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It’s Their Choice?

A major series of articles in the New York Times reported on problematic preemie births due to intrauterine insemination. The series, “21st Century Babies,” by Stephanie Saul, presented numerous case studies of parents who went ahead with fertility treatment and suffered the consequences. One couple was told to reduce the six embryos the mom was carrying or risk losing them all. The mom said no. Four children died after preemie birth. The two others were still in the NICU after three months (when newspaper article appeared). IUI is used because it’s cheaper and easier than IVF. But the pregnancy rate is lower than IVF, and there’s no control over multiples.

In treating women who are having trouble getting pregnant, most doctors try low-potency fertility pills first, then intrauterine insemination with hormone injections and in vitro fertilization as a last resort. Some insurance plans require women undergoing fertility treatments to have several rounds of intrauterine insemination before they will pay for in vitro fertilization. Because of the cost, other plans cover intrauterine insemination but not in vitro. The CDC has long-reported that IUI and IVF are becoming major contributors to the US’s 12.7% rate of preterm births. At least 20% of such pregnancies are multiples. Women who have gone through large multiple pregnancies with poor results say TV shows give viewers a misleading picture of multiple births by failing to talk about babies who are stillborn, spend months in an NICU or have long-term disabilities. The Times reported that some units are taking care of babies for up to five months at a time, and parents are maxing out their insurance. In the case outlined above, insurance would have covered six rounds of IUI. The third time was the (arguable) charm. Some couples don’t understand the implications of multiple births, even when the risks are explained. While doctors generally discuss reduction as a possibility in pregnancies with triplets or more, some criticize such selective reduction as abortion. There’s also a chance that such reduction will result in miscarriage of all the fetuses. The couple profiled above made their decision based on guidance from their Mormon church. (Maybe the church should have then footed the bill.) The mom said she would “let God do what he’s going to do.” But the price was paid for by every American, even those who may not wish to let a deity with such a spotty track record muck about in medical decisions. The mom’s babies were born 14 weeks premature, and the parents were told there was a hundred percent chance they’d have problems. They ranged from 12.3 ounces to just over a pound. Death was by multiple causes. Doesn’t the foregoing defy logic?

While you may not contest the right of infertile couples to try what they can afford in order to have babies, and to make stupid decisions along the way, why should everyone else pick up the tab? Why do doctors provide such procedures? Or, if couples elect to go forward, why don’t we just let the chips fall where they may?

Les Plesko, Editor

Addendum: The New York Times received many responses to its series on twin and multiple births due to infertility treatment. Here is a sample:

The more mundane epidemic of twins actually costs the American health care system and affects the lives of families far more… Even though twin pregnancies carry risks, who is to define what is “medically inappropriate” in day-to-day clinical care? In our non-single payer health care system and in our national cultural context (with its paramount legacy of individual rights over those of the state), patient autonomy will almost always prevail… Nature is too complicated, does not obey regulations and inherently has an impact on our best attempts to reduce risk… There is no chance that the practice of embryo transfer will ever be regulated by legislation in the United States. In a nation still deeply divided over abortion and the moral status of embryos, Continued on page 33…
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PRE-EXISTING

Recently, the Huffington Post's Ryan Grim reported on the fact that in seven states plus the District of Columbia, “getting beaten up by your spouse is a pre-existing condition.” The insurance industry figures that if “you are in a marriage with someone who has beaten you in the past, you’re more likely to get beaten again than the average person and are therefore more expensive to insure,” but what it really does is punish these victims for something that wasn’t their fault. But that isn’t the only policy that health insurers have that primarily discriminate against women. First of all, most individual health insurance markets don’t cover maternity care. In fact, according to the Kaiser Family Foundation, only 14 states have a requirement for such coverage, and the number of plans without maternity coverage continues to rise dramatically. Why? Anthem Blue Cross—which has been actively fighting healthcare reform—considers pregnancy optional and therefore not necessary to insure: “The point of insurance is to insure against catastrophic care costs. That’s what you’re trying to aggregate and pool for such things as heart attacks and cancer,” said an Anthem Blue Cross spokesman. “Having a child is a matter of choice. Dealing with an adult onset illness, such as diabetes, heart disease breast or prostate cancer, is not a matter of choice.” Even Louisiana Gov Bobby Jindal (R) spoke an unintentional truth when he said of his parents: “When they arrived in Baton Rouge, my mother was already four-and-a-half-months pregnant. I was what folks in the insurance industry now call a pre-existing condition.” When a woman isn’t currently pregnant, she often still cannot get coverage. Many insurers consider a C-section pregnancy a pre-existing condition and refuse to cover women who have had the procedure. From a 2008 New York Times story about a Colorado woman who had Golden Rule Insurance: She was turned down because she had given birth by cesarean section. Having the operation once makes the odds that it will be performed again, and if she became pregnant and needed another C-section, Golden Rule did not want to pay for it. A letter from the company explained that if she had been sterilized after the cesarean, or if she were over 40 and had given birth two or more years before applying, she might have qualified. The number of C-sections performed in the United States has been growing steadily, with approximately 30% of women having the procedure. Other insurance companies that don’t necessarily reject women with C-sections often do charge them higher premiums or factor in chronic or recurring problems that might have led to the cesarean. What’s even worse is that once you’re denied by one company, it’s harder to get coverage somewhere else because you’ve been red-flagged.

PHEW!

Yahoo News reports: an Indonesian woman has given birth to an 8.7 kg baby boy, the heaviest newborn ever recorded in the country. The baby, 62 cm long, was born by cesarean section at a public hospital. The delivering surgeon said. “This heavy baby made the surgery really tough, especially the process of taking him out of his mum’s womb. His legs were so big.” The boy was healthy despite having to initially be given oxygen to overcome breathing problems. “He’s got strong appetite,” the doctor said, “every minute, it’s almost non-stop feeding.” The boy’s huge size, doctors posited, was likely the result of his mother having diabetes. Indonesia’s previous heaviest baby weighed in at 6.9 kilos.

US & AFRICA

The March of Dimes reported that North America (Canada and the US) recorded 500,000 preemie births in a recent survey, but its preterm birth rate is close to that of Africa, at 10.6%. More than 1 million babies born prematurely die each year before they are a month old, according to a comprehensive study by the March of Dimes. About 10% of infants, 12.9 million, are born before 37 weeks, and more than 85% of preemie births occur in Africa and Asia. The highest rate is Africa, where 11.9% of births are preterm. In the United States, the rate of preterm births has increased 36% in the past 25 years, with births between the 34th and 36th week of gestation accounting for the majority of the increase. The high rate is linked to more pregnancies after the age of 35 and the use of fertility treatments.

NO DEFECTS

Cancer treatment of pregnant women doesn’t result in an increased risk of birth defects, according to a study by Kristeler Van Calsteren. Nor do these children suffer from any discernible negative effects in the long term. The placenta functions as a filter for most of cancer drugs and it protects the fetus against the damaging effects of chemotherapy. In addition, chemotherapy is not administered during the first trimester. For her study, a team of pediatricians and psychologists monitored 64 children. The project examined the treatments that are currently administered to pregnant women with cancer. Furthermore, it researched the influence of these therapies on fetal development and the health of the child at birth. In cases of specific types of cancer and specific cancer treatments, growth retardation in the womb was observed, but the children made up for this delay after birth. The number and types of congenital defects were found to be no different in cases where chemotherapy was administered to mothers. Researchers analyzed the pharmacokinetics of chemotherapy drugs in pregnancy and the transplacental transfer of the medication. It was found that cancer medication is distributed over a greater volume and is also excreted more quickly by the body of pregnant women. Some medications barely penetrate the placenta, while in cases of other drugs the same concentration is found in both the mother and fetus. The 64 children examined by pediatric neurologists and neuropsychologists were in a normal condition at birth. As they grew older, the children’s...
GETTING INVOLVED
It's important that doctors involve the whole family in NICU decisions, according to an article in the Wall Street Journal. The paper reported on the Washington University School of Medicine, which has an active family centered care program, one that views families as not just visitors, but part of the intensive care team. Parents can stay in the NICU 24 hours a day. They're urged to offer observations during rounds, participate in treatment decisions and learn as much as they can before taking an infant home. The idea has been slow to catch on. But while there have been no cost-benefit analyses, small studies have found that family-centered NICU practices lessen behavioral stress and improve weight gain for preemies, and reduce the need for breathing and feeding tubes. And while bringing families around involved a Japanese woman and her baby, who both developed leukemia. The researchers used genetic fingerprinting to prove that the leukemia cells found in the baby had originated from the mother and demonstrated that both patients' leukemic cells carried an identical mutated cancer gene. They found that the cancer cells lacked some DNA which played a crucial role in giving them their own specific molecular identity. As a result, the child's immune system was unable to recognize the cells as foreign, and thus was not mobilized to attack them.

COOL IT
Babies who are starved of oxygen at birth have a much lower risk of brain damage if they are given mild hypothermia, according to researchers at Imperial College London. More than 300 babies were involved in a trial carried out at 33 hospitals in the UK and in five other countries. Researchers found full-term babies who suffered oxygen loss at birth were 57% more likely to survive without brain damage if their bodies were cooled. The babies' body temperature was brought down by about 4°C using a fluid-filled mat under their sheet. Doctors believe that slowing the infants' metabolism reduces the aftershocks of the birth trauma, giving the brain time to recover. Half of the newborn babies in the study had their body temperature reduced to 33-34°C (91-93°F) for 72 hours followed by gradual re-warming in intensive care. Reported by the BBC, online.

BABY, IT'S COLD OUTSIDE
The Wall Street Journal reports on the belief that children born in the winter months test poorly, don't get as far in school, earn less, are less healthy, and don't live as long as children born at other times of year. Now, economists at Notre Dame have challenged these commonly-accepted findings. One economist who was working on factors involving sibling behavior noticed that children in the same families tended to be born at the same time of year. Meanwhile, the other economist was examining the economic factors that lead to multiple births, and finding a relationship between maternal education levels and when children were born. The two economists compared notes. They postulated that if winter babies were more likely to come from less-privileged families, it would be natural to expect them to do more poorly in life. The two economists examined birth certificates from the CDC for 52 million children born between 1989 and 2001, which represents virtually all of US births in
those years. The same pattern kept turning up: the percentage of children born to unwed mothers, teenage mothers and mothers who hadn’t completed high school kept peaking in January every year. Over the 13-year period, for example, 13.2% of January births were to teen mothers, compared with 12% in May, a small but statistically significant difference. The two economists estimated that family background accounts for up to 50% of the differences in education and earnings. This suggested that previous models weren’t necessarily accurate because they mixed privilege and education, instead of isolating them. So now the question becomes, what drives women from different socioeconomic backgrounds to tend to have children at different times of the year. The economists posited that perhaps it had to do with fluctuations in employment, in that married women tend to conceive when unemployment is higher. They also speculated that it might be due to cooler temperatures in springtime, which don’t adversely affect the fertility of poor parents, who may not have air conditioning, like hot temperatures do. Or they wonder if there might even be a “prom” effect at work. January is, after all, about nine months after prom season. From information reported by the Wall Street Journal.

EDUCATION
Contemporary Forums (at contemporaryforums.com) has published its schedule of educational conferences dealing with neonatal issues. Its sessions will be presented at the National Conference on Neonatal Nursing March 16-20 in Las Vegas; Neonatal Pharmacology, May 12-15, Orlando; and Neonatal & Pediatric Nutrition, May 17-19, San Diego.

MY WOMB OR YOURS
Uterine Transplant UK is collecting funds to perform the first human womb transplant, likely within the next two years. Recent successful rabbit-womb transplantation has encouraged the UK scientists. The technique involves transplanting the womb along with its major blood vessels, including the aorta. Previous surgeons had problems connecting a successful vascular graft. Any baby would have to be a c-section. Researchers cautioned, however, that there was a difference between transplants with rabbits and humans.

SCREEN TEST
Comparative genomic hybridization (CGH) is a new fertility screening technique that tests embryos for genetic faults. It is said to be especially useful for older women, whose embryos carry a greater risk of genetic errors. The screening checks chromosomes in the developing embryo when it is a few days old, meaning only those embryos with the best chance of success are used in fertility treatment. Researchers at Oxford University reported that 60% of the women in their test group became pregnant after screening—more than double the number who typically get pregnant without it.

KICKIN’ IT
Fetal kick charts, used to determine if a pregnancy is progressing well, are inaccurate and should be discontinued, according to Irish researchers. Researchers from Cork University say the charts rely on the mother’s perceptions and may lead to miscounts of a baby’s movements. They recommend checking the fetal heart rate instead. The researchers from Cork University College Maternity Hospital questioned a hundred Irish obstetricians and found that only a third had a clinical practice guideline for dealing with reduced fetal movements. In the UK, 70% of obstetricians have these guidelines. Researchers noted that fetal kick charts didn’t compare well to more modern methods such as measuring the fetal heart rate with a cardiotocograph (CTG) and ultrasound. Kick charts, which are in use in many maternity units worldwide, are of no benefit for reducing poor outcomes in low-risk pregnant women. A mother’s subjective perception of diminished movements is a better predictor of problems.

POO ON PEE
Researchers in Tulsa, OK, have found a link between sulfa drugs and nitrofurantoin birth defects. However, antibiotics are also used to treat bacterial infections in fetuses. The CDC-funded research analyzed data from 13,000 mothers in ten states whose infants had birth defects and 5,000 women who lived in the same regions with healthy babies. It was unclear whether the birth defects were caused by the drugs or by the underlying infections being treated. The defects linked to sulfa drugs were anencephaly and heart problems and shortened limbs. Defects linked to nitrofurantoin were heart problems and cleft palate, and these drugs were seen to double or triple the risk.

A LEG UP
Preemies who receive leg movement training display foot-reaching behaviors similar to that of full-term infants, according to a study by Ohio State University. This finding supports foot-reaching play as an early intervention strategy to encourage interaction with physical objects in preterm infants who have movement problems within the first months of postnatal life. Previous studies have shown that full-term infants make contact with toys using their feet before reaching with their hands. In the study, 27 preemies under 33 weeks of gestational age received either movement training or social training by their caregivers for 8 weeks. Movement training consisted of various foot games. The infants were tested and videotaped for a total of five sessions. Infants in the movement training group outperformed infants for foot-to-toy contact. Researchers said their findings provide clinicians with a new intervention strategy for encouraging object interaction within the first months of life in infants at risk for long-term motor impairments.

OPEN ACCESS
The universities Berkeley, Cornell, Dartmouth, Harvard and MIT recently announced a joint commitment to provide their researchers with central financial assistance to cover open access publication fees, and encouraged other academic institutions to join them. The aim of the Compact for Open Access Publication Equity (COPE) is to create a level playing field between subscription-based journals (which institutions support centrally via library budgets) and open access journals (which often depend on publication fees). The Compact commits each university to the timely establishment of durable mechanisms for underwriting reasonable publication charges for articles written by its faculty and published in fee-based open-access journals and for which other institutions would not be expected to provide funds. The two-pronged approach pioneered by Harvard, mandating deposit of faculty publications into the university’s Open Access repository while also providing explicit support for fully open publishing models, was set to provide an extremely influential model. In other BioMed news, under the terms of the UK’s NIHR Supporter Membership arrangement, all NHS researchers supported by the NIHR and its partners will benefit from a 15% discount on publication fees when publishing in any of BioMed Central’s 200 peer-reviewed open access journals. A list of current NIHR-funded research on
BioMed Central can be found at biomedcentral.com/inst/37456...
Also, the organization is again publishing the Journal of Medical Case Reports and Cases Journal, which provide more than 2,000 freely-accessible case reports.

BIRTHING TODAY (A Commentary)
From the Huffington Post, correspondent Christiane Northrup reports: “As an obstetrician/gynecologist, I have spent the last 30 years educating women about the wisdom of their bodies, including their innate ability to birth normally. Yet our so-called healthcare system, which is a direct reflection of the beliefs of our culture, sees the female body and its processes (like labor) as an accident waiting to happen. Media images of birth as an emergency play right into this. The truth is that labor and birth need not be the emergencies we think they are. And the medicalization of birth actually does more harm than good. I was a resident back in the late 1970s when electronic fetal monitoring was first introduced and lauded as a panacea that would prevent cerebral palsy and birth injuries. Thirty years later, data indicates that the only thing EFM has done reliably is increase the rate of C-section births. Although EFM is the most common obstetric procedure today, it hasn’t reduced perinatal mortality or the risk of cerebral palsy. Monitoring also draws the attention away from the laboring woman herself, who needs the support, and transfers it to the monitor screen—as if she and the monitor screen were two separate entities. [As such], it’s little wonder that our C-section rate is now a whopping 33% percent. At least in part, this sky-high rate may be linked to doctors’ fears of being sued… Then there’s the issue of labor inductions. In 2006, more than 22% of all pregnant women in the US had induced labors, a rate that has more than doubled in the last 20 years. Similarly, women have been brainwashed into believing that because a C-section can be planned it’s therefore preferable to a normal birth—which, again, society sees as messy and inconvenient. Labor proceeds on its own schedule. The exquisite timing that is a result of the delicate interaction between a baby and her mother needs to be respected… It troubles me that more women don’t realize that a C-section is major surgery. And it carries with it a risk of maternal death that is five to seven times greater than a normal birth. Unfortunately, the American public (physicians included) has a false sense of security about the safety of C-sections because the statistics on maternal death are misleading. It’s well known that the maternal death rate in any given population is a very good indicator of the overall health status of that population, as is infant mortality. Unlike most other developed countries, pregnancy-related death statistics for the United States include only women who die within a six-week period after a pregnancy ends. Other developed countries include deaths that occur up to one year afterward. According to the Centers for Disease Control (CDC), the number of maternal deaths in the United States is probably up to three times as high as the number reported in our national statistics.” The above is edited from a feature that appeared in the Huffington Post, © 2001-2009 Christiane Northrup, Inc. All rights reserved. For the complete report go to huffingtonpost.com/christiane-northrup/c-section-or-natural-birth_b_323422.html.

LESBIANS & MIDWIVES
Midwives often struggle to meet the needs of pregnant women who are lesbians, with patients reporting that the midwives often focus on the moms’ sexuality rather than their expectancy. Researchers at Linkopings University and Uppsala University Hospital interviewed ten lesbians who all had experience of antenatal care, childbirth or postnatal care. Eight were in a relationship with another woman at the time of the study. The study showed that none of the women were offered any childbirth and parenting education and some assumed that this was because the midwife did not know how to handle two mothers rather than the mother and father unit normally seen in traditional parenting groups. The moms-to-be said they felt vulnerable and defenseless because of the way healthcare staff reacted to them and that healthcare staff focused more on their sexuality than their needs as pregnant women and prospective parents. Some women chose clinics that they knew were experienced in dealing with pregnant women who are lesbians. Interviewees stressed the importance of including the “second mother” in a conscious and natural way, as this conveyed an acceptance and tolerance of same-sex parents. One woman found a delivery ward visit upsetting when the midwife “emphasised the whole time ‘here is where the father can go and get coffee’ and ‘the father can sit here’ even though we were two woman couples present.” All the women saw the forms the midwife had to fill in as a source of embarrassment for both parties. Some were offended by the standard forms and saw them as conservative and stereotyped. Some of the women felt they had to educate their midwife and other staff about lesbian relationships and parenting. As one woman said, it was important for staff to acquire the knowledge, but not through the patients. “I can come and talk about it later, but not when I’m there to have a baby,” one mom said. Researchers said the study demonstrated that, although they are equal in the eyes of the law, pregnant women who are lesbians are not receiving the same care as other mothers-to-be.

IF YOU PUT IT ON, KEEP IT ON
Pregnant women who overeat during the holidays shouldn’t diet until after the baby is born, according to a report by UT Southwestern Medical Center. The report said that while it’s bad to gain too much weight during pregnancy, women shouldn’t overcompensate with a weight-loss diet. Women with high-risk conditions such as diabetes should be vigilant about remaining on a doctor-supervised diet to make sure blood sugar and other factors stay controlled.

IT’S A GUY THING
Adult male monkeys exposed to cocaine while in the womb had poor impulse control and were more vulnerable to drug abuse than female monkeys, even a decade after exposure, according to a study at Wake Forest University School of Medicine. Researchers were surprised to find that, even more than ten years after prenatal cocaine exposure, male monkeys ended up being more impulsive and possibly more susceptible to drug use. Researchers surmised that something was either protecting the females from the effects of cocaine in the womb or made the males more susceptible to its lasting effects. In tests on impulse control using banana pellets, researchers found that male monkeys always went for instant gratification, even when doing so limited their reward. The males who were exposed to cocaine in-utero had no patience or impulse control whatsoever and were less willing to wait for a larger food reward and preferred the immediately available, though much smaller, reward. Female monkeys exposed to cocaine reacted just like the control group.

MAN-SIZED DRINKING
A comparison of breast milk samples from Denmark and Finland revealed a significant difference in environmental chemicals which have previously been implicated in testicular cancer or in adversely affecting development of the fetal testis in humans.
and animals. In some countries, such as Denmark the prevalence of this disease and other male reproductive disorders, including poor semen quality and congenital genital abnormalities is conspicuously high; while in Finland, a similarly industrialized Nordic country, the incidences of these disorders are markedly lower. In the UK, almost 2,000 men are diagnosed with testicular cancer every year, and in the US this number is over 8,000. Environmental endocrine disrupting chemicals (EDCs) are commonly found in fatty foods, paints, plasticizers, pesticides, and the byproducts of industrial processes. Researchers measured levels of 121 chemicals in 68 breast milk samples from Denmark and Finland to compare exposure of mothers to EDCs. Their findings reinforced the view that environmental exposure to EDCs may explain some of the temporal and between-country differences in the incidence of male reproductive disorders. Nonetheless, moms were encouraged to continue breastfeeding.

**REWARDED**

Roxanna Irani, an MD/PhD student at The University of Texas Graduate School of Biomedical Sciences at Houston, has received a $10,000 fellowship for her efforts to better understand pre-eclampsia. Irani was co-author of a recent study in Nature Medicine in which researchers induced pre-eclampsia in pregnant mice by injecting them with autoantibodies isolated from women with the condition. Building on this research, Irani studied the impact of pre-eclampsia on the fetuses of pregnant mice and tested different drugs and proteins. Her findings appeared in the Nov 23 issue of The Journal of Experimental Medicine. She reported: “When we block the effects of the autoantibody in the mouse model, the size of the babies is restored and the placental and organ damage are lessened.” Her findings were lauded as outstanding basic science, with the potential to transform the current understanding, ability to screen for, and approaches to prevent or treat pre-eclampsia.

**RELEASE ME**

A federal appeals court has censured Arkansas prison officials for shackling a woman during labor, noting, “The practice of keeping female prisoners in shackles while they give birth is barbaric.” It’s legal in more than 40 states, and all too common, according to prisoners’ rights advocates. The ruling involved a 29-year-old nonviolent offender whose legs were shackled to the side of a hospital bed as she gave birth, even though there was no reason to consider her a flight risk. She sued prison officials, arguing that the shackles constrained her from moving during the most painful parts of labor and caused a permanent hip injury, torn stomach muscles, an umbilical hernia that required surgery, and a lifelong hip deformity. She won in trial court, lost in circuit court, and won on an en banc appeal. Information ©2009 The Advisory Board Company, nationalpartnership.org, from an editorial in The New York Times, via Medical News Today.

**NOT A CLEAN WIPE**

The use of vaginal and infant wipes soaked with chlorhexidine does not prevent neonatal sepsis, according to a study at the University of the Witwatersrand, South Africa. It also doesn’t prevent mother-infant transmission of disease-causing bacteria. Researchers evaluated the efficacy of intrapartum and neonatal chlorhexidine-coated wipes by studying 8,011 women, who were randomly assigned in a 1:1 ratio to chlorhexidine vaginal wipes or external genitalia water wipes during active labor. Their 8,129 newborn babies were assigned to chlorhexidine full-body (intervention group) or foot (control group) washes with chlorhexidine at birth, respectively. Lower vaginal swabs and neonatal skin swabs were gathered after delivery in order to assess colonization with potentially pathogenic bacteria. Primary outcomes were neonatal sepsis in the first three days of life and vertical transmission of group B streptococcus. The findings indicated that the rates of neonatal sepsis did not differ between the groups (chlorhexidine 3 percent compared to 4 percent in control group). The rates of colonization with group B streptococcus in newborn babies born to mothers in the chlorhexidine (54%) and control groups (55%) were similar. The absence of benefit was corroborated by the lack of effect on vertical transmission of the main sepsis-causing pathogens, and it was noted that further pursuit of such a low-cost and simple-to-deliver intervention should not be abandoned. They noted, “When vaginal and neonatal skin cleansing with chlorhexidine has been examined in high-risk settings, the dual intervention has reduced mortality. We strongly urge further studies of the role of chlorhexidine.”

**PUTTING IT OFF**

Women are delaying pregnancy because of the recession. Demographers at the Population Reference Bureau said the national birth rate fell to its lowest point last year since 2002. The birth rate represents the number of births per 1,000 women of childbearing age. Researchers found that nearly one-third of middle- and low-income women were putting off having a child because of the economy. The study also showed that many women were more careful about birth control but that some reported being less able to afford contraceptives. In Kansas City, MO, the area’s Planned Parenthood clinics have reported a 20% increase in the last year in the number of patients seeking birth control. A fertility study at Duke University estimated a 5 to 10% decline in 2009 in the total fertility rate, which is the number of infants born to a woman throughout her lifetime. The rate has been between 2% and 2.1% for a decade, and it was predicted to fall to about 1.85% by the end of 2009. The decline was expected to last up to two years. Information above is from the Kansas City Star, ©2009 The Advisory Board Company, via Medical News Today.

**NOT SO FATSO**

Scientists have discovered a link between a mother’s diet in pregnancy and non-alcoholic fatty liver disease in her child. Scientists at the University of Southampton noted that NAFLD was once considered harmless but it’s now one of the most common forms of liver disease that may progress to cirrhosis. Too much saturated fat in a mother’s diet can affect the developing liver of a fetus, making it more susceptible to developing the disease later in life.

