Vol. 26 No. 3 May-June 2013

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 Centers for Disease Control and Prevention. (2003) Guidelines for Environmental Infection Control in Health-Care Facilities. Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR, 52(RR10):1-42.

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neonatal INTENSIVE CARE

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Editorial

A message from the publisher

As a neonatal care provider, you should be aware that the Medical Device Tax, a 2.3% excise tax on medical equipment, went into effect on January 1. This tax, which is intended as a funding mechanism for portions of the Affordable Care Act (Obamacare), applies to all medical equipment for human use except those sold directly to the consumer. Pushback against the tax is not merely a political issue. Eighteen Democratic senators, including Harry Reid and Al Franken, had petitioned the President to halt implementation of the MDT, to no avail, with the Administration claiming that the increase in the patient pool as a result of more access to insurance would offset any losses incurred by medical equipment manufacturers. The claim is specious. There's no actual evidence of an increased pool of insureds, since the majority of devices affected under the law are used in acute care settings, where patient care is already mandated. While the Administration also claimed that manufacturers might pass along the cost of the tax to their institutional customers, it should be noted that raising prices in the current economic climate is a nonstarter. Plus, many such medical equipment purchases are fixed contracts. But perhaps the most onerous aspect of the tax is that it is on revenues, not profits. Since most medical equipment manufacturers are in effect small businesses (80% have less than 50 employees), and product manufacturing and innovation is often a long, expensive process, any profit is incremental. This means many companies will have to severely cut back on R&D, staff, and marketing. If fact, as we know from our contacts with manufacturers, this is already happening. In short, the tax is a very bad idea. According to the Medical Device Manufacturers Association, "This tax will stifle innovation, harm patient care and weaken the position of the United States as the global leader in medical device innovation." While the consequences of the tax for neonatal caregivers are not immediately quantifiable, it will decidedly hurt innovation in the field. What can be done? We have contacted our elected representatives to warn them about the fallout from this tax, and are urging its repeal, and I urge you to do the same. (In a bit of possibly good news, to counter the tax, Senators Orrin Hatch (R-UT) and Amy Klobuchar (D-MN) have introduced amendments to bills with broad bipartisan support to repeal the tax.)

Steve Goldstein Publisher

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ISSN 1062-2454 Published seven times each year by

Goldstein and Associates, Inc.

10940 Wilshire Blvd., Suite 600 Los Angeles CA 90024 Phone: 310-443-4109 Fax: 310-443-4110 E-mail: s.gold4@verizon.net Web: www.nicmag.ca

Publisher/Editor in Chief Steve Goldstein

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Design, Typography, Prepress and Production Management http://accugraphics.net

Circulation, Coverage, Advertising

Rates: Complete details regarding circulation, coverage, advertising rates, space sizes, and similar information are available to prospective advertisers. Closing date is 45 days preceding date of issue.

Change of Address notices should be sent promptly to Circulation Department: provide old mailing label as well as new address: include zip code or postal code. Allow two months for change.

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News

□ May-June 2013

ADDENDUM

For the article Safety Assessment of a Novel Neonatal Ventilator Circuit Patient Interface Connector for the Delivery of Aerosolized Medication to Mechanically Ventilated Infants, in the March/April issue, the authors would like to add the following citation: Aerosolized albuterol sulfate delivery under neonatal ventilatory conditions — in vitro evaluation of a novel ventilator circuit patient interface connector. Jan Mazela, Krzysztof Chmura, Maksymilian Kulza, Christopher Henderson, Timothy J. Gregory, Arkadiusz Moskal, Tomasz R. Sosnowski, Ewa Florek, Lucyna Kramer, Martin Keszler. Journal of Aerosol Medicine and Pulmonary Drug Delivery 2013; accepted for publication.

HAVING IT BOTH WAYS

The following is from The Colorado Independent, by John Tomasic, edited for our readers. Lori Stodghill was 31 years old, seven-months pregnant with twin boys and feeling sick when she arrived at St Thomas More hospital in Cañon City on New Year's Day 2006. She was vomiting and short of breath and she passed out as she was being wheeled into an examination room. Medical staff tried to resuscitate her but, as became clear only later, a main artery feeding her lungs was clogged and the clog led to a massive heart attack. Stodghill's obstetrician, Dr Pelham Staples, who also happened to be the obstetrician on call for emergencies that night, never answered a page. His patient died at the hospital less than an hour after she arrived and her twins died in her womb. Stodghill's husband Jeremy, a prison guard, filed a wrongful-death lawsuit on behalf of himself and the couple's then-two-year-old daughter Elizabeth. Staples should have made it to the hospital, his lawyers argued, or at least instructed the emergency room staff to perform a cesarian-section. The procedure likely would not have saved the mother, a testifying expert said, but it may have saved the twins. The lead defendant in the case is Catholic Health Initiatives, the Englewood-based nonprofit that runs St Thomas More Hospital as well as roughly 170 other health facilities in 17 states. [The hospital follows the Catholic Church's directives] forbidding non-natural birth control and abortions... When it came to mounting a defense in the Stodghill case, Catholic Health's lawyers [argued that] state law protects doctors from liability concerning unborn fetuses on grounds that those fetuses are not persons with legal rights. [An attorney for the hospital argued]: the court "should not overturn the long-standing rule in Colorado that the term 'person,' as is used in the Wrongful Death Act, encompasses only individuals born alive. Colorado state courts define 'person' under the Act to include only those born alive. Therefore Plaintiffs cannot maintain wrongful death claims based on two unborn fetuses."

C-SECTION TWEETED

From the Huffington Post: We've heard of moms in labor tweeting from the delivery room, but until yesterday, we had never witnessed surgeons sending minute-by-minute updates during a patient's cesarean section. Dr Sherri Levin at Houston's Memorial Hermann hospital live tweeted a cesarean section being performed by her colleague, Dr Anna Gonzalez. Using tweets, photos and videos, Levin guided viewers through the procedure, while also answering their questions about the surgery. The hospital's social media manager Natalie Camarata told the Associated Press that over 72,000 people from 60 countries watched the procedure as it happened. The 39-yearold patient, who was not identified by the hospital, was having a scheduled c-section for her second delivery. See the story here: http://www.huffingtonpost.com/2013/02/21/cesarean-section-livetweet_n_2733699.html - or see the hashtag: #MHbaby http://bit. ly/c-section.

FAT DADS

BMC Medicine reports new evidence in a study by Cathrine Hoyo and colleagues showing that obesity in fathers is associated with epigenetic changes in their offspring. The study described a decrease in methylation of the insulin-like growth factor 2 gene in newborns, suggesting that paternal obesity may disrupt normal imprinting in germ cells and affect the health of their offspring. However, a cautionary note is provided by Gudrun Moore and Philip Stainer in a commentary, explaining why these results should not be over-emphasized and further evidence should be gathered from whole genome studies. See Paternal obesity is associated with IGF2 hypomethylation in newborns: results from a Newborn Epigenetics Study (NEST) cohort, BMC Medicine 2013, 11:29.

CHINA-BOUND

BioMed Central celebrated the addition of its 250th journal, and also announced its bilingual China Gateway, which aims at providing assistance to researchers based in China and offering up-to-date info to authors, editors, societies and institutions in China. BMC now publishes six journals on behalf of institutions in China, and hopes the gateway will raise its profile still further in the country. Colleagues in London have been visiting BMC's Beijing office and going on the road to hold workshops for potential authors and editors.

EXPOSED

BioMed Central reported on a study in Scientific American that because 1.5-2 million children in the EU are born each year with methylmercury exposures above the safe limit, mercury pollution costs the EU \notin 10,000 million per year. The costs are probably even higher when taking into account heart disease.

LISTEN UP

The House Research Institute and Children's Hospital Los Angeles announced that the FDA has given final approval to begin a clinical trial of an Auditory Brainstem Implant (ABI) procedure for children. The trial is a surgical collaboration sponsored by the House Research Institute in partnership with Children's Hospital Los Angeles and Vittorio Colletti, MD of the University of Verona Hospital, Italy. The ABI was developed at the House Research Institute and is the world's first successful prosthetic hearing device to stimulate neurons directly at the human brainstem, bypassing the inner ear and hearing nerve entirely. The clinical trial is part of a unique international consortium with the University of Verona for teaching and research to advance the use of the auditory brainstem implant (ABI) in children worldwide. The ABI is already a successful treatment with the pediatric population in Italy, and the goal of the partnership is to bring the hearing implants to deaf children in the United States.

GOING DEEP

Family Practice News reported that deep suctioning and long lapses between suction treatments were associated with significantly increased lengths of stay in babies hospitalized with bronchiolitis. Patients who never had deep suctioning stayed a little more than a day, but the length of stay was more than 2 days in patients for whom deep suctioning accounted for 60% or more of their treatments, according to doctors at Cincinnati Children's Hospital Medical Center. It was posited that deep suctioning may aggravate the bronchial swelling and mucus sloughing that already causes breathing problems. The researchers studied 740 patients. The adjusted mean length of stay for infants who had no deep suctioning was 1.75 days. The stay was 1.91 days for those with up to 35% deep suctioning, 1.96 days for more than 35%-60% deep suctioning, and 2.35 days for more than 60% deep suctioning.

TOO MANY DRUGS

Jane Brody writes in the New York Times that the latest findings about drug use during pregnancy have ignited concerns among experts, noting that during the last three decades, use of prescription drugs during the first trimester has grown by more than 60%. Ninety percent of women take at least one medication, and 70% take a prescription drug, according to the CDC. The number of pregnant women who take four or more medications



has doubled, one in ten take a herbal remedy, and others selfmedicate with over the counter drugs. The FDA estimates that at least 10% of births defects result from moms taking meds. In addition, Brody writes, many women are getting advice on the safety of medications for their fetuses from the internet. Brody cites a study in Pharmacoepidemiology and Drug Safety that 25 of the websites it looked at contained misleading, inconsistent, and inadequate information. The study also noted that 79% of the sites provided no info on teratogenic risk. Just 13 sites advised pregnant women to consult their doctors before stopping or starting a medication.

BPA

The levels of BPA in the urine of preemies in the NICU is associated with greater exposure to medical devices, but not with nutritional intake, according to an article on DoctorsLounge.com. Researchers at Simmons College in Boston measured BPA levels in the urine of 55 preemies before and after feeding, and in breast milk or formula from their mothers, and noted the use of medical devices. While BPA concentrations were similar in breast milk and formula, infants exposed to four or more medical devices over the three days of the study time had significantly higher median urinary total BPA than infants exposed to three or fewer devices (36.6 versus 13.9 μ g/L). The authors noted that these BPA concentrations were 16- to 32-fold higher than those found among infants and children in the general population, but were below the EPA reference dose.

FRESH OR FROZEN?

Frozen embryo IVF babies fare somewhat better than fresh embryo IVF babies, according to a report by dailyRx News. A recent study found that women receiving frozen embryos tended to have a slightly lower rate of poor pregnancy outcomes than women using fresh embryos. Women carrying babies not conceived from IVF tended to have slightly better outcomes than women who became pregnant with IVF. The study was presented at a medical conference about pregnancy. None of the outcome differences related to miscarriage or stillbirth.

COFFEE AND BIRTH WEIGHT

BMC Medicine offers a study: Maternal caffeine intake during pregnancy is associated with birth weight but not with gestational length: results from a large prospective observational cohort study [BMC Medicine 2013, 11:42]. Highlights from the abstract: Pregnant women consume caffeine daily. The aim of this study was to examine the association between maternal caffeine intake from different sources and (a) gestational length, particularly the risk for spontaneous preterm delivery, and (b) birth weight (BW) and the baby being small for gestational age. A total of 59,123 women with uncomplicated pregnancies giving birth to a live singleton were identified. Caffeine intake from different sources was self-reported at gestational weeks 17, 22 and 30. Spontaneous PTD was defined as spontaneous onset of delivery between 22+0 and 36+6 weeks. As there is no consensus, SGA was defined according to ultrasound-based, populationbased and customized growth curves. The main caffeine source was coffee, but tea and chocolate were the main sources in women with low caffeine intake. Median pre-pregnancy caffeine intake was 126 mg/day, 44 mg/day at gestational week 17 and 62 mg/day at gestational week 30. Coffee caffeine, but not caffeine from other sources, was associated with prolonged gestation (8 h/100 mg/day). Neither total nor coffee caffeine was associated with spontaneous PTD risk. Caffeine intake from different sources, measured repeatedly during pregnancy, was associated

with lower BW (-28 g, -25 g, -21 g per 100 mg/day additional total caffeine for a baby with expected BW 3,600 g). Caffeine intake of 200 to 300 mg/day increased the odds for SGA (1.62, 1.44, 1.27), compared to 0 to 50 mg/day. The authors concluded: Coffee, but not caffeine, consumption was associated with marginally increased gestational length but not with spontaneous PTD risk.

decisions regarding mode of delivery and infant diet.

MUSSEL POWER

Researchers at UC Santa Barbara have been looking into the tight grip of mussels to see if it has medical applications, reports Sciencemag.org. The researchers have used the mollusk's



binding tricks to try and develop a biocompatible glue that could seal fetal membranes, allowing prenatal surgeons to repair birth defects without triggering premature labor. In water, mussels somehow elbow the water aside and bind themselves to rocks using 15 proteins that comprise threadlike structures to help them hold on, and these proteins contain a lot of the amino acid **DOPA.** Researchers at Northwestern University have created a synthetic, threadlike polymer, polyethylene glycol that mimics the mussel protein, and they've attached a synthetic form of DOPA to the thread's tips. This DOPA-decorated thread could more or less recapitulate the central properties of mussel adhesion. The mussel-based glue has been tested on dogs, successfully sealing an artery in 20 seconds. Testing has also begun on fetal membranes.

variability in the fecal microbiota profiles among the infants. Formula-fed infants had increased richness of species, with overrepresentation of Clostridium difficile, compared to breastfed infants. Infants born by cesarean had lower levels of Escherichia-Shigella and Bacteroides species, with infants born by elective cesarean having particularly low bacterial richness and diversity. The researchers noted that their study illustrated how gut microbiota can be influenced by parent and physician

ULTRASOUND AND AUTISM

Researchers have announced that an ultrasound test conducted after birth can determine a child's risk for developing autism, reports Medical Daily. A study led by Michigan State University found that newborns with low birth weight are seven times more likely to develop autism later in life if ultrasound scans taken immediately after birth show enlarged ventricles, the brain cavities that store spinal fluid. Researchers analyzed data from

The researchers

identified high

a cohort of 1,105 LBW infants born in the mid-1980s. The babies had cranial ultrasounds immediately after birth, so researchers could look for relationships between brain abnormalities in infancy and health disorders that developed later. Participants were screened for autism at age 16, and a subset of them had a more rigorous test at 21, which turned up 14 positive diagnoses.

HUP TWO THREE

Hawaii's Tripler Army Medical Center's new neonatal intensive care unit is the first at a military facility. KPAU AM reported on the unit, which has state-of-the-art technology, with walls, floors and ceilings soundproofed to reduce sound levels.

DON'T TAKE IT

Pregnant women should avoid taking vitamin D supplements because they increase the risk of children developing a food allergy, according to researchers in Germany who looked for a correlation between the concentration of vitamin D in the blood of expectant mothers and in cord blood of the babies. Their research included 622 mothers and their 629 children in the longterm study "Lifestyle and environmental factors and their impact on the newborn allergy risk." In cases where expectant mothers were found to have a low vitamin D level in the blood, the occurrence of food allergies among their two year old children was rarer than in cases where expectant mothers had a high vitamin D blood level. In reverse, this means that a high vitamin D level in pregnant women is associated with a higher risk of their children to develop a food allergy during infancy. These children were also found to have a high level of the specific immunoglobulin E to food allergens such as egg white, milk protein, wheat flour, peanuts or soya beans.



NO HARM

The pregnancy nausea drug Ondansetron doesn't harm the developing embryo or fetus, according to researchers from the State Serum Institute in Copenhagen. The drug's usage has been increasing. Researchers collected data on 1,970 women who had used ondansetron while pregnant and found no evidence of adverse effects. From an article by Christina Nordqvist in Medical News today, copyright Medical News Today.

OMEGA

University of Kansas researchers have found that the infants of mothers who were given 600 milligrams of the omega-3 fatty acid DHA during pregnancy weighed more at birth and were less likely to be very low birth weight and to be born before 34 weeks gestation than infants of mothers who were given a placebo. US women typically consume less DHA than women in most of the developed world. During the first five years of the study, children of women enrolled in the study received multiple developmental assessments at regular intervals throughout infancy and at 18 months of age.

тніск

The walls of the aorta are already thickened in babies born to mothers who are overweight or obese, according to a paper published in the Archives of Disease in Childhood. More than half of women of childbearing age in developed countries are overweight or obese. Twenty three women, whose average age was 35, were included in the study when they were 16 weeks pregnant. The abdominal aorta was scanned in each newborn within seven days of birth to find out the thickness of the intima and media. Intima-media thickness ranged from 0.65mm to 0.97mm, and was associated with the mother's weight. The higher the weight, the greater was the baby's intima-media thickness, irrespective of how much the baby weighed at birth.

GESUNDHEIT

C-section babies are five times more likely to develop allergies by age two than those born naturally, according to researchers at Henry Ford Hospital. It was posited that there is a pattern of "at risk" microorganisms in the gastrointestinal tract of babies born by c-section that may cause them to be more vulnerable to developing the antibody Immunoglobulin E when in contact with allergens. A total of 1,258 newborns were involved in the investigation from 2003 until 2007 and were assessed at 4 different times: at one month old, six months, one year, and two years. From an article written by Sarah Glynn for Medical News Today, copyright Medical News Today.

GET OFF THE FREEWAY

Babies exposed to air pollution in the womb are more likely to have autism than those whose mothers spend pregnancy in clean air, according to a UCLA study, reported by the Huffington Post. Researchers compared levels of air pollutants, mostly related to vehicle traffic, during pregnancy gestation periods of 7,603 children with autism and 75,635 children without autism, born from 1995 to 2006 in Los Angeles. Babies at the 75th percentile of exposure to toxins had 8% to 10% higher risk of autism than babies at the bottom 25th percentile, the study said. Ozone and fine particulates had the strongest association with autism. Using government air monitoring stations, researchers estimated average exposures during pregnancy to carbon monoxide, nitrogen dioxide, nitric oxide, ozone and particulate matter. The study adjusted for factors that include maternal age, birthplace, race and education. Using birth certificates, researchers compared control children with noncontrol children who had matching birth year, sex and gestational age at birth. The UCLA study is the first to suggest a link between autism and ozone. The ozone level in LA is the highest in the nation and violates federal health standards an average of 137 days a year.

DADDY DEAREST

Fathers' support during pregnancy can lower rates of preemie birth and low birth weight, according to researchers at the University of Michigan. Live Science reported on research revealing that when men are scarce in a community, women are more likely to give birth early and to newborns who weigh less than 2,500 grams. The researchers believe the reason could be evolutionary in that when men invest little in a pregnancy, women may respond by investing less physically, as well, unconsciously expecting the baby not to make it to adulthood, a pattern developed in early evolutionary history when infant mortality was high. The researchers pulled together birth records from every county in the United States for the year 2000 and compared the rates of low birth-weight and premature birth with census data on the ratio of men to women in those counties. They also examined other demographic factors, including the economic status of those communities, the proportion of single moms and the educational attainment of residents. The analysis revealed that male scarcity was linked to both low birth-weight and prematurity, with more of each in counties where men were well outnumbered by women. The male scarcity effect remained even when the researchers accounted for socioeconomic status, race and education.

SCREENING

Universal screening of newborns improves the detection of CAH in both girls and boys, according to a new study reported by HealthDay News. It has commonly been thought that boys are at greater risk for delayed diagnosis. Researchers at the Karolinska University Hospital in Sweden analyzed all known cases of CAH in Sweden between 1910 and 2011. There was a significant increase in diagnosed cases in the 1960s and 1970s, following the discovery of the first effective treatment in 1950 and increased awareness of CAH and its symptoms. The number of diagnosed cases increased again after the introduction of newborn screening in 1986.

PILLOW TALK

Parents who used stretching exercises and special sleeping pillows saw improvements in head deformities that can be created when infants lie in the same spot for a long time, according to researchers at the University of Giessen. Katti Gray reported for Reuters Health that the exercises can be easily done at home, while the pillows cost about \$25, compared with previously used special helmets that cost \$2,000. Head deformities increased from 5% in the 1990s to up to 30% in 2008, likely triggered by efforts to curb SIDS by placing sleeping babies on their backs. The researchers followed 50 babies five months old and younger with moderate to severe head deformities that posed no serious physical or neurological risks. Among the 43 babies the researchers could examine after six weeks, about 18% of the stretched babies and 19% of the babies using pillows saw improvements. The researchers added, however, that their study didn't include infants who had neither pillows nor exercises, and noted that there is often spontaneous improvement in infants after they reach five months.

TALK TALK TALK

Researchers have uncovered a link between a lack of talking between a mother and her baby and the risk of the child developing emotional problems and behavioral disorders in later life. A study, at the University of Aberdeen, which analyzed hundreds of videos of mothers interacting with their year-old babies, found that less vocalization by the parent was associated with an increase in the likelihood the child would develop conditions such as depression and ADHD. For every reduction of five communications per minute by the mother, the odds of an infant going on to develop such a condition by the age of seven increased by 44%. The researchers posited that talking may have a protective effect against problems of attention and conduct, or that the reason was genetic, and that perhaps the moms themselves had ADHD and passed it on. Reported by The Herald, Scotland.

REALITY TELEVISION

CBS Station KTVT Dallas reported on Texas Health Presbyterian Hospital Dallas's implementation of cameras and microphones attached to 15 incubators in its neonatal intensive care unit, a system the hospital calls Peek-a-Boo. This allows parents to communicate with their newborns by watching them



 Anatomically designed by an anesthesiologist for pediatric airways.

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on a computer screen and talking to them through a headset microphone. Doctors using the system said they were surprised at how much difference it made, and noted that it helped cut down foot traffic inside the NICU, thus helping decrease the danger of infections.

GUIDELINES

Feeding the Preterm Infant, a supplement published in the March 2013 edition of The Journal of Pediatrics, provides new nutritional recommendations for preterm infants. The supplement includes new science about host defenses in preterm infants, unique needs of different subpopulations and guidance to address existing knowledge gaps in preterm infant nutrition. The supplement was developed by 31 international academic neonatal nutrition experts who attended the Global Neonatal Consensus Symposium sponsored by Mead Johnson Nutrition. The supplement addresses updated nutritional recommendations for preterm infants (protein, micronutrients and lipids), nutritional needs of specific subpopulations of preterm infants including micropreterm infants, small-for-gestational age infants, late preterm infants and post-discharge infants, new science about host defenses in preterm infants, challenges in translating the latest science to practical application, and identification of current knowledge gaps in preterm infant nutrition.

PRODUCTS

KANGAROO CARE DAY

In honor of The Second International Kangaroo Care Awareness Day, May 15, Nurtured by Design is having a couple of contests. Yamile Jackson, CEO and Founder of Nurtured by Design announced: Here are the categories for hospitals and families: • Longest Kangaroo Session of the day (hospital with the baby that was held the longest that day) • Best Kangaroo Picture • Best Kangaroo Tip/Suggestion. Here are other ideas to celebrate Kangaroo Care in your NICU or Post Partum Unit: • Nurses, volunteers and parents make cookies, cakes, cake balls, etc with the shape of a "K" since a kangaroo is hard to find • Training on Kangaroo Care for staff (we will offer some free sessions that day) • Posters and education efforts for parents (we can send you free files for you to print for your unit) • We also have brochures at no cost that explain the basics of Kangaroo Care (the correct position, who is eligible, what to do before kangarooing, who recommends it, benefits, etc). Share other ideas, suggestions, questions, etc in our blog or in the Kangaroo Care Facebook Page. Send an e-mail for more info to social@ nurturedbydesign.com.

ALLIED

Nurtured by Design announced that it has named Alliance Medical as its exclusive distributor for its products and services for hospitals in the USA. The company offers its NeuroDevelopmental Care System: The Zaky and Kangaroo Zak. You can follow Nurtured by Design on Facebook, Twitter and LinkedIn or checked out the company's blog at blog. nurturedbydesign.com.

NEW SOFTWARE

It can be challenging to interpret electronic fetal monitoring (EFM) tracings to determine when a baby is truly in distress and a C-section is warranted, since more than 80% of babies will exhibit some level of aberrant tracing during labor, ranging from minor to serious. Currently, physicians must "eyeball"

the tracings. This is complicated by the fact that the heart rate naturally fluctuates during labor and there hasn't been any standardized methodology for interpretation. A recent NIH study noted that in more than 97% of 100 assessments of FHR tracings from the final hour of labor, three NIH experts agreed with the analysis performed by PeriGen's PeriCALM Patterns software. Additionally, PeriCALM Patterns demonstrated that it can be used for efficient retrospective evaluation of stored FHR data as well as to perform real-time screening when an expert isn't available. The study's results were published in the American Journal of Obstetrics and Gynecology. A second phase of the study will review 5,000 tracings, or about 20 miles of paper. Contact perigen.com.

ACTIVATED

Taylor Regional Hospital in Hawkinsville, GA, and Griffin Hospital in Derby, CT completed activation of PeriGen's PeriCALM perinatal system in their respective facilities' labor and delivery (L&D) departments. The PeriCALM suite includes PeriCALM Tracings, an advanced fetal surveillance system with two unique clinical decision support-based applications: PeriCALM Patterns, a fetal heart rate pattern recognition software and PeriCALM Curve, a dynamic labor progression software. All together, these solutions support and empower OB/GYN clinicians in delivering optimal care of mothers and their babies at the bedside. Taylor Regional Hospital is a 55-bed rural community facility that serves 170,000 residents of Middle Georgia. Griffin Hospital is a 160-bed acute care community hospital serving more than 100,000 residents of the Lower Naugatuck Valley Region. PeriCALM is the facility's first electronic perinatal system. Contact perigen.com.

BIG AWARD

Nurtured by Design has been nominated for a National Design Award bestowed by the Smithsonian Cooper-Hewitt, National Design Museum. The nomination is in the category of Corporate and Institutional Achievement, given in recognition of a corporation or institution that uses design as a strategic tool as part of its mission, and has consistently exhibited ingenuity and insight in the relationship between design and quality of life. Contact nurturedbydesign.com.

PURCHASE

Nonin Medical, Inc announced that the company's EQUANOX Advance Cerebral/Somatic Oximetry System has been selected for use by Poland's five university-based pediatric hospitals. 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 purchase was made possible by the Great Orchestra of Christmas Charity (GOCC) organization, one of the largest non-government charity organizations in Poland. Each year the GOCC meets with hospital leaders to determine what the biggest needs are for medical equipment. Contact noninequanox.com.

STAFF

Audiology Systems Inc announced that it has added Will Jones, AuD, to its expanding sales organization. Jones joins as a regional sales manager with oversight of sales and service throughout North and South Carolina. Contact audiologysystems.com.

PEOPLE

GN Otometrics announced that it has hired Polly Benedict

as inside sales and customer service manager. Benedict will oversee daily operations of customer service and inside sales, including staff management and training, lead generation, systems improvement and development, as well as providing support for marketing initiatives, particularly product launches. Scott Brewer joined the company in the newly-created position of financial director and Ginger Sharp is the new assistant controller. The company announced that it has named Charlotte Greve to run marketing and communication in its US headquarters in Schaumburg, IL. She is a veteran of Otometrics in Denmark. The company has hired Mona Dworsack-Dodge, AuD, as director of audiology services. In this new role, Dworsack-Dodge will be responsible for the general management of the audiology services department. She will work closely with GNO's distributor network and will play a key role in developing and fostering relationships with key accounts and thought leaders. Contact otometrics.com.

