Neonates in the NICU environment are exposed to multiple devices containing DEHP and it is possible to estimate that a 4 kg infant could receive a DEHP dose on the order of 3 mg/kg/day for periods of weeks or months.[5] Children are also at increased risk for the effects of DEHP because they absorb chemicals more efficiently, process them more slowly, and eliminate them with less efficiency than adults.[5] The type, duration and frequency of the procedures performed directly affect the dose of DEHP received by a patient.[2,5] The following procedures have been identified as possibly posing the highest risk for exposure to DEHP: exchange transfusion,[5] ECMO,[5] enteral and total parenteral nutrition in neonates;[5] multiple procedures in sick neonates;[5] nursing infants of mothers on hemodialysis,[5] heart transplantation or coronary artery bypass

surgery (aggregate dose),[2] transfusion of blood,[5] and transfusion in adults undergoing ECMO.[2] Seriously ill patients may require more than one of these procedures, thus potentially exposing them to higher levels of DEHP.[5]

A study conducted with the National Research Council of Italy determined that human exposure to DEHP can begin in utero, suggested that phthalate exposure is significantly associated with shorter pregnancy duration, and found detectable cord blood DEHP concentrations in 88.1% of samples, thus suggesting pregnant women are at increased risk for the health effects of DEHP exposure.[7] Another population that may be at increased risk for the effects of DEHP exposure are patients who use oxygen for prolonged periods, such as those suffering from Chronic Obstructive Pulmonary Disease (COPD), as they are exposed to DEHP for extended periods.[4]

The Challenge and a Solution

Medical products made with PVC require a softening agent (plasticizer) when pliability and flexibility are required. For decades, DEHP has been used as the plasticizer in a myriad of devices. The challenge has been to find a non-DEHP plasticizer that could be used as a viable alternative.

A case in point is the nasal cannula, which has traditionally been manufactured using PVC with DEHP as the plasticizer, and is used to deliver supplemental oxygen to patients in need of respiratory support. Because of its comfort, convenience and ability to deliver low to medium concentrations of oxygen, the nasal cannula is one of the most frequently used oxygen delivery devices across the patient spectrum. Flexibility, toughness and pliability are necessities with this product, which required the use of a plasticizer, and for decades DEHP was the only option.

Recent advances in medical device design and materials have now allowed Hudson RCI to produce the new Softech Plus nasal cannula product offering which uses a new material blend with a non-DEHP plasticizer. With this new breakthrough in material science, the non-DEHP Softech Plus cannulas are exceptionally soft and set a new standard in patient care; ensuring a comfortable fit for both short and long-term use, without the potential risks posed by DEHP.

Conclusion

While the FDA recommends that you should not avoid procedures or devices simply because of the possibility of health risks associated to DEHP exposure in patients at increased risk for the effects of DEHP, they do recommend considering alternatives for the treatment of those patients, including PVC devices made with non-DEHP plasticizers. For other patient groups, the decision to use DEHP alternatives must take into account the medical advantages and drawbacks of the substitutes and their availability.[2]

The Softech Plus cannulas offer an exciting option for providing oxygen therapy to populations identified as at increased risk for the health effects attributed to exposure to DEHP, such as male neonates,[2] pregnant women who carry male fetuses,[2] peripubertal males,[2] children,[5] patients undergoing multiple high risk procedures,[5] and patients who use oxygen for prolonged periods.[4]

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A Complete Digital Eye Exam – Part of a Routine Newborn Examination?

New Perspectives on Newborn Eye Imaging

Recently, an international group of pediatric ophthalmologists gathered in Kunming, China to hold a clinical discussion and debate on the value of universal newborn eye imaging. This clinical recap shares insights from that event. The physicians in attendance included – Lihong Li, MD, Director of Ophthalmology Department, Maternal and Children's Hospital, Kunming, China; Peiquan Zhao, MD, Director of Ophthalmology Department, Shanghai Xinhua Hospital, Shanghai, China; Xin Song, MD, Pediatric Ophthalmologist, Ministry of Health, Children's Eye Care Center, China; Lijun Shen, MD, Vice President of Wenzhou Eye Hospital, Wenzhou, China; Paul J. Rychwalski, MD, Pediatric Ophthalmologist, Cole Eye Institute at the Cleveland Clinic Foundation; Helen A. Mintz-Hittner, MD, Pediatric Ophthalmologist, University of Texas Health Science Center.

What is the Value of Newborn Eye Imaging?

One of the questions the participants explored is whether newborn eye imaging reveals potentially serious conditions. The answer is "yes," based on studies conducted in China and presented to the group.

In Kunming, Lihong Li, MD, Director of the Ophthalmology Department of Maternal and Children's Hospital undertook a study in response to the Vision 2020 initiative. All babies examined were full-term, healthy infants.

The results of this study (see Figure 1) showed significant numbers of clinically important eye abnormalities. Of particular note are the two cases of retinoblastoma. One of those cases represented the earliest detection of retinoblastoma ever recorded in China. Other notable results are the detection of 15 cases of FEVR and 67 cases of macular hemorrhages (1.9%), a more serious condition and potentially clinically significant.

Results of a 2009 clinical study headed by Zhan Li, MD, Director of Ophthalmology at Zhuhai Maternal and Children's Hospital, Zhuhai, China were also reported to the group. This study supported Dr Lihong Li's findings that imaging of all newborns provides early detection of potentially harmful eye diseases.

Dr Li's results are as follows:

- A total of 4,283 newborns were imaged
- 3,812 were normal babies and 471 were premature
- Abnormalities (including retinal hemorrhage) were found in 14.5% of the newborns
- The incidence of abnormalities was 1.4% when excluding retinal hemorrhage

Looking at the data presented by Drs Li and Li, it is clear that newborn eye imaging helps physicians diagnose significant abnormalities, many of which warrant follow up. Comparing the rate of eye abnormalities found in newborns (1:70 in Dr Lihong Li's study) to the rate of hearing abnormalities (1:300-500),[1] eye imaging of all newborns should be as much a part of standard newborn care as hearing screening.

Many conditions diagnosed by physicians using RetCam imaging could result in vision impairment, if not blindness. Early detection can lead to appropriate treatment and preservation of vision. Because vision accounts for 83% of human sensory input,[2] the importance of good eyesight cannot be overstated. A child with good vision has better social, educational and psychological development and is more capable throughout life.

Dr Hittner suggested that a patient's family can also benefit from newborn eye imaging. For infants found with an eye disease, other siblings can be evaluated to determine whether they also have a similar eye condition.

As more healthy newborns are imaged, the accumulated data may help answer questions about the causes and effects of retinal hemorrhage and other eye diseases. For instance, Dr Li in Kunming is investigating why the incidence of retinal hemorrhage seems to be higher in Kunming than in other parts of China, and whether preventive measures can be taken. Dr Li is also hoping to learn whether macular hemorrhage in infants is related to amblyopia later in childhood.

What is the Value of Newborn Eye Imaging?

The existing data about cost is encouraging. In Zhuhai, the hospital charged the equivalent of US$65 per patient. In Kunming, the charge equated to US$45 per infant. Based on the number of patients and the fees, a hospital would recover the cost of a RetCam device in about one year. After that, the device could generate a profit for the hospital. Efficient workflows for the imaging equate to about 3,000 patients imaged annually for each RetCam device.

The procedure takes 10 minutes or less and can be done along with the other typical newborn tests. Trained professionals can capture the RetCam images. Pediatric ophthalmologists or other

This article was provided by Clarity Medical Systems.

Number of newborns imaged:	3,573	(100.0%)
Abnormalities found: (including retinal hemorrhage)	769	(21.5%)
Retinal hemorrhage in both eyes:	509	(14.3%)
Level 3 retinal hemorrhage:	215	(6.0%)
Macular hemorrhage:	67	(1.9%)

Other abnormalities:
FEVR: 15 cases
Retinoblastoma: 2 cases
(one case was the earliest ever found in China)

Figure 1

physician specialists can then evaluate the images and make diagnoses.

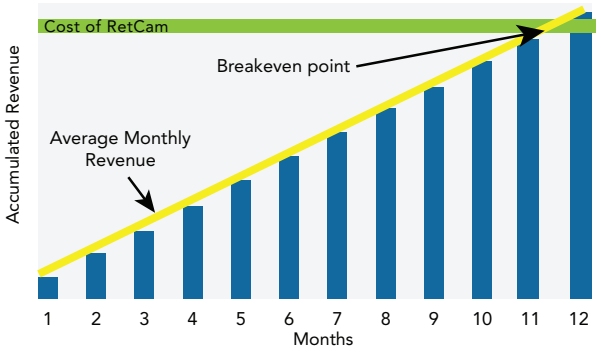
In Wenzhou, China, Lijun Shen, MD works in a hospital that specializes in ophthalmology. She chose RetCam as the tool to capture images used to evaluate and diagnose eye disease. Dr Shen has been able to diagnose several different newborn eye diseases, thus offering a better chance for early treatment. Dr Shen has established a relationship with children's hospitals in the Wenzhou area, and actively encourages newborn imaging. The medical college and hospital now provide skilled staff to visit local children's hospitals several times a week. The visiting staff acquires images of all newborns with RetCam, and electronically sends patient images to a central site database for evaluation and diagnosis by eye specialists. This protocol demonstrates that patients can benefit from RetCam eye imaging without placing an undue burden on the patient, hospital staff or medical specialists.

Is Newborn Eye Imaging Safe?

Another area discussed by the participating physicians was patient safety during newborn eye imaging. Here, the data is positive. In a patient population of approximately 8,000 newborns (from Drs Li and Li's studies) who were imaged using the RetCam, there were no reports of infections or corneal damage, and no adverse effects from dilation or anesthetic drops.

These favorable results reflect a well-designed and careful protocol for patient imaging. First, imaging is not done for a patient with an existing infection. Practitioners use dilation drops. And, the test is done close to the newborn intensive care unit for added safety. When these practices are followed, physicians believe the imaging is safe.

Example of Newborn Eye Imaging Revenue Stream



Do Parents Accept the Procedure?

Parents intuitively understand the importance of their child's eyesight. When they learn that imaging with RetCam is brief, safe, and non-invasive, the majority willingly accepts and appreciates the procedure as an important part of their infant's care and are willing to pay for it.