**SEX STATS**

According to a new report from the Guttmacher Institute, a sexual health organization, worldwide rates of abortion and unintended pregnancy are falling all over, primarily due to increased use of contraceptives, but significant disparities remain in that the developed world abortions are mainly carried out safely and legally, whereas in the developing world, 70,000 women a year die as a result of unsafe, illegal abortions. Worldwide, the number of abortions fell from an estimated 45.5 million in 1995 to 41.6 million in 2003. While both developed and developing countries show the same trend, the decline is faster in the developed world. Rates of decline vary more widely in the developing world than in the developed world because of differences in the availability of safe abortion services and in the rate of contraceptive use.
developing world, with Africa lagging behind the rest. The fall in numbers of abortions worldwide is in line with a global trend toward more liberal abortion laws. Nineteen countries have relaxed laws restricting abortions since 1997, compared to three countries that have substantially tightened legal restrictions. The report also noted that 40% of the women worldwide live in countries with highly restrictive abortion laws, nearly all in the developing world. Abortion rates are the same in regions where it is broadly legal and regions where it is highly restricted. About 5 million women are treated every year for complications arising from unsafe abortions, while 3 million who need it don’t get any treatment, said the report. The rate of unintended pregnancy fell from 69 per 1,000 women aged 15 to 44 in 1995 to 55 per 1,000 in 2008. The proportion of married women using contraception in 1990 was 54%; in 2003 it was 63%. Seventy-one percent of married women in Latin America and the Caribbean were using contraceptives in 2003, only 28% per cent of married African women were. In 2002 to 2007, 25% per cent of married women in Africa who needed contraception were not able to get it. From an article written by Catharine Paddock, PhD Copyright: Medical News Today.

CAN’T BREATHE
Children born with low birth weight are at a higher risk of developing asthma later in life, according to a study by the Krolinska Institute. Data on asthma in 9- and 12- year old twins was linked to the national Swedish Medical Birth Registry. Twins were used because they have the same gestational age and share DNA, uterine environment and conditions of early infancy, and as such are an excellent way to examine the relationship between fetal growth and childhood disease. The study revealed a definite correlation between fetal growth and asthma, independent of gestational age and environmental or genetic factors.

FOLLICKING
Pregnant women who take folic acid as part of their prenatal care are being warned about taking medications that block the acid during the first trimester. Reserchers at Ben-Gurion University examined birth and abortion data collected from 84,832 babies in Israel between 1998 and 2007. They concluded that first trimester exposure to folic acid antagonists is associated with increased risk for neural tube, cardiovascular and urinary tract defects. They considered the effects of dihydrofolate reductase inhibitors and antiepileptics. Exposure to these folic acid antagonists in the first trimester more than doubled the risk of congenital malformations in the fetus, and neural tube defects, such as spina bifida and malformations of the brain, increase more than six-fold. For the full study see I. Matok, et al, Exposure To Folic Acid Antagonists During The First Trimester of Pregnancy and the Risk of Major Malformations; British Journal of Clinical Pharmacology (2009).

NO GAS NO PROB
H2 blocker drugs for acid reflux pose no significant risks for the fetus, according to a study by Ben-Gurion University of the Negev. Researchers studied, predominantly, Famotidine, typically prescribed to pregnant women. The study linked a database of medications dispensed over 10 years to moms of the 84,800 infants born during the investigation. The rate of major congenital malformations identified in the group exposed to H2 blockers during the first trimester was 5.7% percent, compared with 5.3% in the unexposed group. The results were unchanged when therapeutic abortions of exposed fetuses were included in the analysis. Also, infants exposed in utero had no increased risk of perinatal mortality, low birth weight or premature birth.

FATAL COMPLICATIONS
More than 2 million infants and women around the world die each year from childbirth-related complications, according to a study at Johns Hopkins funded by the Gates Foundation. More than a million babies are stillborn and another 904,000 die soon after birth. By comparison, 820,000 children die from malaria and 208,000 die from HIV/AIDS worldwide. Forty-two percent of the world’s 536,000 maternal deaths also occur during childbirth, according to the study. Deaths in Africa and South Asia account for three-quarters of the maternal and infant deaths. The report also examines the 60 million neglected home births a year, noting that 600,000 babies per annum could survive if healthcare was improved. Only about a million out of 8 million doctors worldwide work in countries where 77% of childbirth deaths occur, and these are focused in urban areas. The foregoing was reported by the Associated Press, globalhealth.kff.org. ©Henry J. Kaiser Family Foundation.

TRANSCUTANEOUS MONITORING

TCM4/40: A Case Report

The following was provided by Radiometer.

The condition of a sick neonate or infant can take a turn for the worse in a matter of minutes. However, being able to constantly monitor and immediately react to changes in oxygen and carbon dioxide levels can help to avoid organ damage and failure.

Monitoring oxygen and carbon dioxide
There are several methods of monitoring oxygen and carbon dioxide in neonates and infants. These include:

- Transcutaneous monitoring of pO2/ pCO2
- End tidal CO2 monitoring
- Pulse oximetry
- Blood samples

Each method poses certain advantages—and limitations. Transcutaneous monitoring offers an effective, non-invasive and continuous monitoring of pO2 and pCO2. For optimal results, a combination of methods is typically recommended. This case provides essential combined monitoring information on the oxygen delivery and the circulatory status.

Case: Combining monitoring methods
A term boy with birth asphyxia and meconium aspiration syndrome requiring HFO and surfactant instillation. At age 35 hours, with an FO2 (I) of 0.45, a mean arterial blood pressure of 45 mmHg (6.0 kPa), and an infusion of dopamine of 6 mg/kg/min, tcpO2 started decreasing from 52 mmHg (6.9 kPa) to 44 mmHg (5.9 kPa) within less than an hour. All other parameters including blood pressure, pulse oximeter readings, and tcpCO2 were stable. When tcpO2 decreased with stable pulse oximeter saturation, it was most likely caused by peripheral vasoconstriction. The stable arterial oxygen status and normal lactate concentrations were confirmed by a blood sample. A bolus of saline was administered, leading to an increase in tcpO2.
One hour later, tcpO2 started to decrease again without changes in other values. An echocardiography revealed poor contractibility of the heart, and infusion of dobutamine was initiated, leading to rapid normalization of tcpO2.

PRODUCT FEATURE

**NeoMed Inc**

Recent Joint Commission Sentinel Event Alerts (2006, 2008) highlight the critical misconception errors that take place when different devices utilizing the same Luer lock system are erroneously connected. NeoMed Inc (Woodstock, GA) has developed a system to eradicate such errors, enhancing patient care and safety when enteral feeding is a component of overall medical attention. At the cornerstone of NeoMed’s Enteral Safety System (ESS) are oral/enteral dispensers (1cc, 3cc, 6cc, 12cc, 20cc, 35cc, 60cc) that facilitate pump feedings and deliver nutrition through an enteral only extension set down to an enteral only feeding tube, removing the risk of a tube misconception. NeoMed's enteral system includes oral/enteral dispensers, oral extension sets and feeding tubes that are designed to be incompatible with IV or Luer locking devices. The unique ESS design includes a 2-dimensional barcode printed on the barrel of the syringe, making device and content tracking seamless while safeguarding patients against dangerous misconnection and dosing errors. NeoMed offers the only complete enteral delivery system that complies with all recommendations set by the JCAHO and the Association for Advancement of Medical Instrumentation (AAMI). By utilizing ESS, the risk of unintended clinical line connection is eliminated.

NeoMed's SafeBaby, a secure feeding and milk management system, was developed to ensure that every baby in the NICU receives the right breast milk, donor milk or formula, risk free, at the bedside by way of 2-dimensional (2-D) bar coding technology driven by our SafeBaby proprietary software. SafeBaby's 2-D bar coding technology eliminates patient misfeeds while monitoring the entire inventory of milk for FIFO (first in first out), fresh/frozen/thawed, location, donor milk, fortification and more. SafeBaby recently released version 2.1 that improves current reporting and offers a robust user interface designed to enhance ease of use. NeoMed's Breast Milk Tracking System was recently highlighted in Nutrition in Clinical Practice by Guenter, et al as a comprehensive system that combines both enteral devices (syringes, feeding tubes) and technology to enhance patient safety. SafeBaby's 2-D bar code/ESS syringe combination protects these vulnerable patients from potential misfeeds and dangerous tubbing misconctions, making it the gold standard of feeding and milk tracking management for your NICU.

Recently, several GPOs (Group Purchasing Organizations) have signed supply agreements with NeoMed for its line of enteral/oral syringes and neonatal products. Novation (Irvine, TX) presented to its members on July 1, 2009 access to NeoMed’s oral/enteral syringe product line under the New Technology program. Beginning September 1, the complete line of NeoMed products, including SafeBaby, was made available to MedAssets’ (Alpharetta, GA) members.

1 The Joint Commission Journal on Quality and Patient Safety, Position Paper on Tubing Misconnections, 4-16-08.

PRODUCTS AND COMPANIES

**TRACH IT EASY**

The new Size 1 Sil.Flex Stoma Pad from B&B Medical Technologies provides a long-needed solution to improve comfort and care for infants with tracheostomies. The patent-pending Sil.Flex Stoma Pad is an ergonomically designed device that provides a cushion between the rigid flange of the tracheostomy tube and stoma site. The contoured surface of the Sil.Flex Stoma Pad provides a stable, comfortable interface between the flange and the patient’s skin. Use of the Sil.Flex may assist in lowering irritation of the skin at the stoma site. Sil.Flex Stoma Pads are made of a soft, fillerless elastomeric silicone encased in polyurethane. Pliable and flexible, the Sil.Flex Stoma Pad is available in three unique shapes and sizes to provide a safe and cost effective solution for the smallest infant to the largest adult. Hypoallergenic and latex-free, each sterile Sil.Flex Stoma Pad is individually packaged. Contact bandb-medical.com.

**SECURE**

Beevers Manufacturing announced that it will soon be offering a new cannula and NG/OG securement adhesive for the smallest premature babies. Through the collaboration of caregivers, hospitals and experts in the neonatal field, BMS is soon to announce the worldwide product release of the New Mini Whiskers Product. For those NICUs and caregivers who demand only the best care for their little ones, Beevers will offer a full range of securement products for protection against skin irritations and skin breakdown when NCPAP, oxygen and NG/OG therapies are required. Contact beevers.net.

**CONTRACTIONS**

The University of Pennsylvania Health System, one of the largest health systems in the US, has awarded a $135 million contract for Integrated Service Management to Siemens Healthcare. Over the next seven years, Siemens will be servicing and ensuring around-the-clock availability of diagnostic systems and biomedical devices from diverse manufacturers in the Health System's various hospitals. While the diagnostic systems involved include MRI scanners, CT scanners and ultrasound systems, the second group comprises, for example, laboratory systems, surveillance monitors and anesthesia units. Many diagnostic systems are constantly monitored via a data link for remote services. This can make it possible to prevent or repair faults without having to dispatch a service engineer to the installation site. Another important aspect of Integrated Service Management is that Siemens provides consulting services to the clinic on workflow optimization and offers advanced training for service engineers and operating personnel. The new contract represents a continuous extension of the preceding eight-year service agreement. Contact usa-siemens.com.

**SHHH**

Bunnell Incorporated announced a sound reduction upgrade for the Life Pulse High-Frequency ventilator. The upgrade reduces sound output from an average 56 dB to 41 dB (using an A-weight averaging meter). The upgrade results in a 15 dB decrease that is perceived as a 60% reduction in sound level compared to the current Life Pulse model. The Life Pulse is now 4 dB below the...
American Academy of Pediatrics’ recommended sound level of 45 dB for NICUs. This current effort represents Bunnell’s second sound reduction upgrade in the last five years. Contact bunl.com.

**WARMER**

Enthermics Medical Systems has added another product to its WarmRight line of combination blanket and fluid warmers. The EC1260bl is a dual-chambered fluid warming cabinet with an 18” (457mm) depth that’s perfect for built-in applications. The upper fluid compartment has a single pull-out basket that holds up to 29 liters and can be set to warm either irrigation or injection fluids. Temperature range for injection fluids is 95° to 104°F, while the range for irrigation fluid is 95° to 150°F. WarmWatch is an additional option. The lower blanket chamber has a capacity of 8.7 cubic feet. The temperature can be set as high as 200°F—up to 50°F warmer than most other warmers—keeping blankets warmer longer. Glass door for inventory at-a-glance, locking casters, rugged hinges and latches as well as heavy-duty stainless steel construction keep our warmers up and running for years of trouble free service. Enthermics fluid warming chambers help manage core body temperature to reduce the risk of hypothermia and the complications that can result from it. For this very reason, Enthermics pioneered the WarmRight concept. The warmers offer three different temperature environments—one for blankets, one for injection fluids, and another for irrigation fluids—with variable heat control within each environment. Contact enthermics.com.

**TO LIFE**

GE Healthcare is dedicated to providing care throughout a patient’s lifespan, beginning with the very fragile first few days. Community Regional (Fresno, CA) is the latest facility to implement the proof behind this pledge, by going live on Centricity Perinatal in their level III Neonatal Intensive Care Unit (NICU). Community Regional is part of a two-hospital Wide Area Network (WAN) and has used Centricity Perinatal in their Labor and Delivery and Postpartum units since 1998 to assist with the medical center’s 10,000+ deliveries per year. By expanding use of GE’s clinical information system into the NICU, Community Regional’s RNs and providers will be able to document electronically, allowing information to flow into the patient’s EMR. In the NICU, Centricity Perinatal allows important patient data to flow into all areas of the perinatal care environment. The Mother Baby Link decreases transcription errors and helps increase patient safety while neonatologists have improved workflow by freeing themselves from the weight and difficulties of paper records. Using ADT, Laboratory and COLD Feed interfaces, Centricity Perinatal allows for seamless integration with the hospital HIS system and provides clinicians with the babies’ physiological data. Contact ge.com.

**TAKING CARE**

GE Healthcare announced the FDA-cleared CARESCAPE Monitor B850, which provides caregivers with a unique level of integration between patient monitoring data and hospital information systems. Unlike traditional patient monitors, CARESCAPE Monitor B850 directly links hospital networks, electronic medical records (EMRs), diagnostic images, lab results and third-party devices with real-time patient monitoring data, to support efficient clinical decision-making. This enables CARESCAPE Monitor B850 to integrate its continuous clinical measurements with other elements of the patient record, delivering it at the point of care. The CARESCAPE Monitor B850 brings together the strong clinical heritage of Datex-Ohmeda’s anesthesia and Marquette Electronics’ cardiac expertise. It provides customized clinical information displays by care area and clinician preference, while also enabling hospitals to standardize on a monitoring platform throughout the organization. Developed with thousands of hours of field and in-house testing, the CARESCAPE Monitor B850 is the latest product in the GE Healthcare CARESCAPE portfolio, designed to deliver streamlined access to critical patient information for enhanced decision-making. Contact ge.com.

**IMAGINE**

GE announced that it will spend $3 billion over the next six years on healthcare innovation that will help deliver better care to more people at lower cost. In addition, the company will commit $2 billion of financing and $1 billion in related GE technology and content to drive healthcare information technology and health in rural and underserved areas. These investments are the foundation of GE’s healthymagination initiative, which is built on the global commitments of reducing costs, improving quality and expanding access for millions of people. Under healthymagination, by 2015 GE will invest $3 billion in research and development to launch at least 100 innovations that lower cost, increase access and improve quality by 15%. GE will work with partners to focus innovations on four critical needs to start: accelerating healthcare information technology, target high-tech products to more affordable price points, broaden access to the underserved, and support consumer-driven health. The company will expand its employee health efforts by creating new wellness and healthy worksite programs while keeping cost increases below the rate of inflation. It plans to increase the “value gap” between its health spend and GE Healthcare’s earnings to drive new value for GE shareholders. GE will engage experts and leaders on policy and programs and create a GE Health Advisory Board, which will include former US senators Bill Frist and Tom Daschle and other global healthcare leaders. The company’s business growth strategy centers on better healthcare for more people at lower cost, using an “ecomagination” model. Healthymagination will draw on capabilities from across GE, including GE Healthcare, GE Capital, GE Water, NBC Universal, the GE Global Research Center as well as the GE Foundation, the philanthropic arm of GE. The company will work with partners to address critical healthcare needs, and will launch 50 low-cost products that offer powerful technology capabilities with simple operation and application. GE will also seek to increase the use and capability of electronic medical record (EMR) technology and other information technology that speed communications, limit variation and control costs. Along these lines, GE, Intermountain Healthcare and the Mayo Clinic have developed physician decision support through IT in the form of evidence-based care and will launch it commercially this year. Among other features of its program, GE will expand its maternal infant care product offerings by 35% and will invest and scale its work with Grameen Bank to 10 countries by 2015. GE previously partnered with the Nobel Prize-winning organization and has now agreed to the joint goal of creating a sustainable rural health model that reduces maternal and infant mortality by more than 20%. Contact healthyimagination.com.

**PASSIONATE**

Instrumentation Laboratory (IL) announced the three recipients of their Passion & Results Award. The winners were presented with their awards by IL during ceremonies at the Congress for the International Society on Thrombosis and Haemostasis (ISTH) held in Boston and at the Annual Meeting for the
American Association for Clinical Chemistry (AACC), in Chicago. The award honors healthcare providers who have demonstrated true passion for their profession, resulting in improved patient care. The company received an overwhelming number of nominations for professionals involved in critical care and hemostasis diagnostics, all around the world. The winners were Dr Cesare Manotti, president of the Italian Federation of Centers for the Surveillance of Anticoagulant therapies (FCSA) in Milan, Giacinto Gervasi, MS, MT(ASCP), Lead Technologist in the laboratory Department of Syosset Hospital, NY, and Diane Davis, MT(ASCP)SH, Clinical Laboratory Specialist, Pathology/Laboratory Medicine, All Children’s Hospital, St Petersburg, FL. Dr Manotti developed new tools and processes in diagnostics. He pioneered the development of PARMA OAT Software and contributed heavily to quantifiably improving Oral Anticoagulant Therapy (OAT) quality throughout Europe with PARMA and other related software. Giacinto Gervasi was chosen for an exemplary career as a laboratory technologist. His career began in 1966, and ever since, he has been recognized as being “invaluable to the lab” for his intelligence, enthusiasm, good judgment, and for being a resource for the entire staff. Diane Davis developed an entire POC testing program—from scratch and with no set of directions or an existing model. Davis’s point-of-care-testing (POCT) program has been heralded as “one of the best in the US.” It provides testing for three pediatric ICUs, an 80-bed neonatal ICU, a cardiovascular OR, the cath lab, and the emergency room. Contact ilww.com.

RESEARCH
MedImmune announced the first observational prospective study designed to assess the burden of respiratory syncytial virus among preterm infants 32- to 35 weeks gestational age in outpatient settings during their first year of life. The study also seeks to gather virology data regarding the national onset of the RSV season across the four geographic regions established by the Centers for Disease Control & Prevention. Additionally, this two-year observational study will look to identify the preterm infants that may be most susceptible to serious RSV infection and the factors that may elevate that risk. The intent of this first-of-its-kind prospective study is to add to the body of evidence surrounding RSV burden of disease, gaining a snapshot of when the RSV season starts and stops, as well as gathering insight into what risk factors may make preterm infants most susceptible to RSV infection and to serious RSV-related illness. This observational, prospective study will cover two consecutive RSV seasons and began patient enrollment in the fall 2009, with a target of 3,000 participants across 100 outpatient sites in the United States. The study population includes infants born at 32-to-35 weeks who do not receive RSV prophylaxis during their first RSV season. Contact medimmune.com.

SYRINGES, ETC
Novation LLC, the supply contracting company of VHA Inc, University HealthSystem Consortium and Provista, awarded a contract to NeoMed Inc for NeoMed’s line of enteral/oral syringes. This agreement was awarded under Novation’s New Technology program and highlights NeoMed’s innovative, enteral only design that includes a 2D barcode on the barrel of the syringe facilitating device and content tracking. NeoMed’s products are at the core of ensuring patient safety by avoiding dangerous misconnection and dosing errors. In other company news, NeoMed recently released a software update to its SafeBaby BreastMilk Tracking System. Software enhancements include improved and more comprehensive reporting and user interface to enhance ease-of-use. NeoMed combines innovative enteral delivery devices (ie, feeding tubes, enteral syringes etc, and breastmilk tracking technology to ensure that enteral misconnections and mis-feeds are eliminated). Contact neomedinc.com or gopreemie.com.

MILKING IT
Medela hosted a Virtual Human Milk (breastmilk) Collection Campaign in honor of the March of Dimes’ National Prematurity Awareness Month and the thousands of dedicated neonatal healthcare professionals nationwide. Throughout the month of November, individuals could register their vote for their preferred NICU. The winners in four geographic regions received $5,000 each worth of Medela products or education services for their facility, including Symphony Preemie program cards, Symphony breastpumps, Waterless Milk Warmers, Creamatocrit Plus, Transport/Discharge Bags, BabyWeigh scales and/or Medela NICU Education programs. Contact medela.com.

PARTNERS
Somanetics Corporation announced that it has signed an Exclusive Sublicense Agreement with Raba Equity Partners II, LLC (“Raba coreFoundry”). Under terms of the agreement, Somanetics has obtained exclusive rights, subject to specified rights of the US Government and rights retained by Johns Hopkins University, to new cerebral autoregulation technology developed at The Johns Hopkins University. Integration of this technology into Somanetics’ INVOS Cerebral/Somatic Oximeter would yield the first noninvasive monitor providing cerebral autoregulation data for routine clinical use. The cerebral autoregulation technology is associated with two pending patents. Somanetics has provided Raba coreFoundry an up-front, non-refundable payment of $1.8 million and will pay a royalty on future revenue associated with the technology. The up-front payment is accounted for as a research and development expense in the fourth quarter of fiscal 2009. Somanetics plans to utilize this patent-pending method of combining blood pressure measurements and signals from the INVOS System to continuously monitor and display cerebral autoregulatory function information. Somanetics plans to file a new 510(k) pre-market notification with the FDA to support marketing the new module in the US by late 2010 and initiate product shipments for sale early in 2011. Contact somanetics.com.

CHECK PLEASE
Royal Philips Electronics announced the launch of BiliChek, its updated, feature-enhanced bilirubin assessment tool. BiliChek is a noninvasive, transcutaneous assessment device that can quickly determine a neonate’s risk for hyperbilirubinemia, store the results, and then forward them to a hospital’s electronic information system to automate patient charting. Instead of a needle, BiliChek uses advanced light technology to instantly and accurately assess the risk of an infant for hyperbilirubinemia. Resting lightly on a baby’s head or sternum, only a disposable plastic tip touches the baby, reducing the risk of infection or possible cross contamination. The new BiliChek incorporates an expanded set of features that allow even a first-time user to take high-quality measurements. New features include menu-driven instructions that walk a new or inexperienced user through the measurement process, a new ergonomic design that improves user dexterity, and a barcode scanner that allows accurate verification of patient identification. The new BiliChek also provides the ability to verify, store and track patient information related to bilirubin through a hospital’s electronic medical
IT’S A PEPPER
The new Pepper Medical Inc Pedi-Vent-Tie # 401-P is a patented Ventilator Anti-disconnect Device coupled with a trach tube neckband. This unique combination device offers a margin of safety to ventilator dependent patients and clinicians alike. The easy to use Pedi-Vent-Tie features a quick release Velcro strap that is compatible with all trach tubes, elbow connectors, and closed suction devices. The integral anti-disconnect strap eliminates the use of rubber bands, shoelaces and tape to secure the ventilator circuitry to the trach tube. The Pedi-Vent-Tie neckband is made of a soft, 100% cotton flannel that offers moisture wicking properties to keep skin dry and cool. This disposable, combination product saves time and money by offering an all-in-one device. The economical Pedi-Vent-Tie is priced at $3.95 each, individually packaged in boxes of 20 each. Free samples available upon request. Contact peppermedical.com.

SCREENING
When it comes to assisted reproductive technologies (IVF), the medical experts at Reproductive Medicine Associates of New Jersey (RMANJ) have pioneered and successfully implemented a cutting-edge technology—known as 24-chromosome aneuploidy screening—to more accurately detect healthy embryos, which will lead to successful pregnancies and, ultimately, healthy babies. Other centers have attempted similar testing methods, but RMANJ is the only fertility center in the world to have developed a system of unprecedented accuracy, fully validated through years of rigorous clinical research. RMANJ’s 24-chromosome aneuploidy screening offers advanced embryo selection with extreme accuracy by detecting and eliminating embryos with chromosomal abnormalities prior to implantation and pregnancy. This advanced embryo selection technique will not only eliminate specific conditions such as Down Syndrome, but also dramatically reduce miscarriage rates and reduce the need to implant multiple embryos to achieve conception. The ultimate reproductive medicine goal of “one embryo, one healthy baby” is now one large step closer to fruition. Contact rmanj.com.

CONNECTIONS
Smiths Medical has partnered with the leading enteral syringe companies to allow Medfusion 3500 pumps to now recognize NeoMed, Baxa NeoThrive, and Vygon enteral syringes, which will help reduce the risk of IV and enteral misconnections. Adding enteral syringe data to PharmGuard v5 software for Medfusion 3500 pumps allows clinicians to meet Joint Commission requirements for enteral feedings, differentiate their patients’ IV and enteral lines, and help meet their facility’s needs by providing safe and accurate enteral delivery. NeoMed, Baxa NeoThrive, and Vygon enteral syringes contain unique tips that will not connect to standard IV Luers and have orange or purple coloring for easy enteral identification. Seven of their enteral syringes will be recognized by PharmGuard software for Medfusion 3500 pumps. Contact smiths-medical.com.