ACQUISITION

GN Otometrics announced that it has acquired Audio Electronics, Inc, a Texasbased distributor of audiometric and vestibular equipment. David Dorris, PhD, who most recently was president of Audio Electronics, will remain at the helm of the organization as general manager. Audio Electronics will continue to service all brands of equipment, in Texas, and discontinued the sale of all William Demant products after February 2, 2013. Audio Electronics will sell the following brands: GN Otometrics (AURICAL, ICS, MADSEN), Acoustic Systems, AudioScan, Benson Medical Instruments, Bio-logic, Intelligent Hearing Systems, Otodynamics and Vivosonic. Contact otometrics.com.

READ ALL ABOUT IT

The book. Intensive Parenting: Surviving the Emotional Journey through the NICU, focuses on the experiences, feelings, and relationship issues that families face when a baby is admitted to the NICU). The authors note that while other books explain a baby's medical conditions and treatments, this book explores the parents' experience. Authors Deborah Davis, PhD, and Mara Tesler Stein, PsyD, carry forward themes from their earlier book, Parenting Your Premature Baby and Child, into this new volume, which features updated content for a broader audience, specifically any parent whose baby is in the NICU regardless

of the reason. By focusing solely on the NICU parenting experience, this book offers a concise and accessible guide. Intensive Parenting is also a source for healthcare practitioners who work with NICU families, relatives, and friends who are trying to understand this complex experience while offering parents comfort, support, and strength.

SUPPORT

Covidien announced its support for the Centers of Medicare & Medicaid Services (CMS) proposed quality measure #3040, currently considered for a Medicare program rule. Quality measures help CMS assess the performance of hospitals participating in Medicare and determine reimbursement based on factors that demonstrate compliance with high-care standards and "meaningful use," such as healthcare processes, outcomes and patient perceptions. Proposed quality measure #3040 calls specifically for monitoring respiratory rate, blood oxygenation (through pulse oximetry) and sedation scores in individuals on patient controlled analgesia pumps (PCAs) for longer than 2.5 hours. PCAs, which allow self-administration of pain management drugs, can be associated with dangerous respiratory complications, such as cardiac arrest. Covidien is urging clinicians and other industry leaders to voice their support for quality measure #3040 with guidelines added for continuous monitoring through capnography and pulse oximetry. Contact covidien.com.

AMONG THE BEST

Roche Diagnostics Corporation has been selected to Fortune magazine's annual list of the "100 Best Companies to Work For," joining companies such as Google, Starbucks and Nordstrom. Roche debuted at 89th on the list and is the only Indianabased company selected. In selecting Roche Diagnostics for the list, Fortune cited the company's on-site medical clinic and fitness center, \$30,000 budget for intramural sports, and health insurance plans tiered to income levels. To see the list visit fortune.com/bestcompanies. For more about Roche Diagnostics, visit roche-diagnostics.us.

CASE STUDY/DONATIONS

MediPurpose announced the publication of a new case study, Reinventing a Better babyLance Infant Heel Incision Device: Collaboration with Citrus Valley Medical Center. The case study describes how Citrus Valley Medical Center's Family Birth & Newborn Center in West Covina,



Neo-StatCO₂ < Kg[®]

The first & only CO₂ detector for patients from 0.25 - 6 kgs

Expiratory



0.25 kg - 6 kgs Body Weight

- Vivid breath-to-breath color change
- Detects up to 100 breaths/minute
- 24-hour continuous performance
- Works in 100% humidity

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CA collaborated with MediPurpose throughout its babyLance heelstick device design process to provide "voice of the customer" (VOC) input about the babyLance, shape and validate end-user preferences for the ideal heelstick solution, evaluate new babyLance prototypes, and participate in simulated and clinical use validation studies. The company recently donated 1900 cases of babyLance infant heelsticks to international humanitarian aid and disaster relief organization Matthew 25: Ministries. Working closely with US hospitals, corporations, businesses and individuals, Matthew 25: Ministries has shipped an estimated 115 million pounds of donated humanitarian supplies to the needy in the US and impoverished countries in Central and South America, the Caribbean, the Balkans and Africa. Contact medipurpose.com.

RENEWED

MediPurpose announced that Health Canada has renewed its SurgiLance and babyLance safety blood lancet device licenses. Health Canada requires manufacturers' device licenses to be renewed every three years. The renewal process requires CAN/ CSA-ISO 13485 recertification to validate that a medical product manufacturer's quality management system (QMS) continues to meet the requirements of the international standard ISO 13485 and the Canadian Medical Device Regulations (CMDR). For more information about MediPurpose's medical products and solutions for inventors, innovators, manufacturers and distributors, please visit medipurpose.com.

IMAGING

Kubtec, the leader in innovative technology for digital x-ray systems, is pleased to present the Digiview 250, a low dose, high resolution flat panel detector designed specifically for neonatal, pediatric, and extremity imaging. The Digiview 250 features 96µm pixel and 14-bit contrast with a 20cm x 25cm active imaging area. For added ease of use, it fits directly into the isolette, and images neonatal patients without moving them. The 750ms image readout time allows for immediate image access. The Digiview 250 works with any X-ray source, so purchasing additional X-ray equipment is not required. With its Complementary Metal-Oxide-Semiconductor (CMOS) technology, the Digiview 250 brings high speed, high resolution digital imaging to the most fragile patients. With rapid image acquisition and display, Kubtec's Digiview 250 offers a touch screen monitor and a full complement of DICOM 3.0 compliant, user-friendly image enhancement tools, on-screen measurement capabilities, and the ability to annotate and send images to all PACS systems. The Digiview 250 requires no special training to use. Weighing less than 7 lbs, the Digiview 250 is configured in a durable, custom-molded plastic housing with an integrated handle for easy positioning. It is manufactured in the US, and is FDA approved. Contact kubtec.com.

COLLABORATION

Respiralogics announced its collaboration with Neo NuRT to provide a positive implementation education program for delivery of Bubble CPAP (BCPAP) in the NICU. While BCPAP has been around for many years, it has often been delivered through handmade custom systems with variations in performance and burdened with increases in manpower and diverse procedures for safe and effective operation. With the development of and FDA clearance of the Babi.Plus Bubble Pap Valve and Cannula System, consistent performance and streamlining of bedside procedures are now a reality. To build upon the successes of the early adaptors, Respiralogics has teamed with Neo NuRT to address education and clinical support issues to standardize procedure and ensure success of the BCPAP program. Neo NuRT is a highly specialized neonatal care team managed by Richard Valenzuela, RRT and Karen Korte, RN. They have trained respiratory care practitioners and nurses in the gentle art of Bubble nCPAP for many years. Their training program consists of webinars and in-service workshops for the NICU team. Neo NuRT has designed a specific CPAP workshop for those interested in initiating and implementing a Bubble CPAP program, as well as those who are interested in standardizing and streamlining procedures and technical implementation. These programs cover a comprehensive array of education options to address each institution's need. Specific education and training packages are available by contacting Richard Valenzuela direct at RichardV@Neo-NuRT.com. Visit www.respiralogics.com for all Respiralogics products and information. [Babi.Plus is a registered trademark of A Plus Medical.]

RETIRED

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) announced that Karen Peddicord PhD, RN, its Chief Executive Officer, will retire in September of this year. During Dr Peddicord's nearly five-year tenure as CEO, AWHONN has made critical advances in improving positive outcomes in women's and newborn health. AWHONN serves and represents more than 24,000 health care professionals in the US and abroad. Among the key initiatives and successes under Dr Peddicord's leadership were the publication of the 2010 Guidelines for Professional Registered Nurse Staffing for Perinatal Units, record-breaking attendance at the 2010 Annual Convention, the launch of consumer resources and the recent Go the Full 40 campaign and annual membership growth. Contact awhonn.org.

AGREEMENT

GE Healthcare announced it has entered into an agreement with HealthTrust, a group purchasing organization headquartered in the Nashville, TN area, to provide infant care solutions including phototherapy technology, warmers and incubators to hospitals that are members of HealthTrust. GE Healthcare Life Care Solutions (LCS) develops medical devices that help sustain life and support patient care in every setting throughout the hospital, from anesthesia delivery systems to ventilators and patient monitoring offerings. As well, LCS offers a series of technologies for infant care, including medical devices that provide developmentally-supportive environments designed to manage light and sound, and support an optimal temperature for premature infants. In addition to infant care technologies, Clinical Applications Training is also available to member hospitals through the GE Healthcare's agreement with HealthTrust. HealthTrust member facilities will have access to LCS technologies such as Care Plus incubators and the Giraffe and Panda product lines, which feature the Giraffe Incubator, the Giraffe Warmer, the Panda iRes Warmer, Giraffe OmniBed, Giraffe Shuttle transport solution and phototherapy technology. Each solution is designed to provide healing environments for high-acuity or critically ill newborns in the NICU. Contact gehealthcare.com.

ROP

Shire plc has acquired Premacure AB of Uppsala, Sweden, a privately held biotechnology company developing a protein replacement therapy, currently in Phase II development, for the prevention of ROP. Currently, only symptomatic treatment is available for ROP. This acquisition allows Shire HGT to enter a new therapeutic area — neonatology. With the acquisition of Premacure, Shire HGT will continue the ongoing Phase II study, the primary goal of which is to restore the IGF-1 levels in the preterm infant to those found during normal in utero development. Premacure initiated the clinical development of the preventative treatment with a formulation of recombinant human IGF-1 combined with a recombinant version of its naturally occurring binding protein, insulin-like growth factor-1 binding protein-3 (IFGBP3). A Phase I clinical trial was conducted and results showed that the levels of IGF-1 were increased to within physiological levels and that administration of the investigational protein to preterm infants is generally well tolerated. A Phase II, safety and efficacy multicenter clinical trial has started in Sweden and is on-going. Contact shire.com.

PAS PREVIEW Abbott Nutrition

Booth 201

Abbott Nutrition invites you to Booth 201 to learn more about customizing nutrition for babies in your NICU. We are featuring our two newest innovations—Similac Human Milk Fortifier Concentrated Liquid and Liquid Protein Fortifier. These new additions to our comprehensive product line work together to give you even more flexibility to provide the right nutrition for babies in the NICU.

New Similac Human Milk Fortifier Concentrated Liquid is the only nonacidified liquid fortifier available.

New Liquid Protein Fortifier has extensively hydrolyzed casein protein for easy digestion and absorption. By using them together, you can customize feeding solutions to fit baby's individual needs in the NICU, adjust protein as baby grows, and eliminate the risk of contamination from powders by using commercially sterile liquid products. These options can be mixed with human milk or infant formula.

In addition, Similac preterm infant formulas are designed to support the nutrient needs of preterm infants from the start. Our preterm infant formulas now have lutein for developing eyes. Abbott Nutrition is committed to advancing scientific innovation to provide more solutions for infant nutrition and human milk. Visit Booth 201 to find out more about how you can customize nutrition from the start with the most comprehensive NICU offerings available. We can help give you the flexibility to deliver individual feeding solutions like no other with multiple options for human milk fortification, preterm formulas with lutein, and much more.

Advanced Instruments

Booth 608

Advanced Instruments invites you to learn more about the Advanced Model 3320 Osmometer. Place it in the NICU or dietary department to rapidly monitor the osmolality of feeding solutions including infant formula, human milk, and additives such as fortifiers, or pharmaceutical medications.

The Lactoscope FTIR Advanced from Delta Instruments provides accurate analysis of protein, fat and lactose levels in human milk samples, allowing you to determine the exact nutritional content of breast milk samples. The system is self cleaning and provides fast, accurate results in seconds using a small sample volume. The Lactoscope utilizes proven Mid-IR technology which has been an established component analysis technique in the dairy industry for well over 25 years. The Lactoscope ensures optimal performance and low cost of ownership backed by a worldwide service and support network.

Discovery Labs

Booth 415

What products will you be featuring?

Discovery Labs will be featuring two products at the PAS exhibition:

- Surfaxin the first FDA approved synthetic, peptide-containing surfactant and the only alternative available in the US to animal-derived surfactants.
- Afectair a device recently cleared for marketing by the FDA that simplifies the delivery of aerosolized medication to critical care patients who require ventilatory support by introducing the medication directly at the patient interface.



Flow-controlled, pressure limited with built-in manometer

- Provides consistent PIP & PEEP Pressure
- Built-in Manometer verifies pressures.
- Cost-Efficient

Because they are not miniature adults...



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What educational or training materials will you be offering?

Discovery Labs will make available an Afectair product demonstration, reprints of peer-reviewed publications and other clinical information related to both Surfaxin and Afectair.

Why should our readers visit your display?

With the recent launch of Afectair and pending introduction of Surfaxin, Discovery Labs will share with visitors the most up-todate information on both new products and the potential they represent for the neonatal community.

Fisher & Paykel Healthcare

Booth 340

What products will you be featuring?

Fisher & Paykel Healthcare will be featuring the new Optiflow Junior System which combines revolutionary nasal 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. Also featured will be the Bubble CPAP System with the FlexiTrunk CPAP Interface and CPAP Nasal Masks. The Neopuff Infant T-Piece Resuscitator now provides the first humidified infant resuscitation system using the MR850 Respiratory Humidifier to facilitate the delivery of warm humidified gas to help protect the pulmonary epithelium and reduce heat and moisture loss during prolonged resuscitation. The new Infant Evagua 2 heated breathing circuit uses MicroCell Technology to further minimize expiratory tube mobile condensate, while also withstanding the rigors of the critical care environment.

What educational or training materials will you be offering?

Come and experience hands-on training for all products — from a few controlled breaths using the Neopuff on the Resuscitation Simulator to nasal high flow on the Optiflow Junior Baby to adjusting delivered pressure on the Bubble CPAP System to setting up humidification for invasive ventilation with Infant Evaqua 2. We also invite you to preview the educational programs and workshops that support each of our products.

Why should our readers visit your display?

We continue to expand the range of innovative medical devices and educational programs that we provide to assist clinicians to improve patient care and outcomes. Please join us at the PAS Exhibition in Washington, DC at Booth 340 for a complete review and demonstration of all Fisher & Paykel Healthcare products.

NeoMed and SafeBaby

Booth 700

NeoMed's Oral/Enteral Syringes 1 to 100 mL, Feeding Tubes, Extension Sets, NeoBottle, and NeoGenii partnered with SafeBaby's patented method of electronically tracking human breast milk provides the most comprehensive solution for safe and secure enteral feeding in the critical care environment.

NeoMed Delivers Enteral Safety Solutions for the NICU. Visit booth 700 to see the NeoGenii, the newest product in NeoMed's line of enteral devices. The NeoGenii allows for closed collection, storage, fortification, and delivery of human breast milk from a single device. Closed system collection to syringe pump delivery has not been possible until now. The closed system is important because it reduces oxidation and exposure to bacteria, helping keep breast milk fresher longer. NeoGenii, it's everything you've wished for in a single device for the closed management of HBM for enteral feeds. To learn more, visit NeoMed's website at www.neomedinc.com.

SafeBaby Delivers Software Solutions for the NICU. Top hospitals across the United States rely on SafeBaby Software Solutions to maintain accurate and efficient feed management systems in their NICUs. Is your NICU prepared to promote the best possible nutrition and keep the tiniest patients safe from feeding errors? SafeBaby Software Solutions offers a streamlined process to combine/fortify and fill syringes in one simple procedure. SafeBaby Software Solutions, the most comprehensive solution to: • Track Breast Milk, Donor Milk, Fortification, and Formula • Validate feeds from the existing patient monitor • Report and monitor with advanced administrative features. To learn more, visit SafeBaby's website at www.safebabybmt.com.

PRODUCT REVIEW

Abstract: Evaluation of the Neo-Tee T-piece Infant Resuscitator. Carl R. Hinkson, RRT FAARC, Cynthia White, RRT-NPS FAARC, Thomas A. Barnes, EdD RRT FAARC, Rob DiBlasi, RRT-NPS FAARC. Harborview Medical Center, Seattle, WA, Seattle Children's Hospital, Cincinnati Children's Hospital, Cincinnati, OH, Northeastern University, Boston, MA.

The Neo-Tee is a novel manually-cycled, pressure-limited and flow powered infant resuscitator that allows clinicians to adjust preset pressures and inhalation occurs when the operator occludes a restrictor valve. We hypothesized that there would be no differences between preset pressures on the Neo-Tee and those measured in a test lung following changes in PIP, PEEP, flow, and frequency with the Neo-Tee resuscitator. METHODS: An Ingmar ASL-5000 test lung (C:2, R:50) was attached to a Neo-Tee. The operator manually ventilated the lung model for two minutes with: 1) Pressure (PIP/PEEP) 10/5; 20/5, 40/5; 2) flow (L/ min) 5, 10, 15; 3) rate (f/min) 20, 40, 60 and 4) different flow/PEEP combinations. Each test was repeated in triplicate using new Neo-Tee resuscitators (n=3). Pressures observed on the NeoTee were recorded in a lab notebook and lung model pressures and other test parameters were stored in the ASL software. Wilcoxin signed-ranks test, Kruskal-Wallis H test and Spearman correlation were used to compare differences between pressures. RESULTS: Changing flow from 5, 10, 15 L/min on the Neo-Tee had no effect on the PIP (P = .71) or PEEP (P = .31) delivered to the test lung. There were significant differences between set PIP and PEEP on the Neo-Tee manometer and PIP and PEEP delivered to the lung model but there was good correlation between the set and delivered pressures (PIP: P = .000, [rs: 0.76 r2 0.58]; PEEP: P = .01, [rs: 0.74 r2 0.55]). Changing the ventilatory rate from 20, 40, 60 had no effect on the PIP delivered to the lung model (rs -.03. r2 -.09); however, when Neo-Tee was operated at 60/ min the lung model PEEP was ~1.81 cm H2O greater than the preset value. CONCLUSIONS: Based on these data, the Neo-Tee manual resuscitator operated within a clinically acceptable range for the majority of testing and well within the manufacturer's Continued on page 52...

Do Reproductive Technologies Cause Fetal Anomalies?

N. Ganju, MD; B. Petrikovsky, MD, PhD; K. Zeitoun, MD

Artificial reproductive technology (ART) has become advanced and highly effective over the past few decades in assisting patients to achieve pregnancy. While originally ART, particularly IVF, was used for patients with bilateral tubal occlusion, presently, varieties of ART are offered for patients who suffer from presumed infertility.

As defined by American Society for Reproductive Medicine (ASRM), infertility may be defined as failure to achieve pregnancy within 12 months or more of regular unprotected intercourse.¹ The diagnosis of infertility may be applied sooner, for example after 6 months, in women who are greater than age 35. After this period of time and occasionally sooner, most physicians will initiate clinical evaluation for causes of infertility.² Often a cause for infertility can be determined, including tubal pathology, endometriosis, hormonal, or male factor.

Case report: A 23 year old female tried to get pregnant for 8 months after marriage. She was reassured by her obstetrician that it is normal to take longer to get pregnant provided all the basic infertility test results appeared normal. However, due to community peer pressure (all her friends who were married 8 months ago were pregnant) the couple went to a reproductive medicine specialist who offered IVF due to unexplained infertility. Patient got pregnant on the 1st IVF attempt and delivered a child with Angelman syndrome.

Since her successful IVF pregnancy, she got pregnant naturally 4 times and delivered 5 healthy babies (one set of twins).

It seems that the birth of the abnormal child (Angelman syndrome) most likely has nothing to do with IVF and is merely a coincidence; however, we report literature data on increased number of fetal anomalies associated with reproductive technology.

Infertility

In seeking conception many couples turn to ART including IVF, ICSI, and IUI to achieve pregnancy. In the US most health insurance will not cover these health technologies or will cover only a small portion. In other countries with national health care

The authors are with New York Downtown Hospital/Weill Cornell Medical College, Department of Obstetrics and Gynecology. The authors would like to give special thanks to Sara Stern of ParCare Community Health Network for her support and assistance for completion of this article.

systems, such as the Netherlands, the national health system may cover several cycles of infertility treatment. These countries often have a panel of patients on a waiting list in line for their chance at treatment. The waiting list can range from one year in the Netherlands,³ to up to 2-3 years in parts of UK.

National health based IVF clinics like those in the Netherlands or UK often have stringent criteria and workup guidelines and algorithms for patients to be eligible to receive government aid for infertility treatment.⁴ In the US however, most ART technologies are not covered by insurance and thus many private fertility clinics will offer treatments for patients who can pay outof-pocket, often at a significant cost.

According to the American Society for Reproductive Medicine guidelines, couples should not be considered infertile until they have tried to conceive spontaneously for at least 12 months, unless the medical history and physical findings dictate earlier evaluation and treatment. For example, approximately 25% of couples experience infertility when the woman is age 35, and about 50% experience it when the woman is age 40.

G. Adamson put together a table for when to investigate, treat and refer patients unable to conceive:

Investigate

- After 12 months of unprotected intercourse if age is greater than 35
- After 6 months of unprotected intercourse if age is between 35 to 39
- After 3 months of unprotected intercourse if age is greater than 40
- After 0-6 months if the patient has history or risk factors for infertility

Treat

- Treat identifiable causes of infertility
- Optimize factors influencing fertility:
 - Diet, weight control, exerciseTimed intercourse
- Treat empirically (eg, clomiphene, insemination) for 3-6 months in patients <40

Refer

- History of infertility or significant risk factor
- Significant fertility problems identified during investigation
- Age greater then 40

- After 3-6 months of failed treatment for identifiable causes
- After 3-6 months of failed empiric treatment

ART

While IVF is generally considered safe, it is not without significant risks. In 2005, ACOG committee opinion warned of perinatal risks of ART particularly with multiple gestations.⁵ Several studies have showed significantly higher odds of perinatal mortality, preterm delivery, low birth weight and very low birth weight and small for gestational age status.⁶

Later studies have shown even more significant infant health defects. Hansen et al has shown a 50% more likely major defect diagnosed by 6 years of age in children of ART. These defects include cardiovascular, musculoskeletal, genital, and gastrointestinal defects. There is also an increased risk of hypospadias and cryptorchidism in ART singleton boys. Furthermore, there are sometimes imprinting errors, which cause rare diseases such as Beckwith-Weidemann, Angelman, and Prader Willi syndromes.⁷

Possible mechanisms

The mechanism by which increased birth defects noted in children of ART remains as yet unclear. There is likely at least an underlying increased risk of birth defects in subfertile couples.⁸ It is possible that the techniques of technologies used in ART itself may offer variables. For example, as noted by several studies, the risk of birth defects in IVF or ICSI are lower when frozen-thawed embryo transfer technique was utilized (Hansen and Halliday).⁹ Other studies have suggested laboratory time contribution — infants born after blastocyst stage (day 5/6) have higher rates of preterm delivery as compared to infants born after blastocyst stage (day 3).¹⁰

The increased rates of imprinting birth defects (Angelman Syndrome) are similarly not well understood. Methylation and demethylation processes occur early in the development of oocytes and fertilization.¹¹ The nutritional and hormonal milieu during this early period can affect the methylation process.¹² It is possible that the nutritional/hormonal milieu during vulnerable developmental periods may interfere with the methylation cycle (ie ovarian stimulation, ovulation induction, egg retrieval, embryo manipulation and culture).

Premature diagnosis

As one can see in our case report, our patient didn't experience infertility but rather succumbed to the peer pressure to achieve pregnancy as soon as possible. Her future success in achieving pregnancy on her own proves the fact that she probably didn't require assisted reproduction in the first place.

The increased risk of infant morbidity warrants that ART be utilized with care, not too soon, and as much as possible only in those patients for whom it is truly indicated. Further, many of those patients previously thought to be infertile may become spontaneously pregnant. IVF studies often cite patients that drop out of the study due to spontaneous pregnancy before treatment was initiated. Eijkemans et al reported that 9-25% of women may spontaneously conceive in 1 year without needing ART. This is particularly true for women who are younger, have shorter duration of infertility and secondary versus primary infertility, and for couples in whom infertility is unexplained.¹³ Troude et al have reported that 17% of couples spontaneously conceive after they have previously been diagnosed as infertile and had a successful ART treatment. Further, 24% of unsuccessfully ART treated couples conceived spontaneously. $^{\rm 13}$

Is it possible that in these "sub-fertile" patients, the diagnosis of infertility was premature? For a certain subgroup of patient population, perhaps expectant management may be indicated as spontaneous pregnancy may still be an option. In such subgroups perhaps exposing the parent and the infant to the risk of ART may be avoided and this is generally desirable.

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High Flow Nasal Cannula Therapy in Neonatology

Thomas L. Miller, PhD

List of Terms

High Flow Nasal Cannula (HFNC): generic description for using nasal cannula flow rates which are greater than convention.

High Flow Therapy (HFT): The use of HFNC in a specified way to accomplish specific objectives pertaining to defined mechanisms of action.

Mechanism of Action: Process by which an intervention interacts with physiology to accomplished a specified effect.

Mechanistic Research: Research that is conducted in such a way as to demonstrate which specific aspects of an intervention are associated with the desired outcome (eg pressure vs flushing CO2 vs humidification, etc). This concept differs from observational studies where an intervention is introduced and clinically relevant outcomes are recorded with no means to identify the specific mechanisms of action. Often, mechanistic research requires pre-clinical translational models that allow for thorough instrumentation, whereas clinical studies are often limited to observational models.

Continuous Positive Airway Pressure (CPAP): A pressurebased therapy wherein a nasal or mask interface is sealed to a patient's face and pressure within the device circuit is controlled.

Dead Space (DS): Region of the conducting airways that does not contribute to gas exchange. Under normal circumstances, the DS inadvertently serves as a reservoir of end-expiratory gas that is re-breathed at the onset of a subsequent inhalation.

Anatomical Reservoir: the dead space volume of the upper air passages including the nasal, oral and pharyngeal areas.

Ventilation: The circulation of air or a prescribed respiratory gas mixture into the pulmonary air spaces with an intention to replace expiratory gas that has already exchanged oxygen and carbon dioxide with the blood. In mammalian physiology, this process involves tidal volume exchanges because of the presence of dead space.

Alveolar Ventilation (V_A) : The total volume of gas exchanged

Tom Miller, PhD, is Director of Clinical Research and Education at Vapotherm, Inc, Stevensville, MD and Assistant Professor of Pediatrics at Jefferson Medical College, Philadelphia, PA. in the region of the respiratory tract where gas exchange can take place with the blood. $V_{\rm A}$ = (tidal volume – DS) multiplied by respiratory rate.

Minute Ventilation (V_E): The total volume of gas exchanged in and out of the respiratory tract each minute. V_E differs from V_A as a function of dead space where V_E is always greater than V_A by DS multiplied by breathing rate. V_E = tidal volume multiplied by respiratory rate.

Introduction

Over the past several years, there has been a marked increase in the use of nasal cannulae to deliver high flows of humidified respiratory gas to neonatal patients. During this period, research has been conducted and published examining safety and efficacy as well as exploring means of optimizing the therapeutic impact of high flow nasal cannula. This review provides definitions, an overview of the therapeutic approach and mechanisms of action, as well as a review of published research. Some key terms are listed on this page which are important to distinguish specific concepts in discussing this therapy.

High Flow Therapy (HFT) Defined

Fundamentally, HFT is the delivery of respiratory gas through a nasal cannula at flow rates that exceed a patient's demand, whereby this definition pertains to both the inhalation and exhalation phases of breathing. The technological advances that allow for HFT are related to precise heating and humidification; however, the resultant efficacy is a function of more efficient oxygen therapy and an impact on ventilation by way of dead space washout. The foundational premises of HFT are that cannula flow rates of respiratory gas exceed a patient's spontaneous inspiratory flow rate as well as be sufficient to purge anatomical dead space during exhalation. In this regard, a patient will not entrain room air while taking in a breath, making each breath composed of ideally conditioned gas with a precise fraction of oxygen. Moreover, when the gas flow is adequate, the nasopharyngeal region is purged during exhalation so as to improve ventilation by the elimination of expiratory CO2. In adults, both objectives are typically accomplished by a similar flow rate making flow a matter of exceeding inspiratory flow rate; however, infants are more complex because of the relative differences in the extrathoracic dead space. This will be discussed in greater detail below.

