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They came to you for care...and left knowing that you do.
Editorial

Blast From The Past

What haven’t we said about neonatal care? Instead, here’s a report on neonatal care from 1848, by R. Annan, published in Medical Times 18:109. This article has been slightly edited, and is from Neonatology on the Web, a terrific site for neonatal caregivers and the parents of preemies. I would especially draw your attention to its fine collection of historical articles, photographs and monographs. Copyright © 1998 Neonatology on the Web.

Case of a Child Born Betwixt the End of the Sixth and Middle of the Seventh Month and Brought Up, by R. Annan.

On the 5th of April 1848, at 26 weeks of gestation, the pains of labor came on rather unexpectedly, and in less than two hours [Mrs R, age 38] gave birth to a female child, which I found very carefully wrapped up and placed so as to receive the gentle warmth of a fire. Unloosening the cloths to enable me properly to tie the cord, which had been hastily cut through and tied about six inches from the navel, I found a tiny infant, the proportions of which I did not think it proper then to take time to ascertain. As it was not expected to survive long it was placed on a cushion in an easy-chair, so as to be sheltered from draughts of air, and at the same time so as to receive benefit from the fire, being previously wrapped up in folds of cotton wool and covered over with flannel. An earthenware bottle, filled with warm water, which has been pretty constantly continued, was placed behind the cushion. To attempt otherwise to dress the infant was never once thought of. This was about 10 AM. As the infant showed more signs of vitality, the lips and mouth were gently moistened with a mixture of one part of cream, three parts of warm water, and sweetened with sugar. At first it was not observed to swallow, but in the evening, when I returned, there could be little doubt that this had been the case from the minute quantities of the mixture, given from time to time, not having been rejected. On the following day, to this mixture from three to four drops of sherry wine were added, and continued to be used as yesterday. On the third day the deglutition was very perceptible. Of this advantage was taken, and under the eye of a most careful female relative from three to four drops of sherry wine were given every six hours, in as much of the mixture as the infant was found able to swallow.

On the seventh day the child was weighed and found, including a small flannel roller, to be twenty-four ounces. The roller was under one ounce in weight. At this period the length of the child was not taken, but was supposed to be from twelve to thirteen inches. As the feelings of the mother were most acute, and as, indeed she was considered to be in a dying state, and as it was not expected that the infant could suck, an occasional wet nurse was not got till the ninth day; the other nourishment being supplemented nearly as above. At first the nurse merely milked a proportion into the mouth, but in less than eight days it was found that the child could draw a little, which gradually improved. Occasionally a small portion of magnesiausta or castor oil was given, so as to ensure regularity in the bowels. About the end of the third week very fine oatmeal gruel, sweetened with sugar, was alternated with the cream and water, the quantity of wine being gradually increased; and latterly the quantity given during twenty-four hours has been from one to one and a half teaspoonful.

When six weeks and one day old, the weight was accurately ascertained to be thirty-nine ounces; the length, as nearly as a tape applied to the child would show, showed sixteen and a half inches; and on the 30th of May the weight was forty-three ounces, having gained four ounces since last weighing. At the last period the circumference, by the forehead and occiput, was barely eleven and a half inches.

During the last four weeks the child has been regularly bathed in water, at first tepid, but latterly of the temperature of from 65° to 70° of Fahrenheit; and occasionally, according to the testimony of the very careful female relative, who has hitherto so creditably and successfully super-intended the nursing, sometimes considerably

Continued on page 48…
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- Single-dose success in 73% of treated infants\(^2\)
- Facilitates transition from mechanical ventilation\(^7\)\(^10\)

Clinical studies have not established that fewer doses or lower volume result in superior safety or efficacy based on clinically relevant end points. Physiological end points (eg, faster reduction in FiO\(_2\)) have not been proven to impact key clinical outcomes such as mortality due to RDS.

**Indication**

CUROSURF (poractant alfa) Intratracheal Suspension is indicated for the treatment (rescue) of Respiratory Distress Syndrome (RDS) in premature infants. CUROSURF reduces mortality and pneumothoraces associated with RDS.

**Important Safety Information**

CUROSURF is intended for intratracheal use only. THE ADMINISTRATION OF EXOGENOUS SURFACTANTS, INCLUDING CUROSURF, CAN RAPIDLY AFFECT OXYGENATION AND LUNG COMPLIANCE. Therefore, infants receiving CUROSURF should receive frequent clinical and laboratory assessments so that oxygen and ventilatory support can be modified in response to respiratory changes. CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of preterm infants. TRANSIENT ADVERSE EFFECTS SEEN WITH THE ADMINISTRATION OF CUROSURF INCLUDE BRADYCARDIA, HYPOTENSION, ENDOTRACHEAL TUBE BLOCKAGE, AND OXYGEN DESATURATION. These events require stopping CUROSURF administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring.

**Please see brief summary of prescribing information on reverse.**

**References:**
1. CUROSURF® (poractant alfa) Intratracheal Suspension prescribing information, Cornerstone Therapeutics Inc, April 2010.

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Brief Summary of Prescribing Information

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATION AND USAGE
CUROSURF is indicated for the treatment (rescue) of Respiratory Distress Syndrome (RDS) in premature infants. CUROSURF reduces mortality and pneumothoraces associated with RDS.

WARNINGS
CUROSURF is intended for intratracheal use only.

The administration of exogenous surfactants, including CUROSURF, can rapidly affect oxygenation and lung compliance. Therefore, infants receiving CUROSURF should receive frequent clinical and laboratory assessments so that oxygen and ventilatory support can be modified to respond to respiratory changes. CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of pre-term infants.

Transient adverse effects seen with the administration of CUROSURF include bradycardia, hypotension, endotracheal tube blockage, and oxygen desaturation. Pulmonary Hemorrhage is a known complication of premature birth and very low birth-weight and has been reported both in clinical trials with CUROSURF and in post-marketing adverse event reports in infants who had received Curosurf. The rates of common complications of prematurity observed in Study 1 are shown below.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Curosurf 2.5 mL (200 mg/kg)</th>
<th>CONTROL* n=66</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acquired Pneumonia</strong></td>
<td>17%</td>
<td>21%</td>
</tr>
<tr>
<td><strong>Acquired Septicemia</strong></td>
<td>14%</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Bronchopulmonary Dysplasia</strong></td>
<td>18%</td>
<td>22%</td>
</tr>
<tr>
<td><strong>Intracranial hemorrhage</strong></td>
<td>51%</td>
<td>64%</td>
</tr>
<tr>
<td><strong>Patent Ductus Arteriosus</strong></td>
<td>60%</td>
<td>48%</td>
</tr>
<tr>
<td><strong>Pneumothorax</strong></td>
<td>21%</td>
<td>36%</td>
</tr>
<tr>
<td><strong>Pulmonary Interstitial Emphysema</strong></td>
<td>21%</td>
<td>38%</td>
</tr>
</tbody>
</table>

*Control patients were disconnected from the ventilator and manually ventilated for 2 minutes. No surfactant was instilled.

Immunological studies have not demonstrated differences in levels of surfactant-anti-surfactant immune complexes and anti-CUROSURF antibodies between patients treated with CUROSURF and patients who received control treatment.

FOLLOW-UP EVALUATIONS
Seventy-six infants (45 treated with CUROSURF) were evaluated at 1 year of age and 73 infants (44 treated with CUROSURF) at 2 years of age. Data from follow-up evaluations for weight and length, persistent respiratory symptoms, incidence of cerebral palsy, visual impairment, or auditory impairment was similar between treatment groups.

OVERDOSAGE
There have been no reports of overdosage following the administration of CUROSURF. In the event of accidental overdosage, and only if there are clear clinical effects on the infant's respiration, ventilation, or oxygenation, as much of the suspension as possible should be aspirated and the infant should be managed with supportive treatment, with particular attention to fluid and electrolyte balance.

How Supplied
CUROSURF (poractant alfa) Intratracheal Suspension (NDC Numbers: 10122-510-01 [1.5 mL], 10122-510-03 [3 mL]) is available in sterile, ready-to-use rubber-stoppered clear glass vials containing 1.5 mL [120 mg surfactant (extract)] or 3 mL [240 mg surfactant (extract)] of suspension. One vial per carton.

Store CUROSURF Intratracheal Suspension in a refrigerator at +2 to +8°C (36-46°F). Unopened vials of CUROSURF may be warmed to room temperature for up to 24 hours prior to use.

CUROSURF should not be warmed to room temperature and returned to the refrigerator more than once. PROTECT FROM LIGHT. Do not shake. Vials are for single use only. After opening the vial discard the unused portion of the drug.

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DON’T INTERRUPT

Nurses who are interrupted while administering medication appear to have an increased risk of making medication errors, according to researchers at the University of Sydney. As a result, medication errors occur as often as once per patient per day in some settings, and approximately one-third of harmful medication errors are thought to occur during medication administration. Researchers studied nurses preparing and administering medications in six wards of two major teaching hospitals. Interruptions were noted and two types of errors were tracked: procedural failures, including failure to read labels, check patient identification or record administration on medication chart; and clinical errors, including wrong drug, dose, formulation or strength. Ninety-eight nurses were observed while preparing and administering 4,271 medications to 720 patients over 505 hours from September 2006 through March 2008. Only 19.8% of these administrations were free of both kinds of errors. At least one procedural failure occurred in 74.4% of administrations and at least one clinical failure in 25%. Interruptions occurred during 53.1% of administrations. Each interruption was associated with a 12.1% increase in procedural failures and a 12.7% increase in clinical errors. When nurses were not interrupted, procedural failure rates were 69.6% and clinical error rates were 25.3%, compared with procedural failure rates of 84.6% and clinical error rates of 38.9% if they were interrupted three times. Errors became more severe as the number of interruptions increased. Without interruption, the estimated risk of major error was 2.3% with four interruptions this risk doubled to 4.7% percent. The researchers suggested that nurses might wear vests with signs that said “Do Not Interrupt.”

PARTNERSHIP

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) announced a partnership with University of Virginia Health System. The UVA Health System will implement AWHONN’s EDGE Benchmarking Database, a new technology that extracts data directly from electronic health records. These data will be used by UVA nurses to make staffing, clinical, and quality decisions specific to women and infant’s health. The system allows nurses to compare their unit to that of other institutions, and the database has the ability to track birth patterns. The information helps nurse administrators make staffing decisions and deploy resources wisely. For example, users can see the peak times for births, inductions and c-sections, and staff accordingly.

AT RISK

The risk of autism and/or special educational needs were 1.16 times greater for babies born at 37 to 39 weeks of gestation, compared to those born at the full 40 weeks, according to researchers at the University of Glasgow, who analyzed the birth history of 400,000 schoolchildren. Babies born at 37-39 weeks of gestation were 1.16 times as likely to have a SEN as babies born at 40 weeks.

NO HELP

A lack of skilled attendants at birth accounts for two million preventable maternal deaths, stillbirths and newborn deaths each year, according to the newly released Countdown to 2015 Decade Report (2000-2010). Nearly 50% of women in the 68 countries tracked in the Countdown report, mostly in Sub-Saharan Africa and South Asia, still give birth without the aid of a trained midwife, nurse, doctor, or other skilled birth attendant. Only 10 of the 68 Countdown countries have increased the rate of skilled care at childbirth by at least 10% since 1990. Eleven countries made no progress. The global shortage of midwives is especially severe: an estimated 700,000 new midwives and other trained providers are needed in order to provide skilled childbirth care to all women who need it. On the plus side, a skilled provider attends more than 75% of births in Azerbaijan, Tajikistan, Iraq, Egypt and Indonesia. Almost 100% of births are attended in Turkmenistan and China. Angola, Bhutan, Laos, Nepal, Peru, Burkina Faso, Pakistan, and Rwanda have also shown gains. Among the countries making negative progress are Bolivia, Cote d’Ivoire, Liberia, Malawi, Nigeria, Somalia, Swaziland, and Zimbabwe.

INDUCED

Between 1992 and 2003, the rate of labor inductions in the US nearly doubled, causing earlier births, according to a study at McGill University. Researchers examined US government vital
statistics, finding that labor inductions increased from 14% of full-term births in 1992 to 27% in 2003. During the same period, the proportion of births occurring at the 37th or 38th week of pregnancy increased from 19% to 30%. About 42% of births occurred before week 40 in 1992, compared with more than 60% of full-term births in 2003. The above info is copyright 2010 National Partnership for Women & Families. All rights reserved.

GOOD NEWS
The rate of premature births in the US fell to 12.3% in 2008, following a decrease in 2007 and marking the first two-year decrease in nearly three decades, according to the National Center for Health Statistics. The preterm birth rate was 12.7% in 2007 and 12.8% in 2006. The late preterm birth rate, for infants born at 34 to 36 weeks gestation, declined from 9.1% in 2006 to 8.8% in 2008. The rate of infants born earlier than 34 weeks also fell slightly, from 3.7% in 2006 to 3.6% in 2008. The report also found that the rate of preterm infants delivered via cesarean section dropped from 17.8% in 2006 to 17.1% in 2008. Preterm birth rates dropped in all states except Hawaii, and women younger than age 40 experienced decreases in preterm births. The preterm birth rate among non-Hispanic black infants was 17.5%, compared with 12.1% among Hispanic infants and 11.1% among white infants. Information copyright 2010 National Partnership for Women & Families. All rights reserved.

BLOCKED
Dietary supplement CDP-choline, under study for stroke and traumatic brain injury, may block skull and brain damage that can result from alcohol consumption early in pregnancy, according to researchers at the Medical College of Georgia. Alcohol consumption in early pregnancy increases levels of the lipid ceramide and results in neural crest damage. Researchers said there's a window of about four weeks after conception when neural crest cells emerge for a few days before morphing into other cell types that help form numerous organs. This is often before a woman knows she is pregnant. Researchers found that 25% of mouse embryos exposed to alcohol during the formation of the neural crest had defects in the fibrous joints that connect the skull. If the crest is damaged, the meninges doesn't develop properly and tissue like bone and brain that are regulated by the meninges don't develop properly either. When the researchers added ceramide-neutralizing CDP-choline to the mouse cells, cell death and ceramide levels were reduced. CDP-choline results in the production of less ceramide, preventing damage, providing the drinking stops.

MALE SHOCK
The general stress caused by psychological shock from the 9/11 terrorist attacks may have led to an increased number of male children being miscarried in the US, according to researchers at UC Berkeley and Irvine. The fetal death rate for boys spiked in September 2001, and significantly fewer boys than expected were born in December of that year. According to the researchers, the theory of “communal bereavement” holds that societies may react adversely to unsettling national events. Another study found that women in California miscarried more male babies in the year after 9/11 than they did in other years from 1995 to 2002. Researchers said that an evolutionary adaptation is likely to blame for the increase, in that male fetuses are more sensitive to female stress hormones. When a pregnant woman experiences some sort of crisis her male baby is more vulnerable to be miscarried. Researchers conjectured that female fetuses are harder than males because women have adapted to

When seconds matter most.
Nicolet neurological equipment, supplies, and solutions are now an integral part of CareFusion.
The Nicolet Monitor is used for continuous monitoring of acutely ill patients at risk for brain damage. Minutes and even seconds can mean the difference between life and death and the quality of life after recovery.
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produce the alpha male. In times of prosperity and security, male fetuses are more likely to be brought to term, because there's a greater chance that they'll be healthy and robust. During periods of scarcity or instability, however, male miscarriages are much more common: A woman's body faces an evolutionary decision of whether to carry her male baby to term, or abort the fetus. In other words, if you're pregnant in a time of low resources, there's less impetus for your body to bear that child. Researchers also noted that the phenomenon has been observed during other instances of national stress, like economic recessions or natural disasters. Reported in Medical News Today and by AOL.