[The RetCam Systems are FDA cleared for the following indications: • General ophthalmic imaging including retinal, corneal, and external imaging • Photodocumentation of pediatric ocular diseases including retinopathy of prematurity (ROP) • Screening for Type 2 pre-threshold ROP (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease) or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease) or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease)* in 35-37 week postmenstrual infants. * References: 1. Cryotherapy for ROP Cooperative Group. Multicenter trial of cryotherapy for ROP: preliminary results. Archives of Ophthalmology 1988; 106(4):471-479. 2. Early Treatment for ROP Cooperative Group. Revised indications for the treatment of ROP: results of the Early Treatment for ROP Randomized Trial. Archives of Ophthalmology 2003; 121(12):1684-1694.]

References

1 A hearing test (called brain-stem evoked-response audiometry) is performed routinely with newborn babies in all states. Source: Hearing Loss Fact Sheet: http://www.cdc.gov/ncbddd/actearly/pdf/par- ents_pdfs/HearingLossFactSheet.pdf

2 Oklahoma Cooperative Extension Service www.oces.okstate.edu/washita/uploaded_files/4h_Learn- ing_Styles.doc

TIMELESS MEDICAL™
WOMEN & INFANTS
PATIENT SAFETY SYSTEMS

BREAST MILK & INFANT FORMULA ERRORS

- Studies show 5% of all breast milk feedings have handling errors.
- 80% of NICU administrators at the NICU Leadership Forum feel that prepared infant feedings should use barcode scanning, just like medications.
- Each sentinel event involving a feeding error in the NICU costs a hospital at least $49,000.

BREAST MILK TRACKING

FORMERLY moms™ mother's own milk system

Eliminates human errors in the expressed breast milk and donor milk handling and feeding processes

FORMULA TRAK™

Tracks and traces infant formula preparation, feeding, and inventory within your facility

MILK BANK MANAGEMENT

Tracks and traces donor human milk from donor to baby

NEW FEATURES:

- Prep Calculator
- CPOE integration
- Automatic charting
- Flexible preperation workflows

RESEARCH

Research on our system proves it stops countless errors that occur in traditional breast milk and infant formula protocols. Check out the study on the next page that was conducted at Nationwide Children's Hospital in Columbus, Ohio to see more detail on the efficacy of our Breast Milk Tracking System.

Want to learn more about Timeless? Flip back to **page 21** in the News section, find us on the web at **www.timelessmedical.com**, or give us a call at **1-800-630-3730**. We would love to show you a product demonstration.

A Retrospective Two Year Study of Breast Milk Error Prevention in the Neonatal Intensive Care Unit

Stanley R. Wolford II, BA, BS, MBA; Christine Smith, BA, RN, IBCLC, ANLC; Megan L. Harrison, BSN, RN, CLC, ACLC

Timeless Medical Systems' Breast Milk Tracking System, formerly known as MOMS, was instituted at Nationwide Children's Hospital in 2009 after having 8 reported breast milk errors where the wrong milk was fed to the wrong Neonatal Intensive Care Unit (NICU) infant. How many errors would you guess went unreported in the same year? It's probably a lot more than you'd think... The data in the following research study conducted by Nationwide Children's Hospital indicates that they had critical errors in over 5% of all expressed breast milk feedings.

In the first year after our Breast Milk Tracking System was installed at Nationwide Children's Hospital, it stopped:
- The wrong milk from being fed 541 times
- Expired milk from being fed 1,992 times
- 224 fortification errors

The benefits extend beyond those first year wins. The immediate feedback that our system provided the nurses helped improve their compliance to patient safety policy, reducing the error rate from 5.64% to 1.79% in the second year of use. This study was conducted by Nationwide Children's Hospital without any involvement by Timeless Medical Systems or external funding.

Abstract

Problem Statement: The first question – after two years of continuously using the Mother's Own Milk System (MOMS) breastmilk barcoding system by Timeless Medical Systems, have the clinicians become dependent on the system to prevent errors?

The second question – does having a dedicated milk technician further reduce errors?

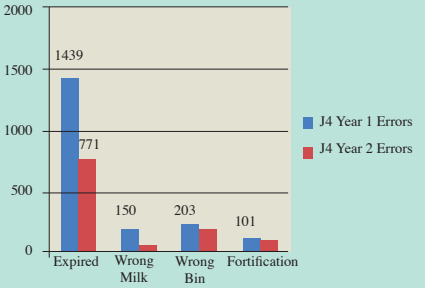
Methods: Reports from the breastmilk barcoding system's database show how many of four types of critical errors were reported. These error types are: attempting to combine dissimilarly fortified bottles, using expired milk, placing a bottle into a different patient's storage bin and feeding a patient another patient's breastmilk bottle. The total number of bottles fed per unit was used to give an error rate.

Summary of Results: Errors have been tracked for two consecutive years with a significant reduction in the error rate on all three units from year one to two. The addition of a milk technician accelerated the reduction in the breastmilk error rate in all four categories except fortification errors on the J4 unit.

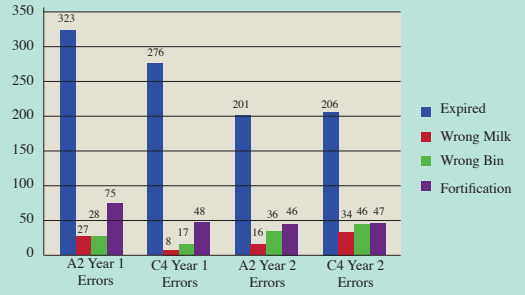
Implications and Lessons Learned: The majority of units that maintain the use of barcoding to manage breastmilk usage in the NICU have continued to improve patient safety by reducing

This article was provided by Nationwide Children's Hospital.

Primary Objective

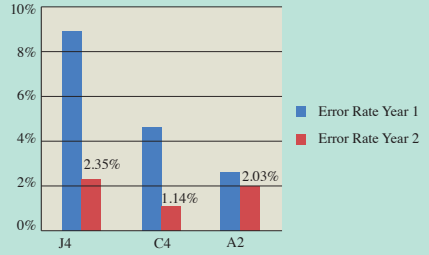


J4 Error Comparison: The J4 NICU reduced the number of errors in every category with some being reduced by nearly 50%.

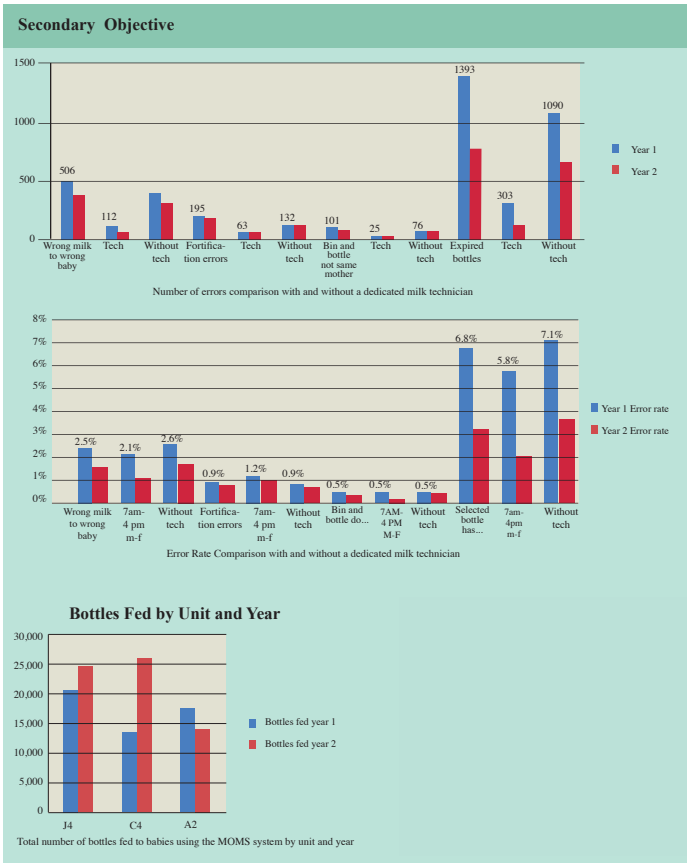


The A2 NICU reduced the number of errors in every category except in placing the wrong bottle in the wrong bin. The C4 NICU reduced the number of incidences of trying to use expired milk but increased in placing the wrong milk in the wrong bin and in attempts to feed the wrong milk to the wrong patient errors.

Error Rate by Unit and Year



Error Rate Comparison Between Units



the number of breastmilk errors. In units that combine a milk technician with barcoding, the error rate is even lower than just barcoding alone.

Purpose

A retrospective analysis to determine the continued effectiveness of implementing a breastmilk barcoding system in the Neonatal Intensive Care Unit (NICU) at Nationwide Children's Hospital (NCH) after two years of continuous use.

Introduction

Nationwide Children's Hospital is a tertiary care children's hospital. The Neonatal Intensive Care Unit is a 99 bed level 3 unit separated into three distinct units, each with their own focus of patients. All infants admitted to the NICU are received by transport or through the emergency room. Breastmilk barcoding was implemented, within a two month period in 2009, into the three NICUs to eliminate breastmilk errors. A milk tech was added to the J4 unit in August 2009.

Primary Objective

Did the staff learn from having the system correct them and increase their vigilance when handling breastmilk or did they become more lax and rely on the system to catch errors?

Secondary Objective

Was there a significant impact on J4's errors by having a milk tech for 40 hours per week?

Description

Four different critical errors were tracked by unit and by type of error through reports available within the barcoding software. These errors were: attempting to prepare/feed expired milk, attempting to feed wrong milk to wrong baby, attempting to place another mother's milk in a different baby's storage bin, and wrong fortification errors. Errors were tracked for two consecutive years with a significant reduction in the error rate on two of the three units. These error rates have also been compared to the total number of breastmilk bottles fed on each unit.

Through informal observation of utilization of the barcoding system on the C4 unit, it was discovered that the nursing staff had created work-around thus not using this safety system to its fullest potential. Changes were implemented into the system to prevent these work-arounds. We theorize that the error rate significantly increased as staff attempted and were unable to use work-arounds that they had become accustomed to using.

Method

Reports were run against the breastmilk barcoding system's (MOMS) database to determine how many of four types of critical errors were reported. The four error types are: attempting to combine dissimilarly fortified bottles, using expired milk, placing a bottle into a different patient's bin, and feeding a patient another patient's bottle. The total number of bottles fed per unit was also pulled from the database to give an error rate. The two time periods being compared are June 2009 through May 2010 and June 2010 through May 2011.

Findings

Errors have been tracked for two consecutive years with a significant reduction in the error rate on two of the three units from year one to two. Statistical analysis shows that the changes in error rates are not related to changes in the number of bottles fed to patients. The breastmilk error rate was further reduced in all categories except fortification errors on the J4 unit with the addition of a milk tech.