BEDSIDE TIP
Corpak MedSystems announces the addition of the NEO MAPCath Stylet to the NAVIGATØR BioNavigation family. This now allows the NAVIGATØR technology to be used with PICCs 1.9 Fr and greater. PICC tip confirmation during the initial sterile insertion procedure increases patient safety, improves the PICC insertion procedure and reduces the cost of insertion. Patient safety is increased by reducing radiation exposure of multiple x-rays, eliminating malpositioned PICCs and reducing the time the patient is removed from a closed, warm isolette. Use of the NAVIGATØR improves the procedure by eliminating catheter repositioning post initial x-ray, raising the efficiency of the procedure and therefore improving the Time to Treatment (TT). The technology lowers costs by reducing multiple x-rays, multiple sterile field set-ups and associated nursing time as well as lessening the chance for fluoroscopy use. For more information please contact corpakmedsystems.com, (800) 323-6305.

REGULATED
Boehringer Laboratories, LLC introduced its new Neonatal Suction Regulator Series. The new Pediatric Series Suction Regulators are designed to meet the unique clinical needs of neonatal intensive care applications by providing safe, low (0-100 mmHg) suction to the patient. The added safety of these products effectively reduces the risk of pneumatic biopsy, resulting in a higher level of confidence for nurses and clinicians. Suction controls can be environmental reservoirs of hospital pathogens. Boehringer Suction regulators offer the only controls that are repeatedly steam autoclavable to assure the clinician confidence in the safety of their controls. The Series comprises the Model 3810 Continuous Pediatric Regulator with on/off selector valve and Model 3814 Continuous Pediatric Regulator without on/off selector valve. Contact boehringerlabs.com.

SPOTLIGHT ON OXIMETRY
REVOLUTIONARY
GEM Premier 4000 is the revolutionary analyzer (BG, Electrolytes, Metabolites, Glu, Lac, Hct, tHb, O₂Hb, COHb, HHb, MetHb, sO₂, BUN*, Creat*, Total Bili*, HCO3,* [*in development]) with integrated CO-Oximetry that quickly provides consistent, accurate, lab-quality results throughout your hospital. Easy-to-use, touch-screen displays make it simple to select and customize parameters. Self-contained cartridges incorporate all components for patient testing and are maintenance-free. IQM automates quality control and continuously detects, corrects and documents to assure quality results and compliance, 24/7, regardless of operator or testing location. GEMweb Plus software enables remote access to any networked analyzer for real-time status updates and supervision of remote locations. Contact liww.com.

FORESIGHT
CASMED announced that its FORE-SIGHT has received expanded labeling that provides absolute accuracy for all patient populations, regardless of age or weight. This includes babies less than 2.5 kg. This makes FORE-SIGHT the only device in its class with absolute accuracy for all patient populations. Combined with a full line of optimized cerebral sensors, including small, medium and large, FORE-SIGHT now offers a complete cerebral oxygenation monitoring solution. With the assurance of high precision, clinicians can be more confident in their patient assessments. CASMED, a leader in vital signs monitoring systems, presents the innovative FORE-SIGHT Absolute Cerebral Oximeter. This non-invasive device provides immediate, reliable data for assessing a patient’s cerebral oxygenation status, allowing clinicians to quickly react to reverse potentially harmful events before they become critical. FORE-SIGHT is the first and only device in its class that provides a non-trend, absolute measure of cerebral tissue oxygen saturation for all patients,
regardless of age or weight. The product’s Intelligent SctO2 monitoring system features patient-based algorithms. It offers proven precision from LASER-SIGHT technology—no baseline is needed. The company offers a full line of optimized sensors including small non-adhesive (for fragile skin), small, small-non-adhesive, medium and large. Also, FORE-SIGHT is the only oximeter in the US with COOL-LIGHT technology; that is, the light source is generated in the box and transmitted via fiber optic cables. This assures zero risk of patient burns at the sensor site.

Contact casmed.com.

PAPERS
CASMed offers a series of white papers and abstracts featuring the latest clinical studies relating to its FORE-SIGHT oximeters. Among the latest research: • Absolute and Trending Accuracy of Oximeters in Healthy Volunteers (The results demonstrate that the FORE-SIGHT cerebral oximeter monitor has much greater precision with respect to measuring both absolute and trend changes in cerebral tissue oxygen saturation than [another] cerebral oximeter monitor; • Absolute Cerebral Oximetry in Benchchair Positioning for Shoulder Surgery; • Cerebral Desaturations in Thoracic Surgery: Possible Positive Correlation with Cognitive Dysfunction; • Non-Invasive Monitoring of Brain Oxygenation for Complex Cerebral Aneurysm Surgery; • Monitoring of Non-Invasive Absolute Brain Oxygenation Measurement of Absolute Viscerosomatic Tissue Oxygen Saturation: Preliminary Results (These preliminary results demonstrate the ability of NIRS to estimate absolute tissue oxygen saturation of the liver. The provision of accurate regional brain and viscerosomatic tissue oxygen saturations by non-invasive measurement could be of important clinical value in both the OR and ICU when treating critically ill pediatric patients.;) • Real Time Monitoring of Cerebral Blood Flow Autoregulation with NIRS during Cardiac Surgery; • Non-Invasive Cerebral Oximetry to Assess Cerebral Perfusion During Resuscitation from CPR; • Anesthesia Management; • The Incidence of Cerebral Oxygen Desaturation Events during Surgery in the Beach Chair Position; • Validation of the FORE-SIGHT Pediatric NIRS Cerebral Oximeter; • Risk of Post-Op Complications Below Different Cerebral Oxgenation Thresholds during Aortic Surgery (decreased SctO2 values and prolonged DHCA times were found to be associated with major complications. The results also demonstrate that absolute cerebral oximetry thresholds are not a function of SctO2 alone, but both SctO2 and time exposure spent below a given threshold.). For more contact casmed.com.

TAILORED & SYNCED
Somanetics offers its INVOS Cerebral/Somatic Oximeter. Somanetics’ INVOS System with sensors tailored for infants and neonates provides continuous, noninvasive monitoring of site-specific blood oxygenation for patients of any weight. Its regional oxygen saturation (rSO2) reflects the surplus of oxygen remaining after tissues have taken what they need. Decreases in this venous reserve reflect increased ischemic risk and compromised tissue perfusion. When rSO2 drops, clinicians can intervene to prevent or lessen ischemic complications. It is the only simultaneous cerebral/somatic oximeter commercially available in the US, and the only one with labeling for improved outcomes after surgery in patients greater than 2.5 kg. Somanetics’ Vital Sync system takes NIRS data to new levels by combining regional oxygen saturation (rSO2) with vital patient parameters you choose—all on one time-synced bedside display. This spotlights the status and inter-relationships of NIRS data and other parameters most relevant to your patient’s condition, facilitating early detection of worsening patient condition. Touch-screen interactivity also enables easy electronic review of patient data monitored over the course of care. With automatic collection and compilation of multiple metrics and out-of-the-box connectivity, the Vital Sync system is well suited for bedside care and research data aggregation. Contact somanetics.com, (800) 359-7662.

OXIMETRY ROUNDTABLE
Somanetics – INVOS Cerebral/ Somatic Oximeter

What oximetry products do you offer?
Somanetics manufactures the INVOS Cerebral/Somatic Oximeter which utilizes near infrared spectroscopy (NIRS) to noninvasively monitor regional hemoglobin oxygen saturation (rSO2) in the brain and other tissues beneath the sensor. The INVOS monitor has a proven history in adult patients since the late 1990s, in pediatric patients since 2000 and was most recently tailored for neonatal patients in 2007. The INVOS monitor is the only commercially available cerebral/somatic oximeter in the US. Clinicians report that cerebral/somatic monitoring (with up to four sensors) is extremely useful as a noninvasive means to track perfusion distribution across cerebral and peripheral vascular beds, and to quicken detection and treatment of ischemic issues. In the NICU, rSO2 monitoring via the INVOS System is currently useful to help identify and manage perfusion-related issues commonly associated with congenital heart abnormalities, necrotizing enterocolitis, ventilatory management, and patients requiring ECMO. A decade of clinical experience in more than 750 facilities across all patient populations has resulted in an extremely robust clinical monitor. With more than 750 clinical references, the INVOS System is the referenced standard for cerebral/somatic oximetry. Applying these study findings to other regional oximeters may not be clinically or scientifically valid since results were derived using the INVOS System and its proprietary measurement algorithm.

What are the latest changes/improvements in oximetry products?
While regional oximetry first emerged for adult cerebral monitoring during cardiac surgery and is standard practice today, use in pediatric and neonatal intensive care settings has quickly equaled that demand. Increasing demand to monitor the smallest of NICU patients has driven continued evolution of the INVOS System to meet this need. Somanetics has introduced its second generation OxyAlert NIRSensor, a smaller more flexible sensor for monitoring very small neonates. We have also provided data to the FDA and secured expanded labeling assuring NICU clinicians with on-label treatment of infants and neonates at any weight. We also recognized the need for a simple system that facilitates comprehensive assessment of patient data—including rSO2 values—so less time can be spent gathering patient data and more time can be spent delivering bedside care. Vital Sync, a system co-developed by a neonatologist for neonatologists—was introduced to address this need. Vital Sync automatically collects patient parameters and displays the most critical data for your patient’s condition at the point of care in a format you choose. This gives you a continuous view of the status and inter-relationships of rSO2 data and other vital parameters, to help you detect worsening patient condition early. The Vital Sync system
also enables easy electronic review of patient data monitored over the course of care, to strengthen communication about patient status and notable events across shift changes and during patient rounds. Vital Sync’s data aggregation capability also makes it valuable for research initiatives.

Discuss your company’s R&D efforts as they relate to oximetry.

Research and clinical case studies have shown that using the INVOS System in tandem with mean arterial pressure (MAP) has proven useful in detecting ischemia reflective of the loss of cerebral autoregulation. Losing this critical protection mechanism makes the brain vulnerable to changes in blood pressure and to potential brain injury. Clinicians most intimate with the INVOS System are in tune with its ability to help reflect dysautoregulation-related ischemia, but the onus is still on the clinician to tie the two parameters together. We are now pursuing FDA clearance for an autoregulation feature that would automatically generate a cerebral autoregulation measurement that’s practical for routine clinical use by all clinicians. To do this, Somanetics has obtained exclusive rights to technology developed at Johns Hopkins University. Initiatives are underway to combine blood pressure measurements with our INVOS System signals to generate continuous readings of cerebral autoregulatory function. Readily arming clinicians with this information will help them define patient-specific blood pressure targets and management techniques, rather than managing to standard ranges of blood pressure for patient size and age. This practice has been thought sufficient for intact cerebral autoregulation, although growing evidence suggests this is invalid for many patients. Additionally, NICUs nationwide are conducting INVOS System studies. The topics are many, and include exploration of the effects of drugs on organ perfusion, normative rSO2 values for newborns, and potential rSO2 correlations with a variety of disease states. As a relatively new technology in the NICU, these findings will be valuable in refining treatment protocols and best practices for INVOS System use in the NICU moving forward.

How has oximetry proven to be cost effective?

The INVOS System is the only cerebral/somatic oximeter with a labeling claim of improved outcomes. At the core of these improved outcomes is a reduction in clinical complications. This, in turn, results in cost avoidance that would have gone towards covering the complications and the resource utilization related to them. For example, peer-reviewed data published on neonates before palliation of hypoplastic left heart syndrome noted a connection between use of NIRS monitoring via the INVOS System and reduced utilization of resources, namely the use of inspired gases and preoperative ventilation. Similarly, a financial proforma based on a peer-reviewed adult outcomes study, estimated an average per patient savings of $2,774 in ICU costs alone.

What type of training and user support programs do you have in place?

Customer training is key to gaining the full clinical utility of INVOS System monitoring. Half of our field sales team are clinical education specialists with clinical backgrounds in nursing, perfusion, and respiratory care. This makes them uniquely aware of clinician and patient needs, as well as adherence to hospital protocols. When providing customer training, all medical specialties serving the NICU are encouraged to participate, such as neonatology, nursing, respiratory care, and ECMO specialists. Emphasis is placed on training across all shifts as well as implementing the “train-the-trainer” model to ensure continuity in staff education and practice of rSO2 monitoring.

Masimo

What oximetry products do you offer?

We offer a variety of bedside and handheld oximetry products and noninvasive sensors that meet virtually every neonatal need and help overcome the clinical challenges of monitoring the delicate physiology of neonates. Masimo neonatal and infant care solutions combine the “gold standard” measure-through motion and low-perfusion performance of Masimo SET pulse oximetry with the breakthrough blood constituent monitoring capabilities of Masimo Rainbow SET Pulse CO-Oximetry technology and a full line of innovative neonatal, infant, and pediatric sensors to help clinicians detect and treat a broad range of life-threatening conditions with greater precision and confidence. The result is unsurpassed accuracy, reliability, and innovation that dramatically reduces the incidence of Retinopathy of Prematurity (ROP), significantly increases the early detection of Congenital Heart Disease (CHD), help speed newborn resuscitation, and greatly improves monitoring capabilities for cyanotic infants.

- **Masimo Oximeters:** The Masimo Radical-7 is a 3-in-1 (bedside, handheld, transport) Pulse CO-Oximeter that provides noninvasive, continuous, immediate measurements of essential blood constituents, including: total hemoglobin (SpHbTM), oxygen content (SpOCTM), carboxyhemoglobin (SpCO), methemoglobin (SpMet), and PVI for fluid responsiveness, in addition to oxyhemoglobin (SpO2), perfusion index, and pulse rate. The ability to continuously measure, track and trend this amount of vital physiological data helps to eliminate the guesswork associated with neonatal patient monitoring and clinical assessments to potentially facilitate faster, easier, safer, and better clinical decisions.

- **Masimo Neonatal & Infant Sensor Options:** The Masimo LNOP Blue Sensor is the first-and-only adhesive sensor proven accurate on cyanotic neonatal patients who may have CHD and low arterial oxygen saturation. With validated accuracy in cyanotic infants with oxygen saturations as low as 60%, the Masimo Blue Sensor provides reliable, continuous pulse oximetry measurements that enable improved management of cardiac medications and ventilation therapy.¹

Masimo Newborn Neonatal and Newborn Infant/Pediatric Sensors automatically configure the oximeter for the fastest response time and highest sensitivity—allowing clinicians to quickly and efficiently get the physiological data they need during resuscitation. Masimo NeoPt and NeoPt-500 Sensors were developed specifically for premature infant monitoring. Uniquely designed for the fragile skin and size of extremely low birth weight (ELBW) infants (<1 kg) who may weigh 500 grams or less, Masimo NeoPt and NeoPt-500 sensors deliver the unmatched sensitivity, specificity, and measure-through motion and low-perfusion performance clinicians need to address the challenging requirements of premature neonatal patients. Masimo Infant, Multisite-L and Multisite-YI Sensors assist clinicians to accurately screen for and improve CHD detection early, helping to reduce the incidence of newborns discharged from the hospital with unrecognized CHD.
What are the latest changes/improvements in oximetry products?
The most notable recent improvements in oximetry products allow clinicians to more closely monitor vital measurements and tightly control therapies, while providing a unique opportunity to minimize medical waste, improve patient safety, and significantly reduce costs. • Continuous and Noninvasive Hemoglobin (SpHb): SpHb monitoring with Masimo Rainbow SET provides clinicians with an important new way of looking at their patients’ hemoglobin levels. Instead of relying on invasive, delayed, and intermittent hemoglobin measurements, SpHb provides real-time hemoglobin measurements that may enable earlier and better clinical decisions, improved patient safety, and decreased costs. • Masimo SpMet: Inhaled nitric oxide (iNO) therapy, gastroenteritis, infantile diarrhea, and extremely low birth weights have all been shown to induce dangerous levels of methemoglobinemia, which has been associated with failure to thrive in infants.3 Masimo Rainbow SET Pulse CO-Oximetry provides the first and only way to noninvasively and continuously assess methemoglobin levels, allowing for appropriate and timely intervention that can save lives and improve outcomes. • Masimo 3D Alarms: The early warning signs of critical events often include measurements trends and groupings that have historically been difficult to identify and track using conventional pulse oximeters that typically alarm based on large, isolated drops in oxygen saturation values. Masimo Desat Index 3D Alarm, a standard feature on the Masimo Radical-7 Pulse CO-Oximeters, provides clinicians with increased visibility and advanced notification of these conditions based on clinician-specified severity, frequency, and period of time. In infants, a common respiratory pattern called periodic breathing—where breathing alternates between rapid, shallow periods and slower periods of hypoventilation can result in repetitive, mild desaturations, any “one” of which is above the threshold, but may present as a train of events. These multiple, mild desaturations may be too small and too frequent to be detected by conventional pulse oximetry technology as individual desaturations. In some cases, when these desaturations repeat with a predictable periodicity, frequent nuisance alarms may result, forcing the caregiver to disable alarms. With Destauration 3D alarm, the software counts “cycles” of repetitive desaturations where SpO2 falls below a fixed threshold for a predetermined period of time. When the patient experiences these stereotyped and repetitive desaturations, an underlying problem is indicated that may lead to respiratory failure and should be captured and diagnosed.5 Similarly, Masimo Desat Index PI Alarm provides continuous tracking of perfusion at the monitored site to identify and notify clinicians of specified decreases in peripheral perfusion occurring within a specific period of time, which may indicate hypothermia, hypovolemia, shock and/or sepsis.4,6

Discuss your company’s R&D efforts as they relate to oximetry.
We believe that research and development is an interactive process. Clinical involvement is key to the development of clinically-relevant solutions that enable clinicians to overcome real-life patient care challenges. That’s why we continuously engage with clinicians worldwide to better understand both the physiological impact and applications of our innovative noninvasive measurements, as well as their role in helping to interpret physiology. This interactive process enables us to develop products that respond to the global differences in environmental and clinical conditions and expand the patient care applications of our measurements. For example, working closely with neonatal and pediatric clinicians provides a better understanding of the unique challenges of pulse oximetry in patients with special conditions, such as CHD, that allows us to develop special products, like the Masimo Blue Sensor to help clinicians overcome the physiological challenges to better care for these patients. Additionally, in some parts of the world, people are exposed to higher environmental levels of chemicals that may increase methemoglobin or carboxyhemoglobin levels, allowing us to expand the clinical applications of our SpHb and SpCO measurements to help clinicians identify and address these conditions much earlier. As a result of this process, we have continued to champion taking noninvasive monitoring to new sites and new applications with breakthrough oximetry innovations, like Masimo Rainbow SET Pulse CO-Oximetry technology, Masimo noninvasive and continuous hemoglobin (SpHb) monitoring technology, and coming soon…Masimo acoustic respiration monitoring (pending FDA clearance).

How has oximetry proven to be cost effective?
Capgemini, a leading supplier of global consulting and technology services, released a study earlier this year showing that a typical 500-bed hospital incorporating Masimo Rainbow SET Pulse CO-Oximetry into its clinical standards and care pathways could generate nearly $500,000 in net annual cost savings and financial gains. The study is the first to both qualify and quantify the significant financial benefits that could be derived from incorporating noninvasive total hemoglobin (SpHb) by helping clinicians prevent unnecessary blood transfusions, identify internal bleeding earlier, and increase patient throughput. When surveyed by Capgemini, a majority of anesthesiologists and two-thirds of surgeons believed that SpHb monitoring could prevent at least one unnecessary blood transfusion in every ten surgical cases on which it was used, contributing to $93,600 in net annual cost savings in a surgical department using 20 SpHb-enabled devices. The study also found that the majority of intensivists believed that SpHb monitoring could reduce intensive care length of stay by at least one day for every 15 or fewer patients on which it was used, contributing to $67,350 in net annual cost savings in an intensive care department using 10 SpHb-enabled devices. The study concluded that “whether considered on a per-patient, department, or hospital-wide analysis, there are significant clinical and financial benefits to implementing Pulse CO-Oximetry technology.”

What type of training and user support programs do you have in place?
We have one of the largest teams of pulse oximetry clinical specialists available. Nearly 50 full-time Masimo Clinical Specialists are on staff to provide customer training and support services, including comprehensive “super users” training. This team is augmented by nearly 100 fully-trained consultant clinical specialists (per diems) across the country and provides the breadth of customer support necessary to ensure unparalleled installation processes and resources. In addition, Masimo’s Technical Support Team is available 24/7 to answer questions and help resolve clinical issues related to pulse oximetry equipment. MasimoU (available online at masimo.com/MasimoU/index.htm) provides accredited and non-accredited courses in a convenient, self-paced online learning environment that allows clinicians to learn about noninvasive pulse oximetry and Pulse CO-Oximetry monitoring capabilities and its patient applications. MasimoU modules accredited for Continuing Respiratory Care Education Continued on page 51…
A Comparative Study of the MB11 BERApone and ABAER Automated Auditory Brainstem Response Newborn Hearing Screening Equipment

Karl R. White, PhD; Terry E. Foust, AuD; Randi L. Winston, AuD; Karen M. Ditty, AuD

Objective
Twenty years ago, most infants and young children with permanent hearing loss were not identified until they were 2-3 years old. According to the US Department of Health and Human Services, such late identification means that “it is difficult, if not impossible, for many [children with congenital hearing loss] to acquire the fundamental language, social, and cognitive skills that provide the foundation for later schooling and success in society. When early identification and intervention occur, hearing impaired children make dramatic progress, are more successful in school, and become more productive members of society. The earlier intervention and habilitation begin, the more dramatic the benefits (p. 460).

The importance of identifying permanent hearing loss has been recognized for decades, but until recently the knowledge and technology for efficiently identifying infants and young children with permanent hearing loss were not available. These circumstances began to change in the mid-1980s with the development of new technology for hearing screening and diagnosis, particularly the measurement in infants and young children of otoacoustic emissions (OAE) and automated auditory brainstem response (A-ABR), and the implementation in the United States of population-based universal newborn hearing screening programs. Based on the evidence about the feasibility and benefits of newborn hearing screening programs, the National Institutes of Health Consensus Development Conference recommended in March 1993, the “screening of all newborns… for hearing impairment prior to discharge.” Growing support for this recommendation was evidenced a few years later when the European Consensus Development Conference concluded that the “Identification by screening at or shortly after birth has the potential to improve quality of life and opportunities for those affected... Implementation of neonatal screening programs should not be delayed.”

The United States is now screening more than 95% of all newborns and national universal newborn hearing screening programs have also been implemented in the United Kingdom, Poland, Austria and Singapore, among others. Even developing countries such as South Africa, Nigeria, Brazil and India are seriously pursuing initiatives to screen infants and young children for hearing loss.

It is widely acknowledged that improvements in hearing screening technology were the prime contributor to dramatically reducing the age at which hearing loss is being identified, but most people agree that this early hearing screening equipment was really not very good. In the first large-scale clinical trial of universal newborn hearing screening that led to the recommendation of the NIH Consensus Development Conference that all newborns be screened for hearing loss, 26% of the newborns failed the screening test by the time they were discharged from the hospital and more than 6% were eventually referred for a diagnostic evaluation. Screening done with A-ABR during that time period also had extremely high referral rates viewed from today’s perspective (for example, Mehl and Thomson reported that 7% of infants were referred for diagnostic evaluations from the statewide newborn hearing screening program in Colorado).

Not surprisingly, attention continues to be focused on improving the equipment and techniques used to screen infants and young children for hearing loss. Much of the current concern about screening equipment focuses on ways to make the process more efficient and less costly with respect to both the cost of the equipment and the cost of consumable supplies, without giving up any accuracy.

A recommendation from several previous studies for improving efficiency and reducing cost of newborn hearing screening is the use of an automated device for measuring ABR known as the BERApone or MB11. According to the user manual available at beraphone.com:

Traditionally, the EEG for brainstem audiometry was obtained by sticking electrodes to the head of the (neonatal) patient.

<table>
<thead>
<tr>
<th>Biologic ABAER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass</td>
</tr>
<tr>
<td>Maico MB-11</td>
</tr>
<tr>
<td>(N=491)</td>
</tr>
<tr>
<td>Fail</td>
</tr>
<tr>
<td>(N=10)</td>
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Figure 1. Comparison of MB11 and ABAER Screening Results

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Table 1. Percent of ears passing the MB11 and ABAER for selected sample characteristics.

<table>
<thead>
<tr>
<th>State of Baby During ABR Testing</th>
<th>MB11</th>
<th>ABAER</th>
</tr>
</thead>
<tbody>
<tr>
<td>sleeping peacefully during test</td>
<td>94.3% (n=217/230)</td>
<td>90.5% (n=191/211)</td>
</tr>
<tr>
<td>awake, but relatively quiet during test</td>
<td>81.1% (n=193/238)</td>
<td>86.9% (n=252/290)</td>
</tr>
<tr>
<td>somewhat fussy during test</td>
<td>87.0% (n=80/92)</td>
<td>80.9 % (n=55/68)</td>
</tr>
<tr>
<td>very fussy during test</td>
<td>60.0% (n=12/20)</td>
<td>27.3% (n=3/11)</td>
</tr>
</tbody>
</table>

The patented BERApone has spring-mounted, stainless-steel electrodes, headphone, and preamplifier integrated in one unit which only has to be held against the (neonatal) patient’s head after the contact points on the head have been rendered more conductive by the application of electrode gel. The time-consuming procedure of sticking electrodes to the head with all the preparation is not necessary anymore. Because of the use of permanent electrodes, no disposable electrodes are required; the costs of use are minimal (only some electrode gel).

Previous studies evaluating the MB11 for use in newborn hearing screening programs have been uniformly positive. For example, Stürzebecher, Cebulla, and Neumann evaluated 114 infants with the BERApone to determine the best click rate for use of this device in newborn hearing screening programs. They concluded that the BERApone was an accurate and efficient device for hearing screening and that it was much faster than other ABR equipment.

Melagrina and his colleagues compared results of the MB11 BERApone with conventional diagnostic ABR for 201 “newborns.” They concluded that, “The results obtained confirm the absolute validity of MB11 screening test in subjects at audiologic risk.” Shehata and colleagues tested 1,349 newborns with an early version of the MB11 BERApone and found 5 infants with permanent hearing loss. They concluded that it was “a quick and easy method with high specificity that can be recommended for newborn hearing screening.” Meier and colleagues evaluated the efficiency and costs of 3 different ABR hearing screening devices (the Fisher-Zoth Echoscreen-TDA, the Algo 3, and the MB11 BERApone) by using each of the instruments with 50 different newborns. They concluded that all of the devices were appropriate to “be used for newborn hearing screen.”