MARKED FOR LIFE
A study in mice at Yale University reveals that prenatal exposure to endocrine-disrupting chemicals like BPA and diethylstilbestrol (DES) may program a fetus for life and as such, adult women who were exposed prenatally to BPA or DES could be at increased risk of breast cancer. Endocrine-disrupting chemicals in the environment interfere with hormone biosynthesis and result in adverse developmental, reproductive, neurological and immune effects in both humans and wildlife. These chemicals are designed, produced and marketed largely for specific industrial purposes. Both have a profound effect on gene expression in the mammary gland throughout life. Researchers treated pregnant mice with BPA or DES and then looked at the offspring as adults. When the offspring reached adulthood, their mammary glands still produced higher levels of EZH2, a protein that plays a role in the regulation of all genes. Higher EZH2 levels are associated with an increased risk of breast cancer in humans. Information copyright Medical News Today.

SAD DADS
Ten percent of dads experience prenatal or postpartum depression, with rates being highest in the 3 to 6 month postpartum period, according to researchers at Eastern Virginia Medical School. Researchers conducted a meta-analysis to determine estimates and variability in rates of paternal prenatal and postpartum depression and its association with maternal depression. The authors included studies that documented depression in fathers between the first trimester and the first postpartum year, and identified 43 studies involving 28,044 participants for inclusion in the analysis. The overall estimate of paternal depression was 10.4% percent, compared to 4.8% in the non-dad population. The 3 to 6 month postpartum period showed the highest rate (25.6%) and the first 3 postpartum months showed the lowest (7.7%). Significantly higher rates were recorded in the US as opposed to internationally. There was a moderate correlation between depression in fathers and mothers.

STOP A MINUTE
The timing of umbilical cord clamping at birth should be delayed just a few minutes longer, suggest researchers at the University of South Florida, because delaying clamping the umbilical cord for a slightly longer period of time allows more umbilical cord blood volume to transfer from mother to infant and, with that critical period extended, many good physiological gifts are transferred through nature’s first stem cell transplant. Several clinical studies have shown that delaying clamping the umbilical cord not only allows more blood to be transferred. Once the blood equilibrates, the cord’s pulse ceases and blood flow from mother to newborn stops. In recent Western medical practice, early clamping, from 30 seconds to one minute after birth, remains the most common practice among obstetricians and midwives, perhaps because the benefits of delaying clamping have not been clear. Throughout human history and in cultures and areas where delivering mothers squat to deliver, gravity helps speed the stem cell transfer. Today, the cord may be clamped early for a number of reasons, including the medical resuscitation and stabilizing of infants or the notion that delaying clamping might lead to adverse effects or, more recently, to quickly facilitate umbilical cord banking. Several randomized, controlled trials, systematic reviews and meta-analyses have compared the effects of late versus early cord clamping. In preterm infants, delaying clamping the cord for at least 30 seconds reduced incidences of intraventricular hemorrhage, late on-set sepsis, anemia, and decreased the need for blood transfusions. Another potential benefit of delayed cord clamping is to ensure that the baby can receive the complete retinue of clotting factors. While there is disagreement about early vs later clamping, the researchers said that many common disorders in newborns related to the immaturity of organ systems may receive benefits from delayed clamping, including respiratory distress, anemia, sepsis, intraventricular hemorrhage and periventricular leukomalacia. They also speculate that other health problems, such as chronic lung disease, prematurity apneas and retinopathy of prematurity, may also be affected by a delay in cord blood clamping. The researchers said that delaying cord clamping should appropriately be delayed for preterm babies and babies born where there is no effort to bank umbilical cords, and for babies born where there is limited access to health care and where nutrition may be poor.

JOINT EFFORT
The Children’s Hospital and the University of Colorado Hospital (UCH) have finalized an agreement to jointly establish a center for advanced maternal fetal medicine offering state-of-the-art care for high-risk pregnant women and their babies. The new center will focus on babies needing highly-specialized surgical care within 72 hours of birth, and both mother and baby will be cared for at The Children’s Hospital. This center will offer personalized support services to families that are unique to this region, including a Perinatal Mental Health Program to support mothers with post partum depression and a Fetal Concerns Program to provide support and education to families who have learned their unborn baby has a medical condition. Children's is regularly named as one of the top children’s hospitals in the nation by U.S. News & World Report, which recently named the Children's neonatal department as one of the top ten in the nation.

NEONATAL ISSUES
The March 2010 issue of Clinics in Perinatology, published by Elsevier, provides neonatologists and maternal-fetal-medicine specialists with the tools and concepts necessary to understand Quality Improvement methodology and to initiate QI projects within their own practices and NICUs. The issue includes articles on topics such as: “Crossing the Quality Chasm” in neonatal and perinatal care, QI methodologies and measurement, human factors related to QI, using evidence-based medicine, and the role of data collection, as well as info on quality-assurance procedures, pay for performance, and collaboration between obstetricians and neonatologists. See Volume 37, Issue 1, Pages 1-10 (March 2010).

HOME OR HOSP?
A study at Maine Medical Center, Portland reported that home birth is associated with a tripling of the neonatal mortality rate
compared to planned hospital deliveries, and results in more deaths due to respiratory distress and failed resuscitation. The message is, however, mixed, and needs to be considered in light of the very few (.5%) births achieved this way. According to the researchers, low-risk women choosing home birth who have given birth before are mostly successful and give birth with less morbidity and medical intervention than those having a hospital birth. But these benefits are associated with a doubling of the neonatal mortality rate and a near tripling for infants with congenital defects. Other studies have expressed results that home birthed babies had significantly more 5-minute Apgar scores <7 as compared to low-risk term hospital births, with the inference that lack of neonatal resuscitation equipment during home births contributed to that method's mortality rate. Researchers investigated data on more than 340,000 home births and 200,000 hospital deliveries. Perinatal mortality rates for both types of birth were about the same. Home birth moms needed fewer medical interventions including epidurals and FHR monitoring, and gave birth to fewer preemies and LBW babies. Information for the above is from Elsevier, published in Medical News Today, written by Christian Nordqvist, copyright Medical News Today.

SIMPLE TEST
Researchers at Maastricht University Med Centre in The Netherlands have come up with a simple molecular genetic probe test on DNA that could reveal fetal chromosomal abnormalities, and the test has identified Duchenne's muscular dystrophy and hemophilia. The technique, called Multiplex Ligation-dependent Probe Amplification, detects fetal DNA in the blood of women who have been pregnant for six to eight weeks. The MLPA test is part of an already used kit that's cheap and fast, with results in 2 to 3 days. Previously, the test has been used only on samples taken during invasive procedures. MLPA test results obtained in 2009 were compared with the results of amniocentesis, chorionic villus sampling and pregnancy outcome. All but one sample correlated with the non-invasive MLPA test results.

SEMENSHIP
Pregnant drinkers’ sons may wind up with less semen, according to researchers at Aarhus University Hospital, Denmark. Researchers measured the sperm concentration of 20-year old guys whose moms had about 5 or more drinks while pregnant and found that their sperm count was a third lower than non-drinking-mom guys. Researchers cautioned that the observational study, as such, couldn’t explicitly establish that alcohol was the cause of the lower sperm concentrations. Researchers studied 347 sons of 11,980 women. Their sons were studied at between age 18 and 21. Sons of mothers drinking 4.5 or more alcoholic drinks a week had average sperm concentrations of 25 million/ml, while the sons who were least exposed to alcohol had sperm concentrations of 40 million/ml. The sons most exposed to alcohol had the lowest sperm counts. Paternal alcohol consumptions had no effect on subsequent sperm count.

HOSPITAL PERFORMANCE
Complication rates for vaginal and C-section deliveries vary between best and worst-performing hospitals, according to a study by HealthGrades, a healthcare rating company. The best hospitals had 51% fewer maternal complications for vaginal births and 74% fewer for c-sections. The top hospitals had a 57.1% less neonatal mortality than poor-performing hospitals, and a 35.2% lower mortality than average-performing hospitals. Top hospitals had the highest episiotomy rates and vacuum-assisted delivery rates and the lowest forceps-assisted delivery rates. The best hospitals handled more deliveries, more than 7,000 over three years, vs 1,700 at the worst-rated hospitals. Fourteen million hospital records from 19 states were examined.

ART AND FAT
Being overweight leads to a greater risk of miscarriage for patients undergoing assisted reproductive technology, according to researchers at Guy’s and St Thomas Hospital. Increased BMI was associated with a higher miscarriage rate after IVF or ICSI treatment. Researchers analyzed all pregnancies from embryo transfer at their facility for four years. The miscarriage rate was significantly lower in women with normal weight (22%) compared to women who were overweight (39%). After adjusting for other variables, researchers demonstrated that being overweight or obese more than doubled the risk of miscarriage. The researchers said their study was more definitive than previous ones because it was limited to single-embryo transfers.

DRUGS AND DEFECTS
A study at the University of Copenhagen showed that use of psychotropic drugs during pregnancy increases the probability of birth defects. Over a ten-year period, psychotropic medications were associated with 429 adverse drug reactions in Danish children under the age of 17. Researchers concluded that more than half of the 429 cases were serious and several involved birth defects, such as birth deformities and severe withdrawal syndromes. They found that 42% of adverse reactions were reported for psychostimulants such as Ritalin, 31% for antidepressants, like Prozac, and 24% for antipsychotics like Haldol. The researchers concluded: a range of serious side effects such as birth deformities, low birth weight, premature birth, and development of neonatal withdrawal syndrome were reported in children under two years of age, most likely because of the mother’s intake of psychotropic medication during pregnancy.

NANN PREVIEW
The companies below invite you to visit them at the NANN convention. Information was provided by the companies.

B&B Medical Technologies
Booth 616

What Products do you plan to exhibit? B&B Medical Technologies will be showcasing our new Babi. Plus product line, which includes the Bubble PAP Valve 0-10 cm H2O for noninvasive ventilatory support of neonates and premature infants, Silicone Infant Nasal CPAP Cannula (prongs) for delivery of comfortable nCPAP, and a single or dual pole clamp for both the Bubble PAP Valve and humidifier system. For post CPAP babies, B&B Medical Technologies will introduce the new Babi.Plus Pacifier Adaptor for nebulized medication delivery via a baby’s own personal pacifier. In addition, B&B will present the new preemie-sized Sil.Flex Stoma Pad for advanced tracheostomy stoma care for the very smallest infants. B&B Medical Technologies is the first and only company to offer an FDA-cleared, professional Bubble CPAP system specifically designed to deliver precise CPAP pressure in the premature infant population. The Babi.Plus Bubble Pap Valve and Infant Nasal CPAP Cannula eliminates the need for hospital personnel

Nasal CPAP Cannula eliminates the need for hospital personnel
to invest time and money manufacturing and maintaining the “homemade” bubble devices previously used for nasal CPAP application.

**What educational materials will be available at the convention?**

B&B Medical Technologies will have complete product brochures and clinical application guides to assist the clinician in the introduction and education of the new Babi.Plus product line.

**What in-booth promotions will you be offering?**

B&B Medical Technologies’ “signature” giveaway, See’s Lollipops, will be available at our booth. Please stop by to see how the New Babi.Plus product line will provide benefits to your small patients by making your life easier in the clinical setting, and enjoy a lollipop from B&B Medical Technologies.

**Bunnell Incorporated**

Booth 116

**What products do you plan to exhibit?**

Bunnell Incorporated is celebrating 25 years in the ventilator industry. The Life Pulse High-Frequency Jet ventilator has passed the test of time. Its therapeutic flexibility makes it an indispensable tool in many NICUs. Jet pulse technology, passive exhalation, and an adjustable I:E ratio make this high-frequency uniquely effective. The most recent improvement has lowered the sound output from 56 to 41 dB.

**What educational materials will be available at the convention?**

Bunnell has developed a three booklet pocket reference set that explains what high-frequency ventilation is, why the Life Pulse is uniquely effective, and how the Life Pulse is used to care for patients. The Life Pulse HFV Training DVD will also be available at the NANN convention. The DVD contains a complete in-service video, a patient management video, an alarms and troubleshooting video and more. It contains everything you need to understand how the Life Pulse works and how to use it. The DVD is organized, for your convenience, into chapters so you can focus in on the information that is important to you.

**Why should our readers stop by your booth?**

The number one reason NICU nurses should stop by the Bunnell booth is to hear how quiet HFV can be, just 41 dB. Noise in the NICU has become an important topic of research and debate. Bunnell is committed to continuous improvement and our new “WhisperJet” proves it. Stop by Booth 116; hearing is believing. Whether you currently use HFV or not our clinical specialists can answer all your HFV questions. Stop by and give us a try.

**CORPAK MedSystems**

Booth 609

**What products do you plan to exhibit?**

CORPAK MedSystems, based in Wheeling, IL, is a leading developer, manufacturer and marketer of innovative medical devices focused on the enteral feeding and bedside location technology markets. The company has established the leading market position in premium branded, adult, long-term nasogastric (“NG”) feeding tubes and offers a broad portfolio of other high quality, branded enteral products, including gastrostomy feeding tubes, gastric relief devices and enteral feeding safety devices. CORPAK MedSystems proudly presents the CORFLO Anti-IV Enteral Feeding System, the FARRELL Valve with CORFLO Anti-IV Connectors as well as the NAVIGATØR BioNavigation System. These products offer safer enteral and vascular access. The CORFLO Anti-IV Enteral Feeding System is compliant to the Joint Commission recommendations on enteral feeding (Issue 36, April 3, 2006). It has been engineered to be compatible only with oral-tip syringes and therefore, prevents the inadvertent feeding into intravenous lines. The FARRELL Valve with CORFLO Anti-IV Connectors is the only closed system that offers passive gastric venting. Patients who have suffered from pain, feeding intolerance or bloating due to gastric distension can use the FARRELL Valve which prevents loss of calories and exposure to caregivers while offering the benefits of an Anti-IV (oral only) system. The NAVIGATØR BioNavigation System confirms PICC/UVC catheter tip location during placement. It uses electromagnetic waves and a sensor stylet to assist in central catheter tip location during the initial sterile procedure; thereby minimizing additional x-rays, time and cost for the PICC/UVC placement procedure.

**CUROSURF**

Booth 405

**What products do you plan to exhibit?**

CUROSURF (poractant alfa) Intratracheal Suspension.

**What educational materials will be available at the convention?**

Get the latest information in RDS and surfactant-reviews on RDS and reviews on available surfactants.

**What in-booth promotions will you be offering?**

A $5 donation will be provided to the March of Dimes for each registered visitor.

**Why should our readers stop by your booth?**

We’re eager to hear your experience with CUROSURF. Come in, discuss and register—Cornerstone will donate $5 to the March of Dimes NICU Family Support Program.

**Dräger**

Booth 305

**What products do you plan to exhibit?**

Dräger will demonstrate its newest product in the field of neonatal ventilation. Visitors will get a first-hand look at the Babylog VN500 neonatal ventilator, a technologically advanced device with a comprehensive array of therapy options designed to support infant ventilation. Conventional and non-invasive ventilation gives the caregiver the entire spectrum of modern neonatal ventilation therapy in a single device. Designed with the clinician in mind, its versatility and range of operation make it well suited for neonatal care and pediatric intensive care units. We will also display a diverse product portfolio of advanced neonatal care and thermoregulation solutions in the areas of warming therapy, jaundice management, and transport. These therapeutic solutions, combined with patient monitoring and ventilation for newborns, enable a comprehensive, connected approach from delivery to discharge.
What educational materials will be available at the convention?
Dräger will offer a selection of new educational materials to include an interactive website for neonatal doctors, nurses, and parents of premature babies; a continuing education supplement on the topic of thermoregulation; and a booklet on ventilation modes for Dräger ventilators. Launched in 2010, BabyFirst.com is an innovative single destination where neonatal doctors and nurses can exchange information and experiences online across a range of neonatal care specialties. With content populated by clinicians and renowned experts, the website also offers parents and families of premature babies a trusted resource to gain a better understanding of neonatal care. They learn what to expect in the Neonatal Intensive Care Unit (NICU) with insights into common terms, procedures, equipment, post-hospital care, and more. We will also release a *CE supplement on thermoregulation*. The supplement includes several important published papers that address the overall environment within the NICU. It also looks at principles and guidelines around resuscitation and interventions to prevent heat loss and cold stress. “Ventilation Modes in Intensive Care” is the latest educational booklet designed to improve the understanding of contemporary modes of mechanical ventilation. The revised nomenclature is an effort in standardizing common understandings of pressure, volume, and spontaneous ventilation modes.