In the current literature, definitions of HFNC are inconsistent, particularly as it pertains to comparisons to other therapies.





Figure 1. During inhalation the cannula flow needs to be adequate to meet inspiratory flow demand.

During exhalation the cannula flow needs to be adequate to purge the nasopharyngeal dead space volume between breaths.

Some investigators define the application of a HFNC therapy as simply using cannula flows greater than convention, which in neonatal medicine is greater than 2 L/min, or in some cases greater than 1 L/min.¹ However, based on the mechanistic research that has demonstrated how HFT affects respiratory function, HFT is correctly defined as the application of flow rates that accomplish the two aforementioned objectives. Again, these objectives pertain to meeting inspiratory demand as well as purging anatomical dead space in the window of time between breaths.

A widespread assumption is that HFNC provides for a continuous positive airway pressure (CPAP) effect. Whereas pressure will develop in the delivery of HFT, mechanistic studies suggest that pressure is not the primary mechanism of action responsible for observed physiologic outcomes. A more detailed comparison of HFT to CPAP is found in a later section of this paper.

An example of why we need agreement on the definition of HFT is the 2011 Cochrane review on the use of "High flow nasal cannula for respiratory support in preterm infants."1 These authors reviewed four studies and concluded that high flow nasal cannula may result in a higher rate of reintubation compared to CPAP. However, these reviews defined HFNC as flow rates greater than 1 L/Min, which may not exceed every infant's inspiratory flow demand and certainly would not be sufficient to purge nasopharyngeal dead space during exhalation. The evidence cited to support that CPAP outperforms HFNC comes from the one study by Campbell and colleagues.² These authors administered HFNC as if it were a CPAP therapy, and used an equation to assign flow rates. Specifically, this equation was proposed to predict flow needed to achieve a certain airway pressure, and as such, the mean cannula flow rate used in this study was only 1.8 L/min.

It is fair to conclude from these data, as well as years of experience with nasal cannulae, that flow at rates less than 2 L/min may not be as effective as CPAP. However, this finding has little relevance to true high flow nasal cannula therapy (ie HFT) which is defined by the mechanistic literature to facilitate purging of the entire volume of nasal, oral and pharyngeal dead space. In this regard, the findings of Campbell and colleagues should not be unexpected and should not be used to represent the efficacy of HFT per its mechanistic definition.

Multiple Mechanisms of Action

There are a number of mechanisms by which HFT can improve respiratory function in patients, including the neonatal population. In subsequent sections of this paper, the principle mechanisms of action are described in detail within the context of therapeutic application. Here, these mechanisms are briefly introduced to note the complex, multifactorial impact of HFT.

Essentially, HFT makes the nasopharyngeal region a reservoir of fresh gas by way of purging the end-expiratory gas from this space during exhalation. Therefore, the patient's subsequent breath is more efficient in that it is composed of more fresh gas and less end-expiratory gas. With this improvement in efficiency, a patient can achieve adequate alveolar ventilation (VA) with less minute ventilation (V_E) , compared to pressure therapies that force greater lung expansion to achieve greater V_E. Vapotherm recommends that HFT should not be used to produce a substantial distending airway pressure, although some pressure inevitably is generated. Rather, HFT should be used so as to minimize resistance to gas exhausting from the nasopharynx around the cannula and through the mouth. In other words, HFT should be used to maximize the purging of the nasopharynx with the least amount of flow and associated pressure. A recent publication validating the dead space washout concept as the principal mechanism of action showed that the least occlusive cannula geometry resulted in an optimal efficacy with less than 75% of the flow and pressure required when snug fitting prongs are used to generate distending pressure.³ Additional studies have shown how flow dynamics and heated humidification contribute to other mechanisms of action that reduce work of breathing and support airway function. These other mechanisms are summarized below and described in a review paper by Dysart et al.4

HFT in the Context of Current Practices in Neonatal Respiratory Care

Since the 1980s, there has been a focus on developing strategies for noninvasive ventilation subsequent to the defining of bronchopulmonary dysplasia (BPD), the relationship to lung bio-inflammatory potential and the recognition of the need for lung protective ventilation strategies. Along these lines, there has been a major emphasis on CPAP and other noninvasive forms of ventilation, such as bilevel CPAP, that have reduced the need for mechanical ventilation.¹² Other major developments have surfaced in the last few decades, such as exogenous surfactant replacement therapy and inhaled nitric oxide, which have been widely adopted and used in conjunction with noninvasive respiratory support. For example, the INSURE technique (INtubate, SURfactant, Extubate) has allowed surfactant delivery to be combined with noninvasive ventilation with notable success.13 Together these combinations of therapies have fostered tremendous improvements in infant mortality, but occurrence of BPD remains high.

In the context of this push for noninvasive ventilation strategies, dead space elimination, and thus HFT, is not a novel concept. Dead space elimination contributes to improved alveolar ventilation without forcing greater tidal volumes. In this regard, we need to reinforce that the term ventilation should not necessarily be synonymous with artificial breathing machines that deliver tidal breaths, but can encompass other, less invasive ways to facilitate exchange of respiratory gases within the lungs. Optimal gas conditioning capabilities have allowed for gas delivery by nasal cannula to exceed the conventional limits without degradation of the nasal tissues.¹⁴

MECHANISM	DESCRIPTION
Dead space washout	Reduce dead space making minute ventilation more efficient. ^{3,5}
Reduce inspiratory work of breathing	Exceed inspiratory flow thus eliminating nasal resistance. ⁶
Improved lung mechanics	Warmed, humidified gas has been shown to improve conductance, compliance and lung elasticity.7
Eliminate metabolic work associated with gas conditioning	Attenuates the energy and water loss associated with conditioning inspiratory gas.
Provision of mild distending pressure	Flow can be restricted such as to provide positive distending pressure for lung recruitment. ⁸⁻¹⁰
Improve secretion mobilization	Ideal humidification of the inspired gas has been shown to restore mucocilliary function and reduce symptoms of airway exacerbations. ¹¹

This advancement has opened the door for a noninvasive way to eliminate anatomical dead space, making ventilation more efficient.

HFT, as we term the use of HFNC in a specified way so as to maximize the elimination anatomical dead space, has many peripheral advantages that are associated with the patient interface being easier to manage than a sealed CPAP system. These include patient tolerance, ease in nursing management, and accessibility for kangaroo care, as well as physiologic concerns such as prone positioning to support spontaneous breathing.^{15,16} As we better define and optimize HFT as primarily a therapy to eliminate dead space, and understand the coinciding ability to generate mild pressure and hydrate the air passages, HFT holds promise to emerge as a significant advancement in neonatal respiratory support.

HFT: A Unique Noninvasive Respiratory Support Modality

The act of ventilation refers to the circulation of air so as to replace stale or noxious air with fresh air. In mammalian physiology this process involves tidal volumes and lung compliance because of our anatomical dead space. In other words, if we were to remove dead space entirely by putting our alveolar surface on the outside of our body (eg gills on a fish), we would not need to have tidal volume excursions to expose the alveolar surface to adequate VA in support of respiration. Obviously, this is not practical for numerous reasons, including the need to condition gas before coming into contact with the blood, and our adaptation to use dead space for retaining CO2 as our innate pH buffering mechanism.

Nonetheless, by reducing dead space we can reduce the $V_{\rm E}$ needed to accomplish adequate $V_{\rm A}$ and therefore reduce work of breathing. Dead space elimination tactics have been used for years in the form of tracheal gas insufflation^{17,18} and transtracheal oxygen delivery.^{19} In the last 10 or more years, advancements in heated humidification devices have made it possible to accomplish ventilation by way of dead space elimination with a nasal cannula.

Translational research has shown that the primary mechanism of action for HFT is purging anatomical dead space, thus achieving V_A with lesser V_E . A pivotal mechanistic study was done using neonatal piglets with a severe respiratory distress induced by central venous oleic acid delivery.³ In this model, three conditions were compared: HFT with a low leak around the prongs (ie snug fit in the nares), HFT where no more than 50% of the nares were occluded (ie non-occlusive prongs) and conventional mask CPAP. The low leak condition was created to mimic the situations where clinicians try to get a CPAP effect, whereas the \leq 50% occlusion condition fits our recommendation for the application of HFT. Under these conditions, the model

evaluated titration of flow/CPAP pressure on CO2 removal, oxygenation and pressure development.

As shown in Figure 2, under both HFT conditions, arterial CO2 inversely correlated with flow rate wherein arterial CO2 tension (PaCO2) in these spontaneous breathers could be reduced back to pre-injury levels. Moreover, the PaCO2 in the <50% occlusion condition was significantly reduced at lower flow rates compared to the low leak condition, indicating that a less occlusive prong design facilitates nasopharyngeal purge. CPAP alone was never able to achieve this ventilation effect. With CPAP, PaCO2 was slightly reduced with a mild pressure increase, but then PaCO2 rose as CPAP pressure went above 4 cmH2O, presumably due to overdistension.

As shown in Figure 3, regarding oxygenation, under both HFT conditions a flow dependent increase in arterial oxygen tension (PaO2) was demonstrated until a plateau was reached. This saturation pattern is indicative of dead space washout and fits the hypothesis of the study based on the background modeling of tracheal gas insufflation.²⁰ The concept behind dead space purge techniques is that there is a finite amount of time (late stage exhalation and end-expiratory pause) to purge the space and a finite amount of dead space volume that can be purged. As flow is increased, more of the volume can be purged until flow is sufficient to purge all of the volume in the allotted time, after which additional flow produces no additional effect. With respect to oxygenation, CPAP was as effective as HFT although not a function of pressure titration.

Pressure in this study was measured by direct perpendicular placement of a pressure catheter in the trachea through an anterior cervical cut-down. As shown in Figure 4, the pressure data from this study shows a direct relationship between flow and baseline pressure shift, which is in agreement with the clinical studies. Here the pressure from the low leak condition is always greater than the \leq 50% occlusion condition. Importantly, there was dissociation between oxygenation and the pressure response where pressure continues to rise beyond the flow rate at which oxygenation response reaches a plateau. This dissociation between pressure and physiologic oxygenation response supports dead space flush as the primary mechanism of action. Moreover, because the cannula fit impacted the flow rate needed to accomplish optimal efficacy (ie flow rate where PaO2 plateaued and PaCO2 reached baseline levels), pressure was actually inversely related to physiologic improvement if we consider cannula design as a categorical variable. In other words, the less occlusive prong design accomplished maximal efficacy with approximately 60% of the flow needed to do so with the occlusive prong design, which translates to approximately one-half of the inadvertent distending pressure. Optimized prong fit translates to better outcome with less pressure.



Figure 2. These graphs adapted from Frizzola et al.³ show that high flow therapy (HFT) provides a ventilation effect (impact on arterial CO2 tension) not seen with continuous positive airway pressure (CPAP). Moreover, the effect is more pronounced and occurs at lower flows when the cannulae are fitted to allow a high degree of leakage around the nasal prongs.



Figure 3. This graph adapted from Frizzola et al.³ shows the oxygenation relationship with HFT titration. Arterial oxygen tension rises with increased flow to a plateau, after which more flow has no further effect. This inflexion point is explained in the tracheal gas insufflation literature as the point where flow is adequate to purge all available dead space.



Figure 4. This graph adapted from Frizzola et al.³ shows the end-distending pressure response to nasal prongs which occlude the nares (low leak) versus prongs that occlude no more than 50% of the nares (high leak). In each case pressure rises with increased flow, dissociating this relationship from the oxygenation curve (Figure 3). Referring back to Figure 2, note that the non-occlusive prongs facilitated better ventilation, accomplishing optimal effect at a lower flow, seen here where the extrapolation bars cross the x-axis. By following these bars to the y-axis, note the non-occlusive prongs accomplish this efficacy with significantly less distending pressure.

The clinical side to this translational modeling was done in COPD patients (data presented at the 2011 CHEST meeting and in review for publication). Adults were examined because they can be compliant in ways that an infant cannot, but the resulting evidence regarding ventilation is fundamental to the concept of dead space and translates to the infant as well. This study shows that HFT with room air results in at least a 13% reduction in $V_{\rm E}$ while maintaining the same PaCO2 compared to both no support and supplemental oxygen conditions. As discussed later, this ventilation effect is potentially greater in infants because of the greater relative extrathoracic dead space volume compared to adults.²¹

CPAP versus HFT

CPAP systems are specifically designed to be a closed system in conjunction with the infant's respiratory tract. The proposed mechanisms of action for CPAP are complex and multifactorial, but include the concept that pressure is able to recruit lung alveoli by increasing FRC, thus improving compliance so that a greater V_E can be achieved to account for the necessary V_A .²² From a mechanical perspective, CPAP supports spontaneous breathing by making it less taxing to stretch the lung and by minimizing atelactrauma during lung stretch. HFT, on the other hand, is aimed at achieving V_A with a lesser V_E so as to reduce the necessary lung stretch. Nonetheless, the accompanying humidification and mild pressure effects with HFT would attenuate atelectrauma as well.^{7,23}

HFT is designed to be an open system, wherein the gas is not intended to be contained for the development of a pressurized patient airway. In an HFT system, pressure inside the device circuit is by necessity quite high, in the range of nearly 400 cmH2O.²⁴ This is the result of pushing high flow through the substantial resistance of the relatively tiny nasal prong orifices. Because of this relatively enormous cannula resistance and the fact that the system circuit is not sealed with the patient's airway, physics dictates that circuit pressure does not transmit to the patient. The development of patient airway pressure is a coinciding effect during HFT and is a function of the resistance to the flow exiting from the patient's nasopharynx through the oral cavity and nose.

To keep the coinciding nasal pressure from reaching levels that would need to be monitored, the literature dictates that a cannulae should not occlude more than 50% of the nares. This recommendation is based on the work of Dr Locke and colleagues who showed that nasal prongs having an outside diameter that is no more than 50% of the internal diameter of the nares does not result in distending pressure during low flow O2 therapy. Conversely, cannula having an outside diameter that was three-quarters of the inside nare diameter resulted in significant pressure at low flows. The message here is that keeping nares open by 50% of the diameter represents adequate anatomic release. Note that this 50% diameter rule ensures that the surface area of the unoccluded region of the nares is greater than the surface area of the occluded area, based on the nonlinear, direct relationship between surface area and distance from the center of a circle. Vapotherm's recommendations and cannulae offerings are consistent with this requirement.

When applied correctly, mild airway pressure does develop during HFT and is considered a mechanism of action based on the rationale for CPAP.²² This pressure is a function of both the rate of flow through the patient's upper air space and the anatomical resistance to this flow as it passes through the anatomy;²⁵ however, the pressure is not at the level of closed CPAP system and varies regionally as a function of the gas flow patterns (preliminary data). From a review of the research related to airway pressures in neonates during HFT, data shows that airway pressure with HFT can be expected to be less than or approximately equivalent to airway pressure when a CPAP of 6 cmH2O is applied,^{8-10,23,24,26} and equally as variable as airway pressure during CPAP.²⁴ In interpreting these data it is important recognize that some investigators were trying to create CPAP by minimizing the leak through the nose and mouth. Nonetheless, the data showed only modest pressures.

Application of HFT in the NICU: Flow Rate Titration and Rationale

Despite the inconsistency in the literature defining the flow rates needed for HFT, when used appropriately reports indicate improved extubation success and potentially a reduction in intubation rates.^{27,28} In addition, the simplicity of the cannula interface with loose fitting nasal prongs reduces facial skin and nasal abrasions associated with more intense therapies. HFT is simple to administer and manage compared to positive airway pressure therapies that require intense monitoring to ensure that the patient interface remains properly placed.

The range of flows to be used in infants is between 1-8 L/min. While infants have a very small tidal volume, in the range of 4-6 mL/kg, their respiratory rates are quite high. In sick children, respiratory rates can approach 100 breaths per minute, making peak inspiratory flows very high relative to minute volumes. Another consideration with infants, which pertains to the mechanisms of dead space purge, is the relative size of the anatomical reservoir which consists of the extra-thoracic dead space volume of the nasal, oral and pharyngeal cavities. Infants have a much larger anatomical reservoir compared to older children and adults.²¹ Small infants have an extrathoracic dead space volume around 2.3 mL/kg, whereas in children over six years of age and into adulthood this value drops to approximately 0.8 mL/kg. Therefore, as compared to an adult, an infant may need greater relative flow rates to realize the full benefits of purging the anatomical reservoir in the window of opportunity between breaths (flow rates that go beyond simply meeting inspiratory demand). This three-fold greater anatomical reservoir volume in small infants translates to dead space making up a much greater fraction of their tidal volume as compared to larger children and adults.

As a result of these factors, small infants have a greater propensity to benefit from HFT in that these patients are much more sensitive to changes in dead space. However, cannula flow rates needed to maximize efficacy typically begin at greater than 3 L/min.

Cannula Research in Optimizing HFT: Fluid Dynamics and Flow Patterns

With an understanding that the mechanisms of action are based on creating an internal reservoir of conditioned gas, work has been done to refine the patient interface to optimize this effect. Some of the work that is currently underway involves using computation fluid dynamics modeling to learn more about gas flow characteristics in the nasopharynx with HFT. Using this model, we have already confirmed what is suggested by animal data, that a less occlusive prong design allows for more rapid purge of the nasal cavity at any flow rate. Therefore, as we saw in the animal data, the nasopharynx can be purged in the time between breaths with a lesser flow rate when cannula design is optimized; in this case smaller prong diameter (data being prepared for publication).

Another topic addressed using the computational fluid dynamics modeling pertains to sheer force (or strain rate) on the walls of the nasopharynx as a result of the gas flow velocity from the cannula nozzle (commonly referred to as "jetting effect"). With this model we learned that the strain rate is absorbed between laminae of the gas, and with a smaller cannula dissipates before impacting the wall.

However, with the larger cannula, the strain rate impacts the wall just by nature of its closer proximity (data being prepared for publication). Thus, the larger cannula is more likely to result in a jetting effect. To put this concept in another way, this "jetting effect" is often described as similar to turning a fire hose on a wall; however, this analogy is very much incorrect because it involves jetting one medium (water) though another less dense medium (air). In the case of cannula gas flow, air is jetting through air, and thus a more appropriate analogy would be similar to water jets that are under water such as in a hot tub. In this analogy, you can probably imagine that you would only experience significant strain if you were to hold your hand directly on or around the water jet.



Figure 5. This image from computational fluid dynamics modeling shows the patterns of gas flow through the nasopharynx from the cannula. Note the vortices and varied directionality of flow. These patterns define pressure and other forces throughout the cavity.

Summary

HFT is a unique noninvasive respiratory support modality in the NICU. It is based on the concepts of dead space elimination for breathing efficiency and the delivery of ideally conditioned respiratory gases to an already fragile lung. A misconception that stifles the adaptation of HFT is that it is an uncontrolled form of CPAP. The mechanistic literature, however, does not support this presumption and a significant amount of clinical data suggests that pressure is not a concern when HFT is applied correctly. Importantly, the neonatal community would benefit from the uniform adaptation of a definition that is based on research and guides the cannula design aspects and flow requirement. These studies suggest that cannula fit should not occlude more than 50% of the nares and that flows should be between 3 and 8 L/min.

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Intubating Laryngeal Airway in Children

The journal Pediatric Anesthesia recently published the article Prospective Evaluation of the Self-pressurized air-Q Intubating Laryngeal Airway in Children.* [The product referred to throughout this paper as the air-Q ILA SP or ILA-SP has been rebranded as the air-Q SP.] The objective of the authors was to assess the clinical efficacy of the self-pressurized air-Q ILA (ILA-SP) (Mercury Medical). The purpose of their prospective audit was to evaluate the feasibility of the ILA-SP in clinical practice and generate data for future comparison trials. The ILA-SP is a new first-generation supraglottic airway for children with a self-adjusting cuff that does not require balloon. Over a 4-month period, 352 children with an ASA physical status of I-III, newborn to 18 years of age, undergoing various procedures, were studied. Data points assessed included insertion success rates, airway leak pressures, quality of ventilation, and perioperative complications associated with the use of this device. In 349 of the 352 patients in this study, the ILA-SP was used successfully as a primary supraglottic airway device in a variety of patients. Three patients required conversion to a standard laryngeal mask airway or a tracheal tube. The mean initial airway leak pressure for all patients was 17.8 ± 5.4 cm H2O, and 20.4 ± 5.5 cm H2O when re-checked at 10 min, which was statistically significant (P < 0.001). Complications were limited to 14 patients and related to reflex activation of the airway (coughing, laryngospasm, and bronchospasm) (n = 10), sore throat (n = 3), and blood staining on removal of the device (n = 1). There were no episodes of regurgitation, aspiration, or hoarseness. The authors concluded: Acceptable clinical performance was demonstrated with the ILA-SP for a variety of procedures in infants and children with spontaneous and positive pressure ventilation. Future studies comparing this device to other supraglottic airways may provide useful information regarding the safety of the ILA-SP in pediatric clinical practice.

The authors used a newer version of the ILA self-pressurized air-Q, the ILA-SP, which was introduced into their practice for routine airway maintenance in children. According to the authors, "This device shares structural similarities with the original ILA, including the ability to provide a reliable conduit for tracheal intubation." The new distinguishing features of the ILA-SP are the absence of a pilot balloon and continuity between the airway tube and the cuff through an inner aperture at their conjunction.

According to the authors, these features may allow for several clinical benefits, in that intra-cuff pressures are determined by the airway pressures, because of the equalization of pressures with the movement of gas between the cuff and airway tube. Also, lower intra-cuff pressures are maintained overall as a result of being limited by the peak airway pressures, with the highest pressures exerted during inspiration. Finally, by not exceeding peak airway pressures, the balance between intra-cuff pressures

The resource for this article was provided by Mercury Medical.

and the airway seal of the device may be optimized at lower pressure. As such, the risk of sore throat, neuropraxic injury, and gastric insufflation seen with overinflation of traditional cuffed supraglottic devices may be reduced.

The study sought to assess insertion success rates, airway leak pressures, quality of ventilation, and perioperative complications. The authors recorded the type of inductions, the size of the ILA-SP inserted, and the number of attempts required for successful insertion. The authors wrote: "The airway leak pressure was observed with the head in a neutral position... The expiratory valve was immediately released when the leak pressure was determined by the onset of audible noise or if airway pressure reached 40 cm H2O without an audible leak. A second airway leak pressure was taken at least 10 minutes later to observe whether there was a change in the airway seal."

Participants were 221 male and 131 female pediatric patients of various weights and ages (mean age 5 ± 4 years. The ILA-SP insertion resulted in subsequent ventilation in 351 patients, and successful placement at first attempt was achieved in 336 patients, while 13 needed a second attempt, typically requiring a change in the size of the ILA-SP. "Spontaneous ventilation was reported in 203 patients, mechanical ventilation in 144, and 5 received pressure support ventilation," per the authors, who noted that the design modification of the ILA-SP had clinical advantages, in that insertion techniques were similar to other such devices but there was no need for cuff manipulation, the pressure in the cuff being self-regulated and no longer a closed air space. While ease of placement was similar to the original ILA and LMA, the ILA-SP was found to fit better in infants, in that the wider mask bowl and curved airway tube of the latter may have provided greater lateral stability and better seating of the hypopharynx. The authors wrote: "The ILA-SP may improve the applicability of supraglottic airway devices for the anesthetic management of smaller children."Also, "An improvement in airway leak pressures was seen in the 10-min leak pressure testing, potentially indicating an improvement in airway seal across all cohorts." It was noted that "as a result of the ILA-SP design, airway seals may also have been optimized at lower intracuff pressures."

The authors concluded that "the airway leak pressures and ventilation parameters achieved for a variety of procedures were clinically acceptable throughout all patient sizes, even with the use of positive pressure ventilation."

* Prospective evaluation of the self-pressurized air-Q intubating laryngeal airway in children. Narasimhan Jagannathan, Lisa E. Sohn, Ravinder Mankoo, Kenneth E. Langen, Andrew G. Roth & Steven C. Hall, Department of Pediatric Anesthesiology, Children's Memorial Hospital, Northwestern University Feinberg School of Medicine, Chicago, IL. Pediatric Anesthesia 21 (2011) 673-680 © 2011 Blackwell Publishing Ltd.

Reducing Noise in the NICU to Boost Healing, Family Satisfaction

Brent Lang, Deb Green

Hospital noise may have once been a simple nuisance, but today, it has become a top financial challenge facing healthcare organizations nationwide. Studies have long reported that loud hospital rooms impair the healing process by stressing patients' cardiac systems and driving negative outcomes.¹ Additionally, consistent work in a high volume environment, such as a hospital room, can often be as loud as city traffic² and can increase not only the stress levels of physicians and nurses,³ but also the potential for errors.⁴ Unfortunately, quieting this noise has not been a priority for many hospitals as healthcare leaders have generally placed the value of loud equipment and clinician discussions in day-to-day care over that of noise's effect on patients and staff.

This attitude is gradually shifting as recent Centers for Medicare and Medicaid (CMS) reform policies threaten to reduce reimbursements if patients rate hospital rooms as too loud on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The survey is the national standard for collecting and reporting patients' perspectives of care and is utilized under the CMS Value-based Purchasing (VBP) Program, which went into effect on October 1, 2012. This initiative will increase or decrease hospitals' reimbursements based on whether they achieve specific quality metrics and HCAHPS patient satisfaction scores.

Causes of Hospital Noise

Posing a challenge for hospitals seeking to maximize their HCAHPS scores, noise originates from many places in the hospital and not every source has an equal effect on patient

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experience. Researchers have found that electronic sounds, such as telephones and alarms, are generally more disruptive to sleeping patients than human voices, regardless of how loud the sound.¹ Whether from an alarm on a medical device, the overhead paging system, or clinicians speaking in the hallways, the majority of hospital noise involves communication or a transfer of information.

In fact, the noisiest time in the hospital is generally shift change. Nurses and physicians wander the facility, preparing for the oncoming shift by acquiring details of each patient status from fellow staff members and available equipment. Regrettably, many employees learn to tune out the reoccurring noise of this shuffle and may be unable to accurately quantify it. For this reason, Phoenix Children's Hospital in Phoenix, AZ, opted to measure decibel levels in its neonatal intensive care unit (NICU). It found that the level of everyday background noise compared to that of a jackhammer. Posing additional cause for concern, the high noise level was beginning to cause hearing loss in many of the facility's underdeveloped infants.

Simple Steps to Reduce Noise

Hospital administrators seeking to create a restful environment for patients must address three key roots of noise – hospital acoustics, medical equipment and staff-to-staff communication. Phoenix Children's Hospital has conducted several developmental studies throughout the past 20 years, identifying and implementing various tactics to reduce the audible impact of the hospital on child development. For example, the hospital has experimented with walling off portions of its NICU to decrease noise, and installing carpet rather than tile flooring. As more recent research determined that carpet can be associated with an increased risk of infection, the facility has since moved to rubber flooring to maintain a healthy, peaceful environment for sleeping infants and their families.

A major concern for many hospitals when considering ways to increase patient satisfaction is how to balance noise reduction efforts with the necessity of patient monitors and alarms. Hospital administrators, doctors, nurses and other staff have long believed that a quiet environment is less critical for patient care than the information provided by medical equipment alerts. Innovative new technologies are beginning to provide a solution for this concern. Hospitals are now able to configure alarms so they do not buzz at the patient's bedside, but rather communicate only with the nurse or doctor responsible for that patient via a text message or voice alarm. This can generally be accomplished through the integration of a wireless communications technology with the hospital's nurse call and patient monitoring systems via a middleware solution.