Given the fact that previous studies have not compared the results of the MB11 BERApone with currently used screening equipment for the same babies in a typical newborn hearing screening setting, the objective of this study was to compare the results of the MB11 with the results of the Biologic ABAER widely used newborn hearing screening device marketed by Natus Medical Inc (natus.com). All data were collected as a part of a well-established newborn hearing screening program in the same setting and using the same screening personnel who were working in the program so that the results would be as comparable as possible with what happens in “real-life.”

Methods
Data for the study were collected from August of 2006 through July 2007 for 290 newborns in a hospital in the western United States that had operated a successful universal newborn hearing screening program for more than 10 years. The hospital has approximately 4,000 births per year and has a well-baby nursery and a level III neonatal intensive care unit (NICU). Prior to the commencement of the study, hearing screening for approximately 99% of the newborns in this hospital was completed using otoacoustic emissions (OAE) equipment (Otodynamics Ltd) as a first stage screening and an automated auditory brainstem response (A-ABR) testing using the ABAER equipment for all babies in the well-baby nursery who failed the OAE test. Prior to the study, babies in the NICU were tested with both the OAE and the ABAER equipment.

The goal of the study was to compare the screening results of the MB11 and the ABAER with a sample of newborns in which each baby was screened with both devices.

The MB11 equipment in the study used an automated detection algorithm and a novel, more efficient, broad-band stimulus (CEC) with a calibrated stimulus level of 35 dBnHL that was different from the algorithm used in previous studies with the MB11.

All babies who failed either the MB11 or the ABAER were to be followed up with diagnostic audiologic testing to determine his or her hearing status. Babies were selected and an invitation to participate in the study given to parents so that about 50% of the sample would include babies who had failed the initial OAE screening test and about half would be babies who had passed the initial OAE. Over-representation of babies who failed the initial OAE screening test was done to increase the number of newborns in the sample who had congenital hearing loss.
The hospital's Institutional Review Board (Ethics Committee) reviewed and approved the study but did not require parents to provide written consent since the study was considered a part of the hospital's ongoing quality improvement process. The order of testing was randomly alternated between the MB11 and the ABAER. Results for each baby on each test along with information about the order of testing, time to do testing, and brief demographic information about the baby was recorded on a form designed specifically for this study.

Data was collected by six different screeners who had been screening babies in this hospital using the OAE and ABAER equipment for at least three years. Screeners were trained by their supervisor who had been trained in using the MB11 equipment by a representative of MAICO. Following this training, each of the screeners did screening on at least 25 infants with the MB11 equipment. These infants were not enrolled in the study. A second training session was then conducted by a representative from MAICO who observed each of the screeners doing the MB11 testing, gave feedback, and confirmed that all the screeners were using the equipment correctly and competently.

Babies enrolled in the study had each ear tested with both the ABAER and the MB-11. The equipment used first for each baby was alternated (49.3% of the ears were tested first with the ABAER, and 50.7% were tested first with the MB11). If an ear did not pass the ABAER or MB-11 on the first attempt, a second attempt was made to rule out poor placement of earphone or probe. If the ear still did not pass for that piece of equipment, that ear was considered to have failed the screen.

Each screener was provided with a stop watch to time how long it took to do a screen for each ear with each piece of equipment. Screening time did not include transporting the baby to the location where testing was to be done, but did include the time the screen took for each ear including quieting the baby, documenting results, second attempts at screening when necessary, and other related activities. Times were recorded on the data sheet for each ear for piece of equipment.

The screener also recorded the baby's "state" at the time of testing for each ear on each piece of equipment using the following rating scale:

- Sleeping peacefully during test
- Awake, but relatively quiet during test
- Somewhat fussy during test
- Very fussy during test

The final sample consisted of 290 newborns who had been tested on both ears with OAE and were then screened with both the ABAER and the MB11 in random order. In almost all cases (>95%), the screener completed both tests during the same session. In a few cases where the session had to be interrupted, a different screener completed the second test, but this was rare. Of the 290 babies, 45.6% were female and 54.4% were male. The mean birth weight was 6 pounds 9 ounces (range 3 lbs 10 oz to 9 lbs 6 oz), gestational age ranged from 36 to 41 weeks with a mean of 38.8 weeks, and 87 of the 290 babies (30%) had spent some time in the NICU. A disproportional number of NICU babies were included in the sample to increase the probability of having some babies with permanent hearing loss in the sample.

### Results

Table 1 shows the number of babies included in the sample who failed or passed the initial OAE screening, were tested first by each piece of equipment, and the "state" of the baby during the ABAER or MB11 test. As can be seen, pass rates were very similar for each piece of equipment across the levels of initial OAE Screening Result and Order of Testing, but quite different (as would be expected) for the State of the Baby During ABR Testing. There was also a statistically significant interaction for the percentage of babies passing between screening device and State of Baby During ABR Testing (p<.05) indicating that higher pass rates can be achieved with the MB11 when babies are "fussy." These findings should be interpreted with caution however, since relatively few “fussy” babies were included in the study.

Figure 1 shows the agreement between the screening results for the MB11 and the ABAER for the 580 ears of the 290 newborns who were included in the study. As can be seen, 96.4% of the ears had the same result (84.7% that passed both, plus 11.7% that failed both). The results were very similar when the data were divided into those for whom the MB11 or the ABAER was administered first and those where the baby had passed or failed the initial OAE screening test.

Testing time for the ABAER and the MB11, which included prepping the baby, doing the screening test and documenting the results, was moderately correlated (r=.29). The MB11 testing time was statistically significantly shorter (t=43.8, p<.001) than the ABAER. Mean testing time per ear was 6 minutes and 52 seconds for the ABAER and 2 minutes and 17 seconds for the MB11 (median testing time was 5 minutes 55 seconds for the ABAER, and 1 minute 51 seconds for the MB11).

It is particularly important to know whether any newborns who failed the MB11, but passed the ABAER; or who passed the MB11 but failed the ABAER were eventually diagnosed with permanent hearing loss. Table 2 shows the results of the follow-up diagnostic testing which was available for 80 of the 87 (91.9%) ears of the babies who failed one or both of the tests and survived the neonatal period. As can be seen, all of the babies later diagnosed with hearing loss failed both the ABAER and the MB11.

### Conclusions

Screening results of the MB11 were comparable to those of the Biologic ABAER (one of the most widely used devices for newborn hearing screening in the United States) in terms of overall agreement and refer rates. Testing with the MB11 required less than one-third the time and the fact that no disposable supplies are needed for the MB11 (except for a small amount of electrode gel) means that the operational cost for
doing automated ABR cost is substantially lower than with other typically-used equipment.

References


Improved Compliance in the Second Year of the BEST Program

Dianne Montgomery, NNP; Vickie L. Baer, RN; Renee Rogerson, CCC-SLP; Rachael W. Gardner, RD; Robert D. Christensen, MD

Abstract
In January 2006 we instituted the BEST program with the aim of increasing the use of breast milk feedings among NICU patients <2 kg birth weight. We previously reported that in the first year after instituting this program more patients received human milk exclusively, more received some human milk, and more received banked human milk. In the present study, we sought to determine whether the success of the BEST program continued in its second year of implementation. We discovered that in the second year the percent of NICU patients who received human milk exclusively increased from 50% to 70% (p=0.00). The percent of patients receiving some human milk increased from 82% to 94% (p<0.01). Also, the percent receiving banked human milk increased from 33% to 55% (p=0.00). Thus, the BEST program was even more successful in its second year.

Methods
BEST Program Development
In 2005, a committee of health professionals from the McKay-Dee NICU sought to develop a program aimed at increasing the proportion of our NICU patients that receive human milk feedings. This program involved three aspects; 1) a new NICU paradigm was stated, namely to use human milk only, in so much as possible, for all feedings of infants <2 kg birth weight during their first seven days of feedings, 2) mothers of all patients <2 kg were contacted preferably <3 hours after delivery to encourage them to provide breast milk for their neonate for at least the first seven feeding days, 3) mothers who were unable or unwilling to provide breast milk were invited to sign an informed consent document permitting the use of pasteurized banked human milk for their neonate. This new effort, collectively termed the “BEST paradigm” was instituted on January 1, 2006 and has been in effect since.1

Data Analysis
Two years after instituting the BEST program, the present study was conducted, comparing breast milk utilization in three years (2005, 2006, and 2007). Data were obtained on every NICU admission with a birth weight <2 kg during all three years.

Patients in each study period were identified from the NICU admission records on the basis of date of birth and birth weight (<2 kg). Demographic information, the feeding substance administered to each patient each day for the first seven days of feeding, the diagnosis of NEC (criteria of Bell Stage ≥ II), and the length of hospital stay, were obtained from the medical records. Descriptive statistics were calculated using UCLA statistics (http://calculators.stat.ucla.edu/). Between group means were tested using independent samples t-tests when parametric assumptions were met, and with Wilcoxon Rank-Sum tests for non-parametric comparisons. Dichotomous variables were compared between groups using the Fisher Exact test (http://www.physics.csbsju.edu/stats/fisher.form.html). For all comparisons, 2-tailed tests were used. A P value of <0.05 was deemed significant.

Data Sets
The “Before Intervention” period was January 1, 2005 through December 31, 2005. The “First Year After Intervention” period was January 1, 2006 through December 31, 2006, and the “Second Year After Intervention” period was January 1, 2007 through December 31, 2007. This was a retrospective study using limited and de-identified data sets obtained from medical records of

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all patients admitted to the NICU at the McKay-Dee Hospital with birth weights <2 kg and a date of birth between specified dates. Specific information was gathered which included: birth weight; gestational age; race; gender; Apgar scores; length of stay; discharge weight; percentage of infants discharged home on human milk; diagnosis of necrotizing enterocolitis (NEC), bacterial or fungal sepsis. Data were collected on feeding method during the first 7 days of enteral feeding which were categorized as exclusive Breastmilk, Breastmilk plus formula, and no breast milk.

**Feeding Guidelines and Banked Human Milk**

During the entire period (January 1, 2005 through December 31, 2007), NICU patients <2 kg birth weight were fed according to the Intermountain Healthcare Feeding guidelines proposed by Street et al. These guidelines stipulate the volume and frequency of enteral feedings on each day, including when to use 22 kcal/oz and 24 kcal/oz feedings. Pasteurized human milk was obtained from the Mother’s Milk Bank (1719 East 19th Avenue, Denver, Colorado, USA, 88218).

**Hypotheses**

Our primary hypothesis was that a higher proportion of neonates <2 kg birth weight would receive human milk in the second year after instituting the BEST program than in the first year.

**Results**

Demographic features of the NICU patients in the three study periods are shown in Table 1. No differences were observed between the groups in birth weight, gestational age, race, or gender. A very slight improvement in one and five minute Apgar scores occurred in 2007 compared with the 2005 or 2006. The use of human milk during the first week of enteral feedings is shown in Table 2. In its second year the BEST program was associated with an even higher proportion of patients receiving human milk exclusively, receiving some human milk feedings, with fewer patients receiving no human milk feedings, and with more patients using banked human milk.

**Feeding-related outcomes are shown in Table 3. No statistically significant changes were observed between the three periods.**

**Discussion**

Quality improvement programs that are instituted in the NICU sometimes show initial success, only to be followed in time by a disappointing return to pre-program performance. An example can be seen in NICU sound-level reduction programs, instituted to produce a quieter NICU environment. Such programs can indeed reduce noise exposure, but over time, a return to above-consensus sound level recommendations is very common. Similar recidivism can be seen with quality improvement programs aimed at increasing hospital hand hygiene. Permanent quality improvement in the NICU occurs only if a new program becomes internalized, as a cultural change, into the daily work habits of the NICU staff, and becomes widely accepted by the staff as constituting a better practice.

When we instituted the BEST program in our NICU, in January 2006, it was with the express goal of increasing breast milk feedings, and consequently decreasing artificial formula feedings, among our NICU patients during their first seven days of feedings. We specifically targeted patients <2 kg birth weight because of the widely recognized advantages of human milk feedings for the smallest NICU patients. The three goals of the BEST program were; 1) to increase the proportion of patients receiving human milk exclusively, 2) to increase the proportion of patients receiving some human milk, and 3) to make banked

| Table 1. Demographic Features of Patients Born < 2kg During Three 12-Month Periods; 1) Before Implementing the “BEST Program”(2005), 2) The First Year After Initiating the Program (2006), and 3) The Second Year After Initiating the Program (2007). |
|---|---|---|---|---|---|
| | N infants | Birth weight (g) | Gestational age (w) | Race (% White) | Gender (% M) | Apgar 1 min | Apgar 5 min |
| Before (2005) | 130 | 1397±412 | 30±3 | 72% | 60% | 7±3 | 8±2 |
| First Year After (2006) | 115 | 1469±415 | 31±4 | 77% | 52% | 7±2 | 8±2 |
| Second Year After (2007) | 126 | 1489±485 | 31±3 | 74% | 53% | 8±2 | 9±2 |
| P value 2005 vs 2006 | 0.18 | 0.15 | 0.08 | 0.13 | 0.62 | <0.01 |
| P value 2006 vs 2007 | 0.35 | 0.40 | 0.37 | 0.49 | 0.01 | <0.01 |

**BEST, Breast Milk Early Saves Trouble;**

Shown as mean+SD, Median (Apgars), or percentage.
N = number; g = grams; w = weeks; min = minute; M = male

| Table 2. Human Milk Use During the First 7 Days of Feedings of Patients Born <2 kg During Three 12-Month Periods; 1) Before Implementing the “BEST Program”(2005), 2) The First Year After Initiating the Program (2006), and 3) The Second Year After Initiating the Program (2007). |
|---|---|---|---|
| | Received human milk exclusively | Received some human milk | Received no human milk |
| Before (2005) | 33% | 74% | 26% |
| First Year After (2006) | 50% | 82% | 18% |
| Second Year After (2007) | 70% | 94% | 6% |
| P value 2005 vs 2006 | <0.01 | <0.05 | <0.05 |
| P value 2006 vs 2007 | 0.00 | <0.01 | <0.01 |

**BEST, Breast Milk Early Saves Trouble;**

Shown as percentage
human milk available for patients whose mothers were unable or unwilling to provide milk for them. We reported significant initial success in achieving all three goals,1 and we now report that the level of success in all three goals increased even further in the second year of the program.

The demographics of our patient base did not change between the three years of comparison (Table 1). However, the proportion of patients receiving breast milk feedings increased each year (Table 2). We recognized no statistically significant improvements in feeding-related outcomes over this three-year period (Table 3), but such improvements were not expected with this small sample size. Nevertheless the mean values for length of hospital stay, weight at hospital discharge, and percent discharged breast feeding, were all in the direction of improvement (Table 3).

It seems to us that after an initial hesitation on the part of some of our NICU staff to embrace the goals of the BEST program, they are now uniformly enthusiastic. For instance, our bed-side NICU nurses appear to be very comfortable about explaining the program to families and obtaining permission for banked human milk feedings, whereas initially only the neonatologists, nurse practitioners, and lactation specialists obtained such consent. In the past year (2007) our NICU expanded banked milk usage to include all patients under 2500 grams if mom’s consent. In the past year (2007) our NICU expanded banked milk usage to include all patients under 2500 grams if mom’s consent. In the past year (2007) our NICU expanded banked milk usage to include all patients under 2500 grams if mom’s consent. In the past year (2007) our NICU expanded banked milk usage to include all patients under 2500 grams if mom’s consent.

References
2 Street JL, Montgomery D, Alder SC, Lambert DK, Gerstmann DR, Christensen RD. Implementing feeding guidelines for NICU patients <2000 g results in less variability in nutritional outcomes. JPEN. 2006;30:515-518.

Table 3. Feeding-Related Outcomes of Patients Born <2 kg During Three 12-month periods; 1) Before Implementing the “BEST Program”(2005), 2) The First Year After Initiating the Program (2006), and 3) The Second Year After Initiating the Program (2007).

<table>
<thead>
<tr>
<th></th>
<th>NEC %</th>
<th>Bacterial/ Fungal sepsis %</th>
<th>LOS (d)</th>
<th>Discharge weight (g)</th>
<th>Discharged home breast feeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before (2005)</td>
<td>2%</td>
<td>8%</td>
<td>44+26</td>
<td>2288±549</td>
<td>44%</td>
</tr>
<tr>
<td>First Year After (2006)</td>
<td>3%</td>
<td>10%</td>
<td>42+28</td>
<td>2334±603</td>
<td>53%</td>
</tr>
<tr>
<td>Second Year After (2007)</td>
<td>2%</td>
<td>10%</td>
<td>40+33</td>
<td>2372±613</td>
<td>54%</td>
</tr>
<tr>
<td>P value 2005 vs 2006</td>
<td>0.29</td>
<td>0.30</td>
<td>0.70</td>
<td>0.54</td>
<td>0.09</td>
</tr>
<tr>
<td>P value 2006 vs 2007</td>
<td>0.45</td>
<td>0.67</td>
<td>0.32</td>
<td>0.48</td>
<td>0.40</td>
</tr>
</tbody>
</table>

BEST, Breast Milk Early Saves Trouble; Shown as mean±SD, or percentage.
NEC, necrotizing enterocolitis (Bell stage > II); LOS, length of hospital stay. d, days; g, grams
Abstract

Objective: We sought to determine the feasibility of administering small amounts (0.2 mL) of mother's own colostrum, by every three-hour oropharyngeal swabbing, to very low birth weight (VLBW, <1500 grams) neonates for seven consecutive days.

Study Design: This was a prospective, non-masked, single-centered, pilot program testing the feasibility of a potential new NICU practice recently proposed by Drs N.A. Rodriguez and P.P. Meier (Journal of Perinatology advance online publication, 4 September 2008;doi:10.1038/jp.2008.130).

Results: During the 12-month pilot period (June 1, 2007 through May 31, 2008), 596 patients were admitted to the NICU, of whom 64 were VLBW. Of these, 56 (88%) were deemed eligible for the colostrum program. Mothers of 46 of these patients (82%) supplied colostrum for the swabbing program. The first oropharyngeal colostrum administrations occurred 40±28 hours (mean ± SD) after birth (range, 7 to 113 hours). The feasibility of this potential NICU practice was calculated for each subject by using the formula: “number of oropharyngeal colostrum administrations actually given divided by the number of administrations planned.” The feasibility statistic was 77±36%.

Conclusion: From the present measurements, we judge that the oropharyngeal colostrum practice proposed by Rodriguez and Meier is indeed feasible, within the limits of the problems and issues seen here. Specifically; 1) Eighty to 90% of mothers of VLBW neonates are likely to supply colostrum for such a program, 2) The first colostrum provided will generally not be available until the neonate is about two days-old, and 3) about 75-80% of the planned swabbings will actually be given as proposed. With this information, new studies are now needed to quantify the risks and benefits of this potential new NICU practice.

Introduction

Rodriquez and Meier et al proposed the practice of periodically administering small volumes of mother's own colostrum, by oropharyngeal swabbing, to extremely low birth weight neonates during their first days after birth. They theorized that providing colostrum in this unique way would enhance immunocompetence of ill neonates who were not yet receiving colostrum feedings. They speculated that periodically swabbing colostrum into the mouth would stimulate oropharyngeal-associated lymphoid tissue, while also supplying relevant cytokines and other immunological agents by transmucosal absorption. Moreover, this practice might assist in colonizing the neonate’s gastrointestinal track with maternal commensal organisms.

Despite the logic of the Rodriguez and Meier procedure, we know of no clinical trials testing the feasibility of performing this procedure in actual NICU practice, thus we questioned whether it was achievable as proposed. We herein report a 12-month single-institution pilot program aimed at quantifying the feasibility of oropharyngeal administration of mother’s own colostrum to very low birth weight (VLBW, <1500 g) neonates. We sought to quantify: 1) the percentage of VLBW neonates whose mothers would provide colostrum for this purpose, 2) the time (hours after delivery) at which the colostrum was pumped and administered to the neonate by way of oropharyngeal swabbing by the bedside nurse, 3) the feasibility of this approach as a NICU practice, quantified by the number of colostrum administrations given to each patient divided by the number of administrations planned.

Methods

The Mother’s Own Colostrum Swabbing Program

During the period June 1, 2007 through May 31, 2008, a colostrum swabbing program was tested in the McKay-Dee NICU, Ogden, UT, USA. The program involved swabbing the oropharynx of VLBW neonates, using mother’s own colostrum, every three hours for seven consecutive days. The swabbing was to occur whether or not an endotracheal tube was in place, and whether or not the patient was receiving intragastric feedings.

For each application of colostrum, the bedside nurse would dip a sterile cotton swab (Allegiance Cotton-Tipped Applicators, Cardinal Health, McGaw Park, IL) into a container of mother’s own colostrum, saturating the swab, which would generally hold 0.2 mL of colostrum. The swab was used to gently paint the colostrum inside the mouth, including the tongue, gums, and
Table 1. NICU admissions during the 12-month colostrum program (June 1, 2007 – May 31, 2008); including the numbers of VLBW patients admitted to the NICU, those eligible for the program, and those who actually received oropharyngeal colostrum swabbing.

<table>
<thead>
<tr>
<th>NICU admissions</th>
<th>VLBW NICU admissions</th>
<th>Patients eligible for the colostrum swabbing program</th>
<th>Patients whose mother provided colostrum for the swabbing program</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 6 months</td>
<td>291</td>
<td>31</td>
<td>26</td>
</tr>
<tr>
<td>Second 6 months</td>
<td>305</td>
<td>33</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td>596</td>
<td>64</td>
<td>56</td>
</tr>
</tbody>
</table>

Table 1 displays the first six-months vs the second six-months occurring within eight hours of the NICU admission. Of these eight had been transferred to the McKay-Dee NICU admissions VLBW NICU admissions Patients eligible for the colostrum swabbing program Patients whose mother provided colostrum for the swabbing program.

Electronic Data Collection and Statistical Analysis

Data were collected from Intermountain Healthcare electronic and paper records of patients admitted to the NICU at McKay Dee Hospital, Ogden, UT, born in the colostrum program interval. The program used for data collection was a modified subsystem of Clinical Workstation. The 3M Company (Minneapolis, MN) approved the structure and definitions of all data points for use within the program. Data were managed and accessed by authorized data analysts. Differences in categorical variables were assessed using the Fisher exact test. A Student t test was used to assess continuous variables. Statistical significance was set as P <0.05. The Intermountain Healthcare Institutional Review Board approved the study.

Results

During the 12-month colostrum pilot program 596 patients were admitted to the NICU, of whom 64 (11%) were VLBW. Eight were not deemed eligible for the colostrum program. Seven of these eight had been transferred to the McKay-Dee NICU from another NICU for ligation of a patent ductus arteriosus (generally at seven to ten days of age), with back-transport about 24 hours after surgery. Thus, there was no opportunity to have those seven participate in the colostrum program. One patient delivered at 23 weeks gestation was not deemed eligible because of a problematic resuscitation following delivery, with death occurring within eight hours of the NICU admission.

Table 1 displays the first six-months vs the second six-months of the colostrum program period, listing the number eligible and enrolled during each of these two blocks. The percentage of eligible patients who actually received colostrum swabbing was higher during the second six-month period. During the first six-months 18 of 26 had colostrum swabbing and in the second six-months 28 of 30 did so; (P=0.019). When a mother declined to provide colostrum, after hearing about the colostrum swabbing program, no explanation for her decision was sought.

Table 2 displays the patients according to birth weight category. When all VLBW neonates were considered together, the first oropharyngeal administration of colostrum occurred 40±28 hours after birth (mean±SD; range, 7 to 113 hours). The first intragastric feedings occurred 45±35 hours after birth (range, 9 to 194 hours). When feedings were begun before swabbing, it was always because the feedings of banked, pasteurized, human milk (Mother’s Milk Bank, Denver, CO, or Prolacta Bioscience, Monrovia, CA), were initiated before mother’s own colostrum was available.

The feasibility of the colostrum program, for each participant, was 77±36% (Table 2), meaning that, on average, during the seven-day period, 77% of the every 3-hour swabbings that were planned were actually given. No adverse events were reported in association with the colostrum administrations. We made no effort to assess immunological, infectious, feeding-related, or nutrition-related outcomes, because this program was designed expressly as a feasibility analysis.

Discussion

Oropharyngeal administration of colostrum, as performed in this program, is inherently different than the feeding of colostrum. Feeding colostrum to newly born VLBW preterm neonates involves tubal intragastric administration, bypassing the mouth, oropharynx, and esophagus. There is a general reluctance to administer intragastric feedings to very small and ill neonates on the first days following birth. This is illustrated by a recent National Institute of Child Health and Human Development Neonatal Network report authored by Meinzen-Derr et al,14 where, on average, the first intragastric feedings of ELBW neonates (<1000 grams) occurred seven to 10 days after birth.
birth. In contrast to intragastric tubal feedings of colostrum, the small amounts of colostrum we periodically swabbed into the oropharynx were not intended to reach the stomach or to undergo intestinal absorption, nor were they intended to provide nutrition in the traditional fashion. Rather, small amounts of colostrum were painted into the mouth with the expectation that it would be absorbed through the mucous membranes of the mouth, oropharynx, or proximal esophagus.\(^1\)

Benefits could, in theory, accrue to small and ill neonates from the practice of oropharyngeal swabbing of colostrum. First, stimulating the mucosa-associated lymphoid tissue in this way could provide a measure of active protection against infection.\(^1\) Second, the cytokines and growth factors absorbed from colostrum might passively enhance immunocompetence.\(^4,5,15-17\) Third, colostrum contains maternal commensal organisms, and perhaps early oral administration could colonize the mouth and oropharynx with beneficial microbes.\(^11,13\)

Rodriguez and Meier et al recently provided rationale supporting oropharyngeal administration of colostrums.\(^3\) Some of that rationale is based on the anti-infective factors in colostrums,\(^15,18\) and some is based on the actual reduction in infections\(^19-22\) and necrotizing enterocolitis\(^23-27\) among NICU patients fed human milk. However, we reasoned that before studies can be designed to quantify any benefits of this potential NICU practice, studies were first needed to assess feasibility. Thus, during a 12-month period, we invited mothers of VLBW neonates to provide their colostrum for every three-hour oropharyngeal swabbing of their neonate, for seven consecutive days. In general, we found mothers accepting of this program, with 82% providing colostrum. In the second half of our test period the proportion of mothers providing colostrum increased to 93%. We speculate this improvement was the result of increasing enthusiasm for the program by our nursing staff and lactation consultants.