Why should our readers stop by your booth?
We invite you to stop by the Dräger NANN 2010 booth to see how our therapeutic solutions work together for a new level of simplicity, connectivity, efficiency, and synergy. Ask to see a demonstration of our new dedicated infant ventilator, designed specifically for clinicians to provide maximal effectiveness at the bedside for the special needs of neonates and infants. We also encourage you to take a tour of our new interactive website focused exclusively on neonatal care and supported by Dräger and NICUniversity, a Web-based medical education center for clinical professionals.

Fisher & Paykel Healthcare
Booth 520
Fisher & Paykel Healthcare, Inc (F&P) understands and appreciates the critical role neonatal nurses undertake in infant care. This is the reason F&P is dedicated to improving patient care and outcomes. With over 20 years of worldwide use and acceptance involving millions of safe and effective resuscitations, the F&P NeoPuff Infant T-Piece Resuscitator has recently been updated to further enhance functionality and usability while providing optimal resuscitation and continuing to raise the standard of care for infant resuscitation.

What products do you plan to exhibit?
In addition to the launch of the newly enhanced NeoPuff Infant T-Piece Resuscitator, F&P is excited to announce that attendees at the NANN Conference will be the first to see the launch of our new family of resuscitation circuits. Among the many benefits of the new resuscitation circuits, is the ability for the clinician to provide suction and deliver surfactant during resuscitation. This is another reason to visit our booth.

An integral component of the NeoPuff Infant T-Resuscitator and family of circuits is the unique line of resuscitation masks, including the first ever micro-preemie mask for very low birth weight patients. The masks are specifically designed to conform comfortably to the infant’s face, facilitating a seal for optimum resuscitation. The masks come in five sizes ranging from micro-preemie to pediatric size.

F&P will also be exhibiting the first humidified infant resuscitation system using the MR850 respiratory humidifier. The NeoPuff Infant T-Piece Resuscitator facilitates the delivery of warm humidified gas to help protect the pulmonary epithelium and reduce heat and moisture loss especially during prolonged resuscitation. Conditioning cold, dry gas to body temperature and saturated with water vapor can help reduce the risk of an inflammatory response occurring in the infant’s airway.

What educational materials will be available at the conference?
We look forward to discussing and demonstrating the F&P Infant Respiratory Care Continuum and sharing CNE opportunities with you.

Why should our readers stop by your booth?
Attendees are invited to experience all of the above-mentioned demonstrations and hands-on stations, including the opportunity to test their resuscitation skills on our simulator. Please join us at the NANN Conference in Las Vegas at booth 520 for a complete review and demonstration of all Fisher & Paykel Healthcare products that include our newly enhanced NeoPuff Infant T-Piece Resuscitator and new family of circuits.

GE Healthcare Maternal-Infant Care
Booth 204
What products do you plan to exhibit?

Why should our readers stop by your booth?
GE Healthcare Maternal-Infant Care is dedicated to the clinical needs of the NICU and Labor & Delivery, and to the mothers and babies they serve. We are continuing to create leading technologies and innovations that support developmental care, seeking the best possible environment for patients and caregivers. We’re committed to helping hospitals deliver the special care these most fragile patients need and to improve outcomes and reduce stress for babies, families and clinicians. Visit our booth to see our latest innovations for the NICU and visit us online at gehospitalcare.com/perinatal. (See also “Taking Care” in this issue’s products section, page 26.)

HALO
Booth 125
What products do you plan to exhibit?
HALO SleepSack Swaddle wearable blankets for modeling Safe Sleep practices in the NICU.
What educational materials will be available at the convention?
Our mission at HALO is to keep babies sleeping safely. That’s why we’ve been educating parents on how to help reduce the risk of SIDS for over 15 years. We are providing Free SIDS risk reduction materials to help hospital professionals educate parents on safe sleep practices for babies.

What in-booth promotions will you be offering?
Through HALO’s Safer Way to Sleep Initiative, HALO can now help your institution implement an In-Hospital Safe-Sleep Modeling Program FREE for ONE FULL YEAR. Our Safe-Sleep Modeling Program has been shown to effectively influence how parent’s place their babies to sleep (supine) and create a safe sleep environment.

Why should our readers stop by your booth?
Attendees should be sure to stop at the HALO Innovations booth for ideas on how to educate parents through modeling of safe sleep practices to ensure a successful transition from NICU to home. At our booth we will provide product demonstrations of the HALO SleepSack Swaddle, free SIDS risk reduction materials and details on our special trial offer: free one year In-Hospital Safe-Sleep Modeling Program.

Maico Diagnostics
Booth 614

What products do you plan to exhibit?
MB11 Newborn Hearing Screener

What educational materials will be available at the convention?
Product brochure

Why should our readers stop by your booth?
To learn about a newborn hearing screening system that can save their organizations thousands of dollars a year in costly disposables.

Medela
Booth 411

Products
Medela’s system of innovative, evidence-based products, services and education helps you deliver more milk to your vulnerable patients every step of the way. Our system will help you improve outcomes, reduce costs, and improve patient satisfaction.

Visit our booth and learn more about the research showing that higher doses of human milk can help NICU professionals achieve better outcomes for their patients. Learn about the clear dose-response effect between the dose of human milk and a reduction in risk for several disabling morbidities such as necrotizing enterocolitis, late onset sepsis and enteral feed intolerance. Medela’s Symphony Preemie+ is the first pumping program clinically shown to produce more milk for NICU moms. Medela’s new Waterless Milk Warmer is the safer, easier way to warm human milk. The Waterless Milk Warmer eliminates risk associated with warming in water, consistently warms milk to temperatures of expressed human milk, and safely thaws human milk.

Show special
Warmer Summer Special: Deadline Extended Through NANN Convention: Purchase 10 Waterless Milk Warmers through September 21, 2010 and get a great deal on disposable inserts. For every 5 cases of disposable inserts purchased you’ll get 1 case free through December 31, 2011. If you purchase 20 Waterless Milk Warmers, in addition to the disposable insert special you’ll also get a free online education course for your staff, available through 2010, that provides detailed information on the dose response relationship of human milk and its impact on serious morbidities, a review of water contamination sources and its impact on sepsis and nosocomial infection and the effect of temperature on enteral feeding tolerance with very low birthweight babies.

NeoMed, Inc
Booth 410

What Products do you plan to exhibit?
NeoMed, Inc is proud to present a unique line of products specifically designed to enhance the safety and outcome of the neonatal patient. Our products include: Enteral Safety System (Extension Sets, Feeding Tubes, and Oral Dispensers), Urinary Drainage Kits/Catheters, Lumbar Puncture Products, Specialty Kits, NeoDrape, and the SafeBaby Breast Milk Tracking System. Our product line features the latest clinical innovations that meet or exceed enteral safety recommendations set forth by the Joint Commission and ASPEN (American Society of Parenteral and Enteral Nutrition).

What educational materials will be available at the convention?
NeoMed will provide clinical documentation from ASPEN, the Joint Commission, ISMP and various case studies that highlight the importance of neonatal patient safety and how our products eliminate or mitigate misconnections, mis-feeds, enteral contamination, and patient misidentifications. NeoMed will also have our full line of products and product information sheets available to all attendees at NANN.

What speakers will your company be featuring?
Ms Robin Bissinger, NNP is the creator and instructor at The Golden Hour Symposium. Ms Bissinger is an Associate Professor at the Medical University of South Carolina and directs the Neonatal Nurse Practitioner Program. During the presentation, Ms Bissinger will discuss the importance of The Golden Hour and how industry led products help the first hour of life be a success. With her expertise in neonatal care, a preview of the latest clinical practice and products will be a focal point.

NeoMed manufactures the NeoDrape which plays a vital role in maintaining thermo regulations of very low birth weight babies during delivery and invasive procedures.

What in-booth promotions will you be offering?
NeoMed will be providing a hotel room drop including a tote bag with our NeoDrape and an oral/enteral NeoMed syringe. These bags will also be available at our booth. All attendees will be eligible to register for a chance to win prizes such as Apple iPods and an iPad, plus much more.

Why should our readers stop by your booth?
NeoMed is committed to providing clinicians with the highest quality and most cost effective neonatal products on the market.
delivering patient safety, protection against misidentifications, misconnections, and improved clinical outcome of the patient. Please visit our website: neomedinc.com, for more details.

**ONY, Inc**

**Booth 618**

**Featured Products**

Infasurf (calfactant) Intratracheal Suspension: ONY Inc is the manufacture of Infasurf a newborn lung surfactant. Among the lung surfactants available in the USA, Infasurf, is the only lung surfactant derived from pure natural surfactant, not from a minced whole lung. This natural origin provides the composition for Infasurf contributing to its positive characteristics.

**Educational materials**

Infasurf representatives will have available for your review educational and scientific materials on:
- How lung surfactant compositions determine activities
- Clinical use of lung surfactant
- Clinical trial comparisons of lung surfactants.

**Staffing the Infasurf booth**

Infasurf representatives available at our booth have an extensive background as neonatal practitioners. These clinicians have an understanding of both the science of surfactant replacement therapy, as well as the clinical application of surfactant as it applies to today’s NICU patients. Infasurf’s representatives are available to discuss with you:
- What makes your surfactant work effectively?
- How soon should your surfactant be administered?
- Instillation procedures for delivery of surfactant.
- Complications associated with surfactant replacement therapy.
- Patient response to surfactant replacement therapy
- Any other surfactant related issues you may have.

**Paragon Data Systems**

**Booth 412**

**What products do you plan to exhibit?**

SafeBaby, 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 2-dimensional (2-D) bar coding technology driven by our SafeBaby proprietary software. Our system starts with a bar code label printer and mobile handheld 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. The SafeBaby system also has the ability to track volume of feeds, additives, fortifiers, donor milk, and is HL7 compatible with hospital EMR systems. SafeBaby will be exhibiting in the same booth/vendor space as NeoMed Inc.

**What educational materials will be available at the convention?**

SafeBaby system software live demo version; handheld computers, thermal printers, SafeBaby labels.

**Why should our readers stop by your booth?**

Readers should stop by our booth to learn about the benefits of breast milk tracking, positive patient identification using bar coding; patient safety in the NICU using a breast milk tracking system, benefits of bar code systems and inventorying breast milk; SafeBaby software in work flow efficiencies; SafeBaby and EMR charting, and SafeBaby’s newest display features using hospital monitors. In addition, there will be an opportunity for the attendee to review and use the software and handheld equipment in a live setting.

**Philips Children’s Medical Ventures**

**Booth 205**

Philips Children’s Medical Ventures (PChMV) is committed to improving the quality of care and developmental outcomes of hospitalized infants. In collaboration with leading clinical experts, we develop and offer a broad array of innovative products, process improvement programs and consulting services that support developmental care across the NICU and well-baby nursery. To learn more, visit us at NANN, booth 205.

**What products do you plan to exhibit?**

We will introduce a new line of specialty-use oral/enteral syringes designed to help reduce feeding errors and to help clinicians avoid potential tubing misconnections. For use in the neonatal and pediatric intensive care units, these syringes are available in seven sizes (1 ml, 3 ml, 5 ml, 10 ml, 20 ml, 30 ml and 60 ml) and include highly visible text on the barrel that reads “ORAL/ENTERAL ONLY.” An oral only tip distinguishes it from medication syringes and will not attach to a standard luer lock connector. Because standard 1 ml syringes are commonly used to administer medication in the hospital setting, PChMV’s 1 ml oral/enteral syringe is a highly noticeable orange color. A one-piece design eliminates tip separation during filling, and an airtight, brightly colored cap does not allow air or water in, or breast milk to leak out, during prep, storage and warming.

**What educational materials will be available at the convention?**

We will present a preview of our soon-to-be-released Late Preterm Infant education program as part of our continuing commitment to establish developmental care practices throughout neonatal units worldwide. During a pre-conference seminar, Sharyn Gibbins, NNP, PhD, a clinical consultant for PChMV, and our own Kay Johnson, will present a preview of the four-hour workshop on how to support the baby during admission to the NICU, care strategies that involve positioning and feeding, and techniques on how to transition home after the hospital stay. Participants will also learn about possible long-term medical complications, costs associated with caring for these special infants, and techniques for involving and supporting the family.

**Why should our readers stop by your booth?**

We will also provide an opportunity for you to experiment with developmentally supportive products such as Frederick T. Frog,
the SnuggleUp, and other positioning products from the Bendy Bumper and Prone Plus families. Or you can meet with one of our clinical education consultants to discuss how our one-day education workshops or comprehensive process improvement programs can help to provide a standardized approach to care delivery in your unit. Visit us at booth 205.

Salter Labs
Booth 531

What products do you plan to exhibit?
Salter Labs will be featuring a number of new and exciting respiratory care products at the NANN meeting that were developed and designed specifically for premature, neonate, infant and pediatric patients. Also at this year’s meeting, we will be showing our extensive line of premature, neonate, infant, and pediatric sized Salter-Style Cannulas—the “worldwide standard for clinical comfort and efficacy.” These small, lightweight cannulas are manufactured using unique designs, manufacturing processes and materials that ensure an anatomically correct fit that is very gentle to delicate skin. We will also be featuring Salter Labs’ • Innovative infant and newborn Tender Grip skin fixation systems that gently and safely hold tubes in place on baby’s tender skin; • The aptly named “Comfort Care pediatric and infant headband cannulas for your active or restless “little patients”; • Special aerosol or oxygen delivery solutions for pediatrics or infants; • The pediatric I-Guard aerosol delivery system that diminishes the possibility of aerosolized medication entering a patient’s eyes; • Infant Salter-Style end-tidal (ETCO₂) monitoring cannulas for O₂ delivery and simultaneous sampling; and • Sleep diagnostic cannulas and sensors that can be utilized on infant and pediatric patients.

What educational materials will be available at the convention?
We will be providing product demonstrations at our NANN Booth (531) and visitors will have access to the most recent clinical studies and educational materials regarding Salter Labs’ products.

What in-booth promotions will you be offering?
All visitors to the Salter Labs’ Booth (531) are eligible to enter an American Express Gift Card drawing.

Why should our readers stop by your booth?
• To learn about the wide range of Salter products designed specifically for your “little patients.” • Explore how Salter’s products can help you meet the various NANN guidelines for patient care and improve patient outcomes. • To be the first to see several new, innovative products such as new skin fixation offerings. • To obtain a unique and useful small gift (while supplies last) to use when you get home • And enter the drawing to win a $50 American Express Gift Card at Booth 531.

Teleflex Medical
Booth 221

What products do you plan to exhibit?
Concha Therm Neptune, Hudson RCI Infant Nasal CPAP line, and Comfort Flo high flow nasal cannula. Our mission at Teleflex Medical is to provide respiratory products that help you simply and safely address the complex needs of the intensive care infant. From the ConchaTherm Neptune Heated Humidifier to the Hudson RCI Infant Nasal CPAP line, these products offer effective solutions to the challenging clinical requirements of the NICU and PICU. These products will be featured at our booth, in addition to the Clinical Foundations Newsletter focused on neonates.