Summary

From Year 1 to Year 2, the number of scans of expired bottles in the barcoding system was reduced by 40% (from 1,992 to 1,185 bottles) over the three units combined. During this same period, the number of bottles of wrong milk that were attempted to be fed to the wrong baby was reduced by 22% (from 541 to 426 bottles). One unit had an increase in the number of attempts to feed wrong milk to wrong baby. During this time, there were two sets of higher order multiples on this unit. Knowing that in the barcoding system, once milk has been fortified for a particular infant, it cannot be fed to siblings, which staff attempted to do, therfore staff required re-training on how to prepare milk for multiples while conserving the supply.

On the unit with the milk tech, the total number scans of expired bottles during her working hours were reduced by 58% (from 303 to 128 bottles) from the 1st to 2nd year. During this same period, the number of expired bottles that were scanned during her non-working hours were reduced by 40% (from 1,090 to 650 bottles).

Conclusion

The use of barcoding to manage breastmilk usage in the NICU has continued to improve patient safety by reducing the number of breastmilk errors. In units that combine a milk technician with barcoding, the error rate is even lower than just barcoding alone. This reduction in error rates with a milk tech shows that having a dedicated staff person(s) committed to breastmilk preparation adds to the safety environment and gives an added level of protection to a vulnerable population.

Clinical Research Case Study: Cytokene Screening

The HRC index monitor, HeRO, from Medical Predictive Science, was employed in generating results, as presented in the paper, "Cytokine screening identifies NICU patients with Gram-negative bacteremia," by Ranor, et al, published in Pediatric Research.

According to the Abstract: "Biomarkers and physiomarkers may be useful adjunct tests for sepsis detection in neonatal intensive care unit patients. We studied whether measuring plasma cytokines at the time of suspected sepsis could identify patients with bacteremia in centers in which patients were undergoing continuous physiomarker screening using a heart rate characteristics (HRC) index monitor. Six cytokines were higher in Gram-negative bacteremia (GNB) than in Gram-positive bacteremia or candidemia (GPBc). A cytokine score using thresholds for granulocyte colony-stimulating factor (G-csF), interleukin (IL)-6, IL-8, and tumor necrosis factor (TNF)-α had 100% sensitivity and 69% positive predictive value (PPV) for GNB. A single cytokine marker, IL-6 < 130 pg/ml, had 100% sensitivity and 52% PPV for sepsis ruled out (sRO). The average hRc index was abnormal in this cohort of patients with clinical suspicion of sepsis and did not discriminate between the final sepsis designations."

According to the authors, "The standard paradigm for diagnosing and treating late-onset sepsis is to perform a blood culture and initiate empiric two-antibiotic therapy after an infant displays signs possibly attributable to sepsis. With this approach, mortality is high, particularly in cases of Gram-negative septicemia… On the other hand, avoidance of unnecessary antibiotic therapy is also a worthy goal. To this end, biomarkers and physiomarkers associated with neonatal sepsis have been investigated.

"Cytokines have been proposed as promising biomarkers because some of them rise very early in the course of bacteremia… Abnormal HRC have been identified in NICU patients with sepsis and often occur prior to clinical deterioration… To address this problem, our group developed a system for continuous physiomarker (heart rate characteristics (HRC)) screening for sepsis in NICU patients… In NICU patients, abnormal HRC associated with sepsis are not apparent to clinicians using conventional cardiorespiratory monitoring, prompting development of a monitor that detects HRC predictive of impending clinical deterioration. Through analysis of electrocardiogram data from hundreds of preterm infants, an HRC index was derived that incorporates decreased variability and decelerations to calculate the fold increase in risk that a patient will be diagnosed with sepsis in the next 24 h… After testing and validating the HRC index for sepsis detection, the impact of continuous HRC index monitoring on outcomes of very-low-birth-weight preterm infants was tested in a randomized clinical trial of 2,989 patients in eight centers, completed in 2010. This trial showed a significant decrease in mortality in preterm infants whose HRC index was continuously displayed to clinicians." The researchers noted, "Further refinement is essential for optimizing biomarker and physiomarker screening for sepsis in NICU patients. We undertook this study for two purposes: (i) to determine if cytokine screening could discriminate between patients with sepsis ruled out and those with clinical or blood culture – positive sepsis, and (ii) to determine the relationship between abnormal HRC index and elevated cytokine levels in NICU patients with clinically suspected late-onset sepsis." The authors emphasized: "The advantage of HRC index monitoring is that, unlike biomarker blood tests, it is a continuous, noninvasive measurement that can alert clinicians to physiologic changes associated with sepsis-like illness, sometimes prior to onset of clinical deterioration. In this study, we found that the HRC index was correlated with two cytokines but not with the final designation of sepsis ruled in or out… In clinical practice, sepsis-like signs, a rising HRC index, or a combination of the two may prompt clinicians to initiate antibiotic therapy until sepsis is ruled out with negative cultures. Cytokine screening may be useful for reducing antibiotic exposure in patients with a low index of suspicion for sepsis, and also for identifying the highest-risk group of septic patients, those with GNB, thus ensuring earlier institution of effective antibiot- ics and adjunct sepsis therapies to improve outcomes." To achieve HRC monitoring, "The FDA-cleared HRC index monitor (HeRO; Medical Predictive Science, Charlottesville, VA) takes electrocardiogram data from existing ICU monitors and calculates the standard deviation of normal R wave to R wave intervals, sample entropy, and sample asymmetry. These three characteristics are used to generate the HRC index, the fold increase in risk that a patient will be diagnosed with sepsis in the next 24 h. The HeRO monitor continuously displays the HRC index, which is calculated every hour and reflects heart rate variability and decelerations over the previous 12 h. For the purpose of this study, maximum HRC index in the 12 h preceding blood culture was recorded."

Plasma samples for this study were collected during a randomized clinical trial in which very-low-birth-weight infants were randomized to having their HRC index displayed to clinicians or not displayed. HRC index data for this study were collected after completion of the randomized clinical trial.

The authors concluded, "In summary, in NICU patients with suspected late-onset sepsis, plasma cytokines can identify those with SRO and those with GNB, potentially aiding in decisions regarding therapy. Seven cytokines were measured in 226 plasma samples from patients >3 d old with sepsis suspected based on clinical signs, abnormal HRC index, or both. Cases were classified as sRO, clinical sepsis (CS), GPBc, or GNB."

The above information and quotes are from the article, "Cytokine screening identifies NICU patients with Gram-negative bacteremia," by Laura L. Raynor, Jeffrey J. Saucerman, Modupeola O. Akinola, Douglas E. Lake, J. Randall Moorman and Karen D. Fairchild, in Pediatric Research, Volume 71, Number 3, March 2012, pages 261-266, nature publishing group, copyright 2012 International Pediatric Research Foundation, Inc.

The paper summarized in this article was provided by Medical Predictive Science.

Crib Notes: An Electronic Health Record for Neonatal Intensive Care Units

Sheila M. Gephart, RN, PhD; Linda Hundley, DNP; Michael Paulsen, RN, BS-BA; Jamie Fogel

Advances in information technology have the potential to enhance the quality of healthcare, solve well recognized safety issues, and if carefully designed, may improve clinical productivity. Yet, success of even the best technological innovations depends on more than technology alone. Organizational and contextual factors, the "fit" between the technology and the organization, and the methods used to plan and implement a new technology must be understood and managed for a successful outcome.[1-3] Growing pressure to adopt electronic health records (EHRs), one form of health information technology (HIT) by payers and regulatory groups, has spawned expansive growth in their use. Unfortunately, it is not uncommon that hospital-wide enterprise systems do not adequately meet the requirements of neonatal intensive care unit (NICU) work.

While NICU leadership may be resistant or even unwilling to make a change to non-NICU specific EHRs, paper record-keeping can perpetuate inefficiencies and errors. Paper records limit access to one user at a time in spite of multiple users needing simultaneous access to complete their work. If a two-chart solution is used, lab reports, orders, progress notes, and prenatal records may not be readily available at the bedside. Calculations, including those for nutritional analysis, when done by hand, are subject to mathematical errors, increasing the risk for critical medication or fluid administration errors. When records are paper-based, staff time is wasted to manually obtain and file maternal prenatal records including prenatal lab results, prenatal procedures, and radiology results. Handwritten orders that are illegible or incomplete lead to wasted time and potentiate error as nurses, clerks, and pharmacy staff frequently call to clarify handwritten orders. Redundancy and increased risk for transcription errors exist due to manually entering handwritten orders into separate hospital systems for billing, materials management, medications, lab, and radiology orders. Hemodynamic monitoring output requires manual entry of vital signs, apneic episodes and bradycardic episodes into the paper chart. Finally, to query paper records to identify trends, determine compliance with safety goals, and mine data for reporting in registries is time consuming. Results may be incomplete and labor intensive, taking valuable time away from direct patient care.

Issues associated with paper charting in the NICU are solvable with adoption of EHRs but if a system is implemented that is naive of NICU workflow and requirements or is simply a modification of an adult EHR, safety can be undermined.[4] In-depth evaluation and analysis of the current documentation system and NICU workflows are necessary to define requirements for an EHR to fit NICU work. The purpose of this paper is to describe steps to take when planning for, purchasing, implementing, and evaluating an EHR to fit NICU work and describe functionality of one EHR designed for the NICU, Crib Notes.

Gephart is with the University of Arizona College of Nursing; Paulsen is with Grand Rounds Software, LLC, Crib Notes. Hundley and Fogel participated in prior versions of the manuscript. This article was provided by Crib Notes.

Pre-Implementation

Conduct an Environmental Risk Analysis

Several important steps should be completed for a successful adoption of a new health information technology, specifically an electronic health record (EHR) for the NICU. We recommend completing an environmental risk and organizational analysis prior to identifying requirements. An environmental risk analysis begins with an assessment of the clinical and physical environment. Engineering support staff can ensure adequate wiring and structural supports are present. The analysis should include assessment of the adequacy of the hospital server, facility support to remodel to accommodate the physical components of the structure and analysis of existing hardware to ensure it is up to date and functional. As important as the availability of technical hardware and wiring support, is the level of commitment from end users, specifically NICU staff. The EHR must be accessible to users across roles including physicians, neonatal nurse practitioners (NNP), nurses, dietitians, respiratory therapists, unit clerks and managers.