We found it practically impossible to administer colostrum during the first 24 hours after birth, and on average, neonates were nearly two days-old when colostrum was first available for swabbing. Sometimes ill health of the mother, or recovery from cesarian section delivery, probably interfered with prompt pumping of colostrum. In some instances intragastric tubal feedings were initiated before the colostrum swabbing began. This occurred when feedings were begun using pasteurized human milk before mother's own colostrum was available. Whether oropharyngeal swabbing of colostrum provides any benefits after colostrum feedings have begun is speculative, as is, at this point, the benefit of the entire oropharyngeal swabbing program.\(^1\)

We found that once the first colostrum swabbing was given, the subsequent administrations were usually completed as planned. This resulted in what we termed a “feasibility statistic” of 77%, meaning 77% of the swabblings planned were actually carried out. When not carried out, it was invariably because no colostrum was available.

Given our findings, we judge that the procedure proposed by Rodriguez and Meier (1) can be accomplished in NICU practice, but with three complicating issues; 1) Ten to 20% of mothers will be unable or unwilling to provide colostrum, 2) colostrum will probably not be available for swabbing until about two-days after delivery, unless specific new programs are instituted to obtain it sooner and 3) colostrum will be available for only about 75 to 80% of the every three-hour swabblings that are planned.

Now that the feasibility of oropharyngeal colostrum swabbing is better understood, new studies are needed to quantify any benefits and risks of this practice. From our 12-month experience, we uncovered no specific risks. Whether the theoretical benefits proposed by Rodriguez and Meier will indeed accrue to recipients of this practice is a pivotal question awaiting investigation.

**References**

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THE LITTLE THINGS MATTER MOST
Patent Omphalomesenteric Duct
Pratibha A. Ankola, Chinyere Oarhe, Leena Benoy

Abstract
A Patent Omphalomesenteric Duct is a relatively rare anomaly of the spectrum of Vitellointestinal anomalies. An awareness of the diversity of these malformations in type and symptomatology is essential to their proper and optimal management. Diagnosis is made clinically and confirmed radiologically. Treatment is surgical resection.

Introduction
A patent ophalomesenteric duct (OMD) is a persistent open vitello intestinal duct that connects the umbilicus (yolk sac in the fetus) to the ileum. The discharge in a patent OMD may be serous, sero-purulent, bilious or feculent because the duct represents a direct communication between the umbilicus and the small bowel. It may also present as Umbilical granuloma or as one of its complications that include small bowel prolapse, intussusception of Ileum, obstruction, intestinal inflammation and hemorrhage, and infection (Omphalitis).

The presence of an umbilical discharge in a neonate could indicate other diagnoses besides a patent OMD and include a patent Urachus, Umbilical sinus or Umbilical granuloma with clear discharge or Omphalitis with purulent discharge.

Case Report
A 3,270g male neonate delivered to a 33 yr old Gravida 3 Para 1101 woman at 39 weeks by normal spontaneous vaginal delivery. APGAR scores were 9 and 9 at 1 and 5 mins respectively. Maternal history was significant for HIV infection with a last viral load of <50 copies/ml and CD4 count of 444 cells/mm3. Maternal genital swab was positive for Group B Streptococcal infection.

Physical examination at birth was normal. Baby was started on Zidovudine at 2mg/kg/doses every 6 hours. On the second day of life, meconium stained fluid was draining from the umbilicus. A patent omphalomesenteric duct was suspected and a radiographic study was done to establish the diagnosis (fig 1). A fistulous connection between the umbilicus and loops of small bowel in the right lower quadrant (likely representing distal ileum) was demonstrated. An echocardiogram was normal. Pediatric surgery was consulted. Omphalomesenteric duct was resected on the third day of life (fig 2). Post operative course was unremarkable and baby was sent home after tolerating feeds by mouth and having normal bowel movements.

Discussion
The OMD is a normal structural component of the intrauterine fetal development, formed between the 5th and 9th week of gestation, connecting the fetal gut with the yolk sac. The yolk sac and the allantois are vestigial structures which usually undergo degeneration by the 3rd month of gestation. Regression of the allantois results in a fibrous cord known as Urachus. This ligament passes from the apex of the bladder to the umbilicus.1

In both structures, regression may remain incomplete and portions may persist into later life. The persistence of the remnant of the vitelline duct in the newborn is classified as an Omphalomesenteric duct malformation. The varieties of these malformations vary from complete patency of the duct to a simple diverticulum (Meckel’s) arising from the antimesenteric border of the distal ileum.

These malformations are found in equal frequency among both sexes, but a significantly greater incidence of symptoms is encountered in males. Although one of the very most frequent
malformation to be found is Meckel's diverticulum (2-3% of the population), it is one of the most unlikely to cause symptoms. Although OMD remnants are relatively common, occurring in 2% of the population, it is uncommon for them to be symptomatic. In a series of 217 children who were discovered to have this anomaly, only 40% had symptomatic lesions. The male to female ratio in this series was 2:1. The likelihood of a symptomatic presentation of OMD remnant was age dependent; 85% of infants younger than 1 month, 77% of children aged 1 month–2 years had symptomatic presentation. In contrast, only 15% of children older than 2 years had symptomatic presentation of this anomaly. Of children with symptomatic lesions, the most common presentations were rectal bleeding associated with Meckel's diverticulum (58%) and intestinal obstruction associated with volvulus around a fibrous vitelline band extending from the distal small bowel to the umbilicus (33%). Obstruction from intussusception, with Meckel's diverticulum as a lead point may also occur.

Symptomatic omphalomesenteric duct remnants require surgical resection. Early surgical management is necessary in infants to prevent complications, even if the anomaly is asymptomatic. In older children and adults with asymptomatic remnants that are found incidentally, resection is not necessary.

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5 Roger M Hinson, MD, Newborn Medicine Services, Department of Pediatrics, Madigan Army Medical Center, Tacoma, WA 98431.
7 Minutoli, F MD‡; Pecorella, G Restifo MD*; Pulizzi, S MD*; Turiaico, N MD†; Zuccarello, B MD†; Baldari, S MD*—Volume 33(8), August 2008, pp 577-578.

Addendum…continued from page 4

politicians have little interest and no stomach for opening up a public debate on any aspect of infertility treatments… I can't really see why the increased number of twin births through IVF merits the attention. Sure, it is a lifestyle choice that imposes a cost on society. But so do obesity, smoking and drunk driving… I've stood by quietly watching family and friends have children through IVF. In one case with twins, the mother was morbidly obese at the time of implantation, the children were born at 25 weeks gestation (related to the mother's obesity), spent 4 months in the NICU, and have life-long learning and physical disabilities. They were million dollar babies by the time they came home from the hospital. The goal should be to have healthy babies, not babies “now”… If a couple cannot have children without these extraordinary measures, they should adopt a child… For all those who'll immediately start whining about how much they want children, guess what? We don't always get what we want in life. I, for instance, don't want to have to pick up the tab for your IVF procedure, or for the health problems of your artificially-produced children.

The above article is edited from features which appeared in the New York Times, October 12, 2009. The commentary is from the New York Times blog.
Near infrared spectroscopy (NIRS) has been used extensively over the past decade to monitor oxygen delivery to the brain in adults, children and infants during cardiac and other major surgeries, improving outcome and preventing potentially catastrophic results from incidents such as accidental cannula misplacement.1-6 Over the last 6 years the use of NIRS (INVOS 5100C, Somanetics Corporation, Troy, MI) to monitor both cerebral and somatic tissues in infants and children during cardiac surgery and in the ICU has grown steadily, contributing significantly to the management of hemodynamics.7-12

The application of near infrared (NIR) light, 700 to 1000 nm wavelength, for spectroscopic analysis of hemoglobin saturation in vivo is based on the fact that very few substances in tissue absorb light at these overtone (harmonic) wavelengths, allowing for deeper light penetration. Spectroscopic analysis is based on the fact that absorption of electromagnetic radiation is band and wavelength specific and metaloproteins with prophyrin rings are the only biologic structures that absorb much NIR light. The cytochrome enzymes absorb NIR light but to a much lesser extent than hemoglobin. Myoglobin desaturates to a limited extent, allowing the analysis of saturation to be hemoglobin specific.13

The extremely low level of absorption of NIR light by hemoglobin is the dominant factor in achieving accurate measurements, requiring low light intensity in order to avoid overwhelming the signal and a very low level of noise in the system to produce a high signal to noise ratio. While cooximeters utilize multiple wavelengths to differentiate various dyshemoglobins, noise reduction remains the most important factor in improving accuracy and precision in vivo.

NIRS sensors designed for neonates and small infants have been available for the last 2 years (OxyAlert NIRSensor, Somanetics Corp, Troy, MI) and their use has increased in both the OR and ICU, allowing monitoring of premature neonates and infants. While there are baseline values and intervention thresholds established for congenital heart patients14-19 those values have not been defined for normal term and preterm neonates until recently20-22 and from a study of normal term neonates shown in Figure 1.

The accuracy of NIRS for monitoring brain O2 delivery has been validated by comparison to internal jugular vein, hemoglobin saturation (SijvO2) levels reported in independent studies in adults, children and infants23-25 as well as in data submitted to the FDA in support of product clearances.

There are a number of factors that need to be taken into account when validating the accuracy of any NIRS device, including the significant incidence of gross anatomical variability of the vascular anatomy of the brain26 requiring placement of the sensor on the same side of the head as the jugular vein that was sampled. Compensation for skull and muscle is also essential and was developed from empirical observations of injection of indocyanine green dye in the internal and external carotid arteries,27 insuring that cerebral rSO2 is specific for brain. Further, rather than relying on global hypoxia, tissue specific monitoring requires that validation be done by altering O2 delivery to that specific tissue, as was done for brain by altering PaCO2 levels to reduce cerebral perfusion and by arterial occlusion for somatic monitoring.28

There has been recent confusion of the concept of accuracy for spectroscopic devices in the NIRS literature. The issues of accuracy and precision are essential components of analytical techniques and are requisite for validating any monitoring technology but are different from target physiologic values.

Cerebral and Somatic Regional Oxygen Saturation (rSO2) in Neonates

Michael Wider, PhD; Erin Booth, PhD

The authors are with Somanetics Corporation, Troy, MI. This article was provided by Somanetics.
While pulse oximetry measures the saturation of arterial blood (SpO2) by monitoring the pulse interval and has a defined target value, tissue oximetry is a venous weighted measure and hence reflects the arteriovenous difference and the adequacy of oxygen delivery. Tissue oximetry provides a range of “normal” saturations that are associated with venous outflow and have wide variability.

Studies reporting SijvO2 means and range in normal subjects and cardiac patients using cooximetry of blood samples from the internal jugular vein23-25 are consistent with cerebral rSO2 values reported in the literature and obtained in a screen of normal ambulatory adults as seen in Figure 2.

Figure 2. Cerebral rSO2 in normal, ambulatory adults (n=226) showing the lack of impact of skin color and gender. (INVOS 5100C, Somanetics Corporation, Troy, MI IRB approved clinical study, 2008.

It is critical to understanding the value and accuracy of rSO2 to remember that it is venous weighted and hence responsive to all the physiologic factors that influence oxygen delivery such as anatomical variability, Hb dissociation, cardiac output, dyshemoglobinemias, blood pH, vascular permeability and metabolic demand, resulting in an arteriovenous (AV) difference. The greatest value of rSO2 monitoring results from the fact that it is impacted by all these variables and hence, unlike SpO2, reflects the amount of O2 that was actually available to, and consumed by, the tissues.

Independent studies as well as validation data for FDA clearance has demonstrated a high level of accuracy and specificity of cerebral rSO2. Thresholds for intervention have been established for cerebral rSO2 levels in adults and neonates based on clinical14,19,33-35 and animal36,37 data.

Somatic monitoring, however, presents a greater challenge since the NIRS light penetrates potentially thick muscle and fascial layers when applied to the body surface, making shallow tissue compensation essential to limit the impact of intervening tissues. Somatic rSO2 is used as a measure of peripheral perfusion and oxygen delivery and has been demonstrated to be very sensitive to changes in specific organ blood flow in animal experiments.38 The use of somatic monitoring has been well established in hemodynamic management of infant and neonatal neonates.42

The relationship between cerebral and somatic rSO2 has been defined and reduced to practice in congenital heart surgery and the CVICU with the perirenal rSO2 kept higher than the cerebral to insure adequate peripheral perfusion. Normal neonates and term infants, on the other hand, have renal values closer to the cerebral rSO2 while gut rSO2 is lower and more variable.21 consistent with ultrasound studies of superior mesenteric artery flow in premature neonates.42

Animal36,37 and human33 studies in neonates indicate that significant neural damage can be expected when cerebral rSO2 is below 40% for an extended period. The impact on outcome is patient specific, however, due to the potential for ischemic preconditioning.43

The management of hemodynamics in neonates by targeting blood pressure to the gestational age, while standard of practice, is not well substantiated in relation to outcome.44 Tissue and drug specific rSO2 response to pressors and inotropes has been reported45 indicating that simple targeting of pressure is not effective in guaranteeing adequate perfusion balancing between the brain and somatic organs.

Conclusions

The inclusion of rSO2 in a diagnostic assessment provides insight into perfusion distribution and directs attention to the potential causes of change in peripheral or cerebral O2 delivery. Declining peripheral rSO2 with stable cerebral numbers due to autoregulation can obviate a left to right steal, potentially indicating a need to reduce FiO2 to increase pulmonary resistance and decrease shunting. Decreasing cerebral rSO2 on the other hand, with stable somatic rSO2, can be the result of low PaCO2 causing cerebral vascular constriction.

Baseline cerebral and renal rSO2 values for normal term and preterm neonates have been reported and further research in the NICU will confirm these early observations. The use of NIRS in congenital heart patients down to 1 kg has been successful in improving hemodynamic management resulting in better management and improved outcomes.46 Animal and human studies along with the extensive experience in the CVICU demonstrate the value of NIRS and its potential to enhance patient care in the NICU.

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Neonatal Enteral Feeding Tubes as Loci for Colonization by Members of the Enterobacteriaceae


Abstract

Background: The objective of this study was to determine whether neonatal nasogastric enteral feeding tubes are colonised by the opportunistic pathogen Cronobacter spp. (Enterobacter sakazakii) and other Enterobacteriaceae, and whether their presence was influenced by the feeding regime.

Methods: One hundred and twenty-nine tubes were collected from two neonatal intensive care units (NICU). A questionnaire on feeding regime was completed with each sample. Enterobacteriaceae present in the tubes were identified using conventional and molecular methods, and their antibiograms determined.

Results: The neonates were fed breast milk (16%), fortified breast milk (28%), ready to feed formula (20%), reconstituted powdered infant formula (PIF, 6%), or a mixture of these (21%). Eight percent of tubes were received from neonates who were nil by mouth. Organisms were isolated from 76% of enteral feeding tubes as a biofilm (up to 10^7 cfu/tube from neonates fed fortified breast milk and reconstituted PIF) and in the residual lumen liquid (up to 10^7 Enterobacteriaceae cfu/ml, average volume 250 μl). The most common isolates were Enterobacter cancerogenus (41%), Serratia marcescens (36%), E. hormaechei (33%), Escherichia coli (29%), Klebsiella pneumoniae (25%), Raoultella terrigena (10%), and S. liquefaciens (12%). Other organisms isolated included C. sakazakii (2%), Yersinia enterocolitica (1%), Citrobacter freundii (1%), E. vulneris (1%), Pseudomonas fluorescens (1%), and P. luteola (1%). The enteral feeding tubes were in place between < 6 h (22%) to > 48 h (13%). All the S marcescens isolates from the enteral feeding tubes were resistant to amoxicillin and co-amoxiclav. Of additional importance was that a quarter of E hormaechei isolates were resistant to the 3rd generation cephalosporins ceftazidime and cefotaxime. During the period of the study, K pneumoniae and S. marcescens caused infections in the two NICUs.

Conclusion: This study shows that neonatal enteral feeding tubes, irrespective of feeding regime, act as loci for the bacterial attachment and multiplication of numerous opportunistic pathogens within the Enterobacteriaceae family. Subsequently, these organisms will enter the stomach as a bolus with each feed. Therefore, enteral feeding tubes are an important risk factor to consider with respect to neonatal infections.

Background

Recently, considerable attention has been directed at the microbiological safety of PIF.1,2 This has primarily been due to neonatal infections by C sakazakii and Salmonella, which were associated with contaminated PIF.3-6 These products are not sterile, but are expected to comply with international microbiological standards.7 Other Enterobacteriaceae which have been isolated from PIF include Enterobacter cloacae, Klebsiella pneumoniae, K oxytoca, E hormaechei, Citrobacter freundii, and E coli.8,9 The FAO/WHO1,2 categorized these organisms as “causality plausible, but not yet demonstrated” with respect to their potential to cause neonatal illness through

Figure 1. Enterobacteriaceae counts from biofilm material isolated from nasogastric enteral feeding tubes of neonates on various feeding regimes. Error bars indicate 95% confidence intervals. NBM = Nil by mouth (n = 10), BMO = Breast milk only (n = 17), FBM = fortified breast milk (n = 27), RFF = ready to feed formula (n = 21), PIF = Powdered infant formula (n = 8), M = mixed feeding regime (n = 20).
Serratia spp are the third most common causative pathogen.16 In another NICU outbreak, the powdered infant formula was not analysed until after the last neonatal case and the original batch of infant formula would no longer have been available.3 The FAO/WHO proposed that the risk of bacterial infection from powdered infant formula could be reduced by reconstitution with water > 70°C, minimizing the time between reconstitution and feeding (< 2 h), and by not storing reconstituted feed at ambient temperature. These recommendations are reiterated by WHO,10 and various regulatory bodies.11-13 However, there was no consideration that the nasogastric enteral feeding tube may act as a site for bacterial colonization as a biofilm. The tube will be between ambient (outer portion) and body temperature (inner portion), with regular additions of nutrients for bacterial multiplication. Previously, nasogastric feeding temperature (inner portion), with regular additions of nutrients may include the use of thickeners to reduce reflux, and these details may not be sufficiently recorded for later analysis. Few studies have considered the neonatal nasogastric enteral feeding tube in NICU's acting as a site of bacterial colonisation, and any influence of the feeding regime. Mehall et al13 detected Staphylococcus epidermidis, S aureus, Enterococcus faecalis, E cloacae and K pneumoniae at > 10^3 cfu/ml in 71/125 enteral tubes from infants > 4 months, and that necrotizing enterocolitis developed in 7 formula fed infants with tubes containing > 10^5 Gram negative bacteria/ml. This group also reported the isolation of methicillin-resistant S aureus from infant enteral feeding tubes.24 Therefore collating information on hospital feeding regimes, and microbial analysis of feeding tubes will considerably improve our knowledge and understanding of potential risk factors to neonates linked to enteral feeding. This study is important to identify locations of bacterial multiplication which might be of risk to neonates, especially in NICUs.

Results

Neonate feeding regime: A total of 129 nasogastric enteral feeding tubes were collected from two NICUs; 25 and 104 respectively. The neonates’ age range was from < 1 wk to greater than 4 wk, with the major group (42%) being > 4 wk. Four specific feeding regimes were identified: breast milk, fortified breast milk, ready to feed formula, and reconstituted PIF. Additionally, a number of neonates were receiving more than one type of feed. These are described as receiving a mixed feeding regime. This latter category is a heterogeneous population. For example, some neonates received breast milk and fortified breast milk, whereas others received breast milk and reconstituted PIF. A thicker was added to feeds to reduce reflux for neonates receiving fortified breast milk, ready to feed formula, reconstituted PIF, and mixed feed. Ten tubes were received from neonates that were nil by mouth. The frequency of feeding was primarily every 2 h for breast milk, whereas there were equal numbers of every 2 h and 3 h for those receiving ready to feed formula. Eight neonates were fed ready to feed formula, reconstituted PIF and mixed feed continuously. The enteral feeding tubes had been in place for various time periods; ranging from < 6 h (22%) to > 48 h (13%). The gastric pH was measured prior to feeding, and was between 1.5 and 6. The average pH ranged from 2.5 to 4.3 for breast milk and reconstituted PIF fed neonates, respectively.

Microbiological analysis of enteral feeding tubes: Bacterial counts on tubes: Enterobacteriaceae were isolated from the majority (70%) of samples, and from all feeding regimes. The lowest frequency of isolation was 52% of the tubes from breast milk fed neonates, whereas the others ranged from 78 to 88% for mixed feeding regime and reconstituted PIF.

The dataset for NICU 2 (n = 104) was chosen for detailed statistical analysis due to the larger number of samples, and the ‘nil by mouth’ cohort was regarded as a control group for the feeding regimes. Feeding regime had a significant effect on the Enterobacteriaceae counts (F = 3.90, P < 0.001). The lowest values obtained were nil by mouth and breast milk only with an average values ca 1.4 log_10 cfu/tube (Fig 1). The maximum nil by mouth was 2.7 log_10 cfu/tube which was less than the average for the remaining groups. The maximum for the breast milk cohort was 5.3 log_10 cfu/tube. This value was considerable higher than the other neonates in the cohort, and could have been influenced by the exceptionally high pH (6.0) of this one sample. Fischer’s protected least significant difference post-hoc.

Figure 2. Enterobacteriaceae counts from biofilm material on nasogastric enteral feeding tube according to age of neonate. Error bars indicate 95% confidence intervals.

Prior to weaning, the infant intestinal flora is influenced by the feeding regime.21 The initial intestinal flora of infants who are breast fed are dominated by lactic acid bacteria and bifidobacteria, whereas the intestinal flora of formula fed infants is more diverse and dominated by the Enterobacteriaceae and Bacteroides spp.22 However, this is a generalization, as in practice neonates may receive a mixed nutrient source regime for short periods according to their nutritional needs. This may include the use of thickeners to reduce reflux, and these details may not be sufficiently recorded for later analysis.
tests suggested that fortified breast milk, ready to feed formula, reconstituted PIF and mixed formula all gave significantly greater counts than nil by mouth regime. Hence, breast milk and ready to feed gave bacterial counts similar to those on the nil by mouth regime. Statistical analysis showed that although there was a significant number of younger babies (< 1 wk) in this group, there was no statistical significant difference in colonization between age groups (analysis of variance 1-way F = 0.99, P > 0.05). Similarly, within the fortified breast milk group there was no significant effect of age on colonization (analysis of variance 1-way F = 0.89, P > 0.050). Hence, although there were some differences in age profiles within treatment groups and an overall effect of age, there was no evidence from our data that age effects colonization within a feeding group. It is accepted that the numbers within each group are small for these comparisons and it is possible that there were confounding problems of age with feeding regime. Within the mixed feeding regime group, analysis of the various feeding regimes suggested that those fed with breast milk and fortified breast milk, and PIF and breast milk, gave significantly higher counts than nil by mouth (F = 3.19, P < 0.05), but not the ready to feed formula and breast milk group. There was no difference in bacterial counts when a thickener was added to the feed.

The effect of age of the infant on mean bacterial counts is shown in Fig 2. There was a significant effect of age on bacterial counts when data were pooled (F = 4.49, P < 0.001) indicating a progressive increase in numbers with increasing age from 2 wk onwards. There was a significant effect of length of time the tube was in place when data were pooled (F = 6.91, P < 0.001). Compared with data at < 6 h, those at 6-12 h, 18-24 h, 24-48 h, and > 48 h, all had significantly greater bacterial counts, with maximum counts recorded at 48 h. When data are pooled, there was a positive but weak correlation between Enterobacteriaceae numbers and pH (r = 0.24, P < 0.05). However r² suggests only 5.8% of the variance in bacterial numbers can be accounted for by pH. A one-way Anova comparing pH with age showed there was no significant difference in average pH between infant age classes. There were no significant effects of age within the nil by mouth group (analysis of variance 1-way F = 10.00 P > 0.05).

Bacterial counts in residual liquids: During laboratory analysis of the feeding tubes, it was noted that there was residual liquid present. The average volume of residual liquid was 250 μl, and ranged between 30 and 400 μl. The average viable count was 10⁶ cfu/ml, and ranged between < 10² to 10⁸ cfu/ml. Therefore, the number of Enterobacteriaceae present in the residual liquid per tube was up to 10⁷ cfu. This is the potential number of Enterobacteriaceae that would have entered the neonatal stomach with the next feed, if the tube had not been removed.

Bacterial species on tubes and in the residual liquids: The same Enterobacteriaceae species were isolated from both the residual liquids and the biofilms. The Enterobacteriaceae isolated were primarily E cancerogenus (41%), S marcescens (36%), E hormaechei (33%), E coli (29%), K pneumoniae (25%), and R terrigena (22%). Other organisms isolated less frequently included C sakazakii from breast milk and ready to feed formula groups, and a single isolate of Y enterocolitica from the reconstituted PIF group. E cancerogenus, S marcescens, and E hormaechei and were isolated from all feeding regimes, including the nil by mouth cohort. The E hormaechei and E cancerogenus (identified by16S rDNA sequence analysis) were presumptively identified as E cloacae and K oxytoca, respectively, by phenotypic profiling. Non-Enterobacteriaceae which were isolated from VRBGA included P fluorescens, P luteola and Chromobacterium violaceum. Electron microscopy of enteral feeding tube inner wall revealed that a dense, and morphologically diverse flora was present (Fig 3 and 4). This included a variety of short and long rod-shaped bacteria; some with tapering ends (Fig 3). Yeast size cells were also visible (Fig 4). Preliminary experiments with direct plating of enteral tube material on non-selective agar isolated staphylococci, lactic acid bacteria and Candida albicans (data not shown).