What educational materials will be available at the convention?
Clinical Foundations Newsletter focused on neonates.

Why should our readers stop by your booth?
We offer the latest technology for Infant Nasal CPAP, heated humidification, and high flow nasal cannula therapy for neonates.

PRODUCTS

CHECK PLEASE
Royal Philips Electronics announced that its BiliChek noninvasive bilirubin assessment tool has received a Gold award in appliance DESIGN magazine’s 23rd Annual Excellence in Design Awards Competition. An independent panel of three industrial design experts performed judging of the entries based on appearance, human factors, innovation and technical merits as well as the product’s ability to make technology more accessible to the user. Contact philips.com.

OPEN HOUSE
Philips Respironics recently held an open house in its Pennsylvania facility. Opened in 2009, the state-of-the-art facility is devoted to high volume production of sleep therapy systems. Events included guided plant tours, product demonstrations, a mock production line where children and adults alike could build a CPAP device, face painting and balloon art, X-Box Beatles Guitar Hero, giveaways and a picnic lunch. More than 60 employees volunteered their time and talents for the day. Attendees also participated in an auction which raised $570 for Operation Troop Appreciation. The non-profit works with military units to provide “wish list” items for deployed troops. Contact philips.com.

CLOSED LOOP
CareFusion announced the launch of its Closed Loop Controller of Inspired Oxygen system, or CLiO₂, the first automatic oxygen controller of its kind designed to keep the oxygen level in the blood within a safe range for newborns needing mechanical ventilation. This new software algorithm is an enhancement to the CareFusion AVEA ventilator. The CLiO₂ system noninvasively and continuously measures the oxygen level in a newborn’s blood using Masimo SET Measure-Through Motion and Low Perfusion pulse oximetry technology to provide accurate and reliable oxygen saturation (SpO₂) measurements, even under challenging clinical conditions. The CLiO₂ system processes blood oxygen saturation levels by a computer algorithm that then anticipates trends and modifies the amount of oxygen delivered. If necessary, adjustments can be made on a second to second basis, something not currently possible with manual control. The CLiO₂ system is currently available in most Western Europe and Asian countries through CareFusion and its authorized distributors, with future availability in the US and Canada. Contact carefusion.com.
FLOWING
The Infant Flow SiPAP System from CareFusion is clinically proven* to safely deliver noninvasive ventilatory support to thousands of infants worldwide. The Infant Flow SiPAP is the only dedicated nCPAP device to offer both nasal CPAP and Biphasic modes with apnea and low breath rate detection. The Infant Flow generator delivers stable pressure in harmony with the infant's respiratory efforts by using Coanda Effect and Fluidic Flip technology. This empowers clinicians with lung protective strategies to treat the smallest of patients. [*Gianluca L, et al, Nasal CPAP vs. Bi-level Nasal CPAP in Pretermers With RDS: a randomized control study. Arch Dis Child Fetal Neonatal Ed. Published on-line Nov 29, 2009.] Contact carefusion.com.

VITAMINS
Upsher-Smith Laboratories, Inc announced the availability of a new formulation of PreNexa Rx prenatal vitamins with changes to the amounts of folic acid and iron. PreNexa's newest formulation contains 1.25 mg of folic acid and 27 mg of iron. PreNexa also contains essential vitamins and minerals including calcium, vitamins B6, C, D3 and 300 mg of plant-based DHA in one single gel capsule taken once a day. The NDC number for the new formulation of PreNexa is 0245-0178-30. Key product features remain the same. Contact upsher-smith.com.

PREMIER PERFORMER
Hamilton Medical, Inc announced that it is a winner of the Supplier Performance Award, presented by the Premier healthcare alliance. Premier contracts with more than 800 suppliers and Hamilton Medical is one of 65 contracted suppliers to receive the Performance Award. Premier is a performance improvement alliance of more than 2,300 US hospitals and 67,000-plus other healthcare sites working together to achieve high quality, cost-effective care. Owned by not-for-profit hospitals, Premier maintains a comprehensive repository of clinical, financial and outcomes information and operates a leading healthcare purchasing network. For more information, contact hamilton-medical.com, (800) 426-6331.

UPSCALE
DETECTO's model 8450 digital baby scale with DLM digital length measuring features all-digital weighing and length measurement, ensuring speed and accuracy in your patient measurements. The scale base, length measuring device, and padded carrying handles of this lightweight unit are incorporated together, making it easy to transport from one patient room to another as a portable measuring device. Padded side rails and handle covers are slightly contoured ensuring the baby will be cradled comfortably. This versatile baby scale features battery or AC power, large easy-to-read 1 inch/25 mm high LCD display on the scale, lightweight durable construction, and MEMORY/HOLD feature which retains measurements for active babies. Detecto’s 8450DLM features digital length measuring in your choice of units: ft/in, in, or cm. Weight may be displayed in lb, oz, or kg. An optional black carrying case with handle protects the scale for easy transport. The DLM digital length measuring device is also sold separately and may be used stand-alone on an exam table for baby measurement. It runs on (2) AAA batteries which are included. Rubber feet ensure stable footing while measuring. The scale was recently featured on the TV show “How It’s Made” on the Science Channel. Contact detecto.com.

TELEFLEX
The Comfort Flo Humidification System is designed to comfortably deliver flow rates of 1-40 lpm of heated, humidified oxygen through a nasal cannula interface to a broad range of patients. A completely disposable delivery system and line of specialty cannula, the Comfort Flo Humidification System allows clinicians to maximize patient comfort, improve therapy compliance, and avoid more invasive and often more expensive therapies. The Comfort Flo Nasal Cannula is available in premature, infant, pediatric, and adult sizes… The quest for optimal humidification in the NICU/PICU is a balancing act. How do you deliver the right amount of humidity to maximize clinical outcomes without creating additional challenges? Introducing the ConchaTherm Neptune Heated Humidifier. Adjustable airway temperature and gradient control features allow you to customize therapy—maximizing humidity delivered while minimizing circuit condensation. The Neptune can be used across the continuum of care, eliminating the need to change equipment as treatment advances (HFV, IMV, CPAP, and Oxygen Therapy)... Infant Nasal CPAP has been proven to benefit premature infants of very low birth weight. The Hudson RCI Infant Nasal CPAP Prong System was specifically designed to minimize the problems associated with more invasive therapies. The soft, anatomically curved prongs enhance fit and minimize nasal septal necrosis. Additionally, the luer fitting on the expiratory connector allows proximal airway pressure monitoring. Available in six prong sizes to allow greater choice for appropriate sizing of each infant, the Hudson RCI Infant Nasal CPAP offering can help improve clinical outcomes for the critical care infant… The Rüsch Infant TruView EVO is an innovative optical view laryngoscope blade designed to provide indirect laryngoscopy with continuous oxygen insufflation more safely, clearly and easily. Indicated for use in both standard and difficult intubations, the Rüsch Infant TruView EVO illuminates and expands angular view of the larynx and adjacent structures, thereby facilitating endotracheal intubation. The Rüsch Infant TruView EVO uses an optical system within the viewtube which consists of prisms and lenses that extend vision beyond the distal end of the blade. It is designed to decrease laceration and bleeding of the pharyngeal-laryngeal mucosal tissue in addition to reducing the amount of force needed to successfully intubate a patient by greater than 30%. This innovative approach protects patients and minimizes risk of esophageal intubation… Sheridan Endotracheal Tubes, part of the Hudson RCI line of products, includes a wide range of clinical solutions for adult and pediatric use. The Sheridan Ped-Soft line of uncuffed endotracheal tubes is made out of a soft PVC formulation which enhances the tube's compliance to a child's anatomy and makes it an ideal choice for short or long term pediatric intubation. The specially designed distinct black tip incorporated on the Ped-Soft endotracheal tubes aide in visualization during intubation. Additional depth markings are also included to assist in placement during nasal intubation. Contact teleflex.com.

SINGULAR
GE Healthcare has unveiled a new online resource to help empower professionals in the development of Single Family Room (SFR) Neonatal Intensive Care Units. The website, singlefamilyroom.gehealthcare.com, created by GE Healthcare’s Maternal Infant Care division, is a compilation of vendor-neutral information, insights and experiences from US hospitals that have launched SFR NICUs. Subjects range from planning, budgeting and design through construction and workflow,
providing healthcare professionals with advice, successes and lessons learned in the development of SFR NICUs. Contact gehealthcare.com.

FERTILE
Circle + Bloom has announced the release of two new mind-body and relaxation programs for women's health and reproduction. Circle + Bloom's latest programs are designed for women to use while pregnant, as well as with its special program for In-Vitro Fertilization and Intrauterine Insemination. The IVF/IUI Program tracks to the specific regimen and timing of advanced fertility treatments, and includes 18 different sessions. The company has also released its program designed for use during pregnancy.

The Pregnancy Program allows women to reduce their levels of stress. Contact circlebloom.com.

TAKING CARE
New innovations to the Engström Carestation from GE Healthcare are tailored to the needs of neonatal patients in the ICU. The Neonatal Proximal Flow Sensor is now optional, so hospitals can select the ventilator configuration that best matches its protocols and preferences regarding flow sensor equipment at the patient's airway. A new Volume Guarantee Pressure Support (VG-PS) mode is now available with the Carestation. Designed for the specific needs of neonatal patients, the VG-PS mode continuously adjusts the level of support in response to the patient's changing needs. It provides precise volume regulation during spontaneous and mechanical ventilation, breath-to-breath adjustment of the inspiratory pressure delivered, synchrony of both the inspiratory and expiratory phases of a breath, and the ability to control the point at which mandatory mechanical ventilation is initiated.

The clinician can also use the Neonatal Proximal Flow Sensor to increase the accuracy of monitoring and delivery of each breath delivered. The "minimum rate setting" of the VG-PS mode provides safety and can also be set to stimulate a child who becomes apneic. In this case a breath would be delivered to stimulate spontaneous breathing. The point at which breaths are initiated is regulated by a combination of the minimum rate set by the clinician and the baby’s own spontaneous respiratory rate. In other words, mechanical ventilation begins only when needed, and continues only as long as it’s needed. In short, the VG-PS mode offers consistency in volume regardless of the type of breath delivered, and it provides synchrony of both the inspiratory and expiratory phases of a breath, and the ability to control the point at which mandatory mechanical ventilation is initiated.

SPOTLIGHT ON VENTILATION

TOP SCORER
Hamilton Medical, Inc has earned the top composite score for ventilator manufacturers from MDBuyline. Hamilton Medical has earned this rating for the past nine quarters. Hamilton not only rates the highest in the top composite score, it also holds the top score in every rating category, which includes system performance and reliability, installation/implementation, applications training, service response time and service repair quality. Robert Hamilton, President said, “We realize that the hospitals that choose to purchase our equipment are not just our customers but are our partners and we try to conduct our business as such.” Contact hamilton-medical.com.

TEST OF TIME
Bunnell Incorporated is celebrating 25 years in the ventilator industry. The Life Pulse High-Frequency Jet ventilator has passed the test of time. Its therapeutic flexibility makes it an indispensable tool in many NICUs and PICUs. Jet pulse technology, passive exhalation, and an adjustable I:E ratio make this high-frequency uniquely effective. The most recent improvement has lowered the sound output from 56 to 41 dB. Constant improvement—Continued success! For more information or to arrange a free trial contact Bunnell at (800) 800-4358, buml.com.

COMMITMENT
After over two decades of experiences and working with clinicians using the Babylog 8000 plus, Dräger continues its

ultrasound system. The latest acoustic technologies deliver a powerful system optimized with 2D, Doppler and 3D/4D imaging for the most demanding requirements in maternal-fetal medicine. Unique industry applications, such as Skeletal Rendering further enhance the clinical excellence of the system. This Siemens-proprietary 3D/4D rendering technique results in true volumetric imaging, with accurate spatial resolution for enhanced visualization of the fetal skeleton. Compact, portable, and easy to use, the Acuson X300T PE - Women's Imaging offers a complete ob/gyn imaging solution for the clinical routine. The system is scalable to meet a wide variety of clinical and economic needs. A highlight of both the ACUSON S2000 system - Women's Imaging and the ACUSON X300 system PE - Women's Imaging is syngo Auto OB measurements, an advanced clinical tool that automates routine biometry measurements of the fetus. Contact medical.siemens.com.
commitment to Respiratory Care with the newest technology for infant ventilation – the Babylog VN500. Designed to meet the specific needs of the patient and the neonatal care team, the VN500 offers a comprehensive and dedicated mechanical ventilation platform for the special care nursery as well as the pediatric intensive care areas. Call (800) 437-2437 or contact draeger.com.

**SOPHISTICATED YET EASY**
In today’s NICU and delivery rooms, intubation leads to a higher risk of airway trauma and infections. Stand-alone nasal CPAP machines with proprietary interfaces may mean higher costs… not better care. Sophisticated yet easy to use, the Inspiration LS Infant ventilator from eVent Medical is a fully featured, highly capable neonatal ventilator. Now available with NCPAP+ mode—built upon the exceptional performance of its original NCPAP mode—the ventilator allows clinicians to use approved nasal interfaces to provide customized, noninvasive treatment to their smallest patients. Contact (888) 454-VENT, event-medical.com.

**PERFORMANCE AND MORE**
MAQUET SERVO ventilators are known worldwide for performance, reliability, and adaptability. Neonatal to adult, the SERVO-i can be used for transport, Heliox administration, and conditionally in the MR environment. New for 2010, software enhancements for neonatal alarm management help reduce the incidence of unwanted alarms. Updates to non-invasive (NIV) functionality include improved leak compensation in addition to a new portfolio of NIV interfaces. The NAVA mode (Neurally Adjusted Ventilatory Assist), as of 2010, can be used in non-invasive ventilation (NIV NAVA) to provide assist levels capable of matching the patient’s neural demands regardless of leakage or user interface. For more information visit maquetusa.com, criticalcarenews.com, or call (888) 627-8383.

**EXECUTIVE PROFILE**

**Dräger**

Describe your neonatal/perinatal product(s) and their features.
Dräger offers a total neonatal care solution with a full range of products that provide a new level of connectivity, efficiency, and synergy. Beginning in the Labor and Delivery Room, Dräger’s open warmers provide an effective thermoregulation platform, along with the components needed for clinical resuscitation and stabilization. From a compact, mobile, and freestanding warmer to a fully integrated intensive care system, Dräger’s incubators and warmers are clinically proven thermoregulation devices that can support the most compromised infants with a full range of integrated accessories for the Neonatal Intensive Care Unit (NICU). For transport within the hospital or for external transport between hospitals, Dräger provides high-performance transport incubators with integrated neonatal ventilation capability. A range of resuscitation products meet the rigorous demands of the delivery room and the NICU. Our hand-held jaundice screening meter is non-invasive and offers a gentle, pain free alternative to traditional screening. Caregivers have instant access to accurate information for clinical decision-making. As one of the worldwide leaders in mechanical ventilation, Dräger recently introduced the new Babylog VN500 for neonatal ventilation. The most advanced product on the market today, Babylog VN500 offers the latest technology in mechanical ventilation specifically designed for the special needs of neonates and infants.

Discuss your R&D process, including clinician and nurse input.
Our research and development programs are driven by the input and requirements of our customers—the clinicians and nurses who use our products. Our shared goal with our customers is to improve patient outcomes and to facilitate efficiencies for healthcare professionals. We constantly invest in research and development to improve technology and to spur innovation in the medical arena. Part of our R&D process is Dräger’s ability to understand how new technologies will impact healthcare one year, five years, and ten years from now—sometimes even further into the future. While providing practical solutions for today, we consider the long-term impact of new technologies.