Conduct organizational risk analysis

NICU work is highly collaborative, including frequent interaction with professionals across departments including labor and delivery, post-partum, laboratory, radiology and others. Multiple professionals work together in high risk (ie emergent deliveries, premature infant delivery with resuscitation) and low risk situations to deliver optimal, safe, effective and high quality care. As such, NICU staff often must access the L&D systems to anticipate high-risk deliveries and prepare for potential admissions. Communication and physical access between the Mother-Baby unit and the NICU should not be hindered by adoption of the EHR. Any changes in the workflow or communications within the Maternal-Child section resulting from the implementation of an EHR could pose a risk to the continuity of care and communication that are essential for safe, quality care in this clinical environment.

Evaluating the organizational culture within the unit and across hospital units can make the difference between the success

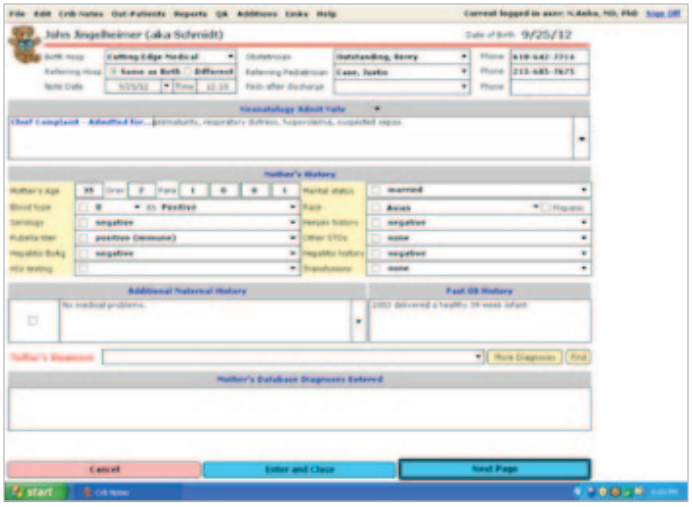


Figure 1. Admission Notes.

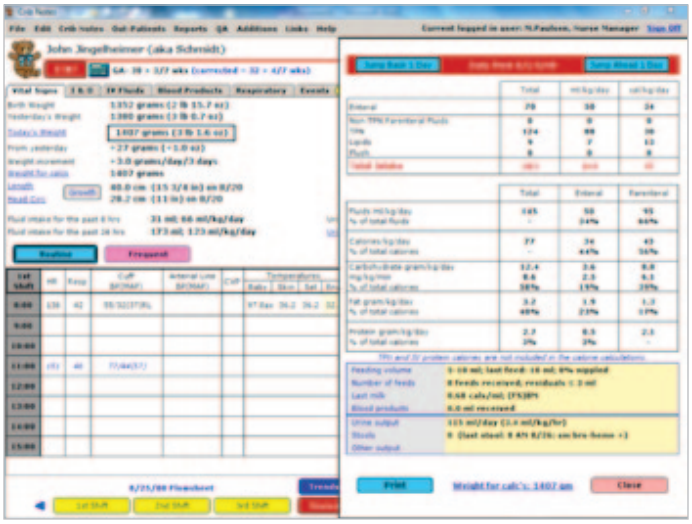


Figure 2. Flowsheet Display.

and failure of the adoption of any innovation and should be considered carefully with EHR adoption.[1,2,4,5] If other practice changes in the NICU have been successful, evaluating how those changes were championed and implemented can enable champions to build on those successes while avoiding any pitfalls found to be barriers.

If the process of selecting, building, implementing and adopting the EHR does not allow involvement in the design and use for all members of the team it could result in feelings of disenfranchisement and lack of staff buy-in, increasing the risk of failure of CIS implementation.

Define requirements

To identify requirements, map out other computer systems being used for care including laboratory, pharmacy, radiology, and material management systems. For optimal function, the EHR should support the existing systems or replace them. If supporting existing systems, assuring interoperability is paramount. Other risks not readily apparent may be identified through interviews and focus groups with stakeholders prior to submitting the request for proposal (RFP) from vendors. NICU workgroups including representatives across professional groups optimally are the best way to enlist user support to complete this important step.

Select an EHR

Although selecting an EHR is a decision that will impact patient care and the financial bottom line, clinicians should know that an EHR is available that is specifically designed for the NICU. Crib Notes is an EHR created specifically for use in the Neonatal Intensive Care Unit (NICU), developed by a neonatologist with more than 30 years of experience in neonatology (R. Stavis, personal communication, November 6, 2008). This EHR integrates fully with existing hospital software, so that information can be shared back and forth between departments and systems. As neonatal care occurs along a continuum and involves multiple professionals acting in separate units, integration is important. For example, information about maternal history, the pregnancy, labor, and delivery, postnatal course, physical exam, lab data, initial stabilization, medical progress notes and problem lists can be imported directly when an admission note is created (Figure 1). Neonatal consults with the mother prior to delivery can be stored in Crib Notes pre-birth and then will be ready if and when the baby is admitted to NICU service.

Because of the extremely delicate nature of the patients in the NICU, even the slightest mathematical error may be fatal. Crib Notes helps to eliminate such errors by automatically calculating correct dosages of medications and changes in the baby's weight from day-to-day. Although Crib Notes does not today have computerized physician order entry for medication, plans to roll out the CPOE module are underway, beginning with the module for Total Parenteral Nutrition (TPN) ordering. Follow up modules will address the remaining order needs in the NICU. Crib Notes is able to integrate into the main hospital's computerized physician order entry system using a Health Level 7 (HL7) interoperability standards to display a medication administration record (MAR) from the enterprise EHRs.

NICU clinicians are accustomed to making decisions based on flowsheet displays of patient data. With its abilities to directly import lab results and make calculations automatic, Crib Notes creates electronic flowsheets and growth charts (Figures 2 and 3). Importantly, the Crib Notes flowsheets can be customized to provide the format desired by the NICU staff to fit clinical workflow.

Crib Notes has several features built in to standardize processes that support patient safety. One error Crib Notes developers sought to prevent is giving a baby breast milk from the wrong mother. To combat this, Crib Notes generates labels to identify the correct infant and mothers are instructed to place the label on the bottle of expressed milk directly after pumping. The system also has a notation for the nurse to confirm they checked the breast milk prior to giving it to the baby. A supervisor or administrator is able to review later who has not been performing this check regularly so that the problem can be identified and corrected. This functionality facilitates process improvement in addition to the basic feature of protecting the infant from receiving the wrong milk.

The technology to analyze milk in the NICU at the time of feeding is now available, and NICUs using analyzers will want be able to enter a nutritional analysis for each individual feeding. Accurate nutritional analysis will help clinicians better manage the critical nutritional issues throughout the infant's hospitalization. Once breast milk analysis becomes readily available, systems that provide calculation of nutritional results must be able to handle this additional information to give an

accurate clinical picture to the clinicians. Babies in the NICU may receive a commercially manufactured formula or human donor breast milk. Manufactured formulas have a consistent composition which does not vary lot to lot, month to month, or year to year. Human breast milk is highly variable, and the composition changes during the feeding, and from feeding to feeding. Most units use an average nutritional analysis of breast milk and until recently, there has been no practical way to determine the composition of the milk at the bedside — much less document and track changes in the EHR over time.

As donated breast milk from breast milk banks is now commonly used and is regarded as a best practice, especially when feeding very low birth weight infants at high risk for necrotizing enterocolitis (NEC) and/or sepsis, best documentation practices can be supported in Crib Notes. Such documentation practices can be supported by the generation and scanning of labels that integrate barcodes applied to the milk received from the breast milk bank make it easier to do this and include details about the nutritional analyses, the lot number and expiration date of the milk.

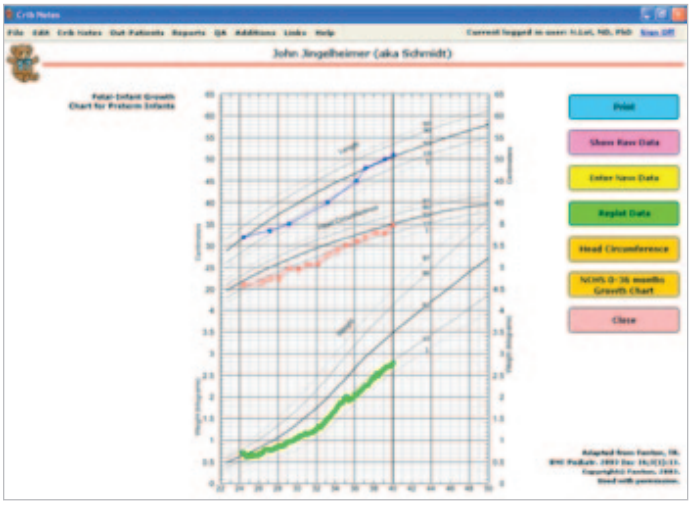


Figure 3. Growth Chart.

Crib Notes donor breast milk verification and analysis program provides feedback in real time on the nutritional makeup of the babies' feedings. The system allows for tracking of donor milk lot numbers for individual or non-patient specific lots. If nutritional analysis for the lot has been completed and is entered into Crib Notes when the lot is analyzed, the nutritional analysis will automatically populate to the baby's record when a feeding of that lot number is given to the baby. These specific nutritional values (ie quantities of protein, fat, carbohydrates and calories) are then used in the automated nutritional calculations provided by Crib Notes.

When a patient is ready to be released from the NICU, Crib Notes compiles all of the patient's clinical summaries into a single discharge summary, eliminating the need to use medical transcription services. The discharge summary is produced in PDF format and can be printed out for the parents and/or faxed to a pediatrician (Figure 4). Another of Crib NotesTM advantageous features is its ability to automatically compile data for the Vermont-Oxford Network (VON) registry. With Crib Notes, compiling data for VON takes mere minutes, eliminating the need for a data coordinator to review each individual chart for the VON information. This task alone can require the economic equivalent of a 0.5 full-time employee (FTE) registered nurse.