Since these were not the focus of the study, they were not investigated further. There was no significant difference in the proportion of samples positive for Enterobacteriaceae between the feeding regimes (chi-square = 7.82, 5DF, P > 0.05). The distribution of bacterial species was different in tubes from nil by mouth samples compared with all other regimes added together (chi-square = 16.28, 7DF P < 0.05). After removing the ‘nil by mouth’ samples from the statistical analysis, there were highly significant differences in the distribution of isolates between feeding regimes (chi-square = 94.95, 28DF, P < 0.001). Comparing each feeding regime with each of the others, showed that the breast milk and mixed
feeding regimes were the only two giving similar distribution of isolates (chi-square = 9.72, 7DF, P > 0.05). Each of the other feeding regimes has a unique distribution of bacterial isolates.

Antibiotic resistance of isolated Enterobacteriaceae: All Enterobacteriaceae isolates were susceptible to gentamicin, ciprofloxacin and meropenem. The majority of strains were resistant to amoxicillin. All S marcescens isolates were resistant to amoxicillin and amoxicillin-clavulanic acid. Of note is the high frequency of resistance to ceftazidime (21% strains) and cefotaxime (23% strains) in E hormaechei. Three of these strains contained ESBL. Four of the 37 E coli strains were also resistant to ceftazidime and cefotaxime.

**Discussion and Conclusion**

In this study, a total of 129 nasogastric enteral feeding tubes with details of the neonates’ feeding regime were obtained from 2 NICUs. The neonates were receiving a variety of feeds including expressed breast milk, reconstituted PIF, and sterile ready to feed formula. In addition tubes were received from infants that were nil by mouth. The ages of the neonates varied with the feeding regime. Those on breast milk were predominantly < 1 wk, whereas those on fortified breast milk were > 4 wk. Neonates receiving ready to feed formula were 1 to > 4 wk in age, whereas the majority of those on reconstituted powdered infant formula were > 4 wk in age. The frequency of feeding was primarily (54%) every 2 h, especially for those on breast milk, and secondly (24%) every 3 h. Eight neonates (6%) were fed continuously. This latter practice is prone to temperature abuse, and has been linked with outbreaks of C sakazakii in USA and France. Three of these strains contained ESBL. Four of the 37 E coli strains were also resistant to ceftazidime and cefotaxime. Three of these strains contained ESBL. Four of the 37 E coli strains were also resistant to ceftazidime and cefotaxime.

Enterobacteriaceae were isolated from the lumen and the inner wall of most (75%) enteral feeding tubes. The organisms were identified using biochemical profiles and thereafter 16S rDNA sequence analysis as the latter is more accurate. The Enterobacteriaceae isolates were primarily E coli, E aerogenes, E hormaechei, K pneumoniae, R terrigena, and S marcescens. These organisms are well recognised opportunistic pathogens causing various gastrointestinal and respiratory diseases. Other organisms isolated included C sakazakii, Y enterocolitica, E vulneris, and Pseudomonas spp. There were some differences in the flora between the feeding regimes, the reasons for which are currently unclear. The flora isolated from our neonatal samples is similar to that of Mehall et al. who reported the isolation of E cloacae, K pneumoniae, S maltophilia and P aeruginosa from enteral tubes of infants aged > 4 months. Other organisms present included Gram positive organisms such as staphylococci, and lactic acid bacteria, as well as Candida albicans. This fungus was also isolated in the study by Mehall et al.

Trimethoprim, ampicillin and co-amoxiclav are commonly used for minor infections in adults. Piptazobactam, amikacin, ceftazidime and cefotaxime are antibiotics that could be prescribed for empirical treatment of serious sepsis in infants on a neonatal intensive care unit. Of note is the high frequency of resistance by the E hormaechei to the 3rd generation cephalosporins ceftazidime and cefotaxime. ESBL were detected in 3 of these strains. The antibiotic resistance patterns of the remaining strains could be due to derepressed chromosomal AMPC β-lactamase production. As already proposed, it is plausible that the empiric use of antimicrobial agents selects for clones of EBSL organisms such as S marcescens and K pneumoniae. Although no link was established with feeding tube isolates, it is notable that these two species were also responsible for neonatal infections in both NICUs during our study. Resistance to these antibiotics would not be recognised until 24-48 h of culturing for the causative agent, during which time an ineffective antibiotic may have been used to treat the ill neonate. This delay in effective treatment could have serious consequences.

The nil by mouth samples received during the study were treated as negative controls for the feeding regime comparison. They demonstrated that sterilisation of the outer tube surface effectively removed any oral-pharynx flora contamination. Therefore the organisms detected were deemed to originate from the inside of the enteral feed tube. It is probable that the few organisms isolated from these tubes originated from the throat by tracking along the outside of the tube into the stomach, or were residual organisms from before feeding stopped. Due to respect for strict patient confidentiality, neonates were anonymous and hence we have no knowledge regarding the feeding regimen of neonates prior to the sampling period. This unfortunately restricts our interpretation of data obtained for neonates that were ‘nil by mouth’ at the time of sample collection. Nevertheless, only low numbers of Enterobacteriaceae (< 3 log_{10} cfu/tube) were recovered from these samples (Fig 1).

The Enterobacteriaceae were isolated from biofilms inside enteral feeding tubes of neonates who received only breast milk, but the numbers were lower than other feeding regimes (Fig 1). Breast milk is not sterile, but does contain antibacterial agents such as maternal antibodies, lactoferrin, and lysozyme. Additionally the standard practice at the 2 NICUs was for expressed breast milk to be kept at 2-4°C for no more than 48 h and therefore very little bacterial growth could have occurred prior to feeding. Feeding tubes from neonates being fed fortified breast milk contained higher numbers of Enterobacteriaceae than unfortified breast milk; 3.6 log_{10} cfu/tube compared with 1.4 log_{10} cfu/tube respectively (Fig 1). Human milk fortifiers may enable bacterial growth by providing free iron which is otherwise unavailable due to chelation in unfortified breast milk. Another factor which may have affected the bacterial counts is that neonates fed fortified breast milk were older than those fed breast milk. Some of the enteral tube flora could have been due to reflux of small intestinal contents into the stomach. Since older neonates will have a more established intestinal flora, increased bacterial numbers would be recovered from enteral tubes in the stomach. The 37 fortified breast milk tube samples were treated as one cohort since to our knowledge only one source of human milk fortifier was in use.

An unexpected result was the recovery of Enterobacteriaceae biofilms in enteral feeding tubes from 81% of neonates receiving sterile ready to feed formula. These products are sterilised inside glass jars by the manufacturer and have tamper-proof lids which would indicate any bacterial growth before use. These feeds were used directly from the sterile jar, and were not kept open for any length of time at temperatures enabling bacteria from extrinsic contamination to multiply. An alternative source of the enteral tube flora was the throat enabling bacteria from extrinsic contamination to multiply. This is common in preterm neonates, occurring 3-5 times per hour. It occurs when the lower esophageal sphincter relaxes, and this may increase the exposure of the feeding tube to the throat flora.
The highest Enterobacteriaceae biofilm levels were from enteral feeding tubes of neonates receiving reconstituted PIF, average 4.2 log, cfu/tube. We have no knowledge regarding the range of PIF products being used on the wards, but it is reasonable to assume that various products had been prescribed by the neonatologists. However requesting further nutritional information was not permissible with respect to patient confidentiality. Therefore all neonates receiving reconstituted PIF were considered as one cohort. The same Enterobacteriaceae species were isolated as per other feeding regimes; E coli, E cancerogenus, R terrigena, and S liquifaciens. Other Enterobacteriaceae isolated were Y enterocolitica, K ozaena and C violaceum. Whether these Enterobacteriaceae originated from the powdered formula or reflux from the gastrointestinal tract is uncertain as no bacteriological analysis of the powdered formula was undertaken. Nevertheless the PIF were reconstituted at room temperature and therefore were not subject to hot water (> 70°C) to reduce the number of any intrinsic bacteria as recommended by the FAO/WHO.1,2 Since, unlike human breast milk, there are no antibacterial agents in PIF any contaminating bacteria would be able to multiply in the formula while the tube was in place for up to 48 h.

As the bacterial biofilms age, the Enterobacteriaceae will break off in clumps. These clumps will inoculate any fresh feed in the tube lumen leading to further bacterial multiplication, and will subsequently enter the neonate stomach. Although the adult stomach is normally highly acidic, and kills the majority of ingested bacteria, this is not true for the neonate. The gastric pH was 2.5 (breast milk) and 3.5 to 4.3 for the remaining feeding regimes. Edelson-Mammel et al32 have shown the acid-sensitivity of C sakazakii. In their study of 12 feeding regimes; E coli, E cancerogenus, R terrigena, and S liquifaciens. Other Enterobacteriaceae isolated were Y enterocolitica, K ozaena and C violaceum. Whether these Enterobacteriaceae originated from the powdered formula or reflux from the gastrointestinal tract is uncertain as no bacteriological analysis of the powdered formula was undertaken. Nevertheless the PIF were reconstituted at room temperature and therefore were not subject to hot water (> 70°C) to reduce the number of any intrinsic bacteria as recommended by the FAO/WHO.1,2 Since, unlike human breast milk, there are no antibacterial agents in PIF any contaminating bacteria would be able to multiply in the formula while the tube was in place for up to 48 h.

The microbiological safety of neonatal feeds should not be exclusively focused on reconstituted PIF due to C sakazakii, but also on the general preparation and practices of enteral feeding to reduce the risk of exposure to other Enterobacteriaceae some of which may carry antibiotic resistance factors. Therefore, the practice of prolonged placement of enteral feeding tubes in neonates needs to be considered with respect to the increased risk of exposure to bacterial pathogens.

Methodology: Powdered infant formula was reconstituted with sterile cold water at room temperature in a sterile bottle. Ready to feed formula was kept in the original bottle. Expressed breast milk (EBM) was obtained using a sterile expressing kit into sterile plastic pots. Fresh EBM was kept for up to 48 hours in a dedicated fridge at 2-4°C. Any EBM which was not to be used as fresh was frozen for up to 3 months in a dedicated freezer at -20°C. When required EBM was defrosted in the fridge and kept for up to 12 hours after removal from the freezer. The neonates were bolus or continuously fed via a nasogastric feeding tube composed of phthalate free PVC (gauge 3.5). Feeds were administered by pouring into a sterile syringe (without plunger) that was attached to the tube, and allowed to flow into the stomach by gravity. Duration of feeding was less than 30 minutes. Occasionally feeds were given by continuous infusion, and the syringe would then be changed every 4 hours. During the period of sample collection, there were 38 episodes of neonatal infections in NICU 1 and 13 in NICU 2. In NICU 1, 10 infections were due to Enterobacteriaceae; 1 E cloacae, and 2 K. oxytoca, 3 K pneumoniae, and 4 E coli. Whereas in NICU 2, 5 infections were due to Enterobacteriaceae; 1 E coli, 2 K pneumoniae, and 2 S marcescens. The remaining infections in both units were primarily attributed to coagulase negative staphylococci. Nasogastric enteral feeding tubes were collected, without pre-selection, over a period of 11 months by nurses as part of their routine care of neonates in intensive care. The tubes were placed in sterile bags, and refrigerated at 5°C until analysis (max 24 h). The outside of the tubes were sterilized with isopropyl alcohol. Any residual liquid in the tube lumen was flushed into a pre-weighted sterile Eppendorf tube, and the volume determined by weight difference. Using aseptic techniques, the tubing was cut into 2 cm lengths and except for the gastric 2 cm end, placed in 5 ml sterile saline in a conical test tube. The tubes were vortex mixed for 1 min, and then ultrasonicated at 40 kHz for 5 min at room temperature.
The tubes were further vortex mixed for 1 min, and decanted into a sterile test tube. The procedure was repeated, and the combined saline rinses were centrifuged in a benchtop centrifuge (2400 g, 10 min). Afterwards, the supernatant was discarded and the bacterial pellet was resuspended in 1 ml sterile saline. The cell suspension was decimally diluted, and 100 μl volumes were spread on Violet Red Bile Glucose agar (VRBG) plates (LabM, UK). The plates were incubated at 37°C, for up to 48 hours. Enterobacteriaceae colonies (red 1-2 mm diameter, usually surrounded by a reddish zone) were counted and representative colony types were subcultured on Tryptone Soya Agar (TSA) plates (Merck, Germany). Isolates were initially identified using phenotypic profiles with ID32 E (bioMerieux), and confirmed using 16S rDNA gene sequence analysis (Accugenix, DE). The GenBank accession numbers of the E. cancerogenus and E. hormaechei isolates sequenced in this study are FM883655 to FM883666. The susceptibilities of Enterobacteriaceae isolates to antimicrobial agents were determined by breakpoint on antibiotic supplemented Iso-Sensitest agar as according to the British Society for Antimicrobial Chemotherapy protocol. The antibiotics tested were amikacin, gentamicin, amoxicillin, cepotaxime, cefuroxime, ceftazidime, ciprofloxacin, amoxicillin-clavulanic acid, gentamicin, meropenem, pipericillin-tazobactam, and trimethoprim (ADATAB; Mast Diagnostics, Bootle, UK). ESBL production was detected using the combination disc method as described in Health Protection Agency QSP 51 using ceftazidime-clavulanic acid, cefotaxime clavulanic acid, and cefpodoxime-clavulanic acid combination discs in comparison to individual-antibiotic ceftazidime, cefotaxime, and cefpodoxime discs according to the manufacturer's instructions (Mast Diagnostics). During tube collection, a questionnaire concerning the feeding regime was completed by the attendant nurse. The feeding regime, any addition of a thickening agent, age of neonate, duration the tube had been in place, frequency of feeding and stomach pH prior to last feed were recorded. The amount of information for each tube was limited in order to comply with patient confidentiality. No record of patient clinical condition was recorded. Consequently, the source of each tube was anonymous. The neonatal enteral feeding tube cells were fixed using 3% gluteraldehyde prepared in a 0.1 M phosphate buffer, tubes were then washed in phosphate buffer and post fixed in 1% (w/v) osmium tetroxide prepared in 0.1 M phosphate buffer, of Enterobacteriaceae as Cronobacter (Enterobacter) sakazakii. Microbiology 2008, 154:3659-3667.


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Incidence and Risk Factors of Hospitalization for Bronchiolitis In Preterm Children: A Retrospective Longitudinal Study In Italy

Patrizio Pezzotti, Jessica Mantovani, Nicoletta Benincori, Eleonora Mucchino, Domenico Di Lallo

Abstract

Background: Bronchiolitis is a distressing, potentially life-threatening respiratory condition that affects infants. We evaluated the incidence and risk factors of hospitalization for bronchiolitis in preterm infants (ie, a gestational age of <36 weeks) born between 2000 and 2006, and the use and impact of Palivizumab, a monoclonal antibody that in randomized clinical trials has been shown to lessen the severity of RSV-related bronchiolitis.

Methods: Retrospective cohort study that linked data from four health administrative databases in the Lazio region of central Italy: the birth register, the hospital discharge register, and two ad-hoc databases that record the doses of Palivizumab administered at two local health units.

Results: Among 2,407 preterm infants, 137 had at least one hospitalization for bronchiolitis in the first 18 months of life, an overall incidence rate of 4.70 per 100 person-years (95%CI: 3.98-5.56); similar incidence rates were observed by calendar year. A multiple Poisson model showed that the following characteristics were associated with higher incidence: younger age of the infant, the period between October-April, male gender, low Apgar score at birth, low birth weight, and low maternal educational level. At least one dose of Palivizumab was administered to 324 (13.5%) children; a dramatic increase of hospitalization for bronchiolitis in the first year of life, the period between October-April, male gender, low Apgar score at birth, low birth weight, and low maternal educational level. Other factors independently associated with more frequent Palivizumab use were older maternal age, Italian-born mothers, female gender, low Apgar score, low birth weight, shorter gestational age, a diagnosis of broncho-dysplasia, and the month of birth. It is of note that none of the 34 children with congenital heart disease were prescribed Palivizumab. Performing several multiple Poisson models that also considered Palivizumab use as covariate, although the point estimates were in agreement with previous clinical trial results, we did not find in most of them a significant reduction for immunized children to be hospitalized for bronchiolitis.

Conclusion: In Italy the incidence of hospitalization for bronchiolitis, and its associated risk factors, are similar to that found in other countries. Although Palivizumab use is associated with the most important characteristics of severe prematurity, other aspects of its non-use in children with congenital heart disease, the age and the birth country of the mother suggest the need for public health measures that can reduce these health disparities. Finally, the estimated effectiveness of Palivizumab in routine practice, although not significant, confirms the results of previous clinical trials, but its impact on modifying the temporal trend in this population is still negligible.

Background

Bronchiolitis is an acute respiratory illness that particularly affects infants and young children characterized by coryza and sometimes low-grade fever that progress over a few days to cough, tachypnoea, hyperinflation, chest retraction, and widespread crackles, wheezes, or both.1

The incidence of bronchiolitis has a seasonal trend with a peak during the winter months in temperate climates, during the cool rainy season in tropical and subtropical areas, and during the cool dry season in South America and South Africa.2 A study in the US in the mid-nineties estimated that around 10% of children have bronchiolitis in the first year of life.2 However, this estimate for Canada in 2003 was around 4%.4

Hospital admission rates for bronchiolitis in the US and Europe are reported to be around 3% for children less than 1 year of age.5 Independent factors typically associated with a high risk of hospitalization are male gender, premature birth without or, especially, with broncho-displasya, congenital heart disease, T-cell immunodeficiency, age <6 months, birth during the first half of the influenza season, and crowding/siblings.5,6

It has been estimated that the respiratory syncytial virus (RSV) is the etiologic agent in more than 70% of the cases (80%-90% during the winter).7 A study in the mid-90s evaluated the safety and efficacy of Palivizumab, a humanized murine monoclonal anti-F glycoprotein antibody preparation, in preterm infants with and in those without chronic lung disease. The study showed the preparation to be safe and efficacious in reducing RSV-associated hospitalizations by 55%.8 A subsequent study conducted between 1998-2002 in infants ≤ 24 months of age...
with documented hemodynamically significant congenital heart disease (CHD) showed a 45% relative reduction in RSV-associated hospitalizations.8

Palivizumab was introduced in Italy in 1999 and it is administered following international and national guidelines.9–12 At-risk children are identified by the neonatologists in the perinatal units, their families are then contacted and offered the prophylaxis free of charge. The proposed schedules repeat administrations every 30 days during the epidemic period. Until now, several studies have evaluated the impact of introducing Palivizumab prophylaxis on the incidence of hospitalization with bronchiolitis13–15 but none of these have been conducted in Italy. The objectives of this study were thus to evaluate the incidence rate and factors associated with preterm infant hospitalizations for bronchiolitis, and the use and the impact of Palivizumab in this country.

Methods
Study design, setting, participants, and data sources: This is a retrospective longitudinal study of preterm infants (i.e., <36 weeks of gestational age) born between 2000-2006 whose mothers at time of delivery were living in the catchment area of two local health units (LHUs) in the Lazio region, central Italy. Both LHUs are located in the county of Rome, one in the city center and the other in a suburban area. During the study period the population in these two LHUs slightly increased from more than 985,000 at the beginning of 2000 to more than 1,055,000 people at the end of 2006. In this period 67,292 children were born to resident mothers identified using the birth database started in 1994 and all hospitals in the region.

Figure 1. Graphical representation of how person-time at risk of being hospitalized for bronchiolitis was calculated for non-prophylaxed and prophylaxed infants. For prophylaxed infants, two different approaches were proposed. Box A shows that person time was calculated since the first date of Palivizumab administration to the first hospitalization for bronchiolitis, or the date the subject turned 18 months of age, or the first of January 2007, whichever comes first. Box B shows that, compared to the previous approach, the person-time does not include the time-periods exceeding the 30 days after each Palivizumab administration. In this case also hospitalizations for bronchiolitis happened in the dashed periods are not considered.

Methods
Study design, setting, participants, and data sources: This is a retrospective longitudinal study of preterm infants (i.e., <36 weeks of gestational age) born between 2000-2006 whose mothers at time of delivery were living in the catchment area of two local health units (LHUs) in the Lazio region, central Italy. Both LHUs are located in the county of Rome, one in the city center and the other in a suburban area. During the study period the population in these two LHUs slightly increased from more than 985,000 at the beginning of 2000 to more than 1,055,000 people at the end of 2006. In this period 67,292 children were born to resident mothers identified using the birth register (“Certificati di assistenza al parto” in Italian, hereafter called CEDAP). Details about CEDAP can be found in previous publications.16–18 Briefly, this register reports information on socio-demographic characteristics of both parents (age, education, occupational status, etc), obstetric history and pregnancy (previous pregnancies and/or abortions, duration, characteristics, etc) and prenatal care (clinical examinations, ultrasounds, amniocentesis, etc.), delivery (place, type, etc), and information on the newborn (gender, birth order, birth weight, gestational age, Apgar score at 5 minutes, etc). Hospital admissions for bronchiolitis were identified in the hospital discharge database of the Lazio region (“Sistema Informativo Ospedaliero della Regione Lazio,” hereafter called SIO). Details about the SIO can be found in previous publications.19–21 Briefly, this database was started in 1994 and all hospitals in the region are required to record data on a standardized form of admission and discharge dates, personal data of the patient (i.e., date of birth, gender, name, surname, municipality of residence, nationality), the principal diagnosis and up to five secondary diagnoses [coded by the International Classification of Diseases - ninth revision (ICD-9)], diagnostic procedures (also coded by the ICD-9), and death, if it occurred during the hospitalization. Hospitalizations for bronchiolitis were identified by the ICD-9 code 466.11 or 466.19, reported either as the first or secondary diagnosis. Although only code 466.11 refers to bronchiolitis due to VRS, we also included codes for “other” or “unknown” etiologies. It is of note that in clinical practice the etiology of bronchiolitis is very often not determined because it does not change the course of treatment in infants. Only subjects hospitalized for bronchiolitis before age three were included. The SIO was also used to identify infants with a diagnosis of broncho-dysplasia and CHD. It is of note that it is extremely unlikely that a hospitalization for bronchiolitis would be missed because SIO covers the entire region, not only the territory of the LHUs involved.

Data about each single dose of Palivizumab were collected in ad-hoc databases that the two LHUs created for administrative purposes. In accordance with the national guidelines the prophylaxis was strongly recommended for children with a
gestational age of <32 weeks and aged <1 year at the beginning of the epidemic period. The prophylaxis is also strongly recommended in children with chronic lung disease and in those with hemodynamically congenital heart disease (excluding those who had a surgical and radical correction and without need of pharmacological treatment) and aged <2 years at the beginning of the epidemic period. The prophylaxis was also recommended for infants born between 32 and 35 weeks, for those aged <1 year at the beginning of the epidemic period and for those with at least two more known risk factors associated with the disease (eg, exposure to passive smoking, not breastfed). If the child was hospitalized, the prophylaxis was offered at the hospital. After discharge, the public pediatric ambulatory, warned by the clinicians, contacts the family if prophylaxis is indicated for the infant. Prophylaxis was usually repeated once a month during the epidemic period.

**Cross linkage of the data sources:** Data from the various sources were initially linked using the complete surname, name, gender and date of birth of the child. This link was performed using the SAS program (version 8.2). For subjects not linked using those criteria, the SALI (software for automated linkage in Italy) program was used to match individual records. SALI reduces false negatives by taking into account possible errors in key fields. Finally, for immunized children and for children hospitalized for bronchiolitis not linked with CEDAP after the previously described automated cross-linkages, the CEDAP was checked manually for all children born on the date of birth of any immunized or hospitalized child unidentified in the previous steps.

**Statistical analysis:** The analysis initially included 2,558 children born between 2000-2006 in the two LHUs for whom the reported gestational age in the CEDAP was <36 weeks. We then excluded 151 of them whose date of discharge after delivery was after 31/12/2006 or not listed, or the gender was not reported, or who died immediately after birth. The outcome of the analysis was initially any hospitalization for bronchiolitis within the first three years of age. However, the analysis we conducted was restricted to first hospitalizations within the first 18 months, because only six cases had more than one hospitalization for bronchiolitis and only two cases were hospitalized after 18 months of age. The incidence rate was calculated as the ratio of the hospitalizations for bronchiolitis within 18 months of age out of the person-time at risk. For each child, the person-time at risk was calculated from the date of discharge after delivery until the first hospitalization for bronchiolitis, the date the child turned 18 months of age, and the first of January 2007. Incidence rates of hospitalization for bronchiolitis were also calculated stratifying for several of the infants’ characteristics at birth (ie, birth weight (<1000, 1000-2000, >2000 grams), gestational age (<32, >32 weeks), gender, year of birth, Apgar score at 5 minutes after birth (≤7, >7), reported diagnosis of broncho-dysplasia during the delivery hospitalization or in subsequent hospitalizations, reported diagnosis of CHD at delivery or at subsequent hospitalizations and of maternal characteristics [ie, age at delivery (ie, ≥32, >32 years, where 32 is the median age), years of education (≤8 years, >8 years, unknown), country of birth (Italy, other), and parity (0, 1, ≥2)]. Incidence rates were also calculated stratifying for age of the infants (ie in months and into three groups: <6, 6-11, 12-18 months) and calendar month. Crude and adjusted incidence rate ratios (IRR) of bronchiolitis hospitalizations for the previously described characteristics were estimated using univariate and multiple Poisson models. Descriptive frequency tables of the previously described characteristics and use of Palivizumab were provided. To evaluate the association of some characteristics with Palivizumab use we calculated the Chi-squared test. To evaluate the independent association of these characteristics with the administration of Palivizumab, a multiple logistic analysis was performed.
To evaluate the impact of the administration of Palivizumab on the risk of being hospitalized, we performed additional Poisson models that estimated IRRs for immunized compared to non-immunized infants using two different approaches of selecting specific at risk time periods among those who received prophylaxis. The first approach evaluated the effectiveness of the immunization in its entirety considering as the at-risk-time the period since the date of the first dose of Palivizumab administered to the first hospitalization for bronchiolitis, or the date the subject turned 18 months of age, or the first of January 2007, whichever comes first (section A, Figure 1). This approach evaluated the effect of the immunization strategy in its entirety and hereafter is referred to as the vaccination-strategy effectiveness. The second approach evaluated the specific effect of Palivizumab in the 30 days after each dose. This means that all time periods and events 30 days after each dose was administered were not considered in the analysis. This approach, hereafter referred to as the dose-effectiveness approach, mimics the proposed scheme of administration and it evaluates the “absolute” effect of the prophylaxis only in the 30 days following each administration (section B, Figure 1). For both approaches a multiple Poisson model, including the previously described characteristics as possible confounders, was performed. Furthermore, this model was also performed restricting only to children born at ≤32 weeks gestation, and restricting the analysis to the time periods from the beginning of October to the end of April (ie, the epidemic period) of each year. The analyses about the effectiveness of Palivizumab were restricted to the first year of life as this prophylaxis is not recommended after one year of age in most preterm infants without chronic lung disease.