Tell us about the educational services you offer for neonatal caregivers.
Dräger supports neonatal workshops at key congresses and events around the world. Dräger’s commitment to clinicians worldwide is to share clinical knowledge around the globe for the NICU community. As a testament to this belief, Dräger created an internet educational platform to support caregivers and parents of premature babies at www.babyfirst.com. Although only recently launched, to date, this website has been a remarkable success. Through internet platforms and web-based seminars, we are using technology to advance educational services for the healthcare community worldwide.

Discuss your technical support and services.
At Dräger, we provide all customers with clinical and biomedical support, along with the highest standards of service. Dräger has a team of neonatal consultants in the field that provide product servicing and training on its thermoregulation and jaundice management products including incubators, open warmers, transport incubators, jaundice screening devices and phototherapy devices. Our neonatal consultants and technicians go through a stringent training program with a focus on continuous education and learning. Dräger also maintains a relationship with Intensive Care On-Line Network, which provides consultation services 24 hours a day, 7 days a week which customers can access by calling (800) 554-1312.

Tell us about the latest neonatal advances germane to your product.
Our latest product advancement is the Babylog VN500, a technologically advanced device with a comprehensive array of therapy options to support infant ventilation. Once again, our customers led the development of the next generation in neonatal ventilation. The Babylog VN500 combines conventional ventilation, nasal CPAP and oxygen therapy in one medical device. Designed with the clinician in mind, its versatility and range of operation makes it well suited for neonatal and pediatric intensive care units.
**CO₂ Reactivity and Cerebral Oximetry**

Erin Booth, PhD; Christopher Dukatz, BS; Michael Wider, PhD

**Introduction**

Brain injury is common in very low birth weight (VLBW) infants and is frequently associated with abnormalities in blood pressure, cerebral blood flow (CBF) or autoregulation. Gestational age is the primary antenatal risk factor for adverse neurodevelopmental outcome involving a number of contributing factors including intraventricular hemorrhage (IVH) and periventricular leukomalacia (PVL) which have both been long associated with alterations in cerebral blood flow. The PaCO₂ level in the first 3 days of life has been implicated in the etiology of IVH and PVL and hence represents a significant risk factor. IVH is frequently observed in the premature infant brain and can lead to cerebral palsy, language delay and severe neurocognitive and motor function deficits in surviving infants. End tidal CO₂ (etCO₂) monitoring in infants can be an accurate reflection of PaCO₂ but is only available in ventilated patients. Further, it is subject to a number of issues that can affect the accuracy of the reading including the type of ventilation and position of the sampling tube. Due to these factors frequent blood gas analysis is required to insure reliability. Transcutaneous CO₂ (TC-CO₂) monitoring provides a means of continuous tracking of CO₂ but while accurate, has to be moved from site to site every 4 hrs requiring recalibration. The system heats the skin to 43°C which has been associated with burns or skin irritation and the use of vasoactive drugs runs the risk of causing vasoconstriction in the skin, potentially compromising accuracy of the reading.

Advances in managing pulmonary immaturity in the preterm infant with surfactants and ventilation assistance have dramatically improved survival of low birth weight infants. These interventions, however, present other challenges for tracking the blood gas response, requiring frequent blood draws for analysis which contributes to neonatal anemia and provides a relatively late indicator of PaCO₂. The impact of CO₂ levels on cerebral perfusion and the association with IVH strongly support close monitoring of CO₂, especially following changes in ventilatory settings.

We report here the results of experiments in normal, term piglets examining the response of common carotid flow and cerebral O₂ delivery to changes in etCO₂ caused by ventilatory rate changes to induce hypercapnia and hypocapnia at normal and reduced body temperatures.

**Materials and Methods**

The procedures used in this study were reviewed and approved by the Providence Hospital Institutional Animal Care and Use Committee (IACUC) and conform to the standards described in the National Institutes of Health Guide of the Care and Use of Laboratory Animals [DHHS Publication No. (NIH) 86-23].

Surgical Preparation: Neonatal Yorkshire Duroc piglets of 10±1 days (range=6-14 days) of age weighing 2.5±0.1 kg (range=1.9-2.9 kg) were mechanically ventilated (Draeger Medical Apollo Anesthesia Machine; Draeger, Germany) and anesthesia maintained with 1.5-3.0% isofluorane following sedation with an intramuscular injection of ketamine (33 mg/kg) and atropine (0.05 mg/kg). Arterial O₂ saturation (SpO₂) and partial pressure of carbon dioxide (PaCO₂) were maintained in the normal range. A warming mat and hot air fan were used to maintain core body temperature at 38±0.5°C. Animals received intravenous (IV) heparin (200 units/kg/hour), and an IV maintenance solution of physiologic saline (10 mL/kg/h) throughout the experiment.

End tidal CO₂ monitoring in infants can be an accurate reflection of PaCO₂ but is only available in ventilated patients. Further, it is subject to a number of issues that can affect the accuracy of the reading including the type of ventilation and position of the sampling tube. Due to these factors frequent blood gas analysis is required to insure reliability. Transcutaneous CO₂ monitoring provides a means of continuous tracking of CO₂ but while accurate, has to be moved from site to site every 4 hrs requiring recalibration. The system heats the skin to 43°C which has been associated with burns or skin irritation and the use of vasoactive drugs runs the risk of causing vasoconstriction in the skin, potentially compromising accuracy of the reading.

Serum glucose, lactate, base excess and electrolyte levels were monitored closely (iSTAT, Abbott Point of Care Inc, Princeton, NJ) and maintained in the normal range using 10 g/dL of dextrose-water (D₁₀W), sodium bicarbonate, potassium chloride and lactated Ringer’s solution as needed.

Arterial blood pressure, heart rate, SpO₂ and body temperature were continuously monitored by Datex-Ohmeda monitor (GE Healthcare, Milwaukee, WI). End-tidal CO₂ (ETCO₂), fraction of inspired oxygen (FiO₂) and pulmonary compliance were also continuously monitored (Draeger Medical Apollo Anesthesia Machine; Draeger, Germany). Regional tissue O₂ saturation of the brain (CrSO₂) was monitored continuously by INVOS regional tissue oxygenation monitor (INVOS 5100C, Somanetics, Troy, MI) throughout the experiments.

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The common carotid artery (CCA) was isolated and instrumented for continuous blood flow measurements using a T400 series ultrasonic flow-meter (Transonic Systems Inc, Ithaca, NY).

All data from the Datex-Ohmeda monitor, Apollo Anesthesia Machine, INVOS 5100C and the T400 were collected real time and stored on a personal computer for offline analysis (The RugLoop Program, Dmed Temse, Belgium).

**Experimental Protocols**

**Hypercapnia and Hypocapnia:** The first series of 5 animals were allowed to stabilize and the body temperature maintained...
at normothermia (39°C) with ventilation settings to produce an end tidal CO₂ (etCO₂) of 25-30 mmHg. The ventilation settings were varied sequentially to reduce or increase the etCO₂ and maintain pH, SpO₂ and PaO₂ within normal limits with initial settings as follows: Pinsp=20, Freq=30, Tinsp=0.4, PEEP=3. The settings were adjusted depending on the individual animal’s response and once stable values were achieved, the frequency was decreased by increments of 10 with 15 minutes between each change. Following the period of hypercapnia, hypocapnia was induced by increasing the frequency of ventilation. The frequency was increased in increments of 10 to a maximum of 80 with 5 or 15 minute periods between each change. Throughout the experiment the SpO₂ and tidal volume were maintained by modifying the fiO₂ and ventilatory pressure respectively.

**Hypercapnia and Hypocapnia During Hypothermia:** In a second set of 5 piglets the body temperature was allowed to decrease passively from 39°C to 32-33°C (103°F to 93°F) and allowed to stabilize with ventilation settings to produce an etCO₂ of 25-30 mmHg. Ventilation settings were then varied sequentially as described above for normothermic animals.

**Results**

The common carotid flow rate and cerebral rSO₂ track etCO₂ closely in the normothermic piglet when the etCO₂ is varied by changing the respiratory rate as can be seen in Figure 1. Periodic blood gas analysis confirmed the etCO₂ accuracy. The animal appeared to be autoregulating cerebral flow during hypercapnia but in the later stage of hypocapnia begins to become pressure passive, indicating the loss of autoregulation. All animals maintained a 100% SpO₂ throughout the experiment.

The results from the same experimental protocol run in animals with reduced body temperature shown in Figure 2 reflects the reduced metabolic rate and the resultant limited etCO₂ changes in response to the same ventilatory change. The etCO₂ and the cerebral regional oxygen saturation of hemoglobin (CrSO₂) no longer track the common carotid flow and there is no significant increase in blood pressure until late in the hypocapnic period.

The lack of change in common carotid flow during hypothermia is likely due to the decreasing flow into the external carotid caused by vasoconstriction from cooling of the skin and counteracted by increasing flow into the internal carotid during hypercapnia as reflected in the increasing CrSO₂. Decreasing CrSO₂ observed during the hypocapnic period is accompanied by a decrease in the carotid flow.

**Discussion**

There is clear awareness of the relationship of hypercapnia and hypocapnia to neurodevelopmental complications. Clinicians have to rely on pulse oximetry and infrequent blood gas analysis to monitor the impact of changes in ventilatory settings which provides limited information for directing ventilatory management. The use of high frequency ventilation and positive airway pressure to keep the lungs open and insure adequate arterial saturation in premature infants has improved the survival rate but can lead to rapid loss of CO₂ and hypocapnia if not closely monitored.

Near infrared spectroscopy (NIRS) provides a means of monitoring O₂ delivery to the brain and periphery in infants. Recent reports have established baseline readings of rSO₂ for cerebral, perirenal and ventral abdominal sites in term and preterm neonates and preliminary reports have demonstrated the use of NIRS to track changes in blood flow to the brain, kidney and gut in a piglet model. The accuracy of CrSO₂ in reflecting internal jugular vein saturation in infants has been established in human and animal studies and the rapid and sensitive response of CrSO₂ to changes in cerebral blood flow was demonstrated in piglets.

Significant changes in CO₂ levels, whether from metabolic or respiratory shifts can alter cerebral vascular resistance, resulting in changes in cerebral blood flow and O₂ delivery. The response observed in these animal studies clearly demonstrates the value of NIRS in monitoring the cerebral response to CO₂.

CrSO₂ gives a venous weighted hemoglobin saturation value that reflects O₂ delivery to the brain and cerebral blood flow. There are a number of factors that can influence venous hemoglobin saturation, however, ranging from changes in blood flow to shifts in the hemoglobin dissociation curve. The impact of temperature and the Bohr Effect (high CO₂ and low pH) as well as 2,3 DPG levels are well recognized and can shift the O₂ dissociation curve to the right, decreasing hemoglobin O₂ affinity and increasing O₂ unloading at the tissue potentially causing a decrease in venous saturation.
The use of hypothermia to prevent tissue and brain damage caused by hypoxia and tissue ischemia in neonates and adults has dramatically increased in the last decade and has improved survival and reduced morbidities. It became clear early on that the depth and duration of cooling as well as the rate of rewarming were critical components to successful improvement of outcome. These initial experiments in piglets have shown that hypothermia has the potential to alter the CO2 response to ventilation changes as well as the vascular response to CO2.

The rapid changes in CrSO2 demonstrated that when CO2 changes, rSO2 will provide a rapid and accurate indication of the magnitude and extent of the change in blood flow. It needs to be kept in mind as mentioned above, however, when using NIRS to track changes in blood flow in response to CO2 that venous hemoglobin saturation and hence CrSO2 can also reflect changes in O2 affinity when supply doesn’t meet demand. Normally reduction in demand is slow and arterial saturation reflects O2 supply changes.

NIRS can be a significant contribution to managing neonatal ventilation, aiding in recognizing dangerous alterations in CO2 and helping to prevent neurocognitive complications of IVH and PVL. Combined with pulse oximetry rSO2 can be used as a management tool to indicate when ventilation settings may be excessive and should be reviewed and blood gases ordered.

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Use of the Edi Catheter in Monitoring Post-Extubation Support in an Infant

This case study was provided by Tom Noblet, Manager of the Respiratory Therapy Department and its staff at St Vincent Women's Hospital in Indianapolis, IN. This case study previously appeared as a white paper from MAQUET Critical Care, Wayne, NJ, in 2009. It was later presented at the Open Forum, International Congress of Respiratory Care, AARC, in San Antonio, TX, in December 2009.1

Case

A 26-week-old preemie was intubated and received ventilatory support on the SERVO-i. The infant was on SIMV PC+PS. An Edi catheter was inserted to monitor and evaluate the diaphragm’s electrical activity. [Edi is the diaphragm’s electrical activity that occurs just prior to a contraction. The Edi is controlled by the brain’s respiratory center, which sends a signal through the phrenic nerve to the diaphragm. The Edi catheter is similar to a nasal or oral tube, but contains an additional 10 sensors, located around the distal tip, that measure diaphragm electrical activity (Edi). This catheter can be used in conjunction with the SERVO-i ventilator. The ventilator can display the Edi waveform on its display screen and use the signal to control the ventilator when NAVA (neurally adjusted ventilatory assist) is selected as the mode.]

Following extubation, the preemie was placed on bubble CPAP of 5 cm H2O, which was increased to 7 cm H2O to improve oxygenation. The Edi catheter was kept in place to continue monitoring diaphragmatic electrical activity (Edi) with the bubble CPAP. Respiratory Therapist Joyce Henderson, RRT, NPS, commented, “The baby’s work of breathing (WOB) appeared excessive during this time. There were sternal and intercostal retractions present and the infant was using accessory muscles to ventilate.”

The medical team was considering re-intubation. However, because the catheter was still in place, the respiratory therapist was able to evaluate the Edi signal. The physical findings correlated with a peak Edi that ranged between 50 and 70 microvolts (from a few microvolts up to 10 microvolts is considered a normal range).2 The high Edi level demonstrated the increased activity of the diaphragm during bubble CPAP.

Figure 1 shows the Edi waveform (bottom waveform) with the patient breathing on 7 cm H2O of bubble CPAP. The range of the peak Edi value averaged 58 microvolts. (In Figure 1, the ventilator is on “standby” and not in use because the catheter was being used for monitoring only.)

Because of the high WOB evidenced on bubble CPAP, the infant was switched to a high-flow nasal cannula (HFNC) at 2 L/min. The amount of positive pressure generated with an HFNC is flow dependent, but it is not possible to measure the airway pressure with an HFNC device. The peak Edi was even higher on the 2 L/min HFNC than with the bubble CPAP. Thus, the drive to breath was not reduced at this flow setting (average 78 microvolts).

The HFNC was increased to 4 L/min and the peak Edi was seen to decrease to an average of 60 microvolts.

The HFNC was then increased to 6 L/min. The peak Edi continued to decrease, with only occasional breaths generating an Edi of more than 70 microvolts. These may have been “sigh” breaths. Most breaths were 35 microvolts or less (average 38 microvolts, excluding sigh) on 6 L/min.

Figure 2: The infant is on an HFNC (Vapotherm) at 6 L/min (Lpm). Edi is the bottom waveform, with an average value of 38 microvolts. Continued on page 56...
Why is the Cesarean Section Rate on the Rise in the USA?

Benamanahalli K. Rajegowda, MD; Muhammad Aslam, MD

The cesarean section (CS) rate in the United States is around 30%. In some regional hospitals the CS rate is even higher, reaching almost 50%. What has resulted in this rapid increase is debatable but several factors are worth considering, which include but are not limited to comfort for doctors or consumers, increase in high risk pregnancies due to the use of fertility drugs and in vitro fertilization, use of intrapartum electronic fetal monitoring (IEFM), fear of litigation, and finally, due to a repetition of the saying, “once a section, always a section.”