Mobile communication technologies can also help hospitals to create more patient-centered environments. For example, hands free, wireless badges or phones allow clinicians to continue to care for patients as they receive status updates or hear monitors from others. They also enable doctors and nurses to call other staff members and departments using intuitive voice commands. As a result, they spend more time at the bedside and less time utilizing overhead pages and telephones.

The impact of hospital acoustics and medical equipment aside, success in reducing noise and improving patient experiences will only be achieved through the embedment of quiet environments and their role in healing in the organization's culture. As such, many healthcare leaders have announced hospital wide campaigns to quell the noise, including a push for quiet shift change. One of the most unassuming ways to reduce the noise of staff communication is to direct staff to take steps to ensure they address only their intended listener. This may be as simple as instructing staff to lower voices and politely mention when conversations are becoming too loud. Phoenix Children's Hospital has also found that mobile technology, whether personal smartphones or organization-provided devices, can be of assistance in localizing communication and doing so quickly.

Noise Reduction Outcomes

On account of early efforts to reduce noise and boost patient perceptions of care, Phoenix Children's Hospital ultimately decided to redesign its NICU to establish private patient rooms. Typical of many such units around the country, the hospital's initial NICU was an 8,000 square foot room holding 50 or more babies. Despite the advantage to clinicians in being able to easily see and hear one another and each infant, the hustle and bustle of the room often startled the newborns, and their parents were generally crowded around each bedside. The hospital's redesigned neonatal facility capitalized on efforts to reduce the noise of the hospital space, equipment and staff. Now, the NICU is ultra-quiet, softly lit and holds 76 private patient rooms.

Most importantly, today Phoenix Children's Hospital has one of the lowest infant mortality rates in the country and families leave happier than ever. Not surprisingly, noise reduction efforts are being replicated on every floor. Targeted efforts by hospitals to reduce noise, such as those displayed by Phoenix Children's Hospital, represent a unique shift in the healthcare industry towards a greater focus on positive patient experiences as an indicator of care quality. By addressing the biggest roots of noise — hospital acoustics, medical equipment and staff-tostaff communication, hospitals can successfully reduce noise, enhance patient satisfaction and ensure reimbursement.

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Practical Application of Osmometry for the Evaluation of Human Milk and Infant Nutritional Products in the Neonatal Intensive Care Setting

Andrea Curria, Kelly Peterson

Abstract

Understanding and monitoring the osmolality of human milk, milk fortifiers, medications, and infant nutritional products is a very relevant topic in the neonatal intensive care setting. It has been well documented that hyperosmolar substances have been associated with a wide variety of gastrointestinal illnesses in neonatal populations, including necrotizing enterocolitis (NEC). The American Academy of Pediatrics (AAP) recommends that the osmolality of formulas for "normal" infants should not exceed 450 mOsm/kg H₂O. Although no formal osmolality guideline has been set for Low Birth Weight (LBW) and Extremely Low Birth Weight (ELBW) infants, it is common practice in the neonatal intensive care unit to supplement the feedings with a host of medications, vitamins, and caloric supplements that have been shown to dramatically elevate the osmolality of the feeding well above the AAP safety threshold. Freezing point osmometry has been a well-documented tool used to accurately determine osmolality in infant formula and human milk. The purpose of this study was to evaluate the suitability and performance characteristics of the Advanced Model 3320 Micro-Osmometer over a broad sampling of infant nutritional products and human milk samples. Seventeen commercially available infant formulas were tested including ready to serve liquid, liquid concentrate, and powder formulations derived from cow's milk, soy, or protein hydrolysate based sources. Twelve (12) different human breast milk samples were tested. All were previously frozen, and were either single donor unpasteurized or pooled donor pasteurized. All samples were tested five times each to obtain a baseline reading, and then tested twenty times each to determine the range, standard deviation and coefficient of variation. The range of the seventeen infant formulas tested were between 170.0 and 385.1 mOsm/kg, and the coefficient of variation ranged from 0.5 to 1.9. The manufacturer reported osmolality claims of the feed products were consistent with experimental findings. The osmolality range of the human milk samples tested was between 261.0 and 316.1 mOsm/kg, and the coefficient of variation ranged from 0.5 to 1.2. The results indicate the Model 3320 osmometer performs well across all types of infant nutritional products and should be considered a valuable quality control tool for infant nutritional research.

Introduction

Osmolality is an important measurement and topic of discussion with regards to infant nutrition and neonatal care. Administration of hyperosmolar feeds have been linked to a wide variety of adverse conditions including altered nutrient absorption, hypertonic dehydration, diarrhea, intestinal ischemia, as well as more severe gastrointestinal abnormalities. Hyperosmolar formulas have also been a reported factor in causing necrotizing enterocolitis.^{1,2,3} To mitigate the risk, the AAP Committee on Nutrition recommends that formulas for normal infants have concentrations no greater than 400 mOsm/L.⁴ This corresponds to an osmolality of approximately 450 mOsm/kg.¹ Although the osmolality of most manufactured infant formulas fall well within these guidelines, it is a routine practice in the NICU to add a host of nutritional supplements, caloric modules, and medications to the feeding. This practice occurs when using either breast milk or commercial infant nutritional products as the base feed.

Currently there is no quality control check in place to monitor the true osmolality of the feeds before they are administered to the infant. To overcome this uncertainly, many NICUs have adopted the use of osmometry as a quality control tool to avoid the incidences of hyperosmolar feedings and improve patient safety.¹²

Common feeding practices utilized in the Neonatal Intensive Care Unit

Human breast milk is widely considered the first choice for feeding preterm infants due to its nutritional superiority and growing evidence of immunological health benefits. The osmolality of human milk is tightly regulated by the body and is approximately 300 mOsm/kg, but can vary slightly for a variety of reasons. Often times mother's own milk is not available so either donor milk or artificial nutritional products must be used. Regardless of the base nutritional feed, nearly always it will be supplemented with any number of pharmaceutical medications, vitamins, supplements or fortifiers prior to administration. Because of this, the true osmolality of the feed is rarely known.

Modification of expressed breast milk (EBM) with therapeutic doses of commonly used additives can result in a significant increase in its osmolality; this could also be further worsened when used in combination with fortified EBM.¹³ Previous reports demonstrated that infants requiring neonatal intensive care are exposed to a large number of medications while in the hospital. One such study found that each infant received an average of

The authors are with Advanced Instruments, Inc, Norwood, MA. Advanced Instruments would like to give special thanks to Indiana Mothers Milk Bank and the Mothers Milk Bank of Iowa for providing the human milk samples used in this study.

6.2 different drugs (range of 0 to 26) while in the intensive care nursery. $^{5.6}$

To confound the issue, studies have shown that 54 commonly used medications in the NICU had a measured osmolality in excess of 2000 mOsm/kg.¹⁴ Several hyperosmolar medications such as calcium lactate, calcium lubionate, and caffeine citrate have even been implicated in the development of NEC.^{16,17,18}

Calculated osmolality values and its inherent risks

There are available equations commonly used to calculate the theoretical estimation of osmolality for neonatal parenteral solutions based on the nutritional components of the solutions.⁷ While these calculations are convenient, they may be inaccurate, especially when calculating the osmolality of a multi-component solution simply by summing up the osmolality values of starting solutions.⁹ To make matters even more difficult, the same medications from different manufacturers may have vastly different osmolalities as a result of their differences in formulations. Often times manufacturers may change the drug formulation without affecting the concentration of the active ingredient. Thus, the osmotic results for some medications cannot be trusted compared to published study results.¹⁴

Some infant formulas come in dry powder or concentrated liquid form and require addition of water and dilution prior to use. Errors in dilution can occur and may cause hyper- or hypoosmolar states. Osmolality of powdered formula has also been shown to vary by as much as 30% due in part to measurement technique and between different lots of the same product.¹⁵ The addition of lipid to human milk lowers osmolality by 9% because of the displacement effect of the osmotic particles.¹⁹ Storage time and conditions of the feed solution must also be taken into consideration. It has been noted that amylase present in the breast milk can actively break down the maltodextrin in the milk and consequently increase the osmolality.⁸

With all of the inherent variability discussed, it is clear that making assumptions of the true osmolality of liquid by using calculated results is speculative at best. A direct osmolality measurement using an osmometer is the only reliable method to measure the true osmolality of a solution.¹⁰

Relevance of osmometry in the milk industry

Ironically, osmometry first found commercial utility over 50 years ago in the milk dairy industry. Historically dairy farmers were paid by the quantity of milk delivered to the processor, and soon realized that adding water to the milk would increase their profits. The added water in milk caused many downstream effects in dairy food processing and degraded the quality of cheeses, yogurts, and milk products. Freezing point osmometers, or cryoscopes, were implemented as a quality control check to determine if water had been added to milk. The milk cryoscopes were extremely effective in determining added water in milk. As a consequence, dairy farmers are now paid for the quality of their milk (ie, fat content) rather than by volume.

Advantages of Freezing Point Osmometers

Osmolality is classically defined as the total number of particles (solute) in a liquid solution (solvent). It is expressed in milliosmoles of solute per kilogram of solvent or mOsm/kg $\rm H_2O$. Freezing point depression is a true colligative property that can accurately measure the concentration of a liquid solution.

Freezing point osmometers have been the widely referenced and accepted as the gold standard for use in research studies involving human milk and infant nutrition products. Compared with vapor-pressure osmometry, the freezing point depression method is preferable when solvent volatile substances are suspected or measured. Vapor pressure osmometers cannot detect volatile compounds and consequently underestimate the true concentration of the sample. Since many pharmaceutical formulations contain volatile compounds and alcohols, or more commonly unknown constituents, freezing point osmometers are preferred.^{10,11, 14}

Materials and Methods

Materials

Туре	Description	Serial or Lot Number
Osmometer	Advanced Model 3220 Micro- Osmometer	SN 04121118A
Osmometer Supplies	50 mOsm/kg Calibration Standard (3MA005) 850 mOsm/kg Calibration Standard (00A085) 290 mOsm/kg Reference Standard (3MA029)	Lot # 0309190 Lot # 0409080 Lot # 0402010
Infant Nutritional	Enfamil EnfaCare Lipil Powder (Cow's Milk Based)	Lot # QL545
Products	Enfamil ProSobee Lipil Powder (Soy Based)	Lot # BD562
	Enfamil Lipil Nutramigen Powder	Lot # MFS22
	Enfamil Premium Lipil 20 Powder (Cow's Milk Based)	Lot # ENFG05
	Enfamil ProSobee Lipil Ready to Use	Lot # MLS18
	Enfamil Lipil Nutramigen Concentrated	Lot # MHS10
	Enfamil Lipil 20 Concentrated (Cow's	Lot # MKS07
	Similac Alimentum Ready to Use	Lot #82542RH
	Similac Sensitive for Spit Up Ready to	Lot # ISADPWO
	Similac Advance Ready to Use (Cow's Milk Based)	Lot # SIMESPW
	Similac Sensitive for Spit Up Powder (Cow's Milk Based)	Lot# SSRSPWD
	Similac Sensitive Powder (Cow's Milk	Lot# SSENFWC
	Similac Alimentum Powder (Protein	Lot # 82927RAD
	Good Start Soy Plus Concentrate (Soy	Lot # HPC3013
	Good Start Gentle Plus Concentrate	Lot# GGC3050
	Good Start Gentle Plus Ready to Use	Lot# GGR3043
	Good Start Gentle Plus Powder (Soy Based)	Lot# GGR3043
Human Milk Samples	Human Milk MMB of Iowa Pooled #1 Human Milk MMB of Iowa Pooled #2	Lot # P463-4
	Human Milk MMB of Iowa Pooled #3 Human Milk MMB of Iowa Single Donor #1 Human Milk MMB of Iowa Single Donor #2 Human Milk MMB of Iowa Single Donor #3	Lot # P496-4
	Human Milk Indiana MMB Pooled #1 Human Milk Indiana MMB Pooled #2 Human Milk Indiana MMB Pooled #3 Human Milk Indiana MMB Single #1 Human Milk Indiana MMB Single #2 Human Milk Indiana MMB Single #3	Lot # P474-1

Methods

The Advanced Model 3320 Osmometer was calibrated based on manufacturer's specification using the 50 and 850 mOsm/ kg calibration standards. At the start of each testing day, a calibration check was performed using the 290 mOsm/kg reference solution five 5 times, and all readings were within the ± 2 mOsm/kg H₂O specification for each testing day. The reference standard was also tested 20 times each to establish the 3320 instrument performance parameters.

Infant formulas were cow's milk based, soy based, or protein hydrolysate based, and the ready to use, concentrated, and powdered formulations were all represented. All powdered and concentrated infant formulas were prepared according to manufacturer instructions. All formulas were tested within the acceptable time period stated by the manufacturer once opened. Each infant formula sample was thoroughly mixed prior to testing. Human milk samples were shipped frozen and thawed prior to each testing day. The human milk was either single donor unpasteurized or pooled donor pasteurized, from two human milk banks. The thawed samples were mixed by gentle inversion prior to testing.

All samples were tested five times each to obtain a baseline reading, and then tested 20 times each to determine the range, standard deviation and CV.

Results

Table 1. Powdered Infant Formulas

Brand Name	Average Osmolality (mOsm/Kg) (n=20)	S.D.	CV	Manufacturer's Label Claim ^{20,21,22}	% Difference Label Claim and Calculated
Enfamil EnfaCare Lipil	333.0	2.8	0.8	300	10.4
Enfamil Prosobee Lipil	187.3	2.1	1.1	170	9.7
Enfamil Nutramigen Lipil	299.7	1.6	0.5	300	0.1
Enfamil Lipil 20	304.8	1.9	0.6	300	1.6
Good Start Gentle plus	226.3	1.5	0.6	250	10.0
Similac Sensitive for Spit-Up	175.7	3.3	1.9	180	2.4
Similac Sensitive	229.4	1.7	0.7	200	13.7
Similac Alimentum	326.0	2.5	0.8	320	1.9

Table 1. Results for the eight (8) powdered infant formulas tested. The osmolality ranged from 175.7 up to 333.0 mOsm/kg, which showed good correlation (0.1% to 13.7% difference) with manufacturer's label claims that ranged from 170 up to 320 mOsm/kg. Coefficient of variation (CV) for all samples tested were very good and were between 0.5 up to 1.9.

Table 2. Infant Formula From Liquid Concentrate

Brand Name	Average Osmolality (mOsm/Kg) (n=20)	S.D.	CV	Manufacturer's Label Claim ^{20,21,22}	% Difference Label Claim and Calculated
Enfamil Nutramigen Lipil	296.4	1.7	0.6	300	1.2
Enfamil Lipil 20	308.3	2.1	0.7	300	2.7
Good Start Gentle plus	260.1	1.8	0.7	250	3.9
Good Start Gentle Soy plus	178.1	1.5	0.8	180	1.1

Table 2. Results for four (4) liquid concentrate infant formulas tested. The osmolality ranged from 178.1 up to 308.3 mOsm/kg, which showed very good correlation (1.1% to 3.9% difference) with manufacturer's label claims that ranged from 180 up to 300 mOsm/kg. Coefficients of variation (CV) for all samples tested were very good and were between 0.6 up to 0.8.

Table 3. Ready-to-use Liquid Infant Formula

Brand Name	Average Osmolality (mOsm/Kg) (n=20)	S.D.	CV	Manufacturer's Label Claim ^{20,21,22}	% Difference Label Claim and Calculated
Enfamil Prosobee Lipil	170.3	1.7	1.0	170	0.2
Good Start Gentle plus	268.6	1.7	0.6	250	7.2
Similac Alimentum	385.1	2.3	0.6	370	4.0
Similac Sensitive for Spit Up	172.9	1.5	0.9	180	4.0
Similac Advance	304.8	1.8	0.6	310	1.7

Table 3. Results for five (5) liquid infant formulas tested. The osmolality ranged from 170.3 up to 385.1 mOsm/kg, which showed very good correlation (0.2% to 7.2% difference) with manufacturer's label claims that ranged from 170 up to 370 mOsm/kg. Coefficients of variation (CV) for all samples tested were very good and were between 0.6 up to 1.0.

Table 4. Pooled Donor Human Milk

Brand Name	Average Osmolality (mOsm/Kg) (n=20)	S.D.	CV
Indiana MMB Pooled #1	279.7	1.8	0.6
Indiana MMB Pooled #2	291.5	1.4	0.5
Indiana MMB Pooled #3	261.0	1.3	0.5
Iowa MMB Pooled #1	307.5	3.7	1.2
Iowa MMB Pooled #2	304.5	2.3	0.8
Iowa MMB Pooled #3	271.7	2.0	0.8

Table 4. Results for the six (6) pooled human milk samples tested. The osmolality ranged from 261.0 up to 307.5 mOsm/kg. Coefficient of variation (CV) for all samples tested were very good and were between 0.5 up to 1.2.

Table 5. Single Donor Human Milk

Brand Name	Average Osmolality (mOsm/Kg) (n=20)	S.D.	CV
Indiana MMB Single #1	312.8	1.7	0.5
Indiana MMB Single #2	310.4	1.4	0.5
Indiana MMB Single #3	283.6	2.0	0.7
Iowa MMB Single Donor #1	316.1	3.1	1.0
Iowa MMB Single Donor #2	296.2	2.7	0.9
Iowa MMB Single Donor #3	313.7	3.6	1.1

Table 5. Results for the six (6) single donor human milk samples tested. The osmolality ranged from 296.2 up to 316.1 mOsm/kg. Coefficient of variation (CV) for all samples tested were very good and were between 0.5 up to 1.1.

Discussion

The purpose of this study was to evaluate the performance of the Advanced Model 3320 Micro-Osmometer over a broad range and types of infant nutritional products and human milk samples commonly found in the neonatal care setting. The research was neither intended to assess the quality nor confirm the label claims of the commercial nutritional products and human milk *Continued on page 39...*



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Questioning Best Practices for Nutritional Warming in the NICU

C. Darabant

Introduction

- Human milk is the gold standard for the human infant because it contains all the necessary components for baby's developmental needs.
- Feeding at the breast is ideal because mom's milk production is aligned with the changing nutritional requirements of the infant.
- Unfortunately, with compromised infants and preterm infants, feeding at the breast is not always immediately possible.

In cases where feeding at the breast is not feasible, we are fortunate to have lactation and clinical staff who educate and encourage moms to pump and store milk. More often than not, the pumped milk is refrigerated or frozen. Before feeding, we warm the milk to what we hope is body temperature. Earlier studies regarding feeding tolerance showed this practice to be correct (Gonzales 1995). As clinicians and scientists we continued to ask why. The understanding we gained is that biochemical reactions which deliver all molecular components of mom's milk to the proper targets in baby's system are in fact temperature dependent. Simply stated, feedings are warmed because of a better understanding to the question: why is mom's milk delivered at body temperature? Enzyme dependent, biochemical reactions require human body temperature for ideal conditions to catalyze necessary reactions. Unwanted consequences occur above and below this ideal body temperature range. Above 104°F enzymes and proteins become denatured, thus compromising the feeding. Below 90°F enzymes do not properly fold and flex to catalyze necessary reaction; the baby has to burn critical calories to warm the feeding. The calories burned are from the most needed and lacking, brown fats or sub-cutaneous fats.

Current Warming Practices and Their Consequences/ Shortcomings

HMBANA provided guidelines for thawing and warming frozen and/or refrigerated human milk. In the NICU and beyond the guidelines are not always followed. Creative warming methods include using cups or pitchers filled not only with warm tap water but also with water from instant heat faucets, a hot coffee pot, microwaved water, hot air-based warmers and steam warmers. As an educated, scientific community we should always remain inquisitive about our actions/procedures. By

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.

remaining curious we can evaluate current procedures and improve upon them for the benefit of our future generations. For example, what are the consequences or shortcomings of our current nutritional warming practices?

- Current methods for warming are subjective and inconsistent. We do not accurately know the final temperature of the feeding. Published studies confirm the inconsistency of feeding temperatures which range from 50°F-120°F^{1,2}
- Clinical staff oversight of the warming process in an effort to address the correct temperature point of feedings is time consuming and distracting. It takes away from critical time for clinical care.
- Overheating the feeding is a common occurrence and results not only in the potential for deactivating anti-infection properties but even more so in denaturing enzymes and proteins in the milk.
- Under-heating the feedings results in unnecessary caloric expenditure by the baby and is counterproductive.



How do you check milk temperature before feeding baby? Do you place the container on your wrist? Does it feel warm? Have you considered that if the container feels warm to you, you may have overshot your body's temperature? 104°F is a mere 5.4 degree departure from body temperature. Can you subjectively sense that slight temperature difference? Studies prove that more often than not, we cannot accurately make that distinction.

Desired result: The feeding container should feel temperature neutral.

Scrutinizing Warming Practice Options

Impetus for a standardized method of nutritional warming is undeniable. However, scientific and evidence-based scrutiny of currently available nutritional warmers is warranted. In addition, it is important to understand the entire approach to nutritional warming and the consequences of the methodology employed. Ease of use and speed of warming must be balanced with science and evidence. Convenience and speed do not necessarily equate to proper health care. A diligent understanding is required to ensure no harm is done to the patient.

Overlooked and Highly Critical Factors Affecting Development

Nutritional warming is sensitive to the type of heating methodology employed. Focus has been on the feeding temperature of milk with a high desire for achieving near body temperature in the Thermo-Neutral Zone (TNZ). How such temperature is achieved is equally important. The method must be controlled and low energy must be utilized to eliminate additional and unwanted chemicals in the feeding.

Plastic containers are commonly used for feedings. These include syringes, bottles, bags, and tubing. Ideally, Polypropylene #5, BPA free plastic is used. Even this consideration of plastics has its inherent issues when plastics are exposed to heat. Plastics manufacturers, by law, must provide a leachable profile for their product. A leachable profile, by definition, shows if the plastic releases harmful chemicals at ambient temperature and under normal conditions. This profile of leachables does not account for warming in the NICU nor for changes to milk's pH based on the mom's diet.

What about warming plastic containers and incorporating pH changes from mom's milk/diet?

At elevated temperature and altered conditions, the term for chemical changes to plastics is known as extractables. No requirement for such studies is mandated for the plastics manufacturers. It is, however, a serious issue. Warming plastic containers can release trace amounts of chemicals into baby's feeding resulting in adverse patient exposure. "Such chemicals become incorporated as complex mixtures. Containers meant to protect a drug (breast milk) from environmental contamination are actually themselves a source of contamination."⁵

Typical extractables in plastics include "additives, processing aids, antioxidants, stabilizers, plasticizers, emulsifiers, colorants, monomers and oligomers of the polymer and other reaction products. Full traceability is hard to obtain."⁵

The issue becomes that the protein interacts with such trace chemicals in such a way as to elicit an immunogenic response. The PQRI working group on leachables and extractables has identified a myriad of growing health concerns. For example, a common antioxidant found in polypropylene is responsible for myelin degradation among other low dose risks including corrosive properties to epithelium, dermal toxicity, and liver and spleen lesions in animal models.⁴

Myelin development in the frontal lobe is last to develop. Therefore, even trace amounts of a compound affecting such development of myelin will impact patient health. In the case of frontal lobe development, this will include cognitive function and behavior.³

According to Dominic Warrino, PhD, immunogenic response to extractables from feeding containers will negatively impact thymus development and \pm T-cell selection. Such unwanted chemicals can have serious consequences to the developing adaptive immune system.

All warming methods should be trialed by every unit planning to standardize the nutritional warming process. Side-by-side comparisons are ideal for testing equivalency.

What to look for:





temperature when the

instrument claims it is ready

Check warming temperature on outside of the container during the entire warming process

In addition:

- 1. Does the warmer work the same for all feeding containers and brands; including milk bank containers?
- 2. Is the feeding consistency (lipids, fortifiers, and temperature) the same throughout?
- 3. What is the noise level of the warmer (below acceptable decibel levels and not adding additional noise to the unit)? Do multiple units add to the noise level?
- 4. Is the milk protected from bacterial, chemical, or other contaminant exposure?

Ultimately, minimizing changes to the milk chemistry and eliminating the risk of unwanted chemicals is the primary goal of a properly standardized process.

Standardizing Warming Practice – The Penguin Nutritional Warmer

The Penguin Nutritional Warmer eliminates the risk of water exposure by employing patented therma-liner technology based on over three decades of FDA driven, biopharmaceutical, cGMP, proven manufacturing practices. The Infectious Control proven therma-liner meets the recommendation set forth by regulating bodies to eliminate water exposure in the NICU. By isolating water in a separate, jacketed compartment, the Penguin Nutritional Warmer is able to safely utilize the properties of a liquid to properly warm baby's feeding.

The short and long term patient health advantage of this practice is the low heat-energy threshold required to achieve a perfect warming result every time. Plastic containers warmed via the Penguin method never exceed temperatures which can cause extractables. This low energy threshold protects the feeding from the damaging properties of extractable chemicals which negatively impact babies' developing systems.

Conclusion

Nutritional warming temperature should never exceed normal, body temperature range. Risk for extractable chemicals is highly increased with increasing temperature. Extractable chemicals pose an unnecessary and undesired health effect on the developing human system. Consequences include damage to the immune system and cognitive/behavioral functions of the brain. Standardizing nutritional warming practice is much more than a matter of comfort to the infant. It is a critical consideration along with the warming method employed. Research is proving that developmental disorders are directly related to gut function and the immune system.³

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Impact of Affordable Care Act Post-Discharge from NICU

Carol Chamblin, DNP, APN, RN, IBCLC

The Affordable Care Act (ACA) is the provision of health insurance for all Americans, leaving no one uninsured for situations such as predisposing illnesses or costs. One aspect of the ACA includes preventive services for breastfeeding support and equipment such as breast pumps. Members of several major health insurances received notifications that policies would reimburse for breastfeeding-related care and supplies. Hospital-grade, double electric breast pumps are necessary when preterm infants are discharged from the NICU either not fully breastfeeding, or when mothers are pump-dependent. Members of insurances were excited to learn their policies would cover costs of an appropriate pump type. Many times insurances are covering the costs of hand-held or purchased breast pumps. These types of pumps are not deemed clinically-sufficient for the maintenance of milk supply for mothers of preterm infants discharged from the NICU.

Expanding Access to Preventive Services for Women

The ACA passed by Congress and signed into law by President Obama on March 23, 2010 is intended to make health care prevention affordable and accessible for all Americans. It requires most health plans and Medicaid to cover recommended preventive services without cost sharing (Healthcare.gov, 2011). Cost sharing (including copayments, co-insurance, and deductibles) reduces the likelihood that preventive services will be used. On August 1, 2011, the US Department of Health and Human Services (HHS) adopted additional comprehensive coverage for women's preventive care. One of the eight additional services included is that of breastfeeding support, supplies, and counseling. Pregnant and postpartum women have access to comprehensive lactation support and counseling as well as breastfeeding equipment. Research findings demonstrate breastfeeding as effective in the prevention of many illnesses and diseases for women and children. One major barrier for breastfeeding is the cost for the purchase or rental of breast pumps and related supplies.

Progress towards the goals of the ACA to provide breast pumps has led to confusion for members, health care providers, and the insurances themselves. Mothers are getting misinformation on types of breast pumps being covered. Having the correct pump type when infants are separated from mothers by extended hospital stays in the NICU is vital for optimizing milk volume in pump-dependent situations. Hospital-grade, double electric breast pumps which are available on a rental basis are deemed by research to be best practice for sustaining maternal milk supply. Pump needs for preterm infants discharged from the NICU not fully breast feeding, or for pump-dependent mothers necessitates the hospital-grade, double electric breast pump. The diversity of pump types being shipped to mothers by insurances are the hand-held, purchased double pump, or hospital-grade, double electric pump. Insurances are misinformed about pump types and providing reimbursement for only hand-held or purchased pumps.