Cutting Edge Medical Center
"Tomorrow's technology today"

CLINICAL RECORD

John J. Jingelheimer (aka Schmidt) Medical Record# 101010
4/21/04 13:55 — Day of Life# 71 Page 1 of 4

Discharge Summary

John J. Jingelheimer (aka Schmidt)
Born: 2/10/04 9:45 (Tuesday)
Admitted: 2/10/04; Discharged: 4/21/04; LOS: 71 days
Mother: Annabelle Jingelheimer
Father: John Schmidt, Sr.
Phone: 610-444-4444(Home), 610-555-5555(Cell)

CHIEF COMPLAINT: 835 gram male admitted for prematurity and respiratory distress.
HISTORY - MOTHER: 40 year old G4P3003 married Caucasian female. The mother has a history of fetal DES exposure. She has had hypothyroidism for 4 years and was on Synthroid and she had had hypertension but was not on medication. Blood type B pos; serology - negative; rubella - positive (immune); Hepatitis B studies - negative; HIV - tested negative during pregnancy; STDs - none; transfusion history - none; herpes history - negative; hepatitis history - negative.
PREGNANCY: EDC 5/13/04 (based on the known date of conceptions) => 26 4/7 wks. The mother was admitted to the hospital at 18 weeks gestation for 2 days with preterm labor and treated with terbutaline. At 21 weeks gestation the mother's blood pressure increased and she was treated with Inderal. Edema and proteinuria developed and she was admitted to Community General Hospital at 25 weeks. Two doses of ß-methasone were given 5 days before delivery and Labetalol and MgSO4 were given. Contractions began and terbutaline was given with a good response. Leakage of bloody amniotic fluid began 2 days before delivery and the mother was transferred to CEMC for further care. At CEMC, Unasyn was given and a vaginal culture was subsequently negative for GBS. There were no contractions and fetal monitoring and a biophysical profile were reassuring.
LABOR & DELIVERY: Beginning a day before delivery, the mother's blood pressure and LFTs increased and the platelet count dropped. She became febrile to 102.5° and contractions developed. There was fetal tachycardia with variable decelerations. The baby was in a breech position so a Cesarean section was done.
INFANT: Male, birthweight 835 grams (1 lbs 13.5 oz); Apgars 2 @1 min, 7 @5 min. Cord gas (arterial) - pH 7.34, pCO2 45, pO2 12, base excess 2.6. The infant initially had a poor respiratory effort and PPV was given with the Neopuff's with a good response. The baby was stabilized on NCPAP and then intubated and given a dose of surfactant at 7 minutes of age. He was extubated, put back on NCPAP, and transferred to the NICU .
FAMILY HISTORY: Negative.
SOCIAL HISTORY: Mother - social worker, Masters degree; Father - newspaper writer, college ed.

ADMISSION PHYSICAL EXAM
Weight - 835 grams (1 lbs 13.5 oz) - 25-50%ile; Length - 34.0 cm (13 1/2 in) - 25-50%ile (estimated)
Head circumference - 24.8 cm (9 3/4 in) - 25-50%ile (estimated)
Vital signs: HR - 140, RR - 36, BP - 49/28 (mean 38), Temp - 97.0°
General: mild respiratory distress; no dysmorphic features
HEENT: NC/AT, AF flat, RR not seen 2° to difficult exam, nares patent, palate normal
Chest: normal configuration with good air entry, mild retractions, no rales or rhonchi on NCPAP
Heart: RRR, no murmur, pulses 2+, good perfusion
Abdomen: soft, non-tender, liver down 1 cm, no splenomegaly, no mass, both kidneys palpable, +bowel sounds
Genitals: normal penis with undescended testes. Anus: patent.
Skeletal: normal clavicles and normal hip exam. Extremities: normal.
Neuro: active, responsive, normal tone for age

Figure 4. Discharge Summary.

Implementation

Crib Notes has a proven implementation methodology using a "train the trainer" approach. In this model, staff training is done by in-house "super-users." The recommended training for end users includes a single four-hour session, significantly less time than other vendors require. As Crib Notes is designed around standard NICU practices, adoption of the software is quick and easy for the end users. They are not forced to change their clinical practices to accommodate the clinical documentation system. During Go-Live, a Crib Notes representative as well as hospital super-users are available for each shift. Crib Notes' typical timeline for implementation is 6 months from the time a formal contract is signed. Training sessions can be conducted on-site or on-line through a web portal such as Health Stream.

Evaluation as a continuous commitment

To optimize the use of an EHR, it is important to commit to the process of evaluation. The evaluation plan should consist of baseline, formative, and summative evaluations. At baseline, determine the computer knowledge and attitudes of the NICU staff through use of questionnaires and interviews. Formative evaluation is necessary to understand how work processes and implementation plans for the EHR can be orchestrated in concert. Specific work processes to evaluate include: 1) time from medication order input to medication administration, 2) usability, 3) staff acceptance of the EHR, and considering how the EHR could impact patient outcomes and safety. Formative evaluations can provide input for immediate and long term adjustments in the EHR. Crib Notes personnel are available for these iterative changes. All parties would agree that thorough

planning of requirements during the process of customization is highly preferred to making changes once implementation has commenced. Summative evaluation can capture success in terms of timeliness, impact on workflow, availability of information for decision making, adherence to unit procedures, time for documentation, the impact on work efficiency, use of the system, and patient safety, including medication errors. As part of all phases of evaluation, cost evaluation is inherently part of the process. At a minimum the cost of implementation will include: software, hardware (computers, printers, scanners, etc), staff time (coverage during "go-live," training and project management), and the cost of the EHR.

As with any type of implementation, problems are certain to arise. Anticipating these potential problems can help to minimize or even eliminate them. Some of the potential areas to consider include privacy and security of the medical record, effects on the social networks and relationships within the organization, ergonomic effects of computerization, economic effects, and need for construction or closures of beds or units during the time in which the new EHR "goes live."

Conclusion

The choice to purchase and adopt an EHR is one that should be made carefully but has the potential to greatly improve the safety and quality of patient care. Continuing with the current paper documentation system may increase the risk of errors, including medication errors, inappropriate administration of breast milk, and documentation and transcription errors. By maintaining the status quo, redundant tasks, inefficient work processes, and wasted time completing administrative tasks will not be solved. Benefits of using an EHR designed for the NICU will change the status quo. Increased staff efficiency with an associated reduction in operating costs, decreased transcription costs, improved patient safety, decreased expenditures on printed forms, and increased revenues from billing that is based on more complete documentation will ensue. By automating creation of admission and discharge notes, procedure notes, transfer summaries, and consultations transcription costs will decrease. By sending out daily email letters to parents in the voice of their infant, Crib Notes supports the process of parents engaging in their infant's care. Satisfaction of families improves revenues by elevating the reputation of the hospital and bringing in more patients. Crib Notes software is a clinical information solution to uniquely meet the needs of vulnerable NICU patients and their caregivers.

Acknowledgements

We would like to thank Dr Judith Effken for her comments on earlier drafts of this product evaluation.

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Improvement of Newborn Hearing Screening Workflow

Anne-Marie Hurteau, MOA; Jane Dala

Introduction

In any size of birthing center, managing patient workflow is a constant preoccupation for an efficient newborn hearing screening program. Adequate, reliable and user friendly equipment is needed to ensure efficient patient workflow. Among important factors in screening devices, international programs have opted for handheld equipment that provides binary response results, sufficient test memory and patient data entry capacity. Total testing time including patient data entry and management, performing the actual tests and daily equipment maintenance are also important factors to take into account.

Manufacturers have made efforts in improving device functionalities in order to accommodate patient workflow. Still, little information is known on which functionalities of a screening device actually help improve patient workflow.

In an effort to evaluate the different screening equipment available in the market, in regard to patient workflow efficiency, the McGill University Health Center UNHS program compared the classic and the new version of the MADSEN AccuScreen from Otometrics.

Methods

Close to 200 ears were assessed with the AccuScreen classic screening device and with the new AccuScreen. Both devices are FDA approved. Each child was screened using Automated DPOAE and AABR. The choice of device used first on each child was randomly selected. Neonates were either seen at birth prior to hospital discharge or during a hospital visit if UNHS was not offered in their birth hospital.

All children were younger than 3 months of age at the time of screening. Screening tests were either performed by trained auxiliary nurses or by audiologists from the hospital. None of the screeners had previous experience using either device. Parents were asked permission to perform the double testing on their child prior to the first test.

Comparison between device functionality was done after each patient test and by each user after the completion of the Beta test.

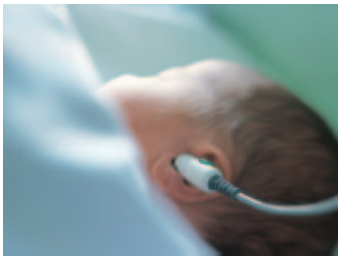
This article was provided by GN Otometrics.

User Friendliness

One of the major improvements with the new AccuScreen is its touch screen. It makes navigating menus very fast. Even data entry, user/patient selection and test selection is much faster and easier.

Seen from a workflow point of view the touch screen requires only a few screen clicks to, for example, switch between screens, enter a new patient, start tests and validate cable functionality, and that is a major improvement compared to the AccuScreen Classic. It saves time, and the fact that the screen is managed by a light touch of the finger makes it preferable for users who test babies all day.

Other user friendly features are of course the size and weight of the device – it is smaller and lighter than the AccuScreen Classic. The docking station that automatically charges the device and interfaces to the PC as well as the new probe also add to the value.



Working with the probe is critical with any screening device. It must be easy to handle, easy to place in the ear canal, and securing a stable fit in the ear is crucial for the measurement time and test result.

The learning curve for getting an acceptable probe placement and to obtain complete results in an infant was found to be

in direct relation to the referral rates. Although screeners encountered probe placement problems with both devices, the new AccuScreen probe was qualitatively found to be easier to get a good placement with.

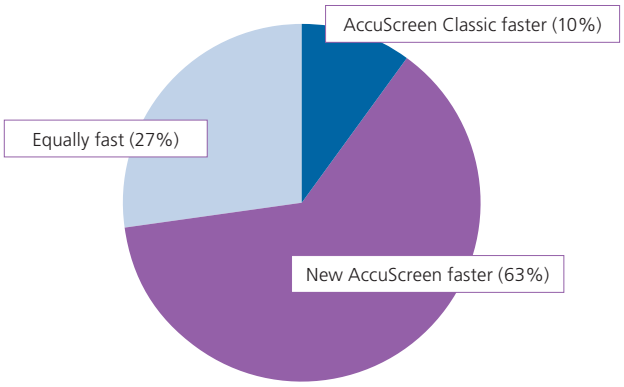
Mounting/demounting of both probe tips and ear tips was qualitatively stated to be easier with the new AccuScreen.

Daily Cable Checks

Securing a fast and reliable workflow requires stable functionality of the screening system, and with the Quality Tests included in the new AccuScreen a daily check of probe and cables takes less than a minute.

The new AccuScreen's built in test cavity was considered to be an improvement that made daily probe checks much easier.

Measurement Times



As soon as you can improve the workflow and shorten the measurement time, you free up time to interact with the baby and parents, prepare for the next patient, etc. The comparison study showed that the new AccuScreen is faster in 63% of the tests.

One of the reasons why the new AccuScreen was generally faster seems to be explained by the new AccuScreen being less sensitive to background noise, which is a major advantage in hearing screening procedures (Maxon et al, 1997).