**Results**

Incidence and risk factors of hospitalization for bronchiolitis: During the period 2000-2006, 67,292 children were born to mothers living in the two LHUs of Rome; the median gestational age was 39 (mean = 38.9) weeks. Among them, 2407 (3.6%) were born at <36 weeks of gestation; the median gestational age among preterm infants was 34 (mean = 33) weeks and 201 (8.3% of preterm infants) were born at <29 weeks.

Table 1 shows the number of cases, the person-years and the incidence rates of a first hospitalization for bronchiolitis by age, by calendar month, and by calendar year among preterm infants. One hundred thirty-seven were hospitalized at least once with a diagnosis of bronchiolitis within the first 18 months of age. Overall, the incidence rate was 4.70 per 100 person-years (PY) (95%CI: 3.98-5.56). Significantly higher incidence rates were observed in the first six months of life and the incidence rates decreased with age (p < 0.01). This significantly decreasing trend was also observed by month of age (Figure 2, section A) (p < 0.01). Incidence rates also varied significantly by calendar month with the highest rates observed in the period October-April (hereafter defined as the epidemic period), with a peak in January (Figure 2, section B); the incidence rate was 7.17 and 1.22 per 100 PY in the epidemic and in the non-epidemic period (p < 0.01), respectively. Table 2 shows the incidence rates of a first hospitalization for bronchiolitis stratified for several characteristics. Significant higher incidence rates were observed for children born to mothers with ≥8 years of education compared to those with <8 years (p = 0.02). Characteristics of the infants that were significantly associated with higher incidence rates included: male gender (p = 0.02), low birth weight (p < 0.01), gestational age <32 weeks (p = 0.01), Apgar score ≤7, and presence of bronchodysplasia (p = 0.04); there was no statistical significance for year of birth (p = 0.61).

Table 3 shows the crude (CIRR) and adjusted incidence rate ratios (AIRR) of being hospitalized for bronchiolitis. After adjusting for all characteristics, statistically significant higher risks were still found for children born to mothers with ≥8 years of education, for males, in the first months of age, for low birth weight infants, for children with an Apgar score ≤7, and in the epidemic period. Similar results were found performing other Poisson models where birth weight and gestational age were entered as categorical instead of continuous variables.

**Use of Palivizumab and estimates of its effectiveness on the risk of hospitalization for bronchiolitis**

Overall, 324 (13.5%) children received at least one dose of
Palivizumab. There were 1291 doses administered with a median of 4 doses received per child. Doses were administered exclusively between October and April, with the mode of administration in December (24.7% of the total). Table 4 shows maternal and infant characteristics stratified for Palivizumab use (ie, no administration and at least one dose). During the study period, the percentage of children who received Palivizumab dramatically increased from 2.8% in 2000 to 19.1% in 2006. Palivizumab was more frequently administered to children born to mothers over 32 years of age, who had no other children, more than 8 years of education, and who were born in Italy; regarding the characteristics of the infants; Palivizumab was more frequently administered to females, with a birth weight of <1000 grams, who were born at <32 weeks, with an Apgar score of ≤ 7, with a diagnosis of bronchodysplasia, and to those born between July and December. It is of note that Palivizumab was not administered to infants with CHD. Among them, only 5 (14.7%) were born at <32 weeks of gestation, while 8 (23.5%) and 15 (44.1%) were born at 34 and 35 weeks, respectively. Multiple logistic regression showed statistically significant adjusted odds-ratio (AOR) >1 of receiving Palivizumab for preterm infants born to mothers ≥32 years old, for those born to Italian mothers, for females, for those born most recently, for those who weighed <2000 grams, for those born at <32 weeks, for those with an Apgar score ≤ 7, for those not born in the spring, and for those with a diagnosis of bronchodysplasia.

Among the 324 preterm children who received at least one dose of Palivizumab, 8 (2.5%) were hospitalized with bronchiolitis in the first 12 months of life. Among them, 6 were hospitalized in the 30-day period just after each administration of Palivizumab. The incidence rate was 5.72 (95%CI: 2.86-11.44; PY = 140) per 100 PY, slightly lower than that observed in non-immunized children (6.97 per 100 PY, 95%CI: 5.84-8.32; PY = 1751). The incidence rate in the 30 days immediately after each administration of Palivizumab was 9.55 (95%CI: 4.29-21.27; PY = 63) per 100 PY. Table 5 shows the estimated crude and adjusted IRRs of hospitalization for bronchiolitis for those who received Palivizumab compared to those who did not, estimated by several Poisson models and with the two different approaches (see methods and figure 1). When adjusting for potential confounders, no significant risk reductions were found in the proposed models, but one (ie, Model 2, vaccination-strategy).

Discussion
We evaluated the incidence and the risk factors of hospitalization for bronchiolitis in preterm children in and around Rome, Italy. Overall, the incidence of hospitalization was 4.70 per 100-PY in the first 18 months of age and this estimate is in agreement with that reported in other studies.6,16,21,24 We found that the incidence strongly declined with age and that hospitalization after 18 months of age is extremely rare. Furthermore, we observed a strong seasonal effect with the highest monthly incidence estimated from October to April. Other independent significant risk factors of being hospitalized for bronchiolitis were: low Apgar score 5 minutes after birth, low birth weight, male gender, and low educational level of the mother (ie, ≤ 8 years). While our results for some of these factors (ie, young age, autumn/winter period, low birth weight, low Apgar score, and male gender) are in agreement with previous publications,2,5,6 low educational level has never before been identified as an independent risk factor for hospitalization for bronchiolitis. This could be a proxy of other factors, such as maternal smoking that was not evaluated in our study. It is of note that other factors, such as increasing birth order, a diagnosis of bronchodysplasia, CHD, and low gestational age, after having adjusted for the other covariates, were not significantly associated with being hospitalized for bronchiolitis, and this contrasts with previous publications.2 The results regarding gestational age can be explained by their strong correlation with low birth weight; regarding increasing birth order, bronchodysplasia, and CHD, the estimated adjusted IRR still suggest that children with these characteristics had a greater risk of being hospitalized with bronchiolitis, and the fact that they were not found to be statistically significant is likely only the result of the limited statistical power due to the low numbers in these groups.
During the 2000-2006 study period we observed a significantly increasing trend of the percentage of preterm children who received at least one dose of Palivizumab. After adjusting for other covariates, year of birth was still strongly associated with the administration of Palivizumab; other factors independently associated were low birth weight, shorter gestation, low Apgar score, reported diagnosis of bronchodyplaasia, female gender, birth country and maternal age. While the first four factors were expected to be associated with Palivizumab prophylaxis, there is no clear explanation for the latter three. In particular, it was expected that male children, being at higher risk of hospitalization, were more likely to have received prophylaxis with Palivizumab than females and not vice versa. One possible explanation could be related to unknown, uncontrolled confounders for which the effect was indirectly expressed through gender.25 Regarding maternal age and maternal birth country, the lower adjusted odds of receiving at least one dose of Palivizumab could reflect, as a proxy, lower social economic status. Furthermore, for mothers born outside Italy there could have been difficulties for the LHUs in contacting or in communicating with them.

We evaluated if there was a risk reduction of hospitalization for bronchiolitis in infants who received at least one dose of Palivizumab with two different analyses trying to identify both the effectiveness of each single dose and of the scheduled immunization program offered. In both cases we did not find, using different multiple models and different selected populations, a significant risk reduction, but in one model (Model 2, Vaccination strategy in Table 5). However, all proposed models have point estimates that are similar ranging between 33% and 53% in Table 5. Although our estimates of the risk reduction were a little bit lower than the two clinical trials performed,8,9 we cannot exclude that this different magnitude of the effect simply resulted from chance. Furthermore, it is of note that all hospitalizations studied in the two clinical trials had RSV antigen positive tests while we studied any hospitalization for bronchiolitis independent of RSV test results.

As we specified in the methods section, the identification of the etiological agent of bronchiolitis in clinical practice is not always performed because it does not change the type of treatment given. Assuming that RSV-related hospitalizations for bronchiolitis were, as reported in the literature,18 70% of the total, and that Palivizumab does not have any effect on non-RSV-related cases of bronchiolitis, we can further reduce our estimates of the effectiveness of Palivizumab on bronchiolitis hospitalizations of 30%. This implies that our risk reduction estimates of hospitalizations for RSV-related bronchiolitis should range between 53% and 67%, very similar to those previously reported in the two clinical trials.

It is of note that our data did not show any impact on the trend of the hospitalizations for bronchiolitis as shown by the incidence rates and the adjusted IRR by calendar year (see table 2 and 3). Even though the use of Palivizumab dramatically increased between 2000 and 2006, less than 20% of the preterm children born between 2004 and 2006 received the prophylaxis and the expected number of cases that were prevented is very low.

Before drawing conclusions we should consider some limitations of this study. First, this study was based on data collected only by two LHUs and results are limited by the small study size. Second, this was a retrospective observational study and the measured characteristics for children at birth, the date of Palivizumab administration, and the hospitalizations were taken from large databases created for other purposes. Third, we identified bronchiolitis hospitalizations using the ICD9-CM diagnostic codes 466.11 or 466.19. It is of note that in many cases the code 466.19 (bronchiolitis associated to a non-RSV or unknown infectious agent) was reported in the hospital discharge form; this most likely occurred because no diagnostic exams had been performed to identify the underlying infectious agent. This did not permit us to perform specific analyses of RSV-associated bronchiolitis. However, many studies reported that between 70% and 90% of hospitalizations for bronchiolitis in infants are RSV-associated. Finally, preterm infants have a high risk of hospitalization for bronchiolitis independent of RSV test results.

Table 3: Crude (CIRR) and adjusted (AIRR) incidence rate ratios of hospitalization for bronchiolitis, Rome, Italy 2000-2006

<table>
<thead>
<tr>
<th>Age of the mother (years)</th>
<th>CIRR (95% CI)</th>
<th>p-value</th>
<th>AIRR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 32 vs. &lt;32</td>
<td>1.13 (0.80-1.58)</td>
<td>0.49</td>
<td>1.08 (0.75-1.55)</td>
<td>0.67</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 vs. 0</td>
<td>1.28 (0.88-1.86)</td>
<td>0.19</td>
<td>1.34 (0.91-1.98)</td>
<td>0.14</td>
</tr>
<tr>
<td>≥ 2 vs. 0</td>
<td>1.04 (0.59-1.83)</td>
<td>0.89</td>
<td>1.09 (0.60-1.95)</td>
<td>0.78</td>
</tr>
<tr>
<td>Years of education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 8 vs. &gt;8</td>
<td>1.74 (1.23-2.46)</td>
<td>&lt;0.01</td>
<td>1.71 (1.18-2.48)</td>
<td>0.01</td>
</tr>
<tr>
<td>Not known vs. &gt;8</td>
<td>9.51 (0.88-102.1)</td>
<td>0.06</td>
<td>9.82 (0.79-122.4)</td>
<td>0.08</td>
</tr>
<tr>
<td>Birth country of the mother</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy vs. other</td>
<td>1.07 (0.65-1.78)</td>
<td>0.78</td>
<td>1.30 (0.73-2.30)</td>
<td>0.37</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male vs. female</td>
<td>1.47 (1.03-2.08)</td>
<td>0.03</td>
<td>1.48 (1.04-2.10)</td>
<td>0.03</td>
</tr>
<tr>
<td>Calendar year (ref. 2001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>1.19 (0.49-2.86)</td>
<td>0.70</td>
<td>0.79 (0.33-1.88)</td>
<td>0.60</td>
</tr>
<tr>
<td>2002</td>
<td>1.21 (0.64-2.28)</td>
<td>0.56</td>
<td>1.28 (0.68-2.43)</td>
<td>0.44</td>
</tr>
<tr>
<td>2003</td>
<td>1.61 (0.89-2.93)</td>
<td>0.12</td>
<td>1.73 (0.95-3.16)</td>
<td>0.07</td>
</tr>
<tr>
<td>2004</td>
<td>0.84 (0.43-1.63)</td>
<td>0.61</td>
<td>0.92 (0.47-1.79)</td>
<td>0.81</td>
</tr>
<tr>
<td>2005</td>
<td>1.02 (0.51-1.92)</td>
<td>0.94</td>
<td>1.24 (0.66-2.34)</td>
<td>0.50</td>
</tr>
<tr>
<td>2006</td>
<td>0.98 (0.51-1.87)</td>
<td>0.94</td>
<td>1.16 (0.60-2.24)</td>
<td>0.66</td>
</tr>
<tr>
<td>Age (months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 vs. ≥ 12</td>
<td>11.75 (5.44-25.35)</td>
<td>&lt;0.01</td>
<td>14.54 (6.75-31.35)</td>
<td>&lt;0.01</td>
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<tr>
<td>6-11 vs. ≥ 12</td>
<td>5.50 (2.47-12.24)</td>
<td>&lt;0.01</td>
<td>5.98 (2.68-13.35)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Epidemic period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes vs. No</td>
<td>5.89 (3.44-10.06)</td>
<td>&lt;0.01</td>
<td>5.48 (3.22-9.35)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Birth weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>per 100 g decrease</td>
<td>1.05 (1.02-1.07)</td>
<td>&lt;0.01</td>
<td>1.06 (1.02-1.11)</td>
<td>0.01</td>
</tr>
<tr>
<td>Gestational age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>per 1 week less</td>
<td>1.08 (1.02-1.14)</td>
<td>0.01</td>
<td>0.97 (0.88-1.07)</td>
<td>0.58</td>
</tr>
<tr>
<td>Apgar score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 7 vs. &gt; 7</td>
<td>2.06 (1.40-3.03)</td>
<td>&lt;0.01</td>
<td>1.57 (0.99-2.48)</td>
<td>0.05</td>
</tr>
<tr>
<td>Broncho-dysplasia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes vs. No</td>
<td>2.08 (0.91-4.75)</td>
<td>0.08</td>
<td>1.70 (0.68-4.28)</td>
<td>0.26</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes vs. No</td>
<td>1.63 (0.51-5.18)</td>
<td>0.41</td>
<td>1.64 (0.52-5.19)</td>
<td>0.40</td>
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risk of death and we cannot exclude that for some of them we could have overestimated the person-time at risk of bronchiolitis if they died before 18 months of age. However, since we excluded those who died during their first hospital admission the impact of this issue on our results should be limited.

Conclusion
In conclusion, this is the first report since the introduction of Palivizumab to evaluate the incidence and risk factors associated with hospitalizations for bronchiolitis in preterm infants in Italy. We highlighted that in Italy the incidence of hospitalization for bronchiolitis and the risk factors associated with it are similar to those found in other countries. Although the use of Palivizumab is associated with the most important characteristics of severe prematurity, its non-use in children with congenital heart disease contrasts with international guidelines; furthermore, its association with maternal age and the country of birth suggests the need for public health measures that can reduce health disparities.

References
EXECUTIVE PROFILES

Baxa Corporation

Describe your product(s) and its unique features.
For more than 30 years, Baxa has been the gold standard for oral dispensers. The first dispenser designed for oral use only, the ExactaMed Oral Dispenser provides safe and accurate delivery of oral unit doses by preventing wrong-route administration. Recently Baxa launched the NeoThrive System to complement the ExactaMed Dispensers. NeoThrive is a luer-free, dedicated enteral feeding system designed for safe feeding of neonates. NeoThrive System components—enteral syringes and enteral pump—are color-coded orange to signify enteral use and were created specifically to meet the needs of fragile NICU patients. The system includes syringes in sizes from 1 mL to 60 mL to meet the feeding needs of all neonates. It also includes a special enteral-only administration pump with rates specific to NICU needs.

How does your product directly affect patient care?
The products in the NeoThrive line make enteral feeding safer for neonates and eliminate the serious risk of tubing misconnections during enteral feedings.

Tell us about the latest advances in the area your product serves.
Enteral feeding is a manual process that has focused on nutritional products until recently. Advances in enteral safety have focused on medical device improvements that reduce the opportunity for human error and make it easier to deliver safe patient care. These include specialty enteral labeling and color-coding devices to set them apart from IV and other applications, designing unique fittings to prevent inadvertent device misconnection and dedicated delivery devices that cannot accommodate IV and other delivery methods and therefore ensure enteral delivery safety.

What sets your product apart from others in the field?
Baxa Corporation developed the first dedicated non-luer dispensers and was the first to design an enteral-only device to ensure safe feeding. In addition, Baxa created unique color-coding and labeling that helps identify the NeoThrive products as enteral-only and not IV or other applications. Also, the NeoThrive System was designed specifically for use in the NICU, which differentiates it from systems used in adult and pediatric settings. The NeoThrive Enteral Pump is the only pump designed, labeled and color-coded specifically for neonatal enteral feeding using syringes.

Discuss your R&D process, including end-user input.
As a medical device manufacturer, Baxa Corporation designs and manufactures its products according to Federal standards for good manufacturing practice (GMPs) and design control. Customer evaluations and feedback are solicited as part of the design requirements for development, and are a big part of ensuring that our products do what they are designed to do. As part of our continuous improvement process, we gather customer feedback on all products and use this information to update and improve existing products, as well as determine ideas for future product development.

What are your goals for R&D in the near future?
Baxa Corporation is dedicated to providing medical products that offer safety improvements for the handling, packaging and administration of liquid medications. We plan to expand our existing line of NICU products in the future to ensure that the enteral feeding process is as safe as possible.

Discuss the educational services you offer for use of your product.
Baxa Corporation provides a complete user manual for the NeoThrive Enteral Pump and comprehensive instructions for use for its NeoThrive Syringes. In addition, we provide onsite, hands-on training for the enteral pump and 24/7 technical support to ensure that all users are properly trained and that the NeoThrive System is used safely and effectively.

Discuss the role of critical care providers in developing and upgrading your product.
In order to ensure that the NeoThrive System—and all Baxa products—meet health system needs, it is important that Baxa Corporation receives regular feedback on their operation. It is also critical for Baxa to know the challenges that healthcare providers face in their daily activities, to ensure that future products address those needs. Baxa continuously evaluates customer contacts and complaints related to its products in order to know what product upgrades and changes are needed to provide enhanced user and patient experiences.

Talk about how you test and evaluate your product in actual day to day use.
Baxa has clinicians on staff that we rely on for day-to-day input on current products and those that are in development for the future. In addition, we survey all sites that trial our NeoThrive System and provide the means for users to provide us with feedback at any time after they have implemented our system. Baxa uses customer feedback to make improvements to our...
What new technology do you see as having the greatest impact on your area of expertise?
The technology that has the greatest opportunity to positively impact healthcare is electronic records management—product
and drug bar coding, electronic medical records, automated
data gathering and management and reporting. Through the use
of electronic technology, healthcare providers can standardize medical information, track dose preparation and manage the
doses from preparation to administration.

Discuss the international scope of your testing/ marketing/development efforts.
Baxa Corporation markets dedicated enteral systems worldwide. The NeoThrive System is primarily marketed in North America,
where orange has been designated as the standard color for indicating enteral. In Europe, Baxa markets purple devices for
enteral feeding, as this is the color that has been designated to indicate enteral.

Tell us how you utilize conferences, seminars and such to promote your product.
Baxa Corporation participates in industry conferences for neonatal nursing and enteral feeding as a means to get our
products in front of key users. We also use industry conferences, seminars and exhibits to learn about current trends and issues
for our users. Baxa Corporation sponsors educational events and
provides funding for industry events and foundations to allow them to continue their educational and research programming.

GE Healthcare
Describe your product(s) and its unique features, and how this affects patient care.
GE has made a commitment to sustainable health, which we call “healthymagination.” Overall, that means providing solutions
that help doctors and hospitals deliver better healthcare to more people at lower cost. To support this goal, we will
more than double our research and development spending on healthymagination products, totaling $3 billion by 2015, to
deliver innovations that: • Reduce by 15% the cost of procedures and processes with GE technologies and services; • Increase by
15% people’s access to services and technologies essential for health, reaching 100 million more people every year; • Improve
quality and efficiency by 15% for customers through simplifying and refining health care procedures and standards of care.
While healthymagination is a strong affirmation, we have always believed in these principles. Our focus on quality for neonates
helped deliver products which provide life-sustaining therapies for critically ill patients, by controlling environmental factors and
allowing premature infants to focus their energy on continued development. GE Healthcare’s neonatal microenvironments facilitate care and promote patient homeostasis by regulating temperature, humidity and oxygen. The Giraffe OmniBed is a proven product for intensive care, and the recent launch of the Giraffe Warmer with integrated SPO2, brings our products to a new level of integrated care. We believe our product success is based on the recognition that each baby has different developmental needs and we have designed our products to allow the clinician to meet these individual needs and to include families in the process.

Tell us about the latest advances in the area your product serves.
We understand the dramatic need and opportunity for system interconnectivity, both technologically and clinically, in the
delivery of care. Our breadth of expertise within GE Healthcare uniquely positions us to deliver more integrated solutions to support our customers and their patients. We also see the accelerating need to improve developmental care for neonates. Building on the clinical capabilities of our Giraffe products, we are actively working to address the challenges posed by younger, smaller, and more critically ill patients and the unique needs of their families. These factors, including the needs for infection control and noise reduction, have led to new clinical practices, such as the conversion of a great number of NICUs to a single family room design, as well as a significant focus on next generation technology to enable new levels of developmental care.

What sets your product apart from others in the field?
For over 50 years, GE Healthcare has offered advanced technology and innovative designs that meet the most demanding clinical care needs in the NICU. To better meet these needs, we work closely with neonatal healthcare professionals. In designing the revolutionary Giraffe line of microenvironments, we gathered valuable insight from those who know neonatal care best: caregivers, clinical research experts and families. We also drew upon our extensive industry experience as Ohmeda Medical and ongoing commitment to developmental and family-centered care. The result: exceptional healing environments for high-acuity newborns. Combining advanced technology, innovative design and exceptional thermal performance, full-featured Giraffe products provide nurturing, life-sustaining environments that foster growth, encourage healthy development and both simplify and standardize care. Helping promote positive outcomes for sick infants—while addressing the needs of caregivers and families, that is the Giraffe family of products.

Discuss the R&D process, including end-user input and the critical care provider role as well as R&D goals for the future.
We are focused on our patients and our customers, which means helping providers take better care of their patients with clinical and functional enhancements, helping make the work that they do easier. In developing the Giraffe platform, we started by asking clinicians to design their “dream” microenvironment. We spend a significant amount of time in hospitals around the world identifying the problems current products caused for the baby, the caregiver, and the parent. In many cases, clinicians simply believe they had to “live with the problem.” Our goal is to design out problems by providing useful solutions. We continue to invest in ways to build upon platforms and improve the patient recovery cycle, clinical workflow and productivity. Additionally, by working closely with leading institutions and clinicians we are developing new technologies that provide the caregiver with a comfortable working space that is flexible and applicable for both labor & delivery and the NICU. The ultimate goal is to address the issues everyone faces for reducing the overall cost of care, increasing quality of care and increasing the access of this kind of care to more babies, caregivers, and parents.

Discuss the educational services you offer for use of your product.
Our Maternal-Infant Care Clinical Education Institute helps bring research into daily clinical practices. GE’s combined offering
assists healthcare professionals in supporting the specialized needs of patients and families across the entire maternal-infant continuum. Our education program offerings are flexible and customizable, ranging from onsite and online courses to Go-Live clinical support. GE’s expert educators, combined with our training offerings, provide a balanced application of practical theory and hands-on exercises for maximum exposure for learning.

**Talk about how you test and evaluate your products in actual day-to-day use.**
We involve external stakeholders throughout the entire design process to ensure that we understand customers’ needs, to develop the right product to address those needs, and to validate that our solutions deliver the value expected. Then, we continuously monitor the performance of our products after they have been introduced into the market, both to make certain that our overall quality remains high, and also to determine how we can improve our product performance and development for the future.

**What new technology are you looking at for having the greatest impact on your area of expertise?**
Since the introduction of the Giraffe OmniBed, our focus has been on creating a developmentally appropriate environment for the premature newborn, to allow them to focus their energies on growth. We are now looking at concepts that will provide a step change in developmental care concepts. Technologies that we could never have considered when Giraffe was first introduced ten years ago, such as active noise cancellation and wireless sensing, are much more feasible, technically speaking. There remain many challenges to making such technology affordable, but this is a much more solvable problem.

**Discuss the international scope of your testing/marketing/development efforts.**
We are complementing the history of our product innovations with a real focus on developing health globally by creating local products based on regional needs. We use “in-country-for-country” business models for R&D, engineering and manufacturing for products to be relevant to their society, economy and clinical practice. One such program demonstrating the success of this approach is where we are designing and developing new technology at GE’s R&D center in India, as part of our “In India, for India” program to make technology more affordable, reliable and more accessible to larger sections of society. Embedded in India, we continue to gain valuable insights into local issues, like the fact that many of the birthing centers don’t have effective phototherapy systems and failure to treat infant jaundice can result in serious brain damage, and even death. Emphasis on earlier detection and treatment of jaundice in newborns is one way our GE Maternal-Infant Care business is making a difference in India. We will continue to invest in our healthymagination goals, increasing quality of care for more people at a lower cost.