Rates of Breastfeeding

In addition to the inclusion of breastfeeding support, supplies, and counseling by the ACA, a national campaign for the promotion of breastfeeding has been implemented to address exclusivity and duration rates which remain low. According to the Centers for Disease Control and Prevention (CDC) Breastfeeding Report Card – United States, 2012, 76.9% of infants ever breastfeed, and exclusivity rates at 3 months and at 6 months were 36% and 16.3% respectively. Duration rates of breastfeeding were 47.2% and 25.5% at 6 months and at 12 months respectively. Participation in the promotion and support for breastfeeding in recent years includes the Healthy People 2020 targets to increase the proportion of infants who are ever breastfed to 81.9%, and targets for exclusivity and duration are:

- exclusivity rates of 46.2% and 25.5% at three and six months respectively
- duration rates to 60.6% at six months and 34.1% at 12 months

Although more mothers are initiating breastfeeding, too many quit breastfeeding shortly after delivery, causing current national rates of duration and exclusivity to fall far below the targets.

Health Benefits for All Newborns

According to The Surgeon General's Call to Action to Support Breastfeeding (2011), breastfeeding for a year provides many health benefits for infants including protection from several infections and illnesses such as diarrhea, ear infections, and pneumonia. Infants who were breastfed are less likely to develop asthma, become obese, and have reduced risks of sudden infant death syndrome (SIDS) (The Surgeon General's Call to Action to Support Breastfeeding, 2011; Policy Statement – Breastfeeding and the Use of Human Milk, 2012; Ip, Chung, Raman, Chew, Magula, DeVine, Trikalinos, & Lau (2007). Besides the health benefits of breastfeeding, there are economic benefits. When optimal breastfeeding practices are followed, the savings on infant formula for the first year of life is estimated to be about \$1,200-\$1,500 (The Surgeon General's Call to Action to Support

This article was provided by Medela.

Breastfeeding, 2011; Policy Statement – Breastfeeding and the Use of Human Milk, 2012). Furthermore, according to Bartick (2010), the cost savings from reduced medical costs if mothers were to breastfeed for six months is estimated to be between three and 13 billion dollars for the United States.

Further Benefits for Preterm and Low Birthweight Infants

According to the United States Breastfeeding Committee (2002), breastfeeding provides benefits not just for full-term infants but also for preterm and low birthweight infants. Preterm infants receiving formula rather than breast milk have future IQs that are 8-15 points lower than those receiving breast milk. For preterm infants, breast milk significantly shortens length of hospital stays, reduces hospital costs, and reduces the risk of life-threatening disease of the gastrointestinal system and other infectious diseases (Meier, Furman, and Degenhardt, 2007).

Cost Benefits

Breastfeeding not only provides health benefits for society, but has economic and environmental benefits. The cost savings for an NICU hospitalization as a goal of the ACA is encountered by insurers, families, and for Medicaid (US Breastfeeding Committee, 2002). Estimated costs spent by families on breast milk substitutes such as infant formula is \$2 billion per year. The US Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants and Children (WIC) spends \$578 million per year to buy formula for infants who are not breastfed. Another aspect of cost-savings is 3.6 to 7 billion dollars spent every year on conditions and diseases preventable by breastfeeding. Weimer's (2001) report on the determination of the costs per case per disease/condition has been reported by the United States Breastfeeding Committee (2009-2013) based on estimates of the current costs to the economy. An estimated \$3.6 billion must be paid each year for private and government insurers to treat diseases and conditions preventable by breastfeeding. Costs for hospital stays related to respiratory infections among 1,000 never-breastfed infants range from \$26,585 to \$30,750 more than for 1,000 infants who exclusively breastfed.

Effective, Efficient Breast Pump

Mothers of preterm infants are dependent on effective hospitalgrade, double electric breast pumps (Symphony, Medela, Inc, McHenry, IL), for the initiation and maintenance of milk supply. Mothers often experience problems with providing enough breast milk for their infants. Access to a hospital-grade pump enables mothers to express enough milk by adequate milk removal (Meier, et al, 2010). Several types of breast pumps are being reimbursed by health insurances that are not based on the evidence for best practice in optimizing milk volume. There is an urgent need for education to occur for the insurances to offer an evidence-based hospital-grade electric breast pump for NICU infants at the time of discharge. According to Meier, et al (2011), mothers need to use an effective pump until their infants consume all milk directly from the breast. Evidence shows that most infants achieve breast feeding post-discharge from the NICU when they are at term or later.

According to Meier, et al (2011), breast pump suction patterns (BPSPs) for preterm infants should mimic the sucking rates and rhythms used by healthy-term infants. The Premie Plus pattern utilized on the hospital-grade, double electric breast pump was designed based on these research findings to maximize milk expression. This new technology provides the most effective

and comfortable pumping strategy for effective stimulation and removal of breast milk. Consequently, future direction for insurances is to understand the necessity to cover the costs of the rental fees for this type of pump for pump-dependent mothers of preterm infants after discharge from the NICU.

Case Scenario

Infant born preterm at 31 weeks gestation and mother is assisted with the initiation of pumping within 6 hours of delivery using the Premie Plus card. Within 14 days of pumping, mother is able to express 750-800 ml of milk output. This preterm infant spends 4 weeks in the NICU before being discharged.

At the time of discharge, mother receives a purchased pump type from her insurance. She returns her Symphony pump to the rental location, and begins using her pump. After 2 weeks she meets with her lactation specialist in her pediatric practice setting and finds out her infant is not having enough milk intake from breast. Mother is expressing only 30ml per pumping 7-8 times in 24 hours (210-240 ml) and does not understand the reason her milk volume has lessened since her preterm infant came home from the NICU.

During the post-discharge appointment, the lactation specialist educates mother on the importance of a correct pump type for maintaining milk volume since her preterm infant is not yet fully taking feeds at breast, and she is still pump-dependent. Mother gains a full understanding that her insurance did not provide her with a clinically-effective breast pump for her preterm infant's needs, and proceeds again to rent the hospital-grade, double electric breast pump (namely, the Medela Symphony). Within 7 days of use, mother's milk volume exceeds her prior 24 hour volume to 800-850 ml. ACA is intended to offer health insurance coverage for all Americans, yet has its limitations in the provision of the right choice for breast pump distribution based on clinical findings.

Summary

Determination of breast pump type for mothers of preterm infants post-NICU stays is being conducted by insurances for purposes of reimbursement and compliance with the new ACA. Many insurances have out-sourced the dispensing of pumps to agencies with a durable medical equipment (DME) license, similar to other healthcare-related equipment, such as nebulizers and oxygen. Insurances need to provide the correct pump type for preterm infants based on evidence to support the continuation of breast milk feedings.

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Osmometry...continued from page 33

samples. More importantly, the study was conducted to establish the baseline performance of the osmometer for the infant nutritional and neonatal research community.

Overall twenty-nine (29) infant formula and human milk samples were tested in the study. The samples consisted of dry powder, ready to serve liquid, and concentrated liquid infant formulations as well as both pooled and single donor human milk samples. Osmolality ranged between 170.3 and 385.1 mOsm/kg. Standard deviations ranged from 1.5 to 3.3, and the coefficient of variation ranged from 0.5 to 1.9 across all sample types.

Conclusion

The health risks associated with hyperosmolar feedings in infant nutrition have been discussed. Common feeding and supplementation practices in the neonatal intensive care unit do little to confirm the actual osmolality of individual feed samples, and in many cases can impact patient safety by increasing the risk of hyperosmolar feedings. The Advanced Model 3320 Micro-Osmometer has been shown to provide accurate test results for all types of infant nutritional products and human milk. With a 60 second test time and low cost per test, it is ideally suited for the NICU or dietary department to rapidly monitor the osmolality of infant feeding solutions including infant formula, human milk, and additives such as fortifiers, vitamins, minerals or pharmaceutical medications. The 3320 osmometer can dramatically improve neonatal patient care, eliminate the risk of unintentional hyperosmolar feedings, and quickly confirm that infant feed mixtures are below the 450 mOsm/kg safety threshold recommended by the AAP.

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Parents' Expectations of Staff in the Early Bonding Process with their Premature Babies in the Intensive Care Setting: a qualitative multicenter study with 60 parents

Sonia Guillaume, Natacha Michelin, Elodie Amrani, Brigitte Benier, Xavier Durrmeyer, Sandra Lescure, Charlotte Bony, Claude Danan, Olivier Baud, Pierre-Henri Jarreau, Elodie Zana-Taïeb, Laurence Caeymaex

Abstract

Background: During the first weeks of hospitalization, premature babies and their parents encounter difficulties in establishing early bonds and interactions. Only a few studies have explored what caregivers can do to meet parents' needs in relation to these interactions and help optimize them. This study sought to explore parents' perception of these first interactions and to identify the actions of caregivers that help or hinder its development.

Methods: Prospective study, qualitative discourse analysis of 60 face-to-face interviews conducted with 30 mothers and 30 fathers of infants born before 32 weeks of gestation (mean \pm SD: 27 \pm 2 weeks of gestational age), during their child's stay in one out of three NICUs in France. Interviews explored parental experience, from before birth up to the first month of life.

Results: Data analysis uncovered two main themes, which were independent of parents' geographical or cultural origin but differed between mothers and fathers. First, fathers described the bond with their child as composed more of words and looks and involving distance, while mothers experienced the bond more physically. Secondly, two aspects of the caregivers' influence were decisive: nurses' caring attitude towards baby and parents, and their communication with parents, which reduced stress and made interactions with the baby possible. This communication appeared to be the locus of a supportive and fulfilling encounter between parents and caregivers that reinforced parents' perception of a developing bond.

Conclusions: At birth and during the first weeks in the NICU, the creation of a bond between mothers and fathers and their premature baby is rooted in their relationship with the caregivers. Nurses' caring attitude and regular communication adapted to specific needs are perceived by parents as necessary preconditions for parents' interaction and development of a bond with their baby. These results might allow NICU staff to provide better support to parents and facilitate the emergence of a feeling of parenthood.

The authors are from various organizations and facilities in France. To see the full list of author information, visit BioMed Central and type the title of the article. Reprinted from BioMed Central, BMC Pediatrics, © 2013 Guillaume et al; licensee BioMed Central Ltd. This is an open access article distributed under the terms of the Creative Commons Attribution License.

Background

In premature babies, the quality of the early mother-child relationship influences subsequent development.¹⁻⁵ Prematurity per se does not necessarily affect the quality of mother-child interactions in the long term.⁶⁻⁹ Maternal depression, on the other hand, has been identified as a risk factor for poor mother-infant interactions.⁶

Mothers and fathers faced with their newborn's admission to the neonatal intensive care unit (NICU) endure a particularly difficult experience that may include parental anxiety, depression, and posttraumatic stress.^{10,11} Factors contributing to the parents' psychological state are their dependence on caregivers, the NICU's rules and organization, and uncertainty about the child's prognosis.¹²⁻¹⁴ In addition, very preterm children and their parents have few opportunities to start developing a reciprocal relationship during the first weeks of life.¹⁵ Finally, the father's support to the mother appears essential to the latter.¹⁵

These data indicate that NICU interventions aimed at restoring maternal self-esteem, reducing maternal stress and depression, and encouraging interactions with the child are an integral part of care necessary for very pre-term newborns.^{3,16,17} Programs to limit maternal stress,¹⁸ to create opportunities for parental empowerment,¹⁹ and to foster skin-to-skin contact,²⁰ and changes in the physical layout of units^{20,21} have all shown positive effects on the well-being of parents of infants in the NICU. Moreover, nurses in these neonatology units seem to play a key role in facilitating the start of positive mother-baby interactions.^{22,23}

Although reports have described the global experience and needs of mothers and fathers in NICUs, few studies have examined parental opinions about how caregivers can help them to interact positively with their babies and to perceive and present themselves as parents, and those have mainly used scales or questionnaires.^{16,24-26}

To better understand what caregivers can do to help mothers and fathers in their early interactions with their newborn in the NICU, we conducted an in-depth qualitative prospective multicenter study among parents of very preterm babies during their child's NICU stay. The objective of this study was to explore, through parents' accounts, how an early bond with their very premature child is established and to identify their expectations of caregivers, and the concrete things that helped and hindered them.

Table 1	Characteristics	of the study	population	(60 parents	and their	· 49	children)*
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Parents' characteristics	Mothers N=30	Fathers N=30	Total N=60
Age (years), M±SD	30.7 +/- 6.6	33.5+/- 6.8	
Current professional activity			
Managerial and professional occupations	11 (37)	11 (37)	22 (37)
Skilled manual and non-manual occupations	18 (60)	15 (50)	33 (55)
Unemployed	1 (3)	4 (13)	5 (8)
Single parent	1 (3)	0 (0)	1 (2)
Parent's place of birth			
Europe	12 (40)	16 (53)	28 (47)
Sub-Saharan Africa	10 (33)	6 (20)	16 (27)
North Africa	3 (10)	6 (20)	9 (15)
Asia or Mideast	2 (7)	0 (0)	2 (3)
Unknown)	3 (10)	2 (7)	5 (8)
History of preterm delivery	3 (10)	3 (10)	6 (10)
Assisted reproduction	6 (20)	5 (17)	11 (18)
Caesarean section	22 (73)	18 (60)	40 (68)
Children's characteristics at the time of the interview			Total N=49
Female			29 (59)
Inborn			36 (74)
Multiple			12 (24)
Cranial ultrasound			
Normal			38 (77)
PVH-IVH grade 1 or 2			10 (20)
PVH-IVH grade 3			1 (2)
PVH-IVH grade 4, PVL			0 (0)
Ventilation at time of interview			
Spontaneous Ventilation			8 (16)
Nasal Ventilation			30 (61)
Endotracheal ventilation			11 (22)
History of Sepsis			23 (47)
History of NEC or GIP			3 (6)
Persistent Ductus Arteriosus, Surgery			11 (22)
Transfusion			30 (61)

PVH-IVH: periventricular-intraventricular hemorrhage (Papile's classification), NEC: necrotizing enterocolitis, GIP: gastrointestinal perforation.

*all values are numbers with percentages in parentheses, except as otherwise stated.

Methods

Face to face interviews with mothers and fathers of preterm newborns while the baby was in the NICU.

Participants and procedure: The study took place at three tertiary care centers in the Paris region, France. All three were open to parents 24 hours a day and provided telephone contact. Visits to the baby were generally limited to the two parents. Meetings to provide news were organized regularly by the physicians. Parents were eligible for this study if they spoke French and if their child was born before 32 weeks of gestation, was 15 to 30 days old at inclusion, and had no recent severe clinical aggravation, according to the attending physician. The sample, defined in advance, comprised 30 fathers and 30 mothers, that is, 10 of each at each site. The nurses participating in the research (SG, NM, EA, CB, and BB) gave eligible parents an informational letter that described the study's objective, organization, and the use of the data for research and teaching

purposes. The parents participated on a voluntary basis, making an appointment themselves with the interviewer.

Data collection and analysis: Semi-directive interviews lasting 60 to 90 minutes were conducted by a social psychologist trained in research and not involved in a NICU. Audio recordings of the interviews were made, with the parents' oral consent. Fathers and mothers were interviewed separately. The interview guide was developed from a review of the literature and from 10 preliminary interviews discussed within focus groups of caregivers, conducted by the researchers. During the interview, parents were encouraged to describe freely how they had experienced the news that the birth would be preterm, the actual birth, and the child's admission to and stay in the NICU. They were encouraged to develop in detail everything that had helped or hindered them in developing a bond with their baby, as well as the activities set up by the caregivers.

Table 2 Caregivers' actions reported by parents as useful for early bonding with their preterm newborn

Before birth	Prenatal visit by neonatologist Explanations: baby's weight and capacities, breastfeeding, child's course
	Introduction of staff and department operation
	Consistency of descriptions of management
At birth	Briefly reassure parents about baby's condition (alive)
	Reassure father about the mother's condition
Between delivery and first visit	Visit mother in her room
	Provide photograph of the baby
	Interact directly with both parents, especially if clinical status of the baby is worsening
In the NICU	Accompany each parent on first visit
	Gentle and attentive attitude toward the baby
	Explanations: machines, alarms, child's capacities and ways of helping him
	Help parents become more autonomous progressively, gently and kindly, avoid judgments
	Suggest closeness: carrying the baby, skin-to-skin (anticipate and support these moments)

Data analysis: Discourse analysis was used to study the interviews.²⁷ The analysis was performed separately by a research psychologist and a research assistant. They conducted a horizontal analysis, with immersion and manual coding of the themes in each interview, and a vertical analysis that compared the themes throughout the corpus, identified the convergences and divergences of the same theme across different interviews and developed interpretative hypotheses. Particular attention was paid to the emergence of new themes and contradictory results as the interviews and analysis progressed and data saturation occurred.

The child's medical data and the parents' medical and sociodemographic data were collected from the medical files before and at the time of the interview.

Ethics: This study was conducted as part of a Quality Improvement Process. The relevant Ethics Committee, the Ile de France 3 Committee for the Protection of Persons, approved the information provided, recruitment mechanism and type of consent, and their compliance with French laws and regulations. Processual consent was obtained throughout the interview.²⁸

Results

Between November 2009 and March 2010, 68 parents were contacted, and 60 agreed to participate in the study — 30 fathers and 30 mothers, including 16 couples and 14 parents of each sex participating without their partner. The study included the parents of 49 children, born at a mean term of 27 ± 2 weeks of gestation, with a mean (±SD) birth weight of 956 (±206) grams. The children's mean (±SD) age at the interview was 24 (±10) days. The social and demographic characteristics of the participating parents and the clinical data about their children are presented in Table 1.

The results are illustrated by direct quotations, followed by the designation m (for mother) or f (for father) and the interview number.

Description of the feeling of an early bond by mothers and fathers: Parents reported that interactions with their child played a role in their feeling of being the child's parent and of having a specific bond with him/her. The mothers consistently described three items that helped them to feel a bond with the child: physical closeness to the baby, increased knowledge with contact, and being able to leave the baby a toy or a fabric permeated with her odor. Most women insisted on their need for maternal gestures such as skin-toskin contact or kisses: "Me, the skin-to-skin, I loved it...feeling her, having her pressed against me. I said to myself, she's really my baby, mine, today. I felt that I was her mother before the skin-to-skin, but there...that's it, she was lying there, peaceful" (m11). "The hardest thing for me today, it's the kisses. The fact that I cannot kiss her, because the bond with her, it's all that: it's playing with all her senses, as much as possible, it's talking to her, touching her, being there, that she feels the love in our gestures" (m15). Being close also implied knowing how to touch one's baby without hurting him/ her.

A majority of fathers spontaneously reported that they agreed to carry their baby but preferred interaction by words and looks; few mentioned a physical need to carry her/him. A minority said they wanted to keep some physical distance from the baby, to keep from hurting him/ her: "Me, for the moment I film him, that's enough now (...). I have stiff hands, I'm afraid of hurting him, he's too little. It makes me happy to see my wife take care of him, for now, not me!" (f9). Most of the fathers also reported that they interacted with the baby to promote their wife's psychological well-being: "My wife is very happy that I do skin-to-skin because my father never took care of me, and she is really worried that I will be the same" (f5). Finally, breastfeeding was considered very important by fathers and breastfeeding mothers in feeling a bond with their child, but the mothers described the numerous problems in pumping their milk and their frustration about the delay between its collection and its administration to the baby.

The nurses' influence on early interactions and on parents' personal perception and presentation as the father/mother and the nurses' caring qualities toward the child and the parents: Most parents described themselves as dependent on the staff to care for their baby and therefore necessarily subject to its authority: "As we are in a place where everything is managed by others and we don't know, we have the impression that we have to ask for permission to touch him" (m17). Nearly all the parents reported that the caring and considerate conduct of the staff was primordial for the interactions they developed with their child. Both mothers and fathers reported that a gentle attitude

towards their child attenuated the strangeness of the intensive care unit: "There are extraordinary nurses, they talk all the time to the baby, 'my sweetheart, I'm going to do this for you.' I love it that she is in such good hands" (m13). Parents described their ability to have contact with the baby linked to the nurses' conduct, because it made the contact possible (or not) and pleasant (or not). Most parents reported a good relationship with the nurses, who anticipated their expectations and had a gentle attitude toward both parents and baby: "There are disparities between the nurses in terms of their characters and their ways of seeing things. Some are very affectionate with the babies, they give parents lots of information. It's great because it creates a human bond" (m5). A gentle attitude towards the child when providing care encouraged the parents to stay close. "The nurse who talks to my daughter and doesn't make brusque gestures... that makes us want to stay" (m5). A minority stressed more distant and colder nurses: "There are others, there's not much of a relationship. They wait for us to ask questions, and their answers are very terse" (m5). Some added that it felt appropriate to take moments of closeness to their child only when the nurse was kind enough to offer them. Some mothers reported feeling judged by the nurses: "I have the impression of being judged if I call too often...and if we don't come, I'm also afraid of being judged" (m8). They therefore behave differently than they would spontaneously. Globally, mothers described themselves as simultaneously dependent on and close to the nurses, while fathers commented more on the nurses' behavior towards their children and wives than towards themselves.

Communication: Communication with the caregivers appeared decisive for fathers and mothers in feeling a bond with their child. Communication included the content of information exchanged, but also the relationship that existed in those moments. Globally, the consistency of communication was always reported as essential. Throughout the stages from the prenatal period to the first weeks in the NICU, mothers and fathers described expectations that were often similar, and sometimes different. Some fathers reported that the staff spoke to them less than to the mother, which seemed normal or more rarely, frustrating in their role of father.

- In the prenatal period, an exchange with a neonatologist, mentioning the baby's approximate weight and height and a possible relationship with him, triggered the first perception of themselves as parents — father or mother: "The pediatrician told me that he knew how to take care of this baby and that opened a door to the future because two weeks before, the ultrasonographer had told me to separate myself from him" (m3). On the other hand, the existence of discordant information about the thresholds for resuscitating preterm babies was described as very upsetting: not knowing if the child would live or not prevented parents from perceiving themselves as such.
- In the delivery room, mothers reported that they had needed explicit communication words about the baby's health, to be reassured that he was really alive: "As soon as I woke up, I asked: He's not dead? He's not dead?' They told me right away that my son was alive" (m19). Seeing the child, even briefly, was also described as an occasion of feeling like a mother. The fathers talked about the delivery as a moment of intense stress with simultaneous worry for their child and their wife: "Paradoxically, I was more worried for my wife than for my daughter" (f14). Several reported not having been

able to feel close to their baby until they had been reassured about their wife's health: "Just after the birth, I went to see my baby with the pediatrician. My wife, I was thinking of my wife. It was hard for the baby but I saw him without really appreciating it" (f18).

- After the delivery, many mothers reported having had to wait a day or two before being authorized to see their baby, for health reasons. The photograph of the baby and the NICU caregivers' visit to the mother's room were the two factors described as very useful for feeling closer to the child in these cases. Almost all the parents reported having received a photograph in the first hours after birth and they appreciated it: "It was good to have this picture. I had two feelings...I was glad and sad at the same time...sad because she was premature" (m9). The fathers saw it especially as helpful for their wife, and indirectly for themselves: "I would have liked my wife to have had a picture from the beginning because for the mothers who cannot see their babies, it's the best solution. She's the mother, she needs to see her baby. I reassured her as much as I could" (f11). They also mentioned the photograph as the evidence of a humane attitude by the caregivers: "I thought that was nice, it showed the mind-set of the nurses; I understood then that they didn't care only about the medical care but also about the attachment between parents and child" (f2). The quality of the photograph had to be good, otherwise it would reinforce the harshness of the preterm birth. Several parents described their poor experience with caregivers who promised a photograph that they finally never gave: this unkept pledge reinforced the absence for mothers and created a feeling of impotence in fathers: "I was a little disappointed because a midwife had told me a photo would be taken, and that never happened. I think that would have helped me, if it had been printed right away" (m4). Both parents also reported the supportive value of a visit by the pediatrician or the nurse to the mother's room, telling them about the baby's health. Some mothers saw it as the occasion of their first meeting with the NICU team: "For 3 days I wasn't able to see my daughter. The doctors came to see me and the nurse also. I found that encouraging: I was very glad to get news about her. The information was clear; they told me that she is small but doing well. She has a catheter, and a feeding tube for eating. Otherwise, we know she's alive, but we don't know how she's doing, it's just total darkness. Their coming cheers me up, and that night I slept well. Saving to myself that she's doing well" (m11). On the other hand, the absence of such visits was described by many mothers as a source of isolation and stress and an obstacle to their self-representation as mothers. Many mothers said that they were frustrated to have to rely on the child's father for new information: "It would have been good if someone from the team had come down to see me, because my husband is not a physician. If the NICU nurse had come and said to me, "I'm the one who saw her first, I did this to her. Had she come for two minutes, that would have reassured me still more because they are the ones caring for my baby" (m5).
- Most mothers and fathers needed a caregiver to receive them for the first visit to the NICU, perceived as very stressful: "You come into this grim place; you need someone to say to you, 'you'll see, it's a little strange, a little dark, but that's normal,' because at the beginning, what's dark, is death" (m28). The fathers accompanied their child from the delivery room but frequently described an anxious wait at the ward entrance: "I would have liked it, when I arrived in the unit, for someone

to come out and say to me, 'Your daughter is in good hands, we are going to take care of her,' just to reassure me that everything was all right. And then I would have had some news for my wife; I didn't have that" (f23). Many mothers mentioned their difficulties in reporting what had been said at their first visit, but the attention of the caregiver, perceived by her presence and words, had reassured them: "I don't remember very well what the nurse said to me, but I know she said, don't worry if that goes off. I admit, I've forgotten a lot, it was a very particular moment" (m22). They mentioned that it had been important to them that the nurse introduced herself by her first name — "Tm X, and I'm taking care of your baby" — with a pleasant attitude. Fathers, on the other hand, remembered the information quite clearly.

• In the first weeks in the NICU, access to regular explanations helped most of the parents to limit their feelings of helplessness and to be able to come see the baby day after day. To be at ease with their child, the parents reported that they needed to understand the environment: "The more I know, the more I am reassured. What I want to know are the upper and lower limits, because I watch the monitor and I have the impression I understand" (f23). The mothers saw a need to be reassured when they were holding their child: "At the beginning of skin-to-skin, I didn't really know what was going on: when it rings, for us, that's disastrous, so if you don't see someone come, you say to yourself, but what's going on? In fact, there are alarms that are not so serious, but they hadn't told me, so it would be good if they said at the beginning what it means" (m11).

The mothers said more frequently than the fathers that they needed explanations of the baby's relational capacities and on the meaning of their reactions, to help them: "It's important to understand her reactions, when she cries or seems nervous. If I don't manage to calm her, I feel like a bad mother who does not understand her child. It's important to understand and also to know what to do next" (m15). Fathers and mothers both insisted on the need to warn them of changes such as intubation, changing the room, or placing a catheter: "I arrive, there are 3 physicians in the room, a blue sheet over my baby. And there, I panic! The doctors say to me, 'You can't come in.' I say to myself, they've put this sheet so that I can't see...They're taking her to the morgue. Fortunately, there was someone who saw that I was stunned and explained to me: 'They're changing the catheter'" (m30). Any situation that was unexpected or not understood created a feeling of panic and kept them from spending peaceful time with the baby. They also described their need to not be kept waiting about exam results, such as ultrasound: "If there is no problem with the examinations, the doctors don't come to tell you the results. (...) If they tell us the results right away, whether they are good or bad, we know them and we can start to enjoy the child" (m18).