Conclusion

When looking at hearing screening workflow you should not only take equipment sensitivity and specificity into account but also testing time, ease of use and patient data management.

Untrained screeners had similar learning curves with both device models but the new AccuScreen was perceived as being much easier and faster in obtaining equally satisfactory data.

Although both models offer the same tests (DPOAE and AABR), the new AccuScreen appears to have noticeable advantages when looking at how to improve the screening workflow.

Although some functionalities of the new AccuScreen were not tested as part of this study, it is equipped with a combination of test parameters that could be used in testing for specificity and sensitivity in a hearing screening program.

Simulated Use Design Validation Study

Introduction

After launching the highly successful and innovative SurgiLance safety lancet in 1999, medical product manufacturer and master distributor MediPurpose introduced a complementary product in 2010, the babyLance infant heelstick.

However, within a few months of launch, MediPurpose learned that babyLance's innovative design was not fully meeting the preferences and expectations of end-users in the US market.

Although a number of US healthcare facilities expressed a desire to continue use of the product, feedback indicated that the device needed some modifications in order to fully satisfy customer demands. For example, some users preferred a "pull" trigger rather than the babyLance's "push forward" trigger.

MediPurpose elected not to withdraw the product from the market, but rather, it reduced its production and marketing programs for babyLance. The company then initiated a year-plus period of intensive research, redesign and testing to learn more about end-users' requirements and to validate that its new babyLance was meeting those expectations.

In early 2012, MediPurpose conducted a series of simulated use studies (SUS) to validate its latest babyLance design.

In those studies, end-users were given pre-production babyLance devices to use on a replica infant heel so they could complete an evaluation survey and report their experiences to MediPurpose.

The SUS results indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements, enabling the company to proceed with the babyLance development project.

End-User Requirements

Throughout the redesign process for its babyLance heelstick device, MediPurpose actively involved end-users to learn more about their requirements and to validate that its new device was meeting their expectations. *[Learn about how MediPurpose engaged end-users to determine their heelstick device preferences, expectations and requirements in the white papers, Understanding the Needs of End-Users and Heelstick Trigger Activation Survey at the 2011 NANN Conference. Also, see the article on page 26 of this journal's Nov/Dec issue.]*

This paper was provided by MediPurpose.

The company's research indicated that end-users wanted a heelstick device with a series of new features, while retaining a number of features from its original babyLance.

New Features

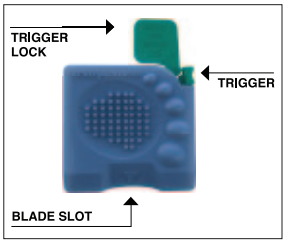
End-users wanted the following new features and characteristics:

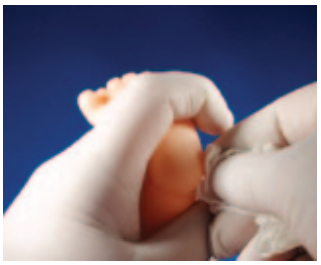
- Changing the trigger activation to a "pull back" mechanism rather than "push forward"
- Reducing the device's propensity to "rock" when placed on infant's heel
- Changing the housing and trigger colors
- Enhancing the device's intuitive visual cues
- Easier removal of trigger lock

Existing Features

Additionally, end-users wanted the new device to maintain the following existing features and characteristics:

- Smooth cutting profile
- Dimples on the sides of the housing for good grip
- Distinctive baby footprint on the sides of the housing
- Curve and arrow indicators at the bottom of the housing

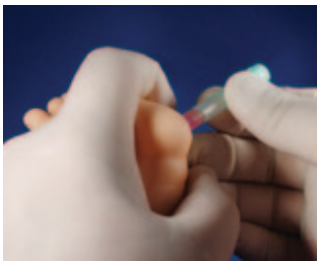




1. Select an incision site on the flat bottom surface of the heel, then clean the area.

2. Remove the Trigger Lock, but do not pull back the trigger until ready for use.

3. Align the Blade Slot with the incision site using the visual marking and pull the trigger back with your index finger. Discard.



4. Gently wipe away the first droplet of blood, then collect the desired quantity. That's it.

Developing the babyLance Simulated Use Study

To validate that its new babyLance heelstick device was meeting end-users' requirements, MediPurpose conducted a series of simulated use studies (SUS) in early 2012.

As compared to a clinical use study where a device is used on living infants, the SUS gave end-users an opportunity to test the new babyLance on an artificial foot that simulates an infant's heel.

To accomplish its goal, MediPurpose carefully planned the SUS, which involved creating the following:

Instructions for Use

Using the instructions for use (IFU) from its original device as a starting point, MediPurpose revised the new device's IFU to provide both written and visual instructions.

Along with providing the IFU so end-users would know how to properly use the device, the company used the SUS as an opportunity to evaluate its new IFU.

Simulated Use Evaluation Form

A simple one-page evaluation form was designed to provide end-users with babyLance characteristics to evaluate.

The form was written so that evaluators could provide one of two types of responses: absolute (pass or fail) and Likert scale (1-5, indicating a response of no/poor to yes/excellent).

The form was structured to comprehensively validate the following:

Safety

- Trigger Lock
  - Needs to prevent accidental activation
- Blade Shield
  - Blade needs to be shielded prior to activation
  - Blade needs to be shielded after activation

Single-Use

- Device need to be unusable after activation

Training

- IFUs need to be concise and easy to understand
- Device needs to be easy to learn how to use

Ergonomics

- Device needs to be comfortable and stable
- Incision location needs to be easily identified
- Device needs to be easy to handle while wearing gloves

Trigger Activation

- Trigger needs to feel comfortable
- Trigger needs to be easy to activate
- Activation mechanism needs to provide an audible click when activated

Usage

- Device needs to be easy to activate with one hand
- Incision site needs to be easy to identify
- Device needs to be as easy to use as user's current device
- Device needs to not require more time to use than user's current device

Simulated Use Protocol

To assure that the new babyLance design was properly tested for acceptability and usability in a simulated environment, MediPurpose created a protocol that included the following:

Test User Population

The test user population needed to include a minimum of 20 health care professionals from at least three different facilities that routinely use heelstick devices.

Test Sample Size

Test users needed to evaluate a minimum cumulative total of 500 units, using artificial baby heels as test patients.

Trainer Responsibilities

Prior to beginning the simulated use tests, trainers were required to review the test protocol and evaluation form and to demonstrate the use of the device with each test user. Additionally, trainers needed to supervise each test user for at least one practice heelstick incision and to ensure the test user's comfort with use of the device before beginning the evaluation.

Test User Requirements

Along with performing the simulated use tests and completing the evaluation form, test users were asked to wear gloves per their institutional procedure.

Acceptance Criteria

Overall acceptance for each characteristic evaluated needed to

be 80 percent or more—except for safety characteristics, which needed to be 100 percent.

Simulated Use Participant Groups

After announcing the SUS opportunity to its extensive network of relationships within the healthcare industry, MediPurpose was invited to five neonatal healthcare facilities in California and Georgia to conduct its study.

Simulated Use Study Results

In April-May 2012, MediPurpose launched a series of simulated use studies (SUS) to validate its latest babyLance design. In those studies, end-users were given pre-production babyLance devices to use on an artificial infant heel so they could complete a survey and report their experiences to MediPurpose.

The SUS results indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements, enabling the company to proceed with the babyLance development project.

Results At a Glance

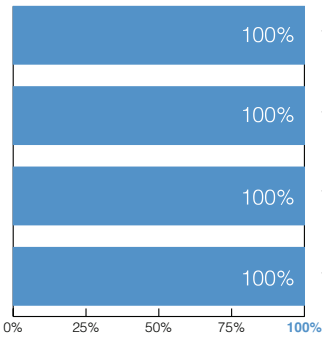
MediPurpose's protocol for the babyLance SUS specified minimum figures for testing and acceptance. The results indicated that it met or exceeded each:

- Test Facilities: 5 (minimum needed: 3)
- Test Users: 33 (minimum needed: 30)
- Test Units: 501 (minimum needed: 500)
- Average Safety Score: 100 percent (minimum needed: 100%)
- Average Usage Score: 4.9 (minimum needed: 4.0)

Detailed Results

A simple, one-page evaluation form was designed to provide end-users with babyLance characteristics to evaluate.

The form was written so that evaluators could provide one of two types of responses: absolute (pass or fail) and Likert scale (1-5, indicating a response of no/poor to yes/excellent). The results were as follows:



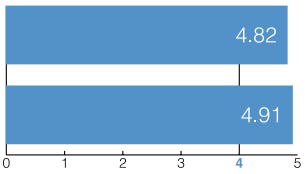
Safety

The trigger lock prevents accidental activation

The blade was shielded prior to activation

The blade was shielded after activation

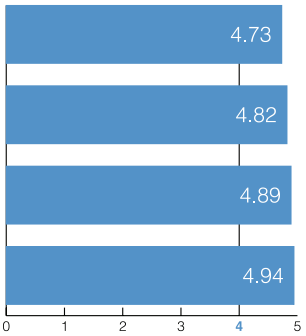
The device cannot be reused after activation



Training

The Instructions for Use are clear and easy to understand

It is easy to learn how to use the device



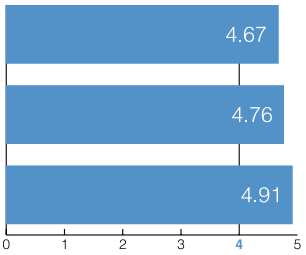
Ergonomics

The device felt comfortable and stable in your hand

The blade was shielded prior to activation

The blade was shielded after activation

The device cannot be reused after activation

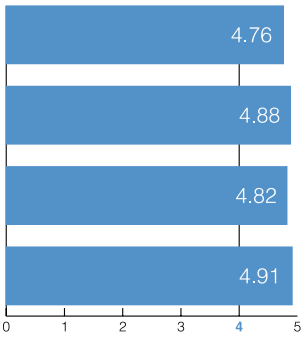


Trigger

The trigger mechanism feels comfortable

The trigger is easy to activate

There is an audible click when the device is activated



Usage

The device was easily activated using one hand

It is easy to target the incision site

The device is an convenient to use as my existing device

The device does not require more time to use than the device I am currently using

With Challenges from Every Angle, NICU Staff Continue to Innovate and Improve

C. Darabant

As we consider the current strides of innovation in NICU medical care, it's hard to believe how some practices remain stagnated by old paradigms. Leave it to the brilliant observations and stubborn resolve of NICU nurses to break down old methods, all for the loving care of their babies.