Let me give you my (BK Rajegowda) experience as a neonatologist for over 40 years: In the 60s and 70s the CS rate was around 6-7%, when CS was mainly done for cephalopelvic disproportion, compound presentation, fetal bradycardia, and maternal hemorrhage. Subsequently—due to improvements in perinatal medicine, with advanced maternal-fetal well-being tests, use of technology in fetal assessment before and during labor, and trained sub-specialization in obstetrics, perinatology, along with improvement in neonatal care—CS has been liberalized and the rate has been going up slowly from the 70s onwards to the present level. There is evidence that fetomaternal risks which are identified during this advanced monitoring, with timely intervention, help to prevent fetal death, birth asphyxia, neonatal seizures, birth trauma, and of course neonatal death, along with improvement in neurodevelopment among survivors.

It has been shown that IEFM has not decreased the incidence of stillbirth, cerebral palsy and perinatal mortality. On the other hand, CS does have a cost, as well as contributing to maternal and neonatal morbidity and mortality.

At present, IEFM is standard for every woman in labor who walks into the hospital. This has replaced the old standard of women who were ambulated until the full dilation of cervix and closely monitored for delivery by a midwife or an obstetrician. According to ACOG, the recent data shows approximately four million, or 85% of live births were assessed with IEFM, making it the most common obstetric procedure. However, IEFM during labor identified varied fetal risks and was the main contributing factor responsible for an increase in the CS rate. IEFM has advantages and disadvantages. If IEFM is used intrapartum along with clinical assessment at the bedside with fully trained staff instead of evaluating the fetal tracings from the office or the desk, this will have significant impact in lowering the CS rate. It has helped to deliver fetuses expeditiously when giving an alarming tracing, but due to normal course at delivery many infants could have been delivered vaginally without intervention. The fear of litigation and lawsuits are related mainly to IEFM tracings showing any form of variability that are used in courts.

Because of this, the practitioner will not take any risk and go for delivery via CS even if the delivery can be accomplished without intervention. There are pitfalls of using IEFM tracings, and any such documented tracings are a root cause for attorneys to argue in favor of plaintiffs. This is the second most common risk factor for using CS.

Liability insurance has gone through the roof and many practitioners have given up their practice, resulting in a shortage of obstetricians in many parts of the country, with other obstetricians slowing down their obstetric practice of delivering babies. In addition, liability insurance has driven out midwives from their practices in delivering babies. A recent survey of professional liability of obstetricians revealed at least one professional liability claim against each surveyed obstetrician during his or her career. Forty-four percent had four or more claims. Many of these lawsuits have no merit but they do produce agony for practicing physicians. Of course no one disagrees that the patient who suffers deserves compensation if any malpractice has occurred. However, as long as the present healthcare system is without tort reform, the practitioner continues to practice defensive medicine, resulting in increased cost of care and a concomitant increase in the CS rate.

The third reason for increase in the CS rate is repeat c-section, although 80 to 85% of women will have successful vaginal deliveries after a cesarean section. However, the obstetricians will not take any risk delivering by VBAC after a previous c-section, given risk of complications and litigation. As such, there will be fewer and fewer vaginal deliveries. In our view, in the future, L&D will be labeled as an operating room procedure, since the CS rate will reach 50%.

The problem in the United States compares with other developed countries where the consumer wants everything done immediately. Physicians prefer CS even when it’s not needed, do unnecessary tests, unnecessary consultations, write needless prescriptions and even prolong life without necessarily considering the need, the cost and the suffering. On the other hand patients want CS so they won’t have to tolerate the pain of labor and its complications. This is a litigious society which assumes no personal responsibilities. Americans spent more than 15% of their budget on healthcare but they are far behind many countries on many healthcare issues. Money cannot buy everything and the citizens must take responsibility and apply the adage, “an ounce of prevention is worth a pound of cure.” Women who want to get pregnant must plan their pregnancy.
Fetal Operation Followed by Cesarean Section May Have a Beneficial Effect Upon Neuromuscular Function in Spina Bifida Aperta

Renate Verbeek, Axel Heep, Natasha Maurits, Reinhold Cremer, Oebele Brouwer, Johannes van der Hoeven, Deborah Sival

Background
Spina bifida aperta (SBA) is associated with neurological dysfunction cranial and caudal to the meningomyelocele (MMC). Fetal surgery may ameliorate cranial abnormalities, but effects upon neuromuscular function caudal to the MMC are unclear. SBA myotomes cranial to the MMC are influenced by cerebral dysfunction, whereas myotomes caudal to the MMC are additionally influenced by the MMC. Increased muscle ultrasound density (MUD) reflects neuromuscular damage. By the intra-individual difference in MUD (dMUD=[MUDcaudal] - [MUDcranial]) the effect by the MMC upon neuromuscular integrity is derived. In the present study, we aimed to compare dMUD and neuromuscular function between fetally and postnatally-operated SBA patients.

Materials and Methods
We compared dMUD and neuromuscular function in 6 (age- and MMC-) matched pairs of fetally and postnatally operated SBA patients [age 0-3.5 years; lumbar (6) and lumbar-sacral (6) MMC]. In all patients, quadriceps muscle was innervated cranial- and calf muscle caudal- to the MMC. Fetally operated patients were delivered by cesarean section (CS) at Bonn; postnatally operated patients were delivered vaginally at Groningen.

Results
The dMUD was smaller in fetally than in postnatally-operated SBA patients [10 (-11 to 37) vs 28 (4 to 47), medians (ranges); p<0.05]. Comparing SBA patients, the results indicated more preserved neuromuscular function in fetally than postnatally operated patients [median difference: 1 and 1.5 myotome (ranges 1-3); motor and sensory function resp.; p<0.05].

Conclusion
In SBA, dMUD provides a diagnostic tool to compare neuromuscular integrity between treatment groups. Present data suggest that fetal operation followed by CS has some beneficial effect upon neuromuscular outcome caudal to the MMC. Future assessment in SBA patients (treated by postnatal operation followed by CS) may allow further differentiation between the effect by operation and way of delivery upon neuromuscular outcome.

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Pulse Oximetry in the Newborn: Is the Left Hand Pre- or Post-ductal?

Christoph Ruegger, Hans Ulrich Bucher, Romaine Arlettaz Mieth

Abstract

Background: Over the past few years, great efforts have been made to screen duct-dependent congenital heart diseases in the newborn. Arterial pulse oximetry screening (foot and/or right hand) has been put forth as the most useful strategy to prevent circulatory collapse. The left hand, however, has always been ignored, as it was unclear if the ductus arteriosus influences left-hand arterial perfusion. The objective of our study was to evaluate the impact of the arterial duct on neonatal pulse oximetry saturation (POS) on the left hand.

Methods: In this observational study, arterial oxygen saturation on both hands and on one foot was measured within the first 4 hours of life.

Results: Two hundred fifty-one newborns were studied: 53% males and 47% were delivered by caesarean section. The median gestational age was 38 4/7 weeks (90% CI, 32 6/7-41 2/7 weeks), the median birth weight was 3140 g (90% CI, 1655-4110 g) and the median age at recording was 60 minutes (90% CI, 15-210 minutes). The mean POS for the overall study population was 95.7% (90% CI, 90-100%) on the right hand, 95.7% (90% CI, 90-100%) on the left hand, and 94.9% (90% CI, 86-100%) on the foot. Four subgroups (preterm infants, babies with respiratory disorders, neonates delivered by caesarean section, and newborns ≤15 minutes of age) were formed and analysed separately. None of the subgroups showed a statistically significant difference between the right and left hands. Additionally, multivariate logistic regression did not identify any associated factors influencing the POS on the left hand.

Conclusions: With the exception of some children with complex or duct dependent congenital heart defects and some children with persistent pulmonary hypertension, POS on both hands can be considered equally pre-ductal.

Background

Cardiovascular malformations are the commonest type of congenital malformation (6-8/1000) and responsible for more deaths in the first year of life than any other birth defects. A sixth of the affected children have a duct dependent circulation, with a persistent ductus arteriosus being necessary for survival.1-3 Over the past few years, great efforts have been made to screen these duct-dependent congenital heart diseases (CHD) in the newborn. As ductal-dependent CHD may not be apparent at the time of early discharge examination,4-5 post-ductal arterial pulse oximetry screening during the first 24 hours of life has been put forth as the most useful strategy to prevent circulatory collapse or death.4-9 The ease of performing, minimal discomfort for the baby, low costs, and excellent detection rates of duct- dependent circulation are strong arguments to implement pulse oximetry as a basic routine in the nursery.10,11

In addition, pulse oximetry has been used for observing newborns with respiratory or cardiac disorders and has been found to be helpful in monitoring neonatal resuscitation. In this context, pre-ductal POS, the sensor applied to the right hand, must be used to monitor oxygen application. This is in contrast to the later measured post-ductal POS (foot) to rule out CHD as described above.

For both purposes, previous studies have focused on obtaining pulse oxygen saturation from one foot (post-ductal) and/or the right hand (pre-ductal). The left hand, however, has always been ignored, as it was unclear if the ductus arteriosus influences left-hand arterial perfusion. By means of pulse oximetry measurements, the purpose of the present study was to clarify if values of the left hand can be differentiated from the pre-ductal (right hand) and post-ductal (foot) values.

Methods

The study population of this observational study included infants born at the University Hospital of Zurich between 5 January and 26 April 2009. Newborn infants with pre- or post-natally diagnosed CHD were also measured, but not included in the overall analysis. The measurements were performed using a Nellcor-65 handheld pulse oximeter with a neonatal OxiMax adhesive sensor. An accuracy of ±2% for the measurement of functional oxygen saturation (SpO2) was stated by the manufacturer. For each newborn, a neonatologist obtained the POS for both hands and one foot within the first 4 hours of life. The probe was secured to the wrist or palm and to the sole of the foot, following a random order. The same oximeter was used for all three sequential measurements. To avoid movement artifacts, the pulse was observed until a good waveform was obtained. It usually required 3-5 minutes for all 3 measurements to be performed.

As post-ductal (foot) pulse oximetry screening has become the standard of care at our institution, the two additional recordings (right and left hands) were considered a modification of the routine examination. In agreement with the Hospital Committee of Ethics, the parents were informed, but no written consent was obtained. On enrolment in the study, the following information of each infant was recorded: gestational age, gender, birth weight, mode of delivery, umbilical arterial pH, Apgar score at 5 minutes, and postnatal age.

Statistical analysis: A sample size was estimated based on the
Results

During the study period, 739 babies were live born at our institution. Of these newborn infants, 254 (34%) were enrolled in the study. Recordings of the remaining newborns were not obtained for the following reasons: lack of staff, several simultaneous deliveries, and movement artifacts. In addition, three recordings were analyzed separately because of known or suspected CHD. The first newborn had trisomy 13 with an interrupted aortic arch; the arterial oxygen saturation showed values of 84%, 79% and 62% on the right hand, left hand, and foot. In a second newborn, echocardiography revealed a double outlet right ventricle with an oxygen saturation of 94%, 88% and 88%, respectively. A third newborn had a saturation of 89%, 80% and 85% on the right hand, left hand, and foot, respectively. A double inlet single ventricle was demonstrated on the echocardiogram. Consequently, data from 251 infants were recorded and analyzed. The median gestational age was 38 4/7 weeks (90 CI, 32 6/7-41 2/7 weeks) and the median birth weight was 3140 g (90 CI, 1655-4110 g). Further patient characteristics are given in Table 1. The median age at the beginning of recording was 60 minutes (90 CI, 15-225 minutes).

Recordings of the study population revealed identical mean oxygen saturations of 95.7% (90 CI, 90-100%) on the right and left hands (p-value<0.41). The post-ductal mean oxygen saturation was 94.9% (90 CI, 86-100%), which was 0.8% lower than both hands. In addition, the same analyses were carried out for different subgroups, such as preterm infants, babies with respiratory disorders, neonates delivered by cesarean section, and newborns measured within the first 15 minutes of life. All of the newborn subgroups were at higher risk for an elevated pulmonary artery pressure, and therefore most likely qualified to demonstrate an eventual effect on left-hand perfusion based on right-to-left shunting through the arterial duct. The results of oximetry measurements of the whole study population and the four subgroups are presented in Table 2.

As described under statistical analysis, the following associated variables for the differences between both hands were identified: Age at recording, respiratory disorder, and cesarean section. None of the variables had a significant impact on the difference between the right and left hand, as shown in Table 3 (p-values >0.05). For the differences between the right hand and the foot, birth weight and age at recording remained in the model [Table
4]. These differences were shown to decreases with postnatal age, as plotted in Figure 1. Again, the cesarean section was not suitable for further analysis.

**Discussion**

**Right Hand-Left Hand:** The present study demonstrates that arterial pulse oximetry measurements on the left hand do not significantly differ from the pre-ductal values on the right hand. Even with regard to the four subgroups, in which right-to-left shunting through fetal circulatory pathways resulting from persistent pulmonary hypertension can be assumed, no statistically significant difference was found. We conclude from our data that perfusion of the left hand is unaffected by the arterial duct and can be considered pre-ductal. In the subgroup consisting of babies with respiratory disorders, a trend, but no statistically significant difference between both hands was detected (p-value 0.06). This trend towards lower values on the left hand can physiologically be explained by a delayed decrease in pulmonary hypertension.

**Right Hand-Foot:** Other results fully correspond to those of previous studies. Our overall post-ductal POS levels were 0.8% lower compared to the pre-ductal POS levels.\(^{12,13}\) In fact, the subgroup consisting of babies recorded within the first 15 minutes of life had post-ductal values that were 2.4% lower. An elevated pulmonary artery pressure during the first minutes of life is the main cause for this difference. Levesque et al\(^{12}\) reported that postnatal age and the activity state, for example fussy and crying infants at the time of measurement were the most important factors affecting post-ductal POS. In the present study, multivariate logistic regression detected age at recording as one of two variables influencing the difference between pre- and post-ductal values. This is consistent with findings of other studies, in which POS has been shown to increase with time.\(^{13-15}\)

The second variable derived from multivariate logistic regression was birth weight, with a positive correlation to the difference between pre- and post-ductal values. This was unexpected and could neither be explained conclusively nor brought in line with the results of previous studies.

Other authors have focused on whether or not the mode of delivery could have an effect on saturation.\(^{14,16}\) They all postulated lower post-ductal saturations due to greater retained fetal lung fluid after caesarean section. This is confirmed by our data which showed a significantly lower mean post-ductal saturation in infants delivered by caesarean section (94.1%) compared to infants delivered vaginally (96%, p-value=0.002). The difference between pre- and post-ductal values, however, was not significantly influenced by the mode of delivery.

**Conclusions**

Arterial pulse oximetry is a powerful tool to screen for life threatening CHD. Within the wide range of pre- and post-ductal oxygen saturation, the present study clearly demonstrates that even during the first hours of life, characterised by the process of adaptation, the right and left hand do not significantly differ. We therefore conclude that with the exception of some children with complex or duct dependent CHD and some children with persistent pulmonary hypertension, POS on both hands can be considered equally pre-ductal.

**References**


Cost Comparison of Heel Stick Procedures and Transcutaneous Sample Methods for Bilirubin Evaluation

Jim McKenzie; Brian Palmer, BSEE, MBA

Abstract
Objective: There is concern about the cost of assessing each healthy term neonate for the risk of hyperbilirubinemia. It has been shown that universal screening does decrease the likelihood of severe hyperbilirubinemia through a blood draw or by using transcutaneous methods.1 Our objective was to determine the cost differences associated with screening neonates prior to discharge per the American Academy of Pediatrics’ guidelines.2

Methods: A multi-centered ethnographic cost-effectiveness analysis of bilirubin screening strategies was conducted at three birthing hospitals. An analytic decision model was used to determine the direct cost impact of transcutaneous bilirubin measurements using the BiliChek (Philips Children’s Medical Ventures) noninvasive bilirubin device versus a total serum laboratory analysis. We analyzed the direct costs by analyzing purchasing records, current average sales prices from industry suppliers, and online hospital suppliers. Indirect costs were analyzed through a modified societal perspective of an online industry compensation analysis system. A depreciation analysis was not included because it would unnaturally bias lower cost equipment.