Some mothers described a feeling of moving backwards in their bond with the baby when his condition grew worse: "What is a little frustrating in the relationship, it's that I had the impression that there was more interaction at the beginning than now, because she has an infection so she isn't very responsive, while before, she took my hand. I arrive, she is grumpy, she cries, so I don't know if it's something to do with me...so I say to myself, "Oh! I'm not going to come anymore" (m13). The telephone was described as a way of staying linked to the baby from home. Most parents reported feeling reassured by ritualized calls morning and evening: "It's very good to have news by telephone...it takes 15 seconds but afterwards, you feel so much better...then pffff! I pump my milk and I fill the bottle" (m7). Some described calls more worrisome than reassuring, in cases where the phone rang repeatedly with no answer, and stressed the importance of always giving news, even succinctly. Most parents preferred to go home at night rather than stay in a room at the hospital, because it helped them to regain their bearings.

The caregivers' actions reported by parents as useful for early bonding with their preterm newborn are listed in Table 2.

Discussion

The objective of this study was to explore in detail how preterm neonates' fathers and mothers describe the early bond with their child in the first weeks of life and to identify the steps caregivers can take to meet parents' expectations. Globally, fathers and mothers described interactions with their child as important steps in starting to feel a bond with him/her. Fathers did not interact with their baby in the same way as mothers, and they described different expectations towards the staff. Both parents however expressed the need for communication with caregivers before birth, at delivery, and in the NICU.

Our study found that receiving explanations about the baby's health status, how the NICU and its equipment operate, and warning about changes were very important for parents to be able to spend feel at ease and thus able to bond with their newborn. Parents made it quite clear that fear of death and anxiety impeded their ability to interact with the baby. Other studies with parents have described periods of panic, depression or joy according to the baby's health status.^{13,29} Parents need reassurance to concentrate on their baby and professional assistance to interact with him/her with a sense of security.

Parents reported that explanations of the baby's sensory and relational capacities and of possible helpful activities were essential for meeting their child and for feeling that they were indeed the baby's parents. This is in agreement with other studies, which highlighted the difficulty in interpreting premature newborns' reactions,² described parents' subsequent feelings of incompetence in caring for them,³⁰ and the importance of information about the infants' reactions, to combat this negative parental feeling.³¹

An important finding of our study is that parents expect these explanations to be transmitted through a caring, humane attitude of exchanges with them, rather than as technical knowledge. This was suggested by Lupton and Fenwick's finding that "chatting" was important to establish family centered care in the NICU.^{23,32} Watching caregivers who address the child with gentleness also helps parents move closer toward the baby they perceive as a tiny and fragile being. Our study suggests that the caregivers' consideration reinforces the fathers and mothers in their role and promotes the emergence of a feeling of being useful, good and irreplaceable for the child. This expertise approaches the concept of family centered care:³³ taking good care of the child is taking good care of the mother, and vice versa.

Our study also observed that fathers interact with their baby differently than mothers do, sometimes staying off to the side: for fathers, the relationship with their baby appeared less based on physical contact. The relationship is also marked by the need to understand machines and treatments, perhaps, as previously reported for fathers,³⁴ to feel some control over the situation. In the first weeks, the mothers' self-esteem and capacity to interact with their baby were rooted in their relationship with the nurses; the nurses' conduct could compensate for, or on the contrary feed into, a feeling of poor self-esteem. Fathers did not feel as dependent on nurses and intervened very little between their wives and the nurses. Mothers conserved especially a memory of the emotions perceived at the time of the communication and found it more difficult than fathers to remember the content of information transmitted.¹⁵ Finally, many fathers also interacted with their child in part as support and reassurance for the mother. The fathers in our study also found it stressful to be unable to be with their partner and their infant; this concern was not mentioned by men in another study.^{15,35}

Our study did not show differences in the parents' expectations according to either their social and demographic characteristics or the child's clinical data. It is possible that needs become more homogeneous in this extreme situation — parenthood in the NICU.¹³

An important strength of our study is the equal proportion of fathers and mothers, quite rare in the literature,¹⁶ which makes it possible to compare the needs of each group. Another strength is the representation of parents of non-European origin, who account for approximately half the participants; even if their French language skills indicate a degree of integration into French society, their participation and viewpoints add cultural perspectives often missing from this type of qualitative study.

Our study also has limitations: First, the timing of the interviews, at between 14 and 35 days of hospitalization, made it possible to direct messages to caregivers more specifically but might also explain that parents describe few attitudes of active parenting, a capacity that develops over time.^{11,15,29} Secondly, only a few negative aspects of the child's care were reported in our study, possibly because parents felt less free to criticize because their child was still in the institution,³⁶ even though the interviewer was independent. Thirdly, clinical characteristics of the participants' children limit the generalizability of our results to families with fairly normal development patterns in the first month; parents of children with life-threatening complications might have different specific needs. Finally, the study took place in a limited geographic zone, and its results might not be transposable to other settings.

The qualitative method allows us to accede to the parents' point of view, and may thus provide information that goes beyond caregivers' stereotypes of parents and increase the former's empathy for the latter. One objective of NICU caregivers is to allow parents to become progressively more autonomous. Help in creating early interactions with the child and attributing value to the parents' role are essential prerequisites to this increasing autonomy. All caregivers can improve their professionalism by learning the concrete actions that can help to repair the psychological injuries to parents due to the delivery of a preterm baby.³⁷

Future research might concern the longitudinal experience of a sample of parents, at different times as they parent their premature child.

Conclusions

Nurses' caring attitudes and caregivers' regular communications, adapted to needs at different times, help parents to interact and create a bond with their premature neonate. These results might enable NICU staff to provide better support to parents.

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The Use of Ciprofloxacin and Fluconazole in Italian Neonatal Intensive Care Units: a nationwide survey

Chiara Pandolfini, Sequi Marco, Manzoni Paolo and Bonati Maurizio

Abstract

Background: Treatment and prophylaxis of sepsis in very low birth weight neonates is a matter of concern and research is being undertaken with the aim to give rise to shared approaches based on solid evidence. As part of a European initiative, a survey was set up to describe the use of two drugs in this area. The Italian national practices concerning neonatal sepsis, as well as calls for related guidance, are described.

Methods: A standardized and previously tested questionnaire was submitted online to all Italian level III NICUs. A 5-point Likert scale was used to analyze attitudinal replies. Categorical variables were compared by χ^2 analysis and 2-tailed P-values are reported.

Results: Data was provided by 38 Italian NICUs (36% of the country's level III centers), 53% of which have 1–10 cases of bacterial sepsis monthly and 90% a prevalence of <1% fungal infections. Ciprofloxacin and fluconazole treatment for neonatal sepsis are scantly used in Italian NICUs (13% and 45%, respectively). Major concerns are related to the safety of ciprofloxacin and the efficacy of fluconazole. On the contrary, prophylaxis of fungal infections is a routine approach in many Italian NICUs. The use of both ciprofloxacin and fluconazole is characterized by a large inter-NICU variability in dose and scheme of use. The lack of adequate, shared evidence is a common consideration made by the survey participants.

Conclusions: Common approaches are needed to standardize and update a national drug strategy for the prevention and treatment of sepsis in very low birth weight newborns. This can be achieved through collaborative initiatives aimed at setting up guidelines, based on available data, and multicenter trials to produce new evidence that will address the knowledge gaps.

Background

Sepsis in neonates can be caused by bacterial or fungal microorganisms and is associated with significant morbidity

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Studies have assessed the use prophylactic measures to prevent infections, but data on treatment and prophylaxis is lacking.¹⁻³ Empirical antibiotic therapy is often used in NICUs,⁴ although it can lead to unnecessary exposure to antibiotics, can increase the risk of neonatal death, and can cause selective pressure for antibiotic resistance, making it fundamental to employ only the best possible options and only when necessary.⁵⁻⁹ Efficacy data on antifungals in the treatment of invasive fungal infections in preterm infants is lacking and more data on their use in the prevention of such infections are needed as well,^{10,11} although partial guidelines do exist.¹²⁻¹⁴

Italy has been playing a lead role in the investigation of neonatal infections, also as a result of the activities of a collaborative network, the GSIN (Gruppo di Studio delle Infezioni Neonatali), specifically dedicated to performing studies in this area.¹⁵⁻¹⁷

A European project called Treat Infections in Neonates (TINN), coordinated by the French National Institute for Health and Medical Research in France and the University of Nottingham in the UK, with the aim to evaluate the safety and efficacy of ciprofloxacin and fluconazole in pre-term and term neonates, is currently running.¹⁸ The project involves partners in 7 countries and is supported by the European Commission. Ciprofloxacin and fluconazole are being studied because they are present in the European Medicines Agency's priority list of therapeutic areas that need specific drug evaluation in preterm and term neonates.¹⁹ As part of the TINN project, a European survey on the use of ciprofloxacin for treatment, and fluconazole for treatment and prophylaxis, of invasive infections in neonates was carried out.^{20,21} The main objective was to describe the current use of the two drugs in NICUs in order to better orient the efforts of the entire TINN project towards the creation of necessary knowledge on the optimal use of these drugs.

Of all European NICUs that participated in the survey, Italy was the most represented country, both in terms of number of NICUs and homogeneity of their profile (all level III units). In the present paper, we focus on the Italian findings of the survey in order to describe the national practices concerning neonatal sepsis.

Methods

All Italian level III NICUs were contacted via email between

December 2009 and May 2010 with both a letter of invitation to participate in the survey and a commitment to provide all participants with a report of the survey's results.

A questionnaire collecting information on the characteristics of each unit, its use of ciprofloxacin and fluconazole, and its involvement in clinical research was created by the TINN partners, based in part on a US survey.²² The survey was tested by a group of partners, and an online version for input was set up and sent to each Italian NICU.

A number of questions assessing the factors that influence the NICU's policies regarding ciprofloxacin and fluconazole were included, and an additional email requesting missing data was sent in June 2010 to NICUs who had almost completed all the questions necessary for their records to be considered in the analysis.

Statistical analysis: A methodology similar to that employed in the US survey by Burwell²² was used in order to enhance comparison of the respective results. Another, more recent study from UK and Ireland also used a similar questionnaire, but it was administered to individual physicians so data does not refer to individual intensive care units.²³ The answers to the questions included in the questionnaire were measured on a 5-point Likert scale (1: least important, 5: most important). The mean and 95% confidence intervals were calculated for the 5-point Likert scale responses. Since most of the means were between 3 and 4, the responses were dichotomized and those ≥ 4 were categorized as important and those ≤ 3 as less important. Respondents were grouped into those who used ciprofloxacin and those who did not, and those who used fluconazole and those who did not. Categorical variables were compared by 2 analysis and P values are 2-tailed. The survey data collected was managed using Microsoft Access and analyzed using SAS (Vers 9.13, SAS Institute, Inc Cary, NC).

Results

Data were obtained from 38 Italian NICUs, 36% (38/105) of the country's level III centers. Over half (53%) the NICUs have 1–10 cases of bacterial sepsis monthly, while 42% have less than 1. The reported prevalence of fungal infections is <1% in 50% of the NICUs and is $\leq 5\%$ in 90%.

In terms of geographical distribution, almost half (47%) of the NICUs that participated are located in northern Italy, while 19% are in central and 34% in southern Italy. The proportion of participating NICUs compared to the number of NICUs present in each of the three geographical areas is similar; no statistically significant difference was found (p=0.36). The data would therefore seem to be representative of the regional distribution of NICUs.

Most of the NICUs (71%) have a standard written protocol on antibiotic treatment in case of suspected bacterial sepsis, 82% have one on routine antifungal prophylaxis, and 70% have one on antifungal treatment. 47% of NICUs have protocols covering all three conditions.

Ciprofloxacin treatment: Only 5 NICUs (13%) ever use ciprofloxacin. The indications for initiating treatment vary between NICUs [Table 1]. All 5 administer the drug intravenously, but at different dosages: three administer an average dose of 20 mg/kg/day (at 12 hour intervals), while the other two administer 10 mg/kg/day (one at 8 hour intervals and the other at 12). Concerning the average duration of treatment, only one center replied, reporting 10 days.

Among the factors influencing the decision to use ciprofloxacin or not, the two ranked most important were uncertainty about the safety of the drug and the fact that ciprofloxacin should be reserved for infections with multi-drug resistant micro-organisms (average rating of each factor, from 1 to 5: 4,2). When NICUs using ciprofloxacin were compared with those not using it, the numbers were unbalanced, but they seemed to show no significant difference in importance attributed to the listed factors.

No guidelines on the use of ciprofloxacin for sepsis were found. The British national Formulary for Children (BNF-C)²⁴ recommends the use of other agents in treating neonatal bacteremia and mentions that ciprofloxacin is used in cases of septicemia caused by multi-resistant organisms, but does not address the drug directly.

Fluconazole prophylaxis: Overall, 30 NICUs (79%) declare using fluconazole for prophylaxis. No significant correlation was found between use of fluconazole prophylaxis and prevalence of fungal infections in the NICUs (Fisher's exact test P-value 1.0000).

In the centers that use fluconazole for prophylaxis, birth weight is an important variable guiding the decision to employ prophylaxis for 90% of them. Of these centers, 48% use <1500 g as a cutoff, 48% use <1000 g, and the remaining NICU uses <750 g as cutoff. There was wide variation in the indications for initiating prophylaxis between NICUs [Table 1].

Differences were found between the 30 NICUs in the dosage schemes used as well. The majority (76%) administer an average dose of 3 mg/kg, while the rest administer 6 mg/kg. Of those who use 3 mg/kg, a little more than 50% administer it every 72 hours, 36% every 48 hours. Of the 7 centers who use 6 mg/ kg, 4 administer it every 72 hours and the rest every 48, 24, or "other" hours (1 each). Most NICUs (89%) administer the drug intravenously, while the rest administer it orally.

Concerning the duration and withdrawal of prophylaxis, almost half (47%) reported having a fixed average duration of prophylaxis, which ranged from 10 to 45 days (median 30). Few centers reported using corrected gestational age or target weight reached as parameters (2 and 1 NICUs, respectively), while 12 (40%) reported unavailability of an IV route as a criterium. In cases of confirmed fungal infection in neonates receiving prophylactic fluconazole, 14 (47%) of the NICUs report using liposomal amphotericin B, 2 report amphotericine, 4 fluconazole at increased, therapeutic dosages, 2 flucytosine, and 1 caspofungin (in cases of resistance).

NICUs who did not use fluconazole prophylaxis were significantly more likely to be concerned about the existing uncertainty regarding the drug's safety in newborns (p<0.01). The need for a statement by pediatric societies in support of the routine use of fluconazole for prophylaxis and the need for additional efficacy studies were also considered important factors (average importance, from 1 to 5: 3.5 and 3.3, respectively) [See Additional file 1 for data].

Fluconazole treatment: Almost half (17) of NICUs administer

Table 1 Indications for initiation of treatment or prophylaxis with the two drugs

Ciprofloxacin treatment (5 NICUs)	N. NICUS
First line therapy (even in association) of:	
Culture-proven sepsis due to multi-drug resistant organisms that are sensitive to ciprofloxacin	5 (100%)
Sepsis resulting from a suspected multi-drug resistant strain infection	1
Sepsis resistant to first line empirical antibiotic therapy (other than ciprofloxacin)	1
Severe sepsis resistant to first line empirical antibiotic therapy (other than ciprofloxacin)	1
Fluconazole prophylaxis (30 NICUs)	
Birth gestational age	21 (70%)
<26 weeks	2
<28 weeks	10
<30 weeks	7
other	2
Birth weight	27 (90%)
<750 g	1
<1000g	13
<1500	13
Neonate receiving antibiotics for a certain number of days	14 (47%)
>2 days	6
>7 days	5
>14 days	3
Presence of a central venous catheter (CVC)	22 (73%)
Peripherally inserted CVC	18
Umbilical venous CVC	15
Only CVC used >7 days	7
Only CVC used >14 days	1
Surgically inserted CVC	5
Endotracheal intubation	10 (33%)
Only if intubated >7 days	8
Only if intubated >14 days	0
Total parenteral nutrition (TPN)	14 (47%)
Only if TPN used >7 days	11
Only if TPN used >14 days	1
Abdominal surgery	12 (40%)
Abdominal disease	7 (23%)
Necrotizina enterocolitis	4
Focal bowel perforation	3
Gastroschisis	1
Omphalocele	0
Antibiotics being used	5 (17%)
Only if s7 days	5
Only if >14 days	0
Colonization status	11 (37%)
Scheduled surveillance cultures±/_ other cultures	7
Determined by clinical features	, Л
Eluconazolo treatment (17 NICLIC)	т
Sensis with identification of Candida spp. in cultures of central samples (blood, cerebrospinal fluid,)	15 (2204)
Sensis with documented fundal colonization	15 (00%)
Sensis resistant to first line empirical antihiotic therapy	7 (/104)
	1 (60%)
Jevere Jepsis	1 (070)

fluconazole for treatment. Of the centers with a protocol (26/38), over half (56%) don't use fluconazole. Overall, 12 NICUs use fluconazole for both prophylaxis and treatment. Most of the NICUs (15/17) use fluconazole in cases of neonatal sepsis with identification of Candida spp in cultures of central samples, although there was some variation in indications for starting treatment also for fluconazole [Table 1].

Fluconazole treatment schemes between NICUs were also found to vary. Dosages ranged from 3 to 12 mg/kg/ daily, considering the different average single doses and the intervals applied between administrations. Most of the NICUs (15/17) administer fluconazole intravenously. The average duration of treatment ranges from 10 to 30 days. The current first line antifungal, other than fluconazole, used in NICUs is liposomal amphotericin B in 8 centers and amphotericin B in 2.

Current guidelines¹³ on treatment of neonatal candidiasis recommend amphotericin B or, as a reasonable alternative, fluconazole at a dosage of 12 mg/kg daily for 3 weeks. Of the 17 NICUS that use fluconazole, 5 administer it at the recommended dosage, and for more or less the recommended length of therapy (3 administer it for 3 weeks, 1 for 28 days, and 1 for 15–21 days). All the rest administer lower dosages, either because of a lower unit dose or because the same dose is given less frequently. When transformed into daily doses: 9 NICUs give 6 mg/kg/day, 1 gives 4 mg/kg/day, 1 gives 3 mg/kg/ day, and 1 does not specify frequency.

The factors potentially influencing the NICUs' choice to use fluconazole for treatment were not considered very important by the NICUs. In fact, the highest average importance attributed was 3.3 and concerned two factors: the need for a statement by pediatric societies supporting the selection of the drug and the need for additional efficacy studies. No significant differences were found in the importance given to the different factors by NICUs who use the drug and those who don't.

Discussion

Although all Italian level III NICUs were invited to join the survey, it is likely that those that participated are more active in research and/or are more interested in self-audit and improvement of a unanimously acknowledged clinical care. Nevertheless, a third of all the Italian NICUs participated and represent the north, center, and south of Italy. Besides the geographic distribution, the estimated rate of admission of newborns <32 weeks' gestational age in participating NICUs (0.85%) is close to that reported in Italy (0.9%)²⁵ and also supports the representativeness of collected data at the national level. The wide variation in dosages used does not seem to depend on area of the country and, in any case, highlights the need for national, or better international, shared guidelines incorporating current knowledge on the treatment of neonatal sepsis.

Ciprofloxacin treatment: Almost three quarters of Italian NICUs have a standard written protocol regarding antibiotic treatment for suspected sepsis, and very few use ciprofloxacin. The Italian data was in line with European data²⁰ in terms of limited use of ciprofloxacin and concern about bacterial resistance and drug safety. Concern about antibiotic resistance, however, was not enough to dissuade centers from using the drug. The ciprofloxacin dosages used varied, but the NICUs using this drug were few so no conclusions can be made.

Fluconazole use: Fluconazole prophylaxis has been found to reduce the incidence of invasive fungal infection in VLBW infants, and recent data on long-term outcomes and antifungal resistance seem positive so far.^{26,27} This study's data show that, in Italy, a majority of NICUs (79%) use fluconazole prophylaxis, a rate much higher than that found in all the European NICUs participating in the survey²⁰ and in the UK/Ireland and US studies.^{22,23} Rates of prophylaxis in different studies may be based on incidence, but rates in infants at the lower gestational ages are high in all studies. No correlation was found between reported prevalence of fungal infections in the NICUs and their choice to use fluconazole prophylaxis. The reported incidence in the survey fits within the range reported by other studies,²⁸ although methodologies in data collection differ and direct comparison with incidence data is not possible. Incidence rates of fungal infection differ between studies, from 2,6 to 9%.^{29,30} A large part of the variation in rates is due to the number of extremely low birth weight infants admitted at each NICU,31,32 but may also reflect differences in clinical practices.33

There was variation between the centers concerning the indications for initiating fluconazole prophylaxis, but birth weight, presence of a central venous catheter, and gestational age were considered the most important and these data are similar to those found by Burwell et al.²² The guidelines addressing prophylaxis^{12,13} only take into account birth weight and rate of disease in hospital units as the factors on which to base prophylaxis initiation, while other factors should also be considered.³⁴ Guidelines use birth weight as an indicator, for example, but gestational age has a more linear relationship with invasive candida infection.35 Furthermore, the guidelines should be updated to reflect the finding that fluconazole prophylaxis can reduce incidence even in NICUs with a low rate of invasive candida infection.³⁴ It has been shown that implementing a guideline that includes specific criteria for identifying high-risk VLBW infants reduced invasive fungal sepsis rates without evidence of fluconazole resistance emerging.³⁶ The possibility of resistance emerging, as well as insufficient safety data, make the creation of standard, more accurate guidelines identifying newborns at the highest risk of acquiring fungal infection, and therefore candidates for prophylaxis, a high priority.

The main guidelines on candidiasis¹³ suggest considering fluconazole prophylaxis in neonates with birth weights <1000 g, and at a dosage of 3 mg/kg iv every 72 hours for the first 2 weeks of life, every 48 hours during the third and fourth weeks, and daily in the fifth and sixth weeks of life. The other cited guidelines¹⁴ offer limited information on prophylaxis, but the initial dose is similar. Dosage data from the NICUs refers to a single dose only, so a comparison with the dosage change over time, as specified in the main guidelines, is not possible, however, 38% of the NICUs report using the same dosage and route as the guidelines, i.e. 3 mg/kg every 72 hours intravenously. Only one center followed the guidelines completely, considering also duration of prophylaxis. The US survey did not assess dose, and data from the UK/Ireland study, which is not directly comparable because it involved individual physicians, had almost half the responses reporting the use of 3 mg/kg and almost onefourth 6 mg/kg, compared to three fourths using the lower dose in the Italian data. Studies have been performed to test less intensive dose regimens, including twice weekly dosing,17,37 and their results were encouraging, but additional trials are needed to identify the most appropriate dosing regimen.¹⁰

Significant concern about safety in using fluconazole for prophylaxis resulted from the data. This differs from the US data,²² which revealed concern especially about resistance, and the UK/Ireland data,23 which emphasized the importance or the perceived level of invasive candidiasis in the unit. Even when compared with the data from all the European NICUs surveyed.²⁰ showing that those that don't use prophylaxis were more likely to be concerned about both resistance and the lack of a statement by pediatric societies promoting routine use in a subset of newborns, concerns seem to differ. To reduce the possibility of resistance in cases of fungal infection in infants following fluconazole prophylaxis, treatment with a different antifungal than fluconazole should be initiated.³⁴ Only 19/30 of the NICUs reported using a drug other than fluconazole in cases of confirmed fungal infection in patients under fluconazole prophylaxis. The guidelines should address this issue specifically.

Half of the NICUs use fluconazole for treatment of fungal sepsis, and only about one third follow the guideline recommendations on dosage, while the rest use lower dosages. Concerning the indications for starting treatment with fluconazole, the majority of NICUs that use the drug follow the guidelines in that they initiate treatment when sterile body fluids test positive for Candida spp. There did not seem to be general concern over safety, but some interest was expressed for both the need for an official statement supporting the choice of fluconazole and for more efficacy studies. These, however, did not seem to be valid indicators in the choice to not use the drug. The emerging picture concerning fluconazole treatment is that there is a need for more guidance for clinicians, through greater acknowledgement of the existing guidelines and acquisition of additional data on the drug.

One of the major limits of this study was the sample size. The Italian data originated from 38 NICUs and this limited data comparison.

Researchers in Italy have attempted to prioritize shared information on the care of extremely low birth weight babies,^{38,39} but the situation needs further developments. The collection of data on rates of infection by a centralized, international public body would permit transparency and homogeneous, accurate data on incidence, and this would, in turn, motivate centers to implement the most effective, evidence based practices.

The TINN project has already begun to improve the availability of information on fluconazole and ciprofloxacin, as also documented in published articles,^{20,40,41} and will provide additional clinical evidence in the early future.

Conclusions

This national survey confirms the existence of very different approaches between NICUs towards the prevention and management of neonatal sepsis. The heterogeneity of the dosage schemes clearly demonstrates the lack of solid, acknowledged guidance, and probable lack of awareness of existing guidance.

The lack of hard evidence leads to different approaches and to the request for indications by third parties (ie scientific societies).

Common approaches are needed to standardize and update a national drug strategy for the prevention and treatment of sepsis in very low birth weight newborns. This can be achieved through collaborative initiatives aimed at setting up guidelines based on available data. The survey described in this article was a first step in acquiring data to stress the need for guidelines, to orient their contents towards the areas in greatest need of information, and to support neonatal societies in their creation. Formal international consensus statements, such as those that will be produced by the TINN network, will contribute to a more homogeneous and rational approach to neonatal sepsis prophylaxis and treatment in NICUs worldwide.

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specifications for all testing conditions. We recommend operating the gas flow >5 L/min and frequently observing airway pressure measurements during resuscitation.

Testing Condition (changes from baseline)	f (rate/min)	I-time (sec)	Insp V _T (mL)	PIP (cm H ₂ O)	PEEP (cm H ₂ O)
Baseline*	40.09 (.60)	.65 (.10)	40.54 (3.16)	21.04 (1.50)	5.37 (1.01)
Flow decreased to 5 L/min	40.36 (.38)	.79 (.34)	30.08 (7.32)	17.13 (4.58)	4.54 (1.51)
Flow increased to 15 L/min	39.29 (.26)	.60 (.16)	41.53 (.73)	21.02 (.39)	5.12 (.82)
PIP decreased to 10 cm H ₂ O	41.26 (2.5)	.67 (.09)	18.19 (5.85)	11.79 (2.13)	4.8 (.28)
PIP increased to 40 cm H ₂ O	39.89 (1.3)	0.9 (.12)	86.88 (7.5)	41.21 (.62)	7.41 (1.86)
f decreased to 20/min	20.33 (.47)	1.01 (.13)	43.74 (1.08)	21.30 (.66)	4.89 (1.02)
f increased to 60/min	60.18 (.46)	.51 (.17)	30.51 (1.72)	20.09 (1.86)	6.81 (1.66)
Flow lowered to 5 L/min PEEP lowered to 2 cm H ₂ O	39.69 (.90)	.98 (.12)	36.90 (.53)	18.80 (1.0)	3.59 (.51)
Flow lowered to 8 L/min PEEP increased to 6 cm H ₂ O	38.56 (3.36)	.85 (.37)	35.99 (4.76)	20.41 (1.85)	6.31 (.79)
PEEP increased to 9 cm H ₂ O	40.09 (.23)	.71 (.19)	34.29 (4.02)	21.68 (1.87)	8.15 (.58)
Flow increased to 15 L/min PEEP increased to 15 cm H ₂ O	41.23 (2.38)	.62 (.13)	22.44 (4.14)	22.28 (3.76)	13.65 (2.09)

All values reported as mean (SD)

*Baseline: f 40/min, flow 10 L/min, PIP 20 cm H₂O, PEEP 5 cm H₂O

f, ventilatory rate/min; I-time, inspiratory time; Insp V_{T} , inspiratory tidal volume; PIP, peak inspiratory pressure; PEEP, positive end expiratory pressure

Unexpected: An interpretive description of parental traumas associated with preterm birth

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Abstract

Background: Preterm birth (PTB) places a considerable emotional, psychological, and financial burden on parents, families, health care resources, and society as a whole. Efforts to estimate these costs have typically considered the direct medical costs of the initial hospital and outpatient follow-up care but have not considered non-financial costs associated with PTB such as adverse psychosocial and emotional effects, family disruption, strain on relationships, alterations in self-esteem, and deterioration in physical and mental health. The aim of this inquiry is to understand parents' experience of PTB to inform the design of subsequent studies of the direct and indirect cost of PTB. The study highlights the traumatic nature of having a child born preterm and discusses implications for clinical care and further research.