The Penguin Nutritional Warmer, for example, was the brainchild of one extremely devoted NICU nurse, Jan Shields. Jan questioned the subjective assessment of feeding temperature and realized there was no consistency. So she invented a system which would simply do a better job.

Jan's realization led to national studies at multiple hospitals. The revelation was that feeding temperatures ranged from 50°F to 120°F; with only approximately 20% of feedings in the desired target range, the Thermo-Neutral Zone (TNZ); often using the current practice of water in a cup. These findings have been independently verified and published by two separate medical systems. The findings unmistakably prove the need for a better, standardized method for nutritional warming practice, a method to increase desired clinical outcomes and reduce errors and hazards, ultimately doing what is best for baby.

Creche Innovations pioneered the original, hospital grade nutritional warming instrument, the Penguin Nutritional Warmer. The Penguin has come a long way. We've learned a lot and so have our customers. In fact, some of the stories along the way are NICU-coffee-table-book worthy. The following are a few of our favorites.

During an in-service, a NICU manager asked how we know that if we drink something cold, our body warms it up. Respectfully we replied with: if you drink a glass of ice water and go potty later, do you go "ice" potty?... and it would hurt if you did…

We have this one in writing, from an NICU manager: "Why does your questionnaire ask for mL volumes? We use cc's." On the returned questionnaire, all "mL" were crossed out and replaced with "cc".

Yes, we have seen nurses place breastmilk in the microwave.

We have seen nurses microwave water, use Insta-hot water, and even use the coffee maker to get hot water to warm feedings.

With support and feedback from the nurses, lactation staff and physicians who use the Penguin, we've continued to learn and innovate. We are grateful for the input and advice as we gear up to launch a number of new, innovative products in 2013.

With the Penguin, one of our biggest challenges was identifying the best warming method. As the original, hospital grade warmer innovator, we looked at all the options; for example steam heating like the retail warmers employ, hot air, and ceramics, sand and metals. After a multitude of tests and research, we realized that nurses have done it correctly all along, using water.

A cup of warm water is the most efficient way to warm milk. The problems with the cup of water method is temperature consistency and microbial exposure. So the team at Creche innovated a patented Therma-Liner to resolve the problems. We used our expertise in pharmaceutical manufacturing to develop a sealed jacket which surrounds the feeding but also completely isolates both the feeding and the NICU from exposure to waterborne microbes. Pharmaceutical manufacturing deals with sensitive and volatile chemical mixtures. Warming such mixtures requires utmost control and finesse. Jacketed flasks and reactors are used to accomplish controlled warming. Figure 1 has multiple representations of the technology used by the industry.

The patented Penguin System works exactly the same way. Water is completely isolated and simply acts as the thermal transfer medium to gently warm milk to TNZ.

C. Darabant is Vice President of Creche Innovations, which provided this article. The Penguin Nutritional Warmer and Therma-Liners are registered trademarks of Creche Innovations.

Figure 2 shows the most current version of the Therma-Liner.

Notice the separate compartments which ultimately isolate the feeding container in a sterile environment. The Penguin Therma-Liner is made in the the USA, is guaranteed leakproof, and is 100% recyclable.

So, why were nurses right all along and why does the pharmaceutical manufacturing industry use a liquid to transfer energy to a reaction mixture? Because it is a consistent, efficient, and controlled process, exactly like Kangaroo Care. Mom and dad are a body of water, just like baby. Skin to skin contact achieves warming quickly, safely, and efficiently. Mom and dad do not need to be a higher temperature than body temperature to do the trick. They remain at body temperature. It does not require an exaggerated and uncontrollable amount of energy to do the job. Steam is very hot, so steam warming systems displace a large amount of heat to warm the feeding; so does air. Sand, metal and ceramics are difficult to mold around the various container sizes used in the NICU and pose additional cleaning challenges.

Nurses had it right all along

There is even more to consider. For example, most feeding containers are made of plastic. The suppliers of the plastics provide leachable profiles for their products. At ambient temperature and under normal conditions, the plastics should not leach any chemicals. What happens with temperature elevation and changes to pH (warming milk and mom's diet changing pH)? Can chemicals be extracted into baby's feeding? The answer is, of course this can happen. What about the rubber on a syringe plunger and the agents used to make it slippery? According to Solvias' Dr Frank Moffatt, "Leachables are trace amounts of chemicals originating from containers, medical devices or process equipment that end up as contaminants in medical products resulting in exposure to patients… In the case of plastic containers, typical extractables and leachables are additives and processing aids such as antioxidants and other stabilizers, plasticizers, emulsifiers… but also monomers and oligomers of the plastic polymer and all kinds of reaction products." According to Solvias, "full traceability is hard to obtain." Ultimately, "containers meant to protect a drug (breastmilk in this case) from environmental contamination are actually themselves a source of contamination." The bottom line is that extractables "can be immunogenic" and can therefore "interact with a protein in such a way as to trigger an immune response." The unintended coincidence in this case is that testing for extractables "is performed under exaggerated conditions of time and temperature." This is exactly what is being done when warming refrigerated or frozen breastmilk at higher temperatures or at temperatures above 120°F. The PQRI working group on leachables and extractables has uncovered a considerable amount of chemical data which includes the negative and dangerous effects of antioxidant extractables on biologic systems. It therefore makes sense that the warming process in the NICU must be controlled and must use low temperature to achieve the correct and desired results. Any other way has a high potential for unwanted exposure to chemicals which can for example, influence thymus development and the maturity of the adaptive immune system. In summary, extractables are a well-recognized beast in the biotech/pharma industry. Leave it to a NICU nurse to point out the consideration for NICU care.

With challenges presenting themselves from every possible angle, NICU staff continue to innovate products which drive the care of our babies. The Penguin Nutritional Warmer is just one example of what a caring and diligent nurse can do to propel health care. The best part of this story is that Jan chose to remain in the NICU as night shift nurse. It's her passion and dedication. She continues to invent and invest in the best care for babies.

It's why all of us at Creche do what we do. We continue to innovate and improve upon NICU products because we believe in applying all the research to put forth only the products which are best for baby. It's because of Jan and all the NICU nurses, doctors and staff like her that my preemie is home, happy, and healthy.

My Pinkerbelle is my reason...

Hand Disinfection in a Neonatal Intensive Care Unit: Continuous Electronic Monitoring Over A One-Year Period

Onno K. Helder, Johannes B. van Goudoever, Wim C.J. Hop, Johannes Brug, Rene F. Kornelisse

Abstract

Background: Good hand hygiene compliance is essential to prevent nosocomial infections in healthcare settings. Direct observation of hand hygiene compliance is the gold standard but is time consuming. An electronic dispenser with built-in wireless recording equipment allows continuous monitoring of its usage. The purpose of this study was to monitor the use of alcohol-based hand rub dispensers with a built-in electronic counter in a neonatal intensive care unit (NICU) setting and to determine compliance with hand hygiene protocols by direct observation.

Methods: A one-year observational study was conducted at a 27 bed level III NICU at a university hospital. All healthcare workers employed at the NICU participated in the study. The use of bedside dispensers was continuously monitored and compliance with hand hygiene was determined by random direct observations.

Results: A total of 258,436 hand disinfection events were recorded; ie a median (interquartile range) of 697 (559–840) per day. The median (interquartile range) number of hand disinfection events performed per healthcare worker during the day, evening, and night shifts was 13.5 (10.8 - 16.7), 19.8 (16.3 - 24.1), and 16.6 (14.2 - 19.3), respectively. In 65.8% of the 1,168 observations of patient contacts requiring hand hygiene, healthcare workers fully complied with the protocol.

Conclusions: We conclude that the electronic devices provide useful information on frequency, time, and location of its use, and also reveal trends in hand disinfection events over time. Direct observations offer essential data on compliance with the hand hygiene protocol. In future research, data generated by the electronic devices can be supplementary used to evaluate the effectiveness of hand hygiene promotion campaigns.

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Background

Staff compliance with hand hygiene protocols in neonatal intensive care units (NICUs) is highly important to limit the spread of pathogens by the hands of healthcare workers and thus to prevent nosocomial infections.[1] Incidences of bloodstream infections in infants admitted to NICUs currently range from 12% to 53%.[2] There is evidence that improved hand hygiene in NICU settings results in infection reduction.[3] Hand hygiene performance used to be determined by direct observation, but electronic counting methods have been introduced as an alternative.

Three previous studies used bedside electronic counting devices designed to record hand rub dispenser lever-presses.[4-6] Cheng et al. and Marra et al. concluded that unobtrusive measurement by electronic devices results in more objective data since direct observations might influence hand hygiene compliance behavior.[4,6] Boyce et al found that hand disinfection was more frequent performed in the adult intensive care setting than in the general medical ward setting.[5] However, these studies had some limitations: data were collected over a relatively short period and detailed information on hand hygiene events distribution over the day was not provided.

We present the results of a study whose objectives were:[1] to monitor the use of alcohol-based hand rub dispensers with a built-in electronic counter in our NICU over a one-year period;[2] to determine compliance with hand hygiene by direct observations; and[3] to compare numbers of hand disinfection events during different shifts and determine differences in distribution of these events over the day.

Methods

Setting: This prospective observational study was performed from January 1st to December 31st of 2008 in a 27-bed level III NICU at a university hospital in the Netherlands. The NICU is organized into three identical sub-units with nine beds each.

Appropriate hand hygiene is considered an important safety issue which is dealt with in education programs since June 2005.[2] The institutional hand hygiene protocol used during the study period dictated that hand hygiene had to be applied before patient and after patient contact as well as before and after invasive procedures. The currently used "My five moments for hand hygiene" approach had not yet been published at the time.[7] Hand alcohol is generally preferred to soap. The only exceptions are visible soiling of the hands, bathroom visits, and

the presence of pathogens that are immune to hand alcohol, such as Clostridium and some gastroenteritis viruses. At least 3 ml of hand alcohol should be applied to rub hands for at least 30 seconds. Hand alcohol dispensers (Baktosept E, Bode Chemie GmbH, Hamburg, Germany) are available at each bedside. Furthermore, non-sterile gloves must be worn when there is a risk of exposure to a patient's body fluid. Then, hand disinfection is applied before and after glove use. In addition, two sinks with soap dispensers are located next to the nurses' station. One of these sinks also has a hand alcohol dispenser (Sterillium, Bode Chemie GmbH, Hamburg, Germany), which is exclusively used for surgical hand disinfection. However, Sterillium is approved for both hygienic and surgical hand disinfection. This dispenser is not provided with an electronic counting device.