Results: Through an observational study and a staff interview process, a work flow pattern for transcutaneous and blood draw procedures was developed. The similarity of the studied facilities allowed for the development of a screening procedure chart (Chart 1). An analysis of procedure time and the use of products were categorized according to costs. The results indicate that the direct costs (procedure products) and indirect costs (cost of labor) of transcutaneous bilirubin measurements are lower than laboratory measurements.

Conclusion: The American Academy of Pediatrics supports screening for the risk of hyperbilirubinemia through laboratory or transcutaneous measurements.2 The use of the BiliChek transcutaneous device is a lower cost screening solution for assessing the risk of hyperbilirubinemia in neonates than blood sampling methods.

Purpose
The purpose of this multi-centered ethnographic study was to observe and record the steps and time needed to conduct a heel stick bilirubin measurement and then determine the direct and indirect costs of performing blood sampling for serum bilirubin. This information would then be compared against the results of observing and recording a transcutaneous bilirubin test performed with the BiliChek noninvasive bilirubin assessment tool. This study compares the cost of performing a noninvasive bilirubin measurement with BiliChek to the cost of a bilirubin serum blood test.

Summary
The American Academy of Pediatrics recommends that all newborn infants be assessed for jaundice at 24 hours after birth and prior to discharge from the hospital.2 Studies show that the visual assessment of jaundice or the estimation of bilirubin levels based on progressive changes in skin coloration to be inaccurate.3 Both serum blood testing and transcutaneous measurements have been shown to be reliable methods for assessing and monitoring neonatal hyperbilirubinemia.4 Customer opinion regarding the BiliChek’s consumable calibration tip suggests that hospitals without a transcutaneous device are unwilling, or require the cost justification, to purchase the BiliChek transcutaneous device. This reluctance to purchase is due to the long-term operational use cost of the BiliChek which is related to the per-test cost of the devices’ calibration and patient interface tip and not the purchase price of the device.5 This study has determined that the true cost of a transcutaneous measurement with BiliChek’s calibration tip and the labor cost involved to complete a transcutaneous measurement is lower in cost compared to the supplies and labor cost required for a heel stick.

Objectives
The objectives for this ethnographic bilirubin measurement study are described below.

1. A flow chart that documents the initiation, the steps of a transcutaneous test and a heel stick from lab draw through the logistical flow of the specimen to the electronic retrieval of the bilirubin test results

a. Purpose
i. To gain a clear understanding of the serum blood test procedures and work flow (Chart 1)
ii. To record and understand the procedures involved in a serum-based bilirubin test measurement
2. A spreadsheet with (a) the supplies required for a heel stick and BiliChek bilirubin measurement, (b) time required to perform a heel stick and BiliChek bilirubin measurement, and (c) cost comparison of the two methods
   a. Purpose
      i. To record the various items used in a heel stick lab draw for indirect and direct bilirubin to calculate cost
      ii. To assess the amount of labor time associated with each test method
3. A recommendation to the clinical leadership and administration teams to incorporate this information into their jaundice management program.

**Conclusion/Recommendation**
The cost of a heel stick performed in accordance with the transcutaneous methodology for bilirubin measurement.

**Chart 1: Comparative flow chart of heel stick blood draw activities for a nursing-based lab draw versus a BiliChek transcutaneous measurement**
The following represents a general flow of activities observed at three different hospitals during the ethnographic study.

**Time required for heel stick lab draws**
The job title and activity information that follow were gathered during the time comparison study (Table 1 and Table 2). Hourly rate information was gathered by researching salaries on www.salary.com and using the 25 percent and 75 percent salaries as end points with Pittsburgh 15213 being the area used. The labor rate is an unburdened labor rate that does not include the cost of fringe benefits.

**Identified heel stick blood draw supplies cost**
The lancet manufacturer for a heel stick lab draw and part number information was gathered from hospitals and summarized in Table 3 according to low, medium and high. The costs also include the costs of warming the sample site with a heel warmer and administering a sucrose solution for pain management in the medium and higher levels of care. Information for pricing of these components was found through a national medical component distribution and through online medical suppliers. Refer to Appendix 1.

**Cost comparison of two methods**
The information presented below describes the mean total costs of a heel stick blood draw and a BiliChek transcutaneous procedure (Table 3). The heel stick procedure is divided into low, medium, and high costs to take into account different practices such as using heel warmers and pacifiers as well as the particular supplies used at each of the studied facilities (Appendix 2 for cost information). There is also a difference in labor costs to account for ranges in salary for a given area (Table 1).

**Cost analysis**
Table 3 describes the mean total costs of heel stick lab draw versus a BiliChek transcutaneous measurement procedure. The heel stick procedure is categorized into low, medium, and high cost to take into account different practices such as using heel warmers and pacifiers as well as the particular supplies used at each of the studied facilities. There is also a difference in labor costs related to low-high percentile ranges in salary for a given area.

**Table 1**

<table>
<thead>
<tr>
<th>BiliChek heel stick blood draw</th>
<th>Job title / discipline</th>
<th>Activity</th>
<th>Unburdened hourly labor rate</th>
<th>Mean time required*</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>Infant lab blood draw</td>
<td>procedure for bilirubin</td>
<td>$25.00-$35.00</td>
<td>15 minutes</td>
<td>$6.25-$8.75</td>
</tr>
<tr>
<td>Lab technician</td>
<td>Centrifuge blood, place in proper container, test sample</td>
<td>$18.00-$23.00</td>
<td>10 minutes</td>
<td>$3.00-$3.83</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$9.25-$12.58</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Transcutaneous bilirubin measurement</th>
<th>Job title / discipline</th>
<th>Activity</th>
<th>Unburdened hourly labor rate</th>
<th>Mean time required*</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>BiliChek transcutaneous measurement</td>
<td>$25.00-$35.00</td>
<td>2 minutes</td>
<td>$6.25-$8.75</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$0.83-$1.16</td>
</tr>
</tbody>
</table>

*Note: Labor for a heel stick blood draw is based on an average of 15 minutes of time for a nurse to complete the procedure plus an average time of 10 minutes for medical laboratory technician to process the specimen. Labor for a BiliChek transcutaneous is based on an average of two minutes of a nurse’s time. See Appendix 1 for heel stick procedure supplies and associated pricing information.

**Table 3**

<table>
<thead>
<tr>
<th>BiliChek heel stick vs. BiliChek transcutaneous</th>
<th>Heel Stick (low)</th>
<th>BiliChek (low)</th>
<th>Heel Stick (medium)</th>
<th>BiliChek (medium)</th>
<th>Heel Stick (high)</th>
<th>BiliChek (high)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies</td>
<td>$4.17</td>
<td>$6.80</td>
<td>$7.04</td>
<td>$6.80</td>
<td>$9.07</td>
<td>$8.80</td>
</tr>
<tr>
<td>Nursing labor cost</td>
<td>$6.50</td>
<td>$0.83</td>
<td>$7.50</td>
<td>$1.00</td>
<td>$8.75</td>
<td>$3.17</td>
</tr>
<tr>
<td>Total supplies/nursing costs</td>
<td>$10.67</td>
<td>$7.63</td>
<td>$14.54</td>
<td>$7.80</td>
<td>$17.82</td>
<td>$7.97</td>
</tr>
</tbody>
</table>

Analysis of the data concludes that the relative market price of supplies needed to conduct a BiliChek noninvasive assessment versus a heel stick blood draw is higher in the low range, $2.63, but lower in the medium and high ranges, $0.24 and $2.27, respectively (Table 3). When comparing the cost of nursing labor and supplies of a BiliChek noninvasive assessment versus...
a blood draw, the study concludes that the low-range BiliChek assessment is 28% ($3.04) less expensive than the heel stick, and in the medium and high ranges, 46% ($6.74) and 45.2% ($9.85) less expensive, respectively (Table 3).

Appendix 1: General interview questions

The following questions/observations were used to discover and gather evidence to support the position and conclusion of this paper.

General interview questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a protocol for jaundice assessment and management?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who makes the decision to obtain measurement?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who performs the measurement?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When are bilirubin tests required?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often are bilirubin tests performed on each infant?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often is the product used on each infant?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long (in minutes) does it take to obtain the results?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Observations

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where do you keep the equipment for bilirubin testing?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have to disturb the infant to perform the test?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, how long (in minutes) does it take to position the infant?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How is infant positioned?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the required equipment in close proximity to where the procedure takes place?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How do you know you have a “good” reading?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many individuals are required to perform the test?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where do they put the device to get the baby ready for the test?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where is the bilirubin test performed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is done with the device once the test is completed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What do you do with the results of the bilirubin test?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Explain the process (the flow of activity) from the time the decision to obtain a bilirubin measurement is made to the time the results are interpreted.

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where is the bilirubin test performed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Transcutaneous interview questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do you decide between transcutaneous and heel stick bilirubin measurements?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who performs the test? (title and hourly rate)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Transcutaneous observations

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do you decide between transcutaneous and heel stick bilirubin measurements?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How do you know what buttons to press on the transcutaneous device?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long does each test take to obtain a result?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heel stick interview questions for nurses

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is a blood sample required for a bilirubin measurement?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who handles the blood?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What are the chances for interchanging blood samples between patients?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the proper light-protected tubes being used?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there complications due to heel stick wounds? How often?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heel stick blood draw observations

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>How are steps required for a blood sample determined?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How are laboratory activities for each blood sample determined?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many people touch the blood?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observe who obtains the blood and how it gets to the lab.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long does it take to perform a heel stick procedure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long does it take to obtain the result?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heel stick blood draw interview questions for biotech department

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who collects the tubes? How long does this take? (title and hourly rate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who performs the blood test? (title and hourly rate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long does this take? Does this test need to be observed or does it run on its own?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is a separate container used to hold blood for this test?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is blood ever lost transferring from test tube to holder?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often is the equipment calibrated?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are quality-control analyses performed? How often?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How are the results captured and sent to the physician? Who does this?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long does this take?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long does it take from the time the physician places the order to obtain the bilirubin level to the time results are returned?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is all of the blood evaluated on one machine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How are the data transmitted after the test?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many people touch the blood?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Parts required for obtaining a bilirubin result

Indicate yes/no. If yes, indicate the number used.

<table>
<thead>
<tr>
<th>Questions</th>
<th>BiliChek</th>
<th>Heel stick blood draw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discipline performing test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gloves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lancets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wipes (alcohol or saline)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bandages</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pacifiers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sucrease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood containers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bio-wipes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel warmers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calibration solutions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood additives / reagents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood holders for machine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilical calibration tip</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Appendix 2: Supply costs for general heel stick blood draw procedure and BiliChek’s calibration tips

<table>
<thead>
<tr>
<th>Item</th>
<th>Manufacturer</th>
<th>Part number</th>
<th>Price per quantity</th>
<th>Price per piece</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubber gloves</td>
<td>Esteem</td>
<td>8812N</td>
<td>$23.95 Box of 100</td>
<td>$0.28 per 2 gloves</td>
<td><a href="http://www.opticplanet.net/cardinal-health-estem-microtextured-stretchy-nitrile-examinationgloves-cardine-blackw.html">http://www.opticplanet.net/cardinal-health-estem-microtextured-stretchy-nitrile-examinationgloves-cardine-blackw.html</a></td>
</tr>
<tr>
<td>Lancets for heel stick</td>
<td>BD</td>
<td>368101</td>
<td>$138.50 Box of 50</td>
<td>$2.78</td>
<td><a href="http://www.microscopes.co.uk/ms-ch-lg-8812n.html">http://www.microscopes.co.uk/ms-ch-lg-8812n.html</a></td>
</tr>
<tr>
<td>Lancing for heel stick</td>
<td>Gentle Heel</td>
<td>GHN (1.0mm depth X 2.5mm length)</td>
<td>$210 for 50</td>
<td>$4.20</td>
<td><a href="http://www.bluemarinemedical.com/medical_supplies.php?id=40-239">http://www.bluemarinemedical.com/medical_supplies.php?id=40-239</a></td>
</tr>
<tr>
<td>Blood containers for infants</td>
<td>Microtainer</td>
<td>36598S</td>
<td>$164.77 50/4 sp/case</td>
<td>$3.30</td>
<td><a href="http://www.opticplanet.net/blurro-media/51436-5.html">http://www.opticplanet.net/blurro-media/51436-5.html</a></td>
</tr>
<tr>
<td>Wipes (alcohol or saline)</td>
<td>Novaplus</td>
<td>V9100</td>
<td>$1.67 box of 200</td>
<td>$0.008</td>
<td><a href="http://www.bluemarinemedical.com/medical_supplies.php?id=40-239">http://www.bluemarinemedical.com/medical_supplies.php?id=40-239</a></td>
</tr>
</tbody>
</table>
| Bandages | Kendall Curity | 100165/963508 | $7.77 box of 100 | $0.007 | http://www.amazon.com/dp/B0028TUIWI/ref=sr_1_8?ie=UTF8&keywords=B0028TUIWI&adid=004280crat10x30333x&sr=8-8-kp-blinki
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Surveys of Mortality in UK Neonatal and Pediatric Intensive Care Trials, BRACELET Study

Claire Snowdon, Sheila E Harvey, Peter Brocklehurst, Robert C. Tasker, Martin P. Ward Platt, Elizabeth Allen, Diana Elbourne

Abstract

Background: The subject of death and bereavement in the context of randomized controlled trials in neonatal or pediatric intensive care is under-researched. The objectives of this phase of the Bereavement and RAndomised ControlLEd Trials (BRACELET) Study were to determine trial activity in UK neonatal and pediatric intensive care (2002-06); numbers of deaths before hospital discharge; and variation in mortality across intensive care units and trials and to determine whether bereavement support policies were available within trials. These are essential prerequisites to considering the implications of future policies and practice subsequent to bereavement following a child’s enrollment in a trial.

Methods: The units survey involved neonatal units providing level 2 or 3 care, and pediatric units providing level II care or above; the trials survey involved trials where allocation was randomized and interventions were delivered to intensive care patients, or to parents but designed to affect patient outcomes.

Results: Information was available from 191/220 (87%) neonatal units (149 level 2 or 3 care); and 28/32 (88%) pediatric units. 90/177 (51%) eligible responding units participated in one or more trial (76 neonatal, 14 pediatric) and 54 neonatal units and 6 pediatric units witnessed at least one death. 50 trials were identified (36 neonatal, 14 pediatric). 3,137 babies were enrolled in neonatal trials, 210 children in pediatric trials. Deaths ranged 0-278 (median [IQR interquartile range] 2 [1, 14.5]) per neonatal unit, 0-7 (median [IQR] 0.5 [0, 1.8]) per pediatric unit. Deaths ranged 0-37 (median [IQR] 2 [1, 14.5]) per neonatal unit, 1-53 (median [IQR] 11.5 [3, 33.8]) per pediatric unit. Deaths ranged 0-37 (median [IQR] 2 [1, 14.5]) per neonatal unit, 1-53 (median [IQR] 11.5 [3, 33.8]) per pediatric unit. Deaths ranged 0-37 (median [IQR] 2 [1, 14.5]) per neonatal unit, 1-53 (median [IQR] 11.5 [3, 33.8]) per pediatric unit. Three trials had a formal policy for responding to bereavement.