Method: Through interviews and focus groups, this interpretive descriptive study explored parents' experiences of PTB. The interviews were audiotaped, transcribed, and analyzed for themes. Analysis was ongoing throughout the study and in subsequent interviews, parents were asked to reflect and elaborate on the emerging themes as they were identified.

Results: PTB is a traumatic event that shattered parents' taken-for-granted expectations of parenthood. For parents in our study, the trauma they experienced was not related to infant characteristics (eg, gestational age, birth weight, Apgar scores, or length of stay in the NICU), but rather to prolonged uncertainty, lack of agency, disruptions in meaning systems, and alterations in parental role expectations. Our findings help to

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explain why things like breast feeding, kangaroo care, and family centered practices are so meaningful to parents in the NICU. As well as helping to (re)construct their role as parents, these activities afford parents a sense of agency, thereby moderating their own helplessness.

Conclusion: These findings underscore the traumatic nature and resultant psychological distress related to PTB. Obstetrical and neonatal healthcare providers need to be educated about the symptoms of Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD) to better understand and support parents' efforts to adapt and to make appropriate referrals if problems develop. Longitudinal economic studies must consider the psychosocial implications of PTB to in order to determine the total related costs.

Background

The birth of a new baby is an exciting and joyful time for most families. The awesome responsibility of caring for a tiny and helpless being can also make it a time of uncertainty and worry. Very quickly after their baby is born, watchful parents become exquisitely attuned to their child's preferences, personality, and daily rhythms. Small changes in bodily functions or routine can become a big concern, even in healthy infants. Why won't she eat? Why is he always hungry? She never naps! I can hardly even wake him up even to eat! What does it mean when ...Is it normal to...? This stress and uncertainty is amplified when a baby is born preterm.

A preterm baby is one born before 37 weeks gestation. More specifically, infants born before 28 weeks gestation are considered extremely preterm; those born 28 to <32 weeks gestation are very preterm; and moderate to late preterm infants are born 32 to <37 weeks gestation. Despite advances in health care, preterm birth (PTB) is the leading cause of infant mortality, pediatric morbidity, and long-term disability.¹ In 2010, an estimated 15 million babies around the globe (>1 in 10) were born prematurely.² More than 1 million of these babies died as a direct result of their prematurity, making PTB the second-leading cause of death among preschoolers.3 Although the causes of PTB are not fully understood, the short-term and long-term outcomes are well-documented in the medical literature. Preterm infants are at increased risk for a range of adverse outcomes, including retinopathy of prematurity,⁴ respiratory distress syndrome and bronchopulmonary dysplasia,⁵ brain injury,⁶ necrotizing enterocolitis,7 and, neonatal sepsis.8 Long-term sequelae include the risk for motor and sensory impairment, learning problems

and neurocognitive impairment, and behavioral problems.⁹⁻¹⁴ PTB and low birth weight are also associated with lifelong chronic conditions such as dyslipidemia and hypertension.^{15,16}

Although there have been many advancements in neonatology, technologies and treatment, the incidence of acute and chronic sequelae of PTB have not decreased.¹⁷⁻¹⁹ These trends result in rapidly rising health care expenditures and place significant emotional and financial burdens on families, finite health care resources, and society as a whole.^{20,21} Newburn-Cook and her colleagues found the direct medical costs of the initial hospital stay for singleton preterm births to be \$20 million (CAD).²² The same authors also reported that the costs per infant for the initial hospital admission and the direct medical costs for the first seven years of an infant's life are inversely associated with gestational age. A limitation of the study was its inability to measure the indirect costs associated with PTB such as adverse psychosocial and emotional effects, family disruption, strain on relationships, alterations in self-esteem, deterioration in general health, mental health, and domestic violence.^{23,24} To rectify this, the 2007 Alberta Consensus Conference on How to Prevent Preterm Birth called for "...research on the economic impact of preterm birth that includes a more comprehensive analysis of both direct and indirect medical costs...to better evaluate the cost-effectiveness of new policies or interventions"²² With this in mind, the aim of this inquiry is to understand parents' experience of PTB to inform the design of subsequent studies of the total direct and indirect cost of PTB. This article highlights the traumatic nature of having a child born preterm and discusses implications for clinical care and further research.

Methods

We employed interpretive description (ID) to inform an understanding of parents' experience of PTB. Developed by Thorne and colleagues²⁵⁻²⁷ as a way to generate clinically relevant knowledge for health disciplines, ID is a qualitative methodology guided by the ontological and epistemological traditions of human science research.²⁸ Like other interpretive methodologies, ID rejects the notion of a single, immutable reality that is wholly accessible through empirical methods. Rather, it assumes the existence of multiple realities, which are context-bound, experientially based, and intersubjectively constructed through social interaction.^{29,30}

As a human science research method, ID represents a blending of hermeneutic practices with qualitative empirical methods. Through hermeneutic practices, researchers aim to describe and interpret the lived world as experienced in everyday situations and relationships. The focus is on the immediacy of human experience in order to produce qualitative portrayals of a particular phenomenon or event-in this case the parental experience of having and caring for a preterm infant. A central feature of hermeneutic practice is the use of qualitative empirical methods to gather lived experience descriptions, from which underlying patterns and structures are drawn. ID acknowledges the experiential, theoretical, and practical knowledge that researchers and participants bring to a project. Knowledge development is viewed as a continuous, inductive process of (re) negotiating shared understandings about phenomena of common interest. Using constant comparative methods, researchers and participants co-construct an ordered, coherent, and persuasive narrative that can inform clinical practice.²⁶⁻²⁸ That said, the goal of ID is not representative sampling in order to generalize findings to a population of interest, but instead to explore,

describe, and explicate possible human experience.

Sample: We used purposive sampling to recruit participants from in and around a large Western Canadian city. This nonprobability sampling strategy is common in qualitative research and rests on the premise that researchers' knowledge of the topic area enables them to identify individuals who can contribute meaningfully to the aims of a study.³¹ Individuals were eligible to participate if they (1) were parents/primary caregivers of infants/children born preterm between January 2003 and February 1, 2009; (2) health professionals who worked with preterm infants/children and their parents/primary caregivers; (3) spoke and read English; and (4) provided written informed consent. All volunteers who met these inclusion criteria were enrolled in the study and the information they provided was pooled for analysis (ie, we made no effort to parse our analysis according to demographics, infant gestational age, length of hospital stay, Apgar score, diagnoses, etc).

Through posters in health-serving agencies, print ads, and wordof-mouth, we invited potential participants to contact the first author (GL), who provided additional information about the study and answered questions. Individuals who consented to participate were assured that they could withdraw at any time without explanation or penalty, although none did. Participants were offered an honorarium of \$20 CAD to compensate them for incidental expenses; several individuals declined the honorarium and asked that the money be donated to a local neonatal intensive care unit (NICU).

Fourteen parents (11 women and 3 men) participated in face-toface or telephone interviews and seven parents (4 women and 3 men) took part in two focus groups to discuss and refine the study findings. Four of the parents who participated in the focus groups also participated in an interview. Parents ranged in age, education, and socioeconomic backgrounds; their infants were born between 25 and 36 weeks gestation. Three sets of parents had more than one singleton child born preterm, but none experienced an infant death. We also interviewed five healthcare providers who worked with preterm infants/ children and their families about their observations of parents' experiences. In total, 22 individuals (17 parents and 5 health professionals) contributed information to the study. Data from the health professionals provided contextual information about local services and alerted us to potential issues of concern to parents; we did not include it in our analysis.

Data collection and analysis: In keeping with ID, data collection and analysis proceeded concurrently, with each iteratively informing the other. Data were gathered through semistructured conversational interviews conducted by the first two authors (GL and TC), both of whom have extensive counseling experience. Participants were interviewed once or twice for 45 to 90 minutes (in person or via telephone) and all were contacted again the following day to ensure that the interview had not engendered any distress and to offer a referral to a mental health counselor if necessary. Most of the parents expressed appreciation for the opportunity to talk about their experience and none required counseling. The conversational interviews were audio-recorded, transcribed, and reviewed to ensure clarity and accuracy of transcription. Participants were assigned a unique code number and all other identifying information was altered to protect privacy.

Holistic and line-by-line readings of transcripts were performed for thematic exploration of lived experience descriptions. We began by immersing ourselves in the transcripts and digital recordings to identify themes and patterns and moved on to open coding, during which each meaningful segment of text was assigned a conceptual code. As the codes became saturated, we moved on to pattern coding whereby specific dimensions of parents' experience of preterm birth were clustered into recurring themes. We asked new participants to reflect and elaborate on these themes as they were identified. Throughout the study, we met regularly to compare and discuss our analyses and to ask, "What is going on here?" and "What are we learning about this?" in an effort to move from the particular to the whole. As the analysis progressed, we endeavored to articulate a holistic understanding of parents' experience of preterm birth.

To ensure methodological rigor we provide explicit and detailed information about our epistemological stance and methods; maintained an audit trail; and grounded our findings in the data.^{32,33} In addition, we presented the final themes to two focus groups of parents of preterm infants/children who confirmed that the identified themes reflected their experience.

Results and discussion

None of the parents in this study expected that their babies would be born preterm and when it occurred, it shattered their taken-for-granted expectations of parenthood. With little warning, they were catapulted into the alien world of the NICU, where frightened and helpless, they were forced to rely on strangers to safeguard the survival of their tiny infants. In the early days after their baby's birth, the normalcy of parents' everyday life faded into the background and their only concern was their babies' precarious survival. They existed in a liminal state, in which their babies had been born and yet not quite born and they were parents, but not really able to parent. Uncertainty remained high and even small changes in their babies' health status could trigger a new crisis. Parents' ability to adapt to their new and shifting reality was facilitated or constrained by their perceptions of their infant's survival/well-being; the suddenness, course, and duration of uncertainty about their infant's survival/ well-being; personal and family resources; quality of their relationships with health care professionals; and availability of social support.

Shattered expectations

For the parents in this study, becoming pregnant was a highly anticipated event that set them on a journey from woman to mother, man to father, and from couple to family. As individuals and together, they prepared themselves psychologically and emotionally for their new roles and began to build a relationship with their unborn child. For women, in particular, the growing being inside of them was always baby and never merely a zygote, tissue, or a fetus and they took seriously the responsibility to safeguard his/her life and well-being. All women had regular prenatal care and actively sought out any available information about pregnancy, child- birth, and motherhood. Some referred to popular books such as What to Expect When You are Expecting,³⁴ which describes a baby's week-by-week development and explicitly reinforced their expectations of a normal pregnancy and the delivery of a healthy, happy, full term infant.

The onset of early labor and the premature birth of their baby was a sudden and unexpected event that shattered the parents' expectations "how things should be," leaving them frightened and disoriented.

I was completely shocked...23 weeks was too soon, too soon...I knew that at 23 weeks there was no chance of survival...I was told, uhm, they don't even try to save babies 'til 25 weeks because of obviously long-term and short-term problems... (Participant, Mother)

...you shut down essentially...we hit a point where both of us were just in total and utter shock. We didn't know what to do, what to say...it's like you're in this really messed up dream and everything's moving faster than you can comprehend it. (Participant, Father)

This distress was apparent even among the women who experienced health problems during their pregnancies and those who knew that their unborn children would likely have congenital health problems. This suggests that having a cognitive understanding about the potential for having a PTB may not alter expectations of a "normal delivery," nor moderate parental shock when it does occur.

For one woman, whose amniotic sac ruptured during her second trimester, being on bed rest for 10 weeks taxed the family's resources and constantly reminded them about the possibility that their baby girl would be born prematurely. During that time, the woman's husband continued to operate the family business, managed the household, and shared the care of the couple's 5-year old twins with their maternal grandmother, who drove five hours every other week to help out. At their weekly appointments, the woman's obstetrician apprised the couple of the probability of their baby's survival and potential for having various disabilities if she was born during the upcoming week. While the woman appreciated her doctor's honesty, she still managed to remain hopeful.

...he never painted this rosy picture for me in a way that he was guaranteeing me a good outcome, but he made it sound like [having a full-term pregnancy] was...doable. (Participant, Mother)

Despite these constant reminders of possible a PTB, when she went into labor at 33 weeks gestation, she struggled to understand and accept it:

[The nurse said] 'We're just gonna let nature take its course and when the baby is born you can hold her until she dies.' She didn't use the word "dies" but that's basically what she was saying...I thought like, this is unbelievable, like how could this be happening? What did I do, what did my husband do, ...why is this happening? (Participant, Mother)

After their babies were born, the parents were further alarmed by the urgent activity of delivery room staff and the immediate transfer of their babies to the NICU.

[It was] all very surreal...it all happened very fast and very slow at the same time...he needed some help breathing...[and] he got taken away pretty quickly...I actually didn't get to see him. I don't remember seeing him. (Participant, Mother)

...they let me kiss his little head before they took him off up to the NICU...it was just a big blur...kinda an out-of-body

experience...(Participant, Mother) ...she wasn't breathing very well, so they took her away, which was horrifying because, you know, you just have this baby and your intention is to hold it and bond with it afterwards and they take it away. (Participant, Mother)

Fathers experienced additional anguish when they had to choose between remaining with their partners or following their infants to the NICU. One man, who waited in an anteroom during his wife's emergency Caesarean section told us, *I was freaked right* out...and then they come out with these kids and [told me] "OK, let's go!" So now I'm up in the NICU and my wife's in this other room...there was a lot of back and forth...I think I went 36 hours without sleep. (Participant, Father)

For some of the mothers, the stress of PTB was compounded by feelings of guilt and inadequacy, which eroded their trust in their bodies, their womanhood, and their abilities as mothers.

...I also felt like that it was all my fault and...I felt a grieving that I couldn't mother him the way that I would if we could a taken him home that, the next day...I wasn't doing my job properly and [I felt] inadequate knowing that, as a woman, I was not capable of doing it the way everyone should do it. (Participant, Mother)

I remember the first time going [into the NICU]...I wanted to throw up, not from being nauseous but because all of a sudden I just felt this overwhelming responsibility, like I did that to her... (Participant, Mother)

Helplessness and horror: the trauma of PTB

The extreme stress of PTB was compounded by the strange and alien environment of the NICU, where parents did not speak the language and where every beep and light signaled another crisis. With their dreams of a normal birth and robust infant wrenched from them, they were confronted with impossibly tiny infants who were being kept alive "betwixt the womb and the world"³⁵ by banks of ominous looking machines. Uncertainty was high and the parents felt horrified and helpless.

...it was horrifying...a healthy baby kinda looks like a frog... their legs are pulled up to their stomach and their arms are bent – [my baby] was just flat and long [because] she had no muscle tone. It was horrible (Participant, Mother)

...my brother-in-law went up with me to the NICU and...it was good to have him there because I pretty much fell on my knees...it was very, very scary...(Participant, Father)

...he was so skinny! I'm like, "That doesn't look like a baby!" How am I gonna' take this kid home and take care of him...I don't know if I'm saying it right – but how are we supposed to take this kid home and get him strong, you know. I don't know if I can handle [it], he looked so frail! (Participant, Father)

Despite being disoriented and overwhelmed, the parents gradually adapted to the NICU and began to negotiate what it meant to be a parent and how to parent in a strange and frightening environment.

As the study progressed, it became obvious that when the parents' spoke about the stress associated with having a preterm infant, their experience exceeded usual or everyday levels of

stress. Our interviews revealed that the threat of an imminent PTB precipitated a crisis for them which, according to Mitchell,³⁶ is a reaction to an acute stimulus or demand (stressor), characterized by disturbances in perception, emotion, and thinking; a failure of usual coping mechanisms; and impairments in function. Like other crises, PTB disrupts parents' fundamental assumptions about their selves, the world, and their place in it. These fundamental assumptions are termed differently by different people. The psychiatrist, John Bowlby^{37,38} referred to them as working models that we construct about our self and the world and which give meaning to our perceptions. Parkes³⁹ used the term "assumptive world" to describe the "strongly held set of assumptions about the world and the self which is confidently maintained and used as a means of recognizing, planning and acting..." Similarly, Epstein⁴⁰ believed that each of us has a personal theory of reality, which includes both a self-theory and a world-theory. This "personal theory of reality does not exist in conscious awareness, but is a preconscious conceptual system that automatically structures a person's experiences and directs his or her behavior."40 For Janoff-Bulman,41 our fundamental assumptions are the "bedrock of our conceptual system" and the foundation of our most basic beliefs about our self, the world, and the relationship between the two. Because they are abstract and, like the air we breathe, ubiquitous; we are largely unaware of them and unlikely to question them. They simply exist in our minds as "the way things are." Janoff-Bulman further contends that unless confronted with evidence to the contrary, most of us share some version of the following three fundamental assumptions: "The world is benevolent. The world is meaningful. The self is worthy."41 PTB challenges these assumptions, compelling parents to reconstruct their systems of meaning in order to make sense of their new reality.

The magnitude of the crisis of PTB is consistent with the American Psychiatric Association's (APA)⁴² definition of a trauma. The APA defines a traumatic event as one that threatens an individual's life or integrity (or the life/integrity of a loved one) and evokes a sense of helplessness and horror. PTB was traumatic for parents in this study as it altered their perceptions, strained their coping resources, and triggered a range of physical, emotional, and behavioral responses including fear, anxiety, grief, depression, changes in appetite and sleep patterns, and social withdrawal. When asked, the parents in the study all agreed that the term "stress" does not fully reflect their experience, but that the term "trauma" does.

Focus on the infant's precarious health depending on their degree of prematurity; the prognosis of some of the infants was guarded especially during their early days in the NICU. A few had serious health problems, with ominous sounding names like respiratory distress syndrome, necrotizing enterocolitis, tetralogy of Fallot, and cerebral palsy. Most of the infants underwent a number of diagnostic and/or surgical procedures, some of which required transfers to other hospitals. As their parents struggled to take it all in, the day-to-day concerns of normal life faded into the background and their only concern was their child's survival.

...I spent all of my time at the hospital. I mean when I thought [my baby] was dying...I had this overwhelming feeling like, this is where I have to be. I have to be with my daughter because if she dies, I mean...however long [she was] on this earth, [she should] be with her mom, right? With her family. (Participant, Mother) ...things that we thought mattered before, you find out really don't matter ...like financial costs...When we did our income tax that year [we realized that we] spent a lotta money, but you don't care...you just don't worry about that stuff because your head's somewhere else. (Participant, Father)

The first hours and days after their baby's birth were particularly difficult. They are strangers in a foreign and frightening environment, where they do not know the terrain and do not speak the language. In shock and terrified, their only concern was their baby's survival. This concern fuelled parental vigilance and a strong desire to remain with their infant. Despite feeling helpless to "do anything" the parents spent long hours in the NICU, often at some cost to their own wellbeing.

...nothing else, nothing for me mattered at all; I mean I barely remembered to eat (Participant, Mother) ...the whole routine was, was hard. It became quite a job, to be honest, get up in the morning, have breakfast, go to the hospital for 12, 14 hours, as long as you could and then come back and do it all over again, 7 days a week...he was in [the NICU] for 54 days...it was draining. (Participant, Father)

In order to stay at the hospital, parents reorganized almost all other aspects of their lives and when it was available, they drew assistance from extended family and friends. Some of the women had to quickly hand-off unfinished work to co-workers and organize an early maternity leave; those who had children scrambled to find care for them. Likewise, most of the men arranged some time off work but as the sole wage earners, many of them felt the burden of ensuring the family's financial stability. The financial strain of having a preterm infant was particularly salient for the women and men who were self-employed and those whose income was already reduced because of other circumstances.

...it was a huge financial cost for me and emotional cost too because I would be at the hospital cafeteria with my laptop trying to deal with work stuff...my dad ended up flying from [another country] and helping me with my business...the company lost quite a bit of money in those months but, you know, again it just was what it was and obviously, it wasn't a priority, right? I mean the health of our of my son and our family was a much bigger priority than the business. (Participant, Mother)

All of a sudden we have a baby and [my wife] went on mat leave 3 months before expected and I was on reduced pay, so that the financial situation was compounded...(Participant, Father)

Other sources of financial stress were related to the transportation and parking costs, the cost of eating at the hospital, childcare costs for older children, and to purchasing special equipment. Some couples borrowed money to help them cover these extra expenses, while others received money and other types of assistance from family and other support groups.

...you just figure well, if we go into debt a little bit now we'll just have to do some catching up later, uhm, because you know this is just what we need to do...(Participant, Mother)

...we were on a tight budget already...it was always in the back of my mind, it's like "OK, I have to go get something to

eat and I only have a limited funds, what's the cheapest thing I can get?"...Eventually our church...collected a fund for us (Participant, Father)

Grandparents, in particular, also bore emotional and financial costs of PTB: ...both grandmothers took some time off of work to help. (Participant, Father) ...if I didn't have [my mom] I don't know what I would have done...she brought me food to the hospital so that I wouldn't have to eat the hospital food...[and] they drove us everywhere, even after [our daughter] came out of the hospital (Participant, Mother)

Prolonged uncertainty: cycles of crisis and adaptation As their infants' health stabilized, the parents slowly regained their equilibrium, began to rebuild their meaning systems, and gradually adapted to their new, but

precarious reality – a reality that was easily disrupted by even small changes in their infant's condition or the NICU routine.

...having a baby in, in, in the NICU is that it really feels like a bit of a rollercoaster...at one moment in time it looks like things are getting better, and then your baby has a really bad night or your baby has a bad few hours ...[it's] two steps forward [and] one step back (Participant, Mother)

...every day was different, you couldn't, you couldn't go in there expecting the same thing that happened yesterday or even a, a good step, 'cause if you, if you went in expecting a weight gain and there was a weight loss it was just a complete downfall...you had to kind of pick yourself up again ... (Participant, Father)

This prolonged uncertainty about their infant's survival was the crux of the trauma of PTB and coupled with their lack of agency, it kept the parents in a heightened state of arousal. From the stress literature we know that the perception of a threat to one's own life or the life of a loved on triggers an automatic, total-body response that Cannon⁴³ dubbed the fight-or-flight response. Within seconds, cascades of hormones and neurotransmitters course through the body marshaling every cell into action.⁴⁴ When the stressor abates or an individual is able to escape from it, the stress response systems return to their resting states. However, as we heard from the parents in this study, when the health/ well-being of their infant is tentative, the threat remains omnipresent.

Fostering adaptation

Parents' ability to adapt to their new reality was influenced by three main factors; (1) their personal and couple resources; (2) the quality of their relationships with the NICU staff; and (3) the presence of social and functional support. These factors appear to buffer the severity of the trauma as parents cope with the precarious health of their infant.

Personal and couple resources included the parents' constitutional and psychological characteristics, past learning, problem-solving strategies, ability to manage their emotions, and the quality of their relationship. Although the Canadian system of publically funded healthcare buffered the economic impact of having a preterm infant, economic factors contributed to parents' stress, particularly for those who were self-employed, lived a distance from a tertiary care hospital, or whose infant was hospitalized for an extended period of time. In the beginning it was very, very taxing and very stressful and very hard on us and, uh, tested a lot of things about our, our marriage and finances and everything (Participant, Father) ...my wife and I have been married 6 years and we really hadn't gone through anything...a hardship together ...so to go through something together that affects you so much emotionally, uhm, and you kinda learn how to, how to support each other...now I think we know each other better... (Participant, Father)

Relationships with NICU staff also influenced parents' adaptive capabilities – not surprisingly, positive relationships enhanced adaptation, while negative relationships contributed to parental stress.

[My doctor] was really good because he was a great advocate for us...some of the, the nurses really wanted to take over and, uhm, do what they felt was best. I was really lucky in that this doctor was a huge advocate for us. (Participant, Mother)

Yeah, it was huge to, you know, when I'd walk in there in the morning and see a nurse that I knew [and] I would just feel better about the day just knowing like, "OK you're, you're a good nurse"...I'd be nervous when she had a new one but she would just be fabulous too. (Participant, Mother)

I wouldn't even look at the nurses, I was so mad...the social worker ended up meeting me...I just went like completely ballistic because [sighs] again...lack of control...like I have no say over what's going on. (Participant, Mother)

Not surprisingly, parents also experienced social support as protective. Those who could rely on friends, faith communities, or other social relationships (including other parents in the NICU parents) for emotional, physical, and psychological support fared better than those who did not have these.

...both of us have lots of family here so we had a ton of offers of support and, uh, you know lots of people were nice and brought us lasagnas and...aunts coming over here during the day and tidying up the house...(Participant, Father)

I sent [my children] to stay with my husband's

grandparents...I cried, I felt like such a bad mom, you know, having to send them away [but] I knew my twins would be OK and they'd be fine with other family ...(Participant, Mother)

From this inquiry, it is clear that like other health crises and life-threatening events,^{45,46} the experience of having an infant born preterm is a very stressful, even traumatic, event for most parents. Traumatic

events sorely challenge an individual's coping resources and evoke a range of physical, emotional, and behavioral responses such as fear, anxiety, grief, depression, changes in appetite and sleep patterns, and social withdrawal.

Recently, clinicians and researchers have applied the constructs of acute stress disorder (ASD) and posttraumatic stress disorder (PTSD) to explain parents' experience of PTB. Diagnostic criteria for ASD³⁷ include exposure to a traumatic event, which an individual perceives as life threatening and to which he/ she responded to with intense fear, helplessness, or horror. In the wake of the distressing event, the individual must also experience increased autonomic arousal, dissociative symptoms (eg, emotional numbing, depersonalization, or amnesia); and reexperiencing of the event through intrusive thoughts, dreams, or "flashbacks"). These disturbances cause significant impairment in social, occupational, or other important areas of functioning and if these symptoms last longer than one month, the individual meets diagnostic criteria for PTSD.

A recent systematic review of research revealed that posttraumatic symptomatology is not uncommon in parents or primary caregivers of premature infants.⁴⁷ One study in that review found that 67% of mothers with preterm infants (vs. 6% of a control group of mothers of full term infants) exhibited PTSD symptoms.⁴⁸ Similarly, Holditch-Davis⁴⁹ and her team found that all of the mothers in their study had at least one posttraumatic symptom, 12 had two symptoms, and 16 had three symptoms, post birth. Kersting's group⁵⁰ reported that compared with mothers of healthy term infants, mothers of very premature infants showed significantly (p < .05) higher rates of traumatic symptoms at 1-3 days, 14 days, 6 months and 14 months post birth. Finally, Wereszczak et al⁵¹ found that even 3 years after a PTB, caregivers reported vivid memories related to their infant's appearance, behavior, pain, procedures, illness severity.

More recently, an Alberta study⁵² employed a prospective cohort within-subjects design to explore the number and severity of ASD symptoms in parents of preterm infants at 7-10 days and one-month post-PTB. The authors found that 25% of respondents (28% of mothers and 17% of fathers) met diagnostic criteria for ASD at both measurement times. The authors also reported significant depression scores among 43% of the mothers at 7-10 days and in 35% of mothers at one month and among 33% and 17% of the fathers respectively. This latter finding is noteworthy because maternal depression has implications for the mother's psychological well-being and the infant's cognitive and emotional development. Prior research demonstrates that the infants of depressed mothers are at greater risk for developmental disturbances,⁵³⁻⁵⁶ which may compound the effect of prematurity. In a similar study, Shaw et al.⁵⁶ found that almost half of the mothers, but none of the fathers, in their study met all diagnostic criteria for ASD. Those authors suggest that women's increased levels of distress may be related to their greater psychological involvement with their infants. Others^{57,58} attribute this to gendered differences in coping styles, whereby men cope by discounting the severity of the problem; deny or minimize their own emotional responses; and focusing their energies on supporting their partners during the NICU hospitalization.