Data collection: All 27 wall-mounted alcohol-based hand rub bedside dispensers have a concealed electronic counter and wireless transmitting equipment (ComSens NewCompliance, Delft, the Netherlands). The counter documents date and time of each individual use of the dispenser. The system does not allow distinguishing between categories of healthcare workers; data are collected anonymously. Each lever-press generates a click of the sensor; a click within a 2-second period of the previous click was considered as one hand disinfection event.[5,6] All dispensers delivered 1.8 ml per full lever-press. Data collected from the dispensers were transmitted to a computer-linked receiver. The study population for which dispenser use was recorded consisted of healthcare workers only (nurses, nurse practitioners, nursing assistants, and physicians). Parents and visitors were strongly encouraged to wash their hands with soap only.

The frequency of hand disinfection events was expressed in two ways: the daily median [interquartile range (IQR)] number of hand disinfection events per bedside; and the daily median (IQR) number of hand disinfection events per healthcare worker. The day shift, evening shift and night shift extended from 8:00 h to 16:00 h; from 16:00 h to 23:00 h; and from 23:00 h to 8:00 h of the next day, respectively.

Additionally, we randomly observed healthcare workers' compliance with the hand hygiene protocol, using a tool described in a previous study.[2] Failure to disinfect hands before or after patient contact, and before or after invasive tasks was recorded as non-compliance. Data were collected during thirty 60-minute observation sessions in each sub-unit, from 8:00 h to 22:00 h on weekdays. Hygienic performance starts at each new patient contact, so in theory a healthcare worker can perform more than one care sequence during an observation period. Observations were carried out from January to February 2008 and from May to June 2008, simultaneously with hand dispenser recordings. Immediate life-saving interventions were excluded from analysis.[2] Three trained researchers and the prevention expert (OH) independently observed hand hygiene events. Interobserver reliability assessed by Cohen's Kappa was high ($\kappa > 0.70$). The number of hand hygiene events for an ideal 100% compliance with hand hygiene was calculated (total sum of recorded hand disinfection events x 100/ compliance).

Statistical analysis: Data are expressed as the median (IQR). The sign test served to compare numbers of hand disinfection events among shifts for each day. SPSS version 17.0 (SPSS, Chicago, IL) was used for analysis, and $p < 0.05$ (two-sided) was considered as significant.

Table 1 Distribution of hand disinfection events per healthcare worker over the different shifts

Shift	Median (IQR#) hand disinfection events per healthcare worker
Day shift	13.9 (10.8-16.7)
Evening shift	19.8 (16.3-24.1)
Night shift	16.6 (14.2-19.3)
Total day	15.9 (13.1-19.3)

IQR: interquartile range

Results

During the one-year study period, a total of 717,445 lever-presses for all dispensers were recorded, equivalent to 258,436 hand disinfection events. The calculated median (IQR) number of hand disinfection events per day was 697 (559–840). The proportion of hand disinfection events during day shifts was 41.0%, which is significantly higher than that during evening shifts (34.9%) and night shifts (24.1%).

The median (IQR) daily number of healthcare workers who provided patient care was 44 (42–45), ie 34 nurses and 10 physicians and nurse practitioners. The distribution of both disciplines (median) during day, evening and night shifts was 14 vs 7; 10 vs 2; and 9 vs 1, respectively. The average number of lever-presses per hand disinfection events was 2.8, which equals 5 ml hand alcohol if all lever-presses were fully completed.

The median (IQR) number of hand disinfection events per healthcare worker per day was 15.9 (13.1-19.3). In Figure 1 the numbers of hand disinfection events per healthcare worker are plotted for each hour of the day, calculated over the one-year study period.

Analysis of hand disinfection events per healthcare worker by hour of the day revealed a significant increase in hand disinfection events from 8:00 h to 10:00 h, which coincides with the start of the dayshift and medical assessments. Another increase was found from 16:00 h to 19:00 h, which correspondents with elevated activities before dinnertime ($p < 0.001$ for both). The number of hand disinfection events was relatively low from 10:00 h to 16:00 h

The distributions for day shift, evening shift, and night shift are presented in Table 1. Differences between shifts were all statistically significant ($p < 0.001$). The median (IQR) number of hand disinfection events per patient-day was 27.6 (23.0-36.3).

In total 1,168 direct observations of events requiring hand hygiene were analyzed; in 65.8% of cases healthcare workers fully complied with the protocol. The interquartile range of compliance with hand hygiene determined at the separate observation days varied from 50% to 71.5%.

Adjusted for the 65.8% compliance rate, the counted number of hand disinfection events should increase by about 50% to approximately 375,000 hand hygiene disinfection events.

Discussion

Electronic dispensers provided data trends on the frequency of hand disinfection events in a clinical setting over an extended period of time. The median number of 15.9 hand disinfection per healthcare worker per day in our study falls within the median 5.0-30.0 range reported by Boyce et al.[1]

Three studies measuring hand disinfection events by electronic dispensers expressed the outcome as hand disinfections per patient-day.[5,6,8] For a pediatric intensive care unit, a surgical intensive care unit and a general medical ward, the mean number was 41.2, 48.7 and 12.2, respectively.[6] Marra et al reported a mean of 53.8 hand disinfections per patient-day in an adult medical-surgical intensive care unit.[6] Another study performed in a general pediatric ward measured the amount of used hand alcohol and translated this into 47 hand rubs per patient-day.[9] McGluckin et al reported a mean of 6.7 hand washings per patient-day in an inpatient rehabilitation unit.[10] We documented a median of 27.6 hand disinfection events per patient-day at our NICU. This relatively low number as compared to two of the studies mentioned above likely reflects our policy to provide care on indication. This approach takes into account the infants' sleep-wake rhythm so that they can sleep longer, which improves recovery from previous interventions. This approach leads to fewer patient contacts.

Combining the electronically collected data and the observational data allows generating an additional tool to monitor hand hygiene practices. The calculated number of required hand disinfection events per day could be an incentive for healthcare workers to strive for and reach 100% compliance. However, this calculated number is ward-specific and may be only adhered to if conditions such as case mix, number of patient days, and patient-healthcare worker ratio, are comparable to conditions of the initial study period.

Additionally, we showed that hand hygiene performance followed a daily pattern: it was most intense after shift handover, and after dinnertime. The median number of hand disinfection events per healthcare worker during day shifts was lower than that during evening shifts. This is probably caused by the fact that the work floor during day shifts counts twice as many healthcare workers than during evening shifts; the number of patient contacts is likely not doubled. The slightly lower number of hand disinfection events per healthcare worker during night shifts in comparison to evening shifts might be explained by the fact that night shifts in general correlate negatively with hand hygiene compliance.[11] Additionally, in the night shifts there are fewer hand disinfection opportunities as healthcare workers only perform routine care and unavoidable interventions.

Direct observation of hygienic behavior is a well-known method to document hand hygiene compliance in a clinical setting. Nevertheless, it is time consuming, and knowing that they are observed may influence the healthcare workers' behavior.[4-6.] In contrast, the described electronic device unobtrusively records all hand disinfection events over an extended period of time. Furthermore, senior staff can motivate members of the healthcare team to improve their hand hygiene practices by relating the recorded number of hand hygiene events to the calculated number required for 100% compliance. Nevertheless, this device is not able to record non-compliance and the quality of hand disinfection. Non-compliance can be defined as failure to disinfect hands, lack of completeness of hand rubbing, or insufficient drying time. Applying both methods together therefore provides a more complete representation of hand hygiene practices.

This study had several limitations. The type of dispenser used is unable to detect whether dispenser use correlates with a defined hand disinfection opportunity. Second, this study was designed and performed before the "My five moments for hand hygiene" approach was published.[7] Three of the five hand hygiene indications were measured: before patient contact, before invasive procedures, and after patient contact. The "My five moments for hand hygiene" approach is nowadays considered the "gold standard" method to monitor hand hygiene compliance. We missed the 3rd and 5th moments: "after touching patient surroundings" and after body fluid exposure risk. However, our hand hygiene protocol dictates that healthcare workers must wear gloves when at risk of exposure to a patient's body fluid. They are also required to disinfect hands before and after glove use. Third, the variance of hand disinfection practices by individual healthcare workers was not documented. Furthermore, we also cannot rule out the possibility that parents or family occasionally used alcohol dispensers, although all NICU professionals instructed parents to wash their hands with soap only. NICU professionals did not report the use of hand alcohol by parents. In addition, healthcare workers also might have used hand alcohol at moments that are not corresponding to any indication for hand hygiene. This possible unnoticed use could have resulted in overestimation of hand hygiene events by healthcare workers. Therefore, the calculated number of hand disinfection events needed for an ideal 100% compliance is of limited accurateness and needs to be considered with caution.

Conclusions

We conclude that the tested type of dispenser provides useful trend data that can be evaluated supplementary to the data obtained form direct observations. Although not tested as such in this study, we believe that electronic devices could be useful to evaluate the long-term effect of hand hygiene promotion campaigns. Direct observations according to the "My five moments for hand hygiene" approach still provide important additional information on non-compliance and quality of hand hygiene.

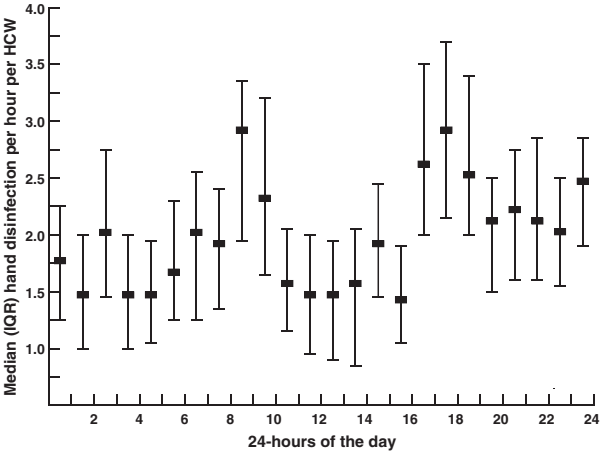

Figure 1 Median (IQR) number of hand disinfection events per healthcare worker plotted for each hour of the day, calculated over the one-year study period.

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Editorial…continued from page 4
has published a Nursing Practice Manual, "Congenital Heart Disease Pulse Oximetry Screening of the Newborn." See: www.archildrens.org/.../heart.../.

Les Plesko, Managing Editor

* Critical Congenital Heart Disease Screening with Pulse Oximetry in the Neonatal Intensive Care Unit, Satyan Lakshminrusimha, MD; Stephen Turkovich, MD; Veena Manja, MD; Jayasree Nair, MD and Vasanth H.S. Kumar MD. You can read the entire paper at http://www.neonatologyresearch.com/?page_id=2592.

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