**Tell us how you utilize conferences, seminars and such to promote your product.**
We have a shared passion to promote the health of neonates with evidence-based, innovative products designed with clinicians. Conferences, seminars and forums provide a unique opportunity for conversation with healthcare providers on how our products solve their challenges. As we’re engaging in these conversations, it offers the opportunity to validate our marketing message, conduct limited user research about trends in the marketplace and present clinical studies. We look forward to conferences as an opportunity to recognize the importance of our common goals, of hosting associations’ missions, and of the overall education of our nursing colleagues from both clinical and product perspectives.

**NeoMed, Inc**

**Describe your product(s) and its unique features.**
NeoMed designs and manufactures neonatal and pediatric enteral delivery systems (oral syringes, feeding tubes, sets), breast milk tracking systems, umbilical catheters and insertion trays, urinary drainage catheters and trays. Some of the unique features include “enteral only” connections, orange color coding as a visual cue to identify enteral paths, open-ended feeding tube designs to prevent pooling of milk solution and minimize potential for bacterial growth and certainly our SafeBaby System.

**How does your product directly affect patient care?**
Our products are designed to deliver enteral nutrition safely to the patient by eliminating the possibility of mis-connection and mis-feeding errors. Our umbilical catheters and insertion trays are known as the “gold standard” in safe catheterization of the umbilicus.

**Tell us about the latest advances in the area your product serves.**
Our SafeBaby Breast Milk Tracking system is the only effective way to manage the proper storage, fortification and delivery of breast milk to the baby. With SafeBaby, the clinician receives 100% validation that the mother’s breast milk is fed to her baby.

**What sets your product apart from others in the field?**
We start with a focus on patient safety and enhanced clinical outcome as we design new products or modify existing products.

**Discuss your R&D process, including end-user input.**
NeoMed’s in-house engineering department has vast experience in medical device design and manufacturing. Our executive team and sales staff continually solicit input from the end users. Integrating their field experiences and assessment of neonatal needs insures that NeoMed directs engineering and product development efforts to the specific needs of the population that we serve. R&D is driven by these findings and new product development is focused toward enhanced safety and improved patient outcome.

**What are your goals for R&D in the near future?**
R&D efforts continually focus on clinical outcome and safety. Introduction of ancillary products that support neonatal nutrition are a major focus of both the long term and short term development. Directing resources into enhanced electronic tracking, shortening engineering development cycles, evaluating performance characteristics of leading edge polymers, and responding to the needs of the neonatal community remain the focus of our R&D efforts.

**Discuss the educational services you offer for use of your product.**
NeoMed’s dealer network is comprised of seasoned neonatal product specialists that have the clinical expertise to provide...
product in-servicing and training. With the release of additional vascular access products in 2010, training of specific procedures and CE credits will be offered.

**Discuss the role of critical care providers in developing and upgrading your product.**

Many of the products we develop spring from needs expressed by neonatal nurses and clinicians. In addition, our design verification process requires input from our clinical expert before development can continue. We continually solicit feedback from end users to assist in continuous improvement efforts.

**Talk about how you test and evaluate your product in actual day to day use.**

Our development efforts include testing to simulate field use. In addition, we sponsor field testing of our products to obtain feedback from health practitioners. This information becomes part of the development process. Once released, we encourage feedback from end users as part of our continuous improvement objective.

**What new technology do you see as having the greatest impact on your area of expertise?**

NeoMed is constantly looking at ways to create devices that will help deliver better nutrition to the baby safely. We see many opportunities to bring devices solutions to the market. The two major technologies would be improved electronic tracking capability and emerging polymer technologies.

**Tell us how you utilize conferences, seminars and such to promote your product.**

NeoMed is committed to the various national and regional conferences throughout the year. Contact with the clinical customer is a vital piece to our understanding of the trends in neonatal medicine and potential uses our products to benefit the patient.

**ONY, Inc**

**Describe your product(s) and its unique features.**

Infasurf (calfactant) is a lung surfactant replacement product approved for both prevention and treatment of RDS in newborns. Infasurf differs from other lung surfactant replacement products in that it contains only surfactant lipids and hydrophobic apoproteins. It contains no tissue or synthetic lipids and has the same ratio of the essential apoprotein SP-B to phospholipids as does the natural surfactant from which it is extracted. In extensive biophysical and biologic testing it parallels natural lung surfactant in potency, durability and resistance to inhibition.

**How does your product directly affect patient care?**

Prophylactic treatment with Infasurf is life saving for prematurely born infants at high risk for RDS. It is also life saving for infants not treated at birth who develop RDS with respiratory failure.

**Tell us about the latest advances in the area your product serves.**

In 2005 it was reported for the first time that a lung surfactant, Infasurf (calfactant) could be effective in changing the course of respiratory failure in patients beyond the newborn period with respiratory failure caused by lung injury (Willson DF et al. Effect of exogenous surfactant (calfactant) on pediatric acute lung injury. JAMA 2005; 293:470-476). A post hoc analysis of the results strongly suggested that patients with Acute Lung Injury/ Acute Respiratory Distress Syndrome (ALI/ARDS) caused by injury to the lung initiated on the epithelial side of the blood-gas membrane in the lung were likely to benefit.

**What sets your product apart from others in the field?**

Natural surfactant remains the standard against which exogenous lung surfactant replacement products are compared for biophysical properties and biological activity. Infasurf consistently equals natural surfactant while the other commercial lung surfactants are less surface active and less biologically active than natural lung surfactant.

**Discuss your R&D process, including end-user input.**

ONY’s R&D has been driven by academic investigators who have approached us with their hypotheses. We have collaborated in a wide variety of basic research into surfactant biophysics and biology, surfactant’s role in pathologic lung conditions, surfactant pathobiology and surfactant as vehicle for transportation of other biologic moieties. ONY has provided materials and funds for clinical investigations of calfactant in newborns and non-newborns. In all its R&D ONY utilizes outside investigators to initiate and conduct its sponsored research.

**What are your goals for R&D in the near future?**

ONY will continue to supply lung surfactant for pre-clinical investigations and to provide study drug and financial support when possible and appropriate for clinical trials that expand knowledge on the role of lung surfactant replacement in medicine. A sister company, Pneuma Pharmaceuticals is conducting a phase 3 pivotal clinical trial of calfactant for children and adults with direct ALI/ARDS. This study involves over 30 institutions in 6 countries. Results of this study are expected this year.

**Discuss the educational services you offer for use of your product.**

ONY provides a small number of educational grants to sponsors of continuing medical education for neonatal intensive care health care professionals. It gives support to an entity called NeoEd which provides “on-site” continuing education programs for RNs and RTs who staff neonatal ICUs. We believe it is important to provide high quality, accessible and accredited continuing education to these professionals.

**Talk about how you test and evaluate your product in actual day to day use.**

Infasurf clinical research follows FDA guideline for Good Clinical Practices when it sponsors research which could result in FDA approval for a new indication. For clinical research that is not aimed at FDA review and approval, projects must pass ONY’s scrutiny for scientific integrity and be approved by the Institutional Review Board at the institutions who are participating. ONY does NOT screen such studies for their potential impact on marketing or sales.

**What new technology do you see as having the greatest impact on your area of expertise?**

ONY continues to collaborate with partners working to make inhaleable preparations of lung surfactant feasible. In theory such a delivery could provide less traumatic and more therapeutic lung surfactant therapy for current usage and potentially expand the lung disease conditions for which lung surfactant supplementation therapy would be helpful.
Discuss the international scope of your testing/marketing/development efforts.
ONY is marketed in Latin America, Europe and Asia. It is investigating additional markets worldwide.

Tell us how you utilize conferences, seminars and such to promote your product.
Starting in October of 2009, Forest Laboratories ceased to market Infasurf and ONY itself assumed marketing and distribution. ONY plans to focus its support primarily on regional and local conferences and seminars for neonatal intensive care professionals because we believe they are more accessible to all the health professionals, while national conferences and seminars tend to draw more from the NICU leadership and supervisors. Product promotion will be aimed at providing to neonatal intensive care professionals (physicians, nurse practitioners, physician assistants, staff nurses, pharmacists and respiratory therapists) all the valid evidence that impacts on the choice of a lung surfactant, the optimal usage of lung surfactants and challenges of lung surfactant therapy. To achieve this goal ONY’s representatives are all health care professionals themselves with extensive (and continuing) expertise in neonatal ICU care. They come to Infasurf users and potential users as peers with an extensive knowledge of all the science of lung surfactants and their clinical use. ONY intends that interactions between its clinical representatives and the health care professionals who utilize surfactants to be sophisticated bilateral exchanges that increases our representatives’ understanding of the decision-making process of the health care professional and updates the knowledge base of the professionals they call on.

Paragon Data Systems, Inc/ SafeBaby

Describe your product and its unique features.
NeoMed’s SafeBaby, a secure feeding and milk management system, was developed to ensure that every baby in the NICU receives the right breast milk, donor milk or formula, risk free, at the bedside by way of 2-dimensional (2-D) bar coding technology driven by our SafeBaby proprietary software. Our system starts with a bar code label printer and mobile hand held computer with a bar code scanner and PC based software. This user friendly system allows you to immediately identify and record the receipts of each milk container, locate it, use it before expiration and make sure it is validated before used for a feeding. SafeBaby system includes oral/enteral dispensers, oral extension sets and feeding tubes that are designed to be incompatible with IV or Luer lock devices. SafeBaby offers the only complete enteral delivery system that complies with all recommendations set by the Joint Commission and the Association for Advancement of Medical Instrumentation (AAMLI).

How does your product directly affect patient care?
SafeBaby’s 2-dimensional (2-D) bar code/Enteral Safety System (ESS) combination protects vulnerable NICU patients from potential misfeeds and dangerous tubing misconnections, making it the gold standard of feeding and milk tracking management for the NICU. SafeBaby’s 2-D bar coding technology eliminates patient misfeeds while monitoring the entire inventory of milk for FIFO (first in first out), fresh/frozen/thawed, location, donor milk, fortification and more. SafeBaby’s Breast Milk Tracking System was recently highlighted in Nutrition in Clinical Practice by Guenter, et al as a comprehensive system that combines both enteral devices (syringes, feeding tubes) and technology to enhance patient safety. The Enteral Safety System (ESS) component protects patients from dangerous tubing connections and promotes an error-free process by way of innovative design for its oral/enteral dispensers and feeding tubes. The Enteral Safety System enhances patient care and safety when enteral feeding is a component of overall medical attention since it eliminates unintended and dangerous line connection errors with its purposeful design: oral/enteral dispensers, oral extension sets and feeding tubes that are incompatible with IV or Luer lock devices.

Tell us about the latest advances in the area your product serves.
The Joint Commission issued a “Sentinal Event Alert regarding tubing misconnections” in April of 2006. Despite these warnings, the incidences of tubing misconnections continue to be a serious threat to patient safety and vitality. ASPEN, (American Society for Enteral and Parenteral Nutrition) in conjunction with Nestle Corporation created ALERT, a bedside program for nurses to raise awareness for healthcare providers and caregivers tasked with delivering enteral nutrition. ASPEN also recently developed an update to its 2001 “Standards of Practice for Nutrition Support Nurses” in April, 2007. The Joint Commission, in conjunction with the World Health Organization and the Joint Commission International, issued a series of action items to reduce the risk of catheter and tubing misconnections. GPOs, such as Novation, are beginning to seek out solutions through progressive purchasing strategies that will allow their members to purchase a “closed-loop” solution, like SafeBaby for safe feeding and milk tracking. In addition to these recent guidelines issued by nursing, nutritional and enteral/parenteral feeding organizations, technology to monitor safe and consistent feeds for NICU patients is relatively new and is gaining major acceptance as the feeding standard of choice by health care providers tending to these vulnerable patients. SafeBaby is at the forefront of this technology and is the only “closed loop” feeding system that ensures patient safety from tubing misconnections and tracks milk, donor-milk or formula inventory as it is received into the NICU. In addition, SafeBaby recently released version 2.1 that improves current reporting and offers a robust user interface designed to enhance ease of use.

What sets your product apart from others in the field?
SafeBaby is a secure feeding and milk management system that was developed to ensure that every baby in the NICU receives the right breast milk, donor milk or formula, risk free, at the bedside by way of a unique 2-dimensional (2-D) bar code located directly on the enteral-only syringe system and driven by our SafeBaby proprietary software. SafeBaby’s 2-D bar coding technology eliminates patient misfeeds while monitoring the entire inventory of milk for FIFO (first in first out), fresh/frozen/thawed, location, donor milk, fortification and more. SafeBaby protects vulnerable NICU patients from potential misfeeds and dangerous tubing misconnections, making it the gold standard of feeding and milk tracking management for the NICU. SafeBaby is the only product of its kind that combines 2-D bar code technology, an enteral-only tube system and proprietary software to ensure a patient’s safety, prevent misfeeds and track expressed breast milk, donor milk or formula in the NICU.
Discuss your R&D process, including end-user input.
SafeBaby's approach to R&D is to create a solution through innovation; design or redesign of a current process; or development of a new product for which the customer has a need. We address the needs of our customers by going out to the market/health care industry and listening to their needs and wants while actively watching work and data flow through a system. Once we have a firm understanding of a process, we diligently strive for a solution that improves upon the current process or product through technology or new product development. Our solutions present new ways of using data to manage care, ensure patient safety and assist the practitioner in constructing an error-free, state-of-the-art environment where the best possible care can be administered. We then introduce the new product or improved process to vertical markets that can be positively affected by the innovation and technological advance. SafeBaby always places the end-user at the front of the R&D process since we are tasked with creating solutions or products that will enhance the patient experience, develop better, safer care for patients and assist in creating a more controlled environment that will support the practitioner in administering the best possible care. We take ideas from start to finish and past implementation since we are continuously striving for excellence in what we present to our customers.

What are your goals for R&D in the near future?
In addition to improving our SafeBaby product based on customer needs, SafeBaby is working on an innovation to its Breast Milk Monitoring System that will automate how NICUs measure caloric composition in expressed breast milk. SafeBaby is pioneering an approach for analyzing the caloric components of breast milk so that fortification of expressed breast milk can be made more precise and accurate since additives will be compared to actual expressed milk values versus textbook averages. This product may be an innovation of the current SafeBaby system or a stand-alone product based on customer needs. In addition, SafeBaby is striving to create feeding guidelines in NICUs based on actual clinical data captured through its proprietary software.

Discuss the educational services you offer for use of your product.
SafeBaby offers educational services through its in-house classroom. In addition, every customer has access to technical phone support, sales support, web-based training, user manuals and white papers.

Discuss the role of critical care providers in developing and upgrading your product.
SafeBaby was developed by a needs-based analysis of NICU workflow processes and requirements for safer and more precise feeding practices. In addition, the proprietary software that drives the SafeBaby system was designed to eliminate misfeeds and reliably track breast milk inventory with confidence. The product was developed with the patient and the practitioner in mind since its design is based on practitioners' requests to enhance NICU safety and care, and for assistance in tracking breast milk so that the right patient receives the right milk, donor milk or formula with the right additives. SafeBaby works hand-in-hand with the facilities which currently have SafeBaby systems operating in its NICUs and gathers user suggestions to enhance the product as often as possible. SafeBaby developers work alongside the entire SafeBaby support team, from technical sales to education, to deliver the best possible system of its kind. The SafeBaby product team also continuously evaluates feedback from nurses, practitioners and anyone involved in the day to day care of NICU patients and that will come in contact with the SafeBaby system. SafeBaby's goal is a complete "closed loop" system that will guarantee a sterile feeding and collection process and is continuously looking for process improvements in work and data flow through the system to maintain that environment.

Talk about how you test and evaluate your product in actual day to day use.
SafeBaby tests and evaluates its products onsite and in-house. User testing and stress testing is continuously done and rigorously performed before the actual implementation of the product. The technical team at SafeBaby monitors all reports and compares actual results against predicted results from scenarios designed by the development team. These tests are performed to measure the accuracy of actual results versus predicted results. The SafeBaby product team also continuously evaluates feedback from nurses, practitioners and health care personnel involved in the care and feeding of NICU patients and that will come in contact with the SafeBaby system. The SafeBaby system strives for a complete, aseptic environment in regard to milk collection, storage and feeding processes and procedures in the NICU.

What new technology do you see as having the greatest impact on your area of expertise?
SafeBaby’s 2-D bar code system driven by our proprietary software is designed so that it can be integrated with any hospital data system, allowing data to be easily exchanged with a hospital's current databases and data warehouses. SafeBaby has the ability to transmit mother and patient data based on its ability to interface with a variety of databases. SafeBaby is HIPPA compliant and is in line with the Joint Commission’s recommendation to use enteral only feeding tubes.

Discuss the international scope of your testing/marketing/development efforts.
SafeBaby’s scope is in the United States at this time. However, there is potential to expand on an international level since NICU feeding, safety and care is a global issue.

Tell us how you utilize conferences, seminars and such to promote your product.
SafeBaby attends NANN, AWHONN, and nutrition-related trade shows to network and demonstrate to the NICU health care provider the efficiency and efficacy of the SafeBaby system via our display items, literature and product representatives. SafeBaby plans to expand its presence at similar trade shows and health care events as they relate to the care and safety of the NICU patient.

Philips Children’s Medical Ventures

Describe your product(s) and its unique features.
Philips Children’s Medical Ventures (PChMV) provides education services and developmentally supportive products for premature babies, healthy newborns and hospitalized infants. Our philosophy of care and product development efforts flow from The Universe of Developmental Care model, a framework for caring that is patient-centric and serves as a guide to provide NICU and step-down nurseries with innovative, evidence-based solutions aimed at protecting the integrity of the developing infant.

How does your product directly affect patient care?
Our broad product portfolio includes therapeutic support aids, safety solutions, noninvasive technologies and monitoring equipment as well as a breath of educational offerings focused on evidence-based, developmentally-supportive care. Our WeePee diapers are an example of how our product solutions go beyond the immediate care need and provide a solution within the context of the developmentally-supportive needs of the infant. These tiny diapers promote developmentally appropriate positioning and postural hip alignment. The BiliChek bilirubin assessment tool uses noninvasive technology to assess bilirubin levels, eliminating painful heel sticks for the hospitalized infant. And our wide range of calming, soothing and feeding products address the comfort, safety and feeding requirements of the premature and at-risk infant population. Our educational offerings present the latest evidence-based research in the field of developmental neonatal care and integrate adult teaching principles to provide a practical learning experience for the neonatal healthcare professional.

Discuss the educational services you offer for use of your product.
PChMV provides customers with expert clinical product inserviceing as well as comprehensive product literature to ensure appropriate use of our neonatal solutions in the clinical setting. Our educational program portfolio complements product inserviceing by presenting the latest body of evidence across a breadth of care activities and demonstrates, through simulation, how our solutions address existing clinical care challenges. Based on The Universe of Developmental Care model, programs such as Preemie for a Day and Wee Care help caregivers understand how the Neonatal Intensive Care Unit (NICU) environment impacts premature and critically-ill infants and how changing care practices impacts developmental outcomes. Educational DVDs help caregivers and family members better understand the world of these special babies, linking knowledge with improved care delivery that supports optimal growth and development.

Discuss the role of critical care providers in developing and upgrading your product.
We depend on clinicians and care providers to provide feedback regarding our products and educational offerings in order to keep them up to date and clinically relevant. We aggressively solicit this type of information and incorporate applicable feedback into new product design requirements. We test new technology in the hospital setting prior to release. Because of our relationship-based philosophy, many of our product ideas arise out of clinical challenges that confront the bedside care giver. This market insight alerts our R&D team to solution opportunities within the neonatal space.

Tell us how you utilize conferences, seminars and such to promote your product.
Philips Children's Medical Ventures attends and exhibits at relevant tradeshows and directly sponsors a number of conferences to keep abreast of industry initiatives. We participate in the National Neonatal Nurses (ANN/NNNC) and the National Association of Neonatal Nurses (NANN) annual meetings and are often included on the speaker's platform. We have also launched new products and developmentally-supportive, evidence-based care initiatives at these meetings. We sponsor the Developmental Therapists in the NICU Conference which is specifically designed to address the needs and issues of occupational and physical therapists, speech and language pathologists, and child life and developmental specialists working in the NICU. In addition, we developed and are the founding corporate sponsor of the NICU Nursing Leadership Conference which provides a forum for networking as well as leadership skill development and continuing education services for NICU nurse managers and directors.

Tell us about the latest advances in the area your product serves.
The latest advances in the field of neonatology and developmental care reflect a commitment to evidence-based practice, quality care delivery and performance improvement. Noninvasive ventilation strategies and monitoring technology, as well as heightened awareness of the effects of the NICU environment on the developing infant, are reflected in our current and emerging product offerings. We strive to align our product development activities with emerging evidence-based best practices to deliver the best solutions possible.

What sets your product apart from others in the field?
PChMV has aligned itself with the principles of The Universe of Developmental Care model which recognizes the patient and his/her experience to a hospitalization as the central focus of all care interactions and product development solutions. PChMV recognizes that product solutions must respond to the infant from a holistic perspective. As demonstrated by the UDC model, care interactions are interdependent and interrelated with the infant experience and accordingly, our philosophy of care and product development efforts focus on ensuring that we meet the holistic needs of the infant, family, clinician and healthcare organization.

Discuss the international scope of your testing/marketing/development efforts.
PChMV’s international team of clinically-active neonatal clinicians, including neonatologists, nurses and therapists, provides practical, clinically-relevant feedback to our product management and engineering teams to ensure that our product solutions and educational offerings are responding to the global concerns of neonatal patients, and the families, clinicians and healthcare organizations who care for them.

Talk about your R&D process, including end user input.
PChMV follows a formalized New Product Commercialization process that considers customer input at each critical stage of the process. The process begins with the creation of a Market Requirements document and culminates in market testing and validation of those requirements.
What are your goals for R&D in the near future?
Our goal for R&D is to continue developing products through the New Product Commercialization process that drive and support the concepts of developmentally appropriate care as depicted in The Universe of Developmental Care model.

Talk about how you test and evaluate your product in actual day-to-day use.
Our products are tested and validated through a process which takes into account the principles of developmental care. We conduct initial validation and verification testing of market requirements as defined by our customers and contained within our Market Requirements document as part of the New Product Commercialization process. The method of testing is specifically selected to minimize impact to individual infants by incorporating laboratory bench testing where appropriate, followed by field and clinical testing to confirm acceptance and effectiveness in the clinical setting.

Utah Medical Products, Inc
Describe your product(s) and its unique features. How does your product directly affect patient care?
Utah Medical Products, Inc (UTMD) develops, manufactures and distributes specialized medical devices that support developmentally-friendly care and meet the unique needs of the NICU and PICU. These devices include both silicone and polyurethane specialized catheters for vascular access, enteral feeding and urinary drainage, as well as disposable oxygen hoods and closed blood sampling/blood pressure monitoring kits.

What sets your product apart from others in the field?
UTMD's neonatal products are designed specifically to reduce patient trauma, risk of injury and infection while undergoing intensive care. The long-term experience and safety record of the structurally robust Gesco catheters and specialty kits provide clinicians with a consistent high level of quality that yields predictable clinical results.

Tell us about the latest advances in the area your product serves.
The Nutri-Cath enteral feeding catheter family now includes polyurethane catheters in addition to silicone. The unique Nutri-Lok enteral-only feeding system has been expanded according to clinician requests to include seven sizes of Monoject dispensing syringes for easy recognition by existing syringe pumps, new syringe packaging to facilitate storage, four versions of extension sets, a special connector set with Kangaroo ePump bag, a universal step adapter, syringe caps and oral dose straws. In 2009, UTMD also standardized additional Deltran Plus closed blood pressure monitoring and arterial blood kits for neonatal application. As always, UTMD regularly assembles custom kits to satisfy specific clinician requests and needs.

Discuss the educational services you offer for use of your product.
UTMD provides educational services for clinicians for all neonatal devices, primarily through direct consultation with UTMD direct representatives. Educational services are augmented with easy to understand instructions for use, product literature, DVDs and, when needed, independent clinical consultants.

Discuss the role of critical care providers in developing and upgrading your product.
The essence of UTMD's product development hinges on listening carefully to the recommendations and requests of knowledgeable clinicians. UTMD's design concepts are fully vetted and continually enhanced through UTMD's relationships with respected clinicians, most of whom have decades of experience.

Tell us how you utilize conferences, seminars and such to promote your product.
UTMD attends well-recognized national and regional neonatal and pediatric clinical conferences every year. These educational meetings allow UTMD the opportunity to increase its knowledge of current trends and experiences happening in the field. Most of the conferences also provide exhibiting opportunities for UTMD to conveniently expose interested clinicians to UTMD's new product concepts.

Oropharyngeal Administration...continued from page 29
Newborn Hearing Screening

MAICO MB 11
Baby Screener

So easy to use
To prepare the baby, put some electrode gel on a finger and rub the respective points on the head. Apply a drop of electrode gel on each of the three electrodes. Place the MB 11 on the head, cover the ear with the earphone and place the electrodes on the respective points.

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• Automatic ABR
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The MB 11 is portable and needs only a USB connection to run. An external power supply is not necessary.

Why Screen with Automatic ABR?
Screening with auditory brainstem response is a direct test of the entire auditory pathway up to the brainstem. It also detects auditory neuropathy and other neural defects which cannot be found with OAE measurements. With the MB 11 you get automatic ABR at the speed and cost of OAE measurement and with very high sensitivity and specificity.
Aerogen nebulizers deliver an incredible four times more medication than traditional jet nebulizers, offering you unsurpassed efficiency and allowing you to give your patients the very best care available. They work independently to the ventilator settings meaning there’s no added flow, no nuisance alarms, no loss of PEEP when opened for refill and no drug wastage. Aerogen truly sets a new standard.

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