Conclusions: A substantial number of deaths after trial enrolment were identified, distributed over many trials and units. Few trial teams had responses to bereavement in place. Those with the largest numbers of deaths might be best placed to collaborate in developing and assessing responses to bereavement.

Background

The current emphasis on the need for good evidence to guide care, and the establishment of the UK Medicines for Children Research Network (MCRN) to encourage and facilitate pediatric research, suggest that increasing numbers of children will be enrolled into randomised controlled trials. This includes extremely sick children in neonatal and pediatric intensive care units, of whom a proportion will die before discharge home. The subject of death and bereavement in the context of trials is, however, under-researched.

It is not known how many participants are enrolled in this setting, or how many survive or die. The parents of those who go on to die subsequent to trial enrolment may have a range of information and support needs and preferences but these have not yet been adequately described and explored. We do not know whether bereaved parents might wish to have further contact with a trial, and what services, if any, they might wish to access; we do not know what approaches clinicians and trial teams might feel able to offer.

An essential prerequisite to considering bereavement and trials is to ascertain the magnitude and distribution of post-trial mortality. This study therefore aimed to determine: 1. trial activity in UK neonatal and pediatric units; 2. the number and proportion of deaths among babies and children participating in trials in intensive care; 3. variation in mortality across units, and across trials; 4. whether any provision is made for bereavement within trials.

Authors Snowdon, Harvey, Allen and Elbourne are with the Medical Statistics Unit, London School of Hygiene and Tropical Medicine; Snowdon is also with the Centre for Family Research, University of Cambridge; Brocklehurst is with the National Perinatal Epidemiology Unit, University of Oxford; Tasker is with the University of Cambridge Clinical School, Department of Pediatrics; Ward Platt is with Newcastle Neonatal Service, and Roger Parslow at Pediatric Intensive Care Audit Network (PICANET) provided advice and helpful information. MCRN staff and MCRN Local Research Networks gave crucial assistance with data collection. The BRACELET Study Advisory Group (Ursula Bowler, Dr Gillian Colville, Professor Richard Cooke, Professor Bobbie Farsides, Merryl Harvey, Dr Andy Leslie, Fiona Lockett) commented on research methods throughout the research process.Reprinted from BioMed Central, Trials, © 2010 Snowdon et al, licensee BioMed Cental Ltd. This is an open access article distributed under the terms of the Creative Commons Attribution License.
extubated). Intubated and ventilated, or unstable non-intubated or recently extubated. At least Level II intensive care (1:1 nurse:child ratio providing pediatric units with a pediatric intensivist in post which provide specialist services such as surgery), and all neonatal and pediatric units to identify trials conducted in the UK over specified time periods and particular specialties can be identified. The BRACELET Study therefore required two linked surveys to achieve its objectives; the first survey involved neonatal and pediatric units to identify trials conducted in the UK in 2002-2006; the second survey involved trials to collate data on deaths across trials and across their collaborating neonatal and pediatric units (Figure 1).

Unit survey: The unit survey aimed to identify all trials open to recruitment in the UK from 1 January 2002 to 31 December 2006. Data were requested from all neonatal units providing care designated as Level 2 (high dependency and some short-term intensive care) or Level 3 (whole range of medical care but not necessarily specialist services such as surgery), and all pediatric units with a pediatric intensivist in post which provide at least Level II intensive care (1:1 nurse:child ratio providing care for those requiring continuous nursing supervision, usually intubated and ventilated, or unstable non-intubated or recently extubated).

Two hundred and twenty neonatal units and 32 pediatric units were identified through a process of cross-checking multiple sources. Units were contacted by post but questionnaires were also made available on the BRACELET website. One hundred and forty nine neonatal units reported their designated level of care as Level 2 or 3 and were eligible to participate in the study. At the 149 neonatal units, and at the 32 Level III pediatric units, were asked to complete a questionnaire in April 2007. This asked respondents to unit surveys.

Methods
Although new trials are increasingly being registered, especially those involving new medical products, there is no single repository of trials through which all trials conducted in the UK over specified time periods and particular specialties can be identified. The BRACELET Study therefore required two linked surveys to achieve its objectives; the first survey involved neonatal and pediatric units to identify trials conducted in the UK in 2002-2006; the second survey involved trials to collate data on deaths across trials and across their collaborating neonatal and pediatric units (Figure 1).

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Trials survey: The unit survey generated a list of trials which was supplemented by searches of specialized websites. Many of the trials were also identified through other sources such as the UK Dept Health National Research Register, PubMed, PICS...
Trials were eligible for the survey if: allocation was randomized; enrollment took place during the five year study period; parental informed consent was required; and the intervention was delivered to babies or children within ICUs or delivered by, or under the auspices of, a neonatologist or pediatric intensivist leading to ICU admission for ongoing care, or the intervention was delivered to parents but designed to affect outcomes for babies or children.

For each eligible trial, the chief investigator, trial manager or other appropriate contact was asked to complete an e-mailed questionnaire. Questionnaires were also made available on the BRACELET website and were followed up by telephone, direct contact and the assistance of MRCN, if necessary. The information received was supplemented by data from published papers, relevant websites and personal communication. Three types of data were generated, for the five year study period only: general data about trials (outcome measures, participating units, numbers enrolled); overall mortality data (UK mortality per trial before discharge from hospital) and unit-specific mortality data (deaths per unit per trial before discharge from hospital). Chief investigators, trial managers or other appropriate contacts were also asked to provide copies of the trial protocol and parent information leaflets for their trial.

Analysis: Descriptive data are presented as proportions and ranges, as appropriate. Analysis used the statistical package Stata 10 (StataCorp, College Station, TX, US). Variations in the denominators for some of the numbers reported in the results reflect different response rates for the unit survey and the trials survey, and incomplete release of mortality data by some units and some trials.

Response rates: Questionnaires were sent to 220 neonatal units; 191 (86.8%) responded, of which 149 were eligible units (82 providing Level 2 care and 67 Level 3). Questionnaires were also completed by 28 (87.5%) of the 32 Level II pediatric units surveyed.

Trials survey: The unit survey and associated searches identified 50 trials (36 neonatal and 14 pediatric trials). Some general data were obtained for 43 trials (32 neonatal, 11 pediatric). Overall UK mortality data were released for 37 trials (28 neonatal, 9 pediatric). Unit-specific mortality data were released for 33 trials (24 neonatal, 9 pediatric) for those ICUs which had permitted release of their data to the study in the unit survey.

Survey findings: The unit survey indicated that overall half of the ICUs enrolled one or more participants in one or more trials during the five year study period (76/149 neonatal units, 14/28 pediatric units) (Table 1).

A minority of the responding Level 2 neonatal units (N=27, 32.9%) and the majority of the responding Level 3 neonatal units contributed to a trial (N=49 (73.1%). Nine (13.4%) of the Level 3 neonatal units ran their own single centre trials but none of the Level 2 neonatal units did so. Five of the 14 responding pediatric units (17.9%) ran single center trials.

General data: Of the 76 neonatal units which enrolled to a trial, 72 provided details of the number of babies enrolled. A total of 3117 babies were enrolled by these neonatal units into the 29 neonatal trials for which some enrolment data for the five year study period were available. The number of babies enrolled per neonatal unit ranged 1-236 (median [IQR] 21.5 [8, 39.8]). An additional 20 babies were recruited into two multicenter neonatal trials by two pediatric units, bringing the total enrolled in neonatal trials to 3137 babies. Of these 480 (15.3%) were recruited into single centre trials and 2657 (84.7%) into multicenter trials (UK and international) (Table 2).

Of the 14 pediatric units that enrolled into a pediatric trial, 11...
provided details of the number enrolled. A total of 210 children were enrolled by these pediatric units into 9 pediatric trials for which some enrolment data for the five year study period were available. The number of children enrolled per pediatric unit into pediatric trials ranged 1-53 (median [IQR] 7; 4 34). Of these 94 (44.8%) were enrolled into single center trials and 116 (55.2%) to multicentre trials (all of which were international) (Table 2).

Overall mortality data: Overall mortality data were available for 28 neonatal and 9 pediatric trials (Table 3). In total, 534/3288 (16.2%) children died following enrolment in these 37 trials. The 28 neonatal trials enrolled 3,088 babies, of whom 522 (16.9%) died. The number of deaths per neonatal trial ranged 0-278 (median [IQR] 2; 1 14.5) (Figure 2). Of the 28 neonatal trials, 24 had at least one death. The highest mortality rate amongst these trials was 29% (80 deaths). Most reported small numbers of deaths (only 8 trials reported >10). The majority of deaths, 429/522 (82.2%), occurred in four trials, three of which were multicenter (N=278 + 80 + 43 and one single center (N=28). Single center trials reported fewer deaths and a lower death rate (47/480 9.8%) than multicenter trials (475/2608 18.2%). In the nine pediatric trials for which mortality data were available, 12 (6.0%) out of 200 children died following enrolment into a trial. Six of the 9 trials had a least one death with the number of deaths ranging 0-4. Very few deaths occurred in single center pediatric trials (294 2.1%) compared to those in the neonatal single center trials (47/480 9.8%) and the pediatric multicenter trials 10/106 (9.4%).

Unit-specific mortality data: Data on 434 deaths were released by 24 neonatal trials for 72 neonatal units with the permission of the neonatal units in question. The number of deaths per neonatal unit ranged 0-37 (median [IQR] 3.5; 0 3.8) (Figure 3). Whilst 54 neonatal units saw at least one death, more than half (42/72 58.3%) saw fewer than five deaths over this five year period (Table 4). Five Level 3 neonatal units had larger numbers (N=37, 29, 26, 22 and 20) and 30.9% of all deaths recorded by the units occurred in these five neonatal units. In around half of the units, the proportion of children who died following trial enrolment was 20% or more (Table 5). Nine pediatric trials released unit specific mortality data for 14 pediatric units. The number of deaths per pediatric unit ranged 0-7 (median [IQR] 0.5; 0 1.8), with 6 pediatric units witnessing at least one death (Table 4). In all these units, the proportion of children who died following trial enrolment was under 20% (Table 5).

Trials survey—Practices in relation to bereavement care: Of the 50 RCTs, investigators for just over half (n=27) provided a copy of the full trial protocol. None of the protocols documented a policy relating to the care of parents bereaved following enrolment of their child into the RCT. Parent information leaflets were provided for 29 of the 50 trials. Two NIC trials (one multicenter and one UK-led international trial) provided a leaflet specifically for bereaved parents, expressing condolences, thanking them for their contribution and offering information about the trial. Details of support organizations were also given in the leaflets.

In one single-center NIC trial the investigator reported a different approach. Three deaths occurred following enrollment into this trial and the investigator sent a personalized letter to each set of parents to thank them for allowing their child to participate and to offer contact should they wish to discuss the trial or the continued use for their child’s data in the trial.

Discussion

The BRACELET Study is the first to investigate randomized controlled trial activity in UK neonatal units and pediatric units, to report the numbers of babies and children enrolled into trials, and to determine the extent and distribution of mortality involved. An important strength of this study is the high response rates achieved. Several evidence-based strategies were used to maximise responses. We are confident that all units were identified, and the comprehensive process of searching relevant research databases and websites as well as surveying these units is likely to have identified most of the trials recruiting in the UK. The establishment of mandatory trial registration will facilitate this process for future studies. There are, however, clear limitations to the study which relate to its narrow focus on mortality figures; in this regard the data raise rather than answer questions about bereavement in this context.

The study shows that in a five year period, over 3,000 babies and children were enrolled into pediatric and neonatal intensive care trials and 16% died, predominantly in the neonatal context. With over 500 deaths reported we suggest that a substantial number of bereaved parents, clinicians and trialists have encountered deaths among trial participants. We would also suggest that this is an underestimate as the BRACELET study focused only on deaths up to discharge from hospital; post-discharge deaths were not included. Other adverse outcomes for parents and families, such as disability and loss of quality of life in surviving babies are also important but were beyond the remit of the study.

As further trials are initiated and accrue more participants, the population of parents bereaved after agreeing to enroll their
child in a trial will accumulate; it is already sufficiently sizeable to warrant attention, but whether and how to respond to this population are complex questions. Provision for bereavement is often made within clinical centres but this body of parents, with potentially diverse experiences and needs, is largely scattered across a number of recruiting clinical centers; most deaths occurred as relatively isolated cases and the majority of centers witnessed small numbers of deaths per year. In the pediatric context where few deaths occurred, only one ICU reported more than one death. This is likely to make it difficult for many of the clinical centres to develop, assess and sustain specialized responses to post-trial bereavement themselves.

The patterns of mortality revealed by the BRACELET Study also suggest, however, that there were pockets of neonatal units and neonatal trials with substantial numbers of deaths. Five particularly research active Level 3 neonatal units saw 20 or more deaths each in the study period, and together they saw over a quarter of all reported deaths. In general, large ICUs draw upon well developed bereavement services, and research-active centers such as these may be appropriate candidates to develop and assess dedicated trial-related bereavement practices.

The vast majority of deaths represented in the BRACELET Study, also occurred in only four trials. In trials where a substantial number of deaths is anticipated, it may be possible to develop and assess trial-related bereavement practices.

What form those practices might take is unclear. They may range from development of formal practices and supporting literature to a more simple policy of offering parents the opportunity to discuss a trial if they so wish.

Parents have not yet been asked about any support and information needs that they might have. Their preferences are likely to be varied and may include the wish for no further contact. It is however possible that some options that parents might appreciate, for instance access to specialized forms of support, may be beyond the capacity and expertise of current routine bereavement services, even in the larger centres, and may be difficult for trial teams to implement.

The BRACELET Study showed that three trials had already developed a response to bereavement such as preparing a bereavement leaflet for use in clinical centers or sending condolence letters directly to parents (for an example leaflet see http://www.npeu.ox.ac.uk/downloads/nest/NEST-Bereavement-Leaflet.pdf). Personal communications have revealed that some trials offer bereaved parents the option of receiving trial newsletters and results; some make a considered choice not to contact bereaved parents at all subsequent to a death.

To our knowledge, none of these policies have been subject to empirical evaluation, although descriptive accounts such as Strohm’s report of a trial-related web-based message board for all parents of babies recruited to a trial, including those who are bereaved, are helpful additions to the literature. Further reflection would be of value to future trials where deaths are likely.

The BRACELET Study has demonstrated that bereavement occurs in relation to trials of any size and type and with a range of clinical foci. The four trials which reported the majority of deaths in the five year period assessed very different interventions, from routine care practices to potentially life-saving technologies. They involved very different populations and were conducted in single centre, multicenter and international contexts. This suggests that bereavement in a trial context may be an issue of broad relevance in specialties such as intensive care, and that it could be particularly appropriate for large trials, or trials focusing on high risk situations, to plan for and assess their approach to bereavement with substantial research populations.

Trials are complex, highly collaborative endeavors between recruiting clinical centers and trial teams, groups which may feel a shared interest in and responsibility for parents bereaved in trials. Their collaboration might be exploited to good effect if experts within these fields take collective responsibility for the potential needs of the population identified here. If those trials and clinical centres with the greatest experience of post-trial bereavement develop effective approaches to care for and support bereaved parents, other smaller trials and centers may draw upon their recommendations and follow their lead. Even in the pediatric context where deaths occurred infrequently, individual trials may still involve severely compromised populations and so find that post-trial bereavement care is a salient issue.

It is, however, important that recommendations in this novel area should from an early stage be based on sound empirical evidence which draws upon views of all relevant parties with their potentially different perspectives and insights. Clinical teams often recruit to a number of trials concurrently and see bereaved parents in a variety of circumstances; they may be best placed to consider the broad range of bereavement-related issues that might occur in clinical contexts. Trial teams by comparison consider parents