Other studies demonstrate that symptoms of parental traumatization after PTB can continue at 6 and 18 month after the infant's discharge from hospital⁴⁸ and take the form of intrusive memories and efforts to avoid reminders of their experiences. In other work⁵⁹ that compared mothers of premature and full-term infants, the former had significantly more symptoms of intrusion, avoidance, and hyperarousal.

Conclusions

Parents in this qualitative study highlight disruptions in meaning systems, prolonged uncertainty, and lack of agency as factors that contribute to the psychological trauma associated with having a preterm infant. This resonates with Shaw et al's finding that parental trauma is less related to infant characteristics (eg, gestational age, birth weight, Apgar scores, or length of stay in the NICU) than it is to alterations in the parental role expectations. This included being unable to help, hold, or care for their baby; protect him/her from pain; or share the baby with other family members. We also speculate that this disruption in parental role expectations are part of global disturbances in their fundamental assumptions about their selves as worthy and agent and the world as safe and predictable.⁴¹ Our findings also help to explain why things like breast feeding, kangaroo care, and family centered practices are so meaningful to parents with an infant in NICU. As well as helping to (re) construct their role as parents, these activities gave participants a sense of agency - of doing something tangible for their baby - thereby moderating their own sense of helplessness.

Given the nature of qualitative research, the findings and conclusions of this study are not generalizable to all parents of preterm infants. The sample size is small and unrepresentative and the data is all self-report. In considering the findings, it is also important to keep in mind that traumatized individuals may not participate in research related to PTB in order to avoid reminders of past experience. That being said, the findings underscore the importance of early identification and treatment of psychological distress related to PTB. Obstetrical and neonatal healthcare providers need to be educated about the symptoms of ASD and PTSD to better understand and support parents' efforts to adapt and to make appropriate referrals if problems develop. The findings also endorse the importance support from healthcare providers in assisting parents to assume a parental role. In addition, this inquiry underscore the need for ongoing efforts to identify parental psychological distress and to develop effective screening and trauma-informed intervention strategies to help parents at risk for psychological distress in the wake of PTB.

Despite the trauma associated with having and caring for a preterm infant, all of the participants in our study stated that they would be willing to participate in long-term, economic studies about the direct and indirect costs of PTB with the some provisions:

Timing: Researchers should approach potential participants in person, while their baby is still in the hospital and after their baby's health has stabilized. Parents emphasized the importance of developing and sustaining personal and trusting relationships with members of the research team.

Altruism and meaning-making: The participants in our study told us that they had very few opportunities to tell their stories of having a preterm infant and they welcome opportunities to participate in research that might make a difference for other parents. The possibility of improving the healthcare experience of others (altruism) helped parents make sense of their own experience and of having something positive come out of something that was difficult. This has implications for recruitment because NICU personnel sometimes feel compelled to "protect" parents from researchers to decrease the demands on them.

Data collection strategies must not increase parental burden Most parents would prefer telephone and/or internetbased data collection strategies as opposed to paper questionnaires or diaries. This is particularly important for parents who are experiencing emotional and psycho-logical distress related to stress/trauma. Flexibility and control: Parents need researchers to be flexible in booking interviews and to work around their schedules.

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Work Satisfaction, Quality of Life, and Leisure Time of Neonatology Fellows and Senior Neonatologists in Israel

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Abstract

Objectives: To examine work satisfaction, quality of life, and leisure time of neonatology fellows and senior neonatologists in Israel.

Methods: A validated questionnaire was delivered during the second half of 2008 to all the neonatology fellows and senior neonatologists in Israel. Descriptive analysis, parametric Student's t-test, and aparametric Mann Whitney and χ^2 tests were conducted.

Results: Of 114 practicing neonatologists in that period in Israel (including both seniors and fellows), 112 (98.25%) participated in the study. The majority of neonatologists were male (53.2%), married (91.7%), 40-60 years old (69.7%), and studied in Israeli medical schools (62.0%). Most did their pediatric residencies and fellowships in Israel (97.2% and 75.7%, respectively). The average number of night/on-call shifts of fellows and senior neonatologists was 8.8 per month (SD \pm 3.425) and the number of active on-call shifts was 4.04 (SD ± 3.194). The satisfaction level of neonatologists in Israeli medical centers with patient care, self-reward, work relations, and quality of life was high, but their satisfaction level with workload, income and prestige, and leisure time was low. The general index of work satisfaction and the general index of indices were both high in relation to the mid-range values. The majority of neonatologists stated that they would choose to practice medicine again. Most of them would encourage medical students to choose the same specialty they had chosen. Only a few neonatologists were contemplating changing their choice of specialty. Most neonatologists want to continue practicing medicine; however, a significant number will not recommend that their children do so.

Conclusions: The satisfaction level of neonatologists in Israel is high, mainly due to satisfaction with their work. High satisfaction levels promise high quality patient care, as well as high satisfaction levels of patients and their families. However, satisfaction with leisure time was low and it will require greater attention and focused steps to correct this.

The authors are from various healthcare facilities in Israel. Reprinted from BioMed Central, Israel Journal of Health Policy Research, © 2012 Mosh et al; licensee BioMed Central Ltd. This is an open access article distributed under the terms of the Creative Commons Attribution License. This article has been edited for our readers. To see the full article, with tables and references, visit BioMed Central and type the full title.

Background

It has been shown that physicians' work satisfaction is influenced by factors such as patient care, workload, income and prestige, self-fulfillment, and relations with fellow co-workers. Factors that negatively influence physicians' work satisfaction include time, pressure, lack of leisure time, and time for one's self, a decline in quality of life, feelings of less autonomy in decision making, less time spent on actual patient care, and more time spent doing administrative work.

No difference in work satisfaction was found among physicians who dedicate most of their time to patient care compared to physicians who dedicate their time to medical research. Nevertheless, physicians who spend more time with patients reported a greater insult to their quality of life. The determining factors for their dissatisfaction were less time for their families, themselves, and leisure activities.

Burnout is a "psychological syndrome of emotional exhaustion, depersonalization and low sense of achievement." Among physicians, it is a long-term stress reaction that influences work satisfaction and derives from some characterizing factors of today's medical profession. These factors include physicians' loss of autonomy and prestige, the financial transformation of health systems, work stress, and time pressure, and to some extent from personality traits of physicians. Personality traits such as obsessiveness and rigidity, together with high levels of intelligence, might lead physicians to feel accountable and overcommitted.

In the beginning of the burnout process among physicians, one can find a group of general background variables such as age, number of children, marital status, and work hours, which interact with mediating variables, namely autonomy at work, home–work relations, and home support. When the background variables combine well with the mediating variables (meaning the physician is practicing in his or her field of choice, is satisfied with work hours, manages to keep a good balance between work and private life, and is getting good support from his or her family), this combination leads to high levels of satisfaction and may prevent burnout. However, when the combination of all the factors is other than perfect, the outcome is most likely to be some degree of burnout.

A sense of burnout is directly related to dissatisfaction, which in turn may lead to a decline in the desire of the physician to treat patients, a tendency to order expensive laboratory examinations, and an ongoing interest in early retirement. Burned-out physicians suffer from social isolation, lack of joy and happiness, depression, and denial. Eventually they become cynical and ironic.

It is likely that the relatively high rates of mental illness among physicians (male and female alike) and the high rates of suicide attempts are related to the combination of problematic work conditions and work dissatisfaction together with some primary predisposing personality factors. In comparison to male physicians, female physicians reported greater levels of dissatisfaction with their autonomy at work and time pressure, and reported 1.6 times greater rates of burnout. Among female physicians who practice surgery there were differences in academic ranking compared to male physicians, as well as differences in level of income, work status, and work relations. The research also showed that almost 30% of the female physicians are seriously considering leaving their work because of these differences. Despite these findings, a large study of 12,474 physicians in the United States did not find any differences between male and female physicians in terms of work satisfaction.

There is a clear connection between work satisfaction and the type of specialty chosen. Physicians who practice "procedural" fields such as obstetrics and gynecology, ophthalmology, and orthopedic surgery, stated greater dissatisfaction with their work than physicians who practice "non-procedural" fields such as geriatric medicine, pediatric medicine, and dermatology. The difference between the groups was caused by the changes in the health care systems in the United States in the last few years, which affected the social status of physicians, their autonomy, and their salaries.

In the survey conducted by Clarke and Associates, which focused on job satisfaction and stress among neonatologists, it was found that almost all neonatologists experienced stress at work: 34% moderately severe and 16% very severe stress. Major causes of stress were excessive work load, on call too often, and calls at night; problems in patient care, especially dealing with infant death; and staff disagreements, especially nurse or house staff conflicts. One-sixth of the neonatologists were either moderately or very dissatisfied with their career. Major dissatisfactions were: too much work, especially managing many sick patients; lack of resources, including inadequate salary; too much stress at work; and administrative demands. Job satisfaction was derived from patient care, teaching, intellectual stimulation, and research. Altering their subspecialty had been considered at some time by 58% (15% very seriously). The researchers also suggested that job stress is a greater problem than job dissatisfaction.

Overall, the satisfaction level of physicians in the last few decades has been declining. Since the 1970s, work dissatisfaction among physicians doubled from less than 15% to more than 30% in the late 1990s. About 40% of the physicians stated they would not have chosen to practice medicine again if given the chance, and a larger percentage said they will not recommend their children do so. In addition, 41% of the physicians have contemplated leaving the medical profession because of their discontent.

Similar to the above mentioned changes, the choice of medical specialty by medical students in the United States went through

great changes in the last few years. A study conducted between 1996 and 2002 found that specialty fields such as dermatology and anesthesiology, which traditionally had very low rates of interest among the graduating students, had multiplied the number of their candidates by tens and hundreds of percentages (anesthesiology - a rise of 500%, dermatology - a rise of 1000%). More than 55% of the students said that the factor that most strongly influenced their choice was the ability to have a "controllable lifestyle," meaning having time that is free of the demands of their work, that could be dedicated to their leisure activities and families, and which is controlled by them. A similar change was noticed among Israeli medical school graduates, which demonstrated a rise in the popularity of specialties such as radiology and anesthesiology between 1980 and 1995. Unfortunately, it is not the case in neonatology in Israel - the number of physicians choosing neonatology as a subspecialty is constantly insufficient, an average of 5 per year in the last 20 years, whereas the number of live births is steadily increasing. The severity of situation, caused the Amourai Committee in 2002 to declare neonatology as one of the "in crisis specialties". In contrast, in the United States, the number of neonatologists rose by 150%, whereas the number of premature babies had risen only by 18%.

The current study aimed to describe the level of work satisfaction, quality of life, and leisure time of senior neonatologists and neonatologist fellows in Israel by age, gender, status in their department, and time in the profession. The term "neonatology fellowship" is being used here to refer to advanced training in neonatology. All participants in the neonatology training programs have already completed a basic residency in pediatrics. In Israel, pediatricians participating in such advanced training are often referred to as "residents in neonatology", with the training in neonatology functioning as a second (advanced) residency.

We asked all active senior neonatologists and neonatologist fellows in Israel, between July 2008 and March 2009, to participate in the current study. In Israel there are 25 medical centers specializing in neonatal care, with a total of 114 practicing neonatologists. Most of these centers provide neonatal services including prenatal counseling for high risk pregnancies, neonatal care in the delivery room, normal postnatal followup and care, services for neonates with congenital defects with follow-up, treatment in special care units and in neonatal intensive care units (NICU), and neonatal counseling. In Israel there were 151,679 live-births in 2007. This number is consistent with a steady rise in live births over the last 50 years. At the same year, according to the Ministry of Health data, the number of beds for special neonatal care in Israel was only 556. In comparison, according to a workforce report from the American Academy of Pediatrics in October 1996, there were at that time 3688 board-certified and board-eligible neonatologists in the United States. This means that in the U.S. there are 1.2 neonatologists per 10,000 people in comparison to 1.4 neonatologists per 10,000 people in Israel. This seems a fair comparison until we compare the live birth ratio, which is 14/1000 in the US vs. 20/1000 in Israel.

Methods

Type of study: Cross-sectional research that examined basic feelings and positions among all senior physicians and fellows in neonatology in Israel.

Study population: In Israel there are 118 neonatologists of working age. Of these, 114 were active and practicing in Israel at the time the survey was conducted; 112 (98.25%) participated in the current research. A neonatologist is defined as a physician who possesses an Israel Ministry of Health certificate in neonatology or one that has begun his neonatology fellowship, but did not yet finish it.

Variables: Dependent variables: satisfaction level, quality of life, and leisure time.

Independent variables: age, gender, place of medical education, and country of origin.

Tools: Research questionnaires: Based on similar questionnaires, a questionnaire was designed by the researchers to include questions about work satisfaction and quality of life. Additional questions about leisure time were composed by the researchers, based on prior studies. The work satisfaction section of the questionnaire was divided into five sub-categories: Patient care, Work load, Income-prestige, Self-reward, and Work relations. The questionnaire used a seven-point Likert scale (1=totally dissatisfied, 7=very satisfied). Each category was summed to create an index measurement. The sum of these five in- dices was used to create a summative index of work satisfaction. Different indices were created for the questions about the quality of life and leisure time. Finally, in order to demonstrate the relation between work satisfaction, quality of life, and leisure time, we created the index of indices that summarizes all the questions regarding these issues. The next stage was the actual mail/fax/hand delivery of the questionnaires to the neonatologists in the hospitals, after receiving their permission. A researcher was available to answer any questions, and received the questionnaires in the same way they were sent. The participants were all promised full confidentiality.

Statistical analysis: The data were coded into the SPSS 13 computer program for Windows (Chicago, IL). In order to make sure there were no errors in entering data, we explored frequency checks for all the variables. Questionable parameters were re-checked with the original questionnaire, and in cases where no decision could be made the values were considered missing. The data were analyzed using descriptive statistics first, and then with parametric Student's t-test and non-parametric Mann–Whitney and χ^2 tests. P value less than 0.05 was considered significant. In order to measure the level of satisfaction, we compared the relevant central measurement with the mid-range value, so that when the central measurement (median or mean value) was higher than the mid-range value the satisfaction was considered high.

Results

Demographic data: In Israel there were 118 senior physicians and fellows in neonatology of working age at the time of the survey. All of them were qualified specialists in pediatrics. Of those, 114 were practicing neonatologists, and 112 (98.25%) participated in the current study. The majority of neonatologists were male (53.2%), married (91.7%), 40–60 years old (69.7%), and studied in Israeli medical schools (62.0%). Most of them did their pediatric residencies and fellowships in Israel (97.2% and 75.7%, respectively). The average number of night/on-call shifts of fellows and senior neonatologists was 8.8 per month (SD \pm 3.425) and the number of active on-call shifts (when the senior physician had to attend the hospital) was 4.04 (SD \pm 3.194). **Satisfaction level:** The satisfaction level of neonatologists in Israeli medical centers with patient care, self-reward, work relations, and quality of life was high, but their satisfaction level with workload, income and prestige, and leisure time was low in relation to the mid-range value. As a result, the general index of work satisfaction and the general index of indices were both high in relation to the mid-range values.

Leisure time: The satisfaction level of the neonatologists in Israeli medical centers when looking at their leisure time was generally higher than the mid-range value. They were not satisfied with the frequency with which they went to the movies and the number of vacations in their home country, but were satisfied with all other mentioned activities.

Neonatologists' opinions about the medical profession: The majority of neonatologists (n=98, 87.5%) stated that, given the chance, they would again have chosen to practice medicine. Most of them (n=78, 69.6%) would encourage medical students to choose the same specialty they had chosen. Only a few (n=7, 6.25%) neonatologists were contemplating changing their choice of specialty. As for leaving the medical profession, most neonatologists (n=99, 88.4%) want to continue practicing medicine; however, a high number (n=39, 34.8%) of the neonatologists in Israel will not recommend that their children practice medicine. We compared the satisfaction level between different groups of neonatologists:

- A) Senior neonatologists, compared with fellows after the pediatric residency alone, were more satisfied regarding personal satisfaction (p=0.009) and more satisfied with their quality of life (p=0.042).
- B) Regarding job benefits, neonatologists who got their medical education in Israel were less satisfied than neonatologists who studied medicine outside of Israel (p=0.008). We failed to detect any difference between male and female fellows regarding quality of life and leisure time. We also compared the satisfaction level between neonatologists and fellows (as described in our previous research). [Our results show that] neonatologists have higher indices such as patient care, workload, income, work satisfaction, leisure time, and the general index than fellows.

Discussion

It is a known fact that work satisfaction of physicians' worldwide has been declining in the last few decades. Important reasons for this decline in satisfaction include lower income levels, reduced autonomy and social status, a change in perception about the physician's place in society, lack of self-fulfillment, enormous time pressure at work, and lack of time for one's family and self. Research has shown that dissatisfaction of physicians leads to burnout, causes ongoing desire to leave the medical profession, and eventually causes dissatisfaction with their patients. The current study is the first report from Israel providing reliable data about work satisfaction, quality of life, and leisure time of neonatologists. It shows that the overall work satisfaction and general satisfaction levels are high, and the reason for this is likely due to a strong sense of self-reward and satisfaction with their quality of life.

Work satisfaction: Work satisfaction level alone, apart from leisure time, among the neonatologists was high, especially with patient care, sense of self-reward, and work relations. High satisfaction levels are well-matched with our findings that a majority of the neonatologists surveyed would choose

to practice medicine again, would recommend that medical students choose their line of specialty, and are not considering a change of internship or contemplating a change in profession. But the satisfaction levels from workload and income were low. These low satisfaction levels matched a significant number of neonatologists who stated that they would not recommend that their children practice medicine. Moreover, it is reasonable to presume that these low satisfaction levels have direct implications on neonatology as a profession in crisis in Israel, and upon the unwillingness of young physicians to choose neonatology as their subspecialty. Dissatisfaction with workload and income level correlates well with similar findings from the United States, where 600 physicians showed a substantial decline in their satisfaction level, especially due to increasing workload (which leaves less time for each patient) and the lack of financial reward for the work being done. Another study points out that the balance between factors that positively influence satisfaction level (such as patient care) and factors that have a negative influence on satisfaction levels (such as workload and the lack of time for patients and for one's self), must be vigorously kept. When this balance fails to be maintained, burnout and dissatisfaction prevail.

Quality of life and leisure time: Despite the high levels of work satisfaction found among neonatologists at Israeli medical centers, we found low levels of satisfaction with their leisure time. Surprisingly, the reported quality of life was high, in opposition to what we found in a recent survey of fellows from one Israeli medical center. These findings are similar to physicians' feelings that their work prevents their having leisure time and emphasizes the importance of leisure time in maintaining a good quality of life. Engaging in leisure time activities, such as spending time with one's family and friends, and being engaged in physical activities, can prevent burnout. The most crucial factors that influence physicians' work satisfaction were their quality of life, time spent with their families, and personal time for themselves and for leisure time. These factors have created a change in the specialty choices of graduating medical students in the United States in the last few years. Specialty fields that are perceived as less time intensive are gaining popularity. This means that the issues of quality of life and leisure time are becoming more and more important as determining factors of physicians' satisfaction.

Female vs male neonatologists: Satisfaction levels were similar among female and male neonatologists. Some studies support our results. However, among 5,704 US physicians differences were found between male and female physicians. Women were more satisfied than men with their work relations and field of choice, but were less satisfied with their autonomy at work, workload, and salary. Differences between genders were also based on salary issues, prestige, and academic ranking. The fact that we did not find any difference between male and female physicians is intriguing, since we would expect that in at least one parameter – academic ranking – women would be less satisfied than men in Israel, the same as abroad, because they do not climb as fast as men in academic ranking.

Neonatology fellows vs senior neonatologists: Satisfaction levels were generally similar between physicians in the course of fellowships and senior neonatologists. Some studies show an inverse relation between the fellow's age and level of work satisfaction. The highest satisfaction level was demonstrated among very young and very old physicians, yet satisfaction

level was directly related to age and experience. In our study we found, in general, that fellows were as satisfied as seniors. The only exceptions were found among neonatology fellows with lower personal satisfaction and quality of life. It is logical to find these results, as it is well known that fellows have more on-call shifts and need to work harder due to their relative lack of experience in the field. These findings add to the results from other studies that emphasize the importance of income level as a factor in determining work satisfaction. Possible explanations for the nearly similar findings between these two groups may be the fact that fellows in neonatology have already completed their pediatric residencies and the length of their neonatology fellowship is shorter.

Neonatologists from Israeli medical schools vs

neonatologists from non-Israeli medical schools: The place of medical education further explains the differences found between the two groups - Israeli fellows were less satisfied with issues regarding personal benefits from the job, as well as their workload. The low levels of satisfaction with workload among Israeli graduates is similar to that reported in another study conducted in Israel, which found that the satisfaction level of immigrant physicians was higher regarding workload and burnout levels. Regarding self-reward, it is possible that the long and difficult course immigrant physicians must go through in order to work in Israel, combined with the difficulties of immigrating to another country, had a less negative influence on their sense of self-reward after becoming senior neonatologists, especially in comparison to Israeli graduates. Another finding that may explain the low satisfaction levels of Israeli graduates is that many more Israeli medical school-trained neonatologists have an additional academic degree, which means they spent more years in the university and thus have higher expectations.

The low levels of satisfaction among Israeli graduates found in the study are worrisome since it is well-established that low levels of satisfaction can eventually lead to burnout. This burnout might have important personal implications for physicians as well as serious consequences for the health system at large. Burned-out physicians tend to be more angry and impatient, and tend to develop signs of depression, substance abuse, and suicide. Burned-out physicians also report greater levels of exhaustion, which may lead to medical errors, impair their ability to learn and concentrate, and damage their professional and personal relations. From a wider perspective, burnout causes poor doctor–patient relations and a decline in the quality of care, and thus surely needs to be addressed.

Neonatologists vs fellows: Neonatologists were found to have higher indices in patient care, workload, income, work satisfaction, leisure time and the general index than fellows. But, this is a very problematic comparison – they compared to fellows, who are the main working force and most battered physicians in the field, and thus this improvement is nothing to brag about. Even worse is the fact that two important indices were not better with neonatologists – the index of self-reward and the index of work relations. This means that at the end of the day senior physicians, our neonatologists, did not fare better than simple fellows in the main issues that cause burn-out – self-fulfillment and work relations, things that should cause us to wonder how this may impact their motivation and working ability.

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Hippocratic Oath – Do No Harm?

Yamile C. Jackson, PhD, PE, PMP

They are called "minor morbidities of the preterm" but who considers them minor? These quote "minor morbidities" carry a heavy social, moral and emotional toll for each child, the parents, the family and the society as a whole.

Care in the NICU that is not individualized, or that does not include the parents as primary caregivers is scarring the developing brain and the quality of life for a lifetime. There is only one opportunity to develop the brain of the premature baby and it is in the hospital. The first experiences in the world shape these infants for the rest of their lives.

These helpless and innocent babies, their families, pediatricians, and the school systems are ill-equipped to deal with the sleeping, feeding, language comprehension and expression, cortical vision, and social, motor, and hearing impairments suffered from the multiple insults to the vulnerable period of brain growth under intensive care. Many of these "minor morbidities" are prevented with the use of best practices of developmental care that expands well after hospital discharge, and that includes the family as the primary developmental caregiver and the guard of the sleep of the baby.

Research tells us that babies in the womb sleep 20-22 hours a day and due to sleep deprivation in the NICU the brains of the premature survivors often times will be structurally different. Preterm survivors who endure NEC, IVH, BPD, ROP, etc are often carried home by parents who think the worst is all behind them only to find that challenges await them for years to come that will feel even more insurmountable, and will leave them perplexed, frustrated and heartbroken.

The literature on the benefits of the physical and developmental environment of the high risk infant from the fields of neuroscience, psychology, architecture, nursing, and medicine continually report advances related to the long term outcomes of the infant's brain related to sleep, human milk feeding, parents as the primary caregivers, individualized developmentally supportive care practices, skin to skin contact and NIDCAP driven units, only to be ignored for the reading of a scale, a tape measure, and the need for a shortened length of stay.

Boosting rapid weight gain, decreased length of stay (without proper training for developmental care at home), improved

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responses for infections caused by the hospital, compliance with hand washing all take a front seat and often negate the care to the preterm's critical period of rapid neurological, psychological, and musculoskeletal development. These babies, as they grow, often need to undergo lengthy therapy sessions that are disruptive, painful, and expensive and that often do not correct the problem.

Support for the trauma inflected on the parents is often ignored. Parents in the NICU experience increases in anxiety, a sense of impotence and stress, and they all take a toll with depression, fatigue, emotional pain and post-traumatic stress disorder that may never be addressed or even acknowledged. These problems are intensified if parents are not taught about their importance in the healing and development process or even included in the care of their baby.

Anthropologically, mothers and infants grow together, sharing the same body, learning each other's rhythms, and it is not before 40 weeks that they are supposed to be introduced face to face. When babies are born sooner there is a trauma induced by the NICU – and it is the systematic and prolonged separation from the mother. Babies need their mothers and mothers need their babies, especially those that are in the rapid growth period before 40 weeks.

While survival rates of preemies are exceptional in our country, currently intensive care of the premature infant and family is showing a very negative effect on brain growth, attachment, stress, depression and anxiety, and later impacting adult brain function. Epigenetically the harsh, traumatic and hostile neonatal intensive care environment is changing the DNA of the extremely low birth weight infant.

There is a rhythm disruption caused by unit designs, insensitive care practices, erroneous goal-driven quality and performance indicators that is leaving in its wake billions of health care dollars, heartbroken parents, nomadic children who do not fit in socially or academically and a system that is not changing to address their unique needs. Socially these survivors, who are many times smaller in stature, are left alone trying to navigate a school system that is ill-equipped to understand and recognize their needs. They are set up to be victimized, bullied and left alone in a system which expects them to process the world as a term equivalent, when they cannot.

At discharge, parents are educated about survival and not about

how to improve the quality of life of these fragile and voiceless babies. Teaching includes CPR, back to sleep, swaddling (which restrains movement and may alter musculoskeletal development), tummy time, SIDS and car seat safety but it does not include developmental care, kangaroo care, attachment, the importance of sleep for developing the brain, or about the social, emotional and educational needs of our most precious resource: our children.

It is past time for our country to stand up for the rights of preterm infants and their families. To reconstruct neonatal intensive care units to minimize separation of the babies and the parents, educate the team on infant driven care, put all efforts into the care of the evolving preterm brain and to close those units that will not change the destructive, hostile care where parents are "visitors" or feel powerless, where infants are denied their mothers' loving touch and healing powers, and where outcomes are measured by survival and the reading on a scale.

Work Satisfaction in Israel...continued from page 64 Conclusion

The satisfaction level of neonatologists in Israeli medical centers is high, mainly due to high satisfaction with their work and to a lower extent to their quality of life. High satisfaction levels promise high quality patient care, as well as high satisfaction levels of patients and their families. However, satisfaction with leisure time was low and it will require greater attention and focused steps so that these issues can be corrected. We recommend that further research be conducted, using the tools developed in our study, that will compare the results in neonatology with physicians in other areas of medicine in Israel and worldwide. Ultimately, a comprehensive picture about the satisfaction level with leisure time in Israel and the world can be created, and ways found to improve it. We also recommend a change in management policies be made in order to resolve these problems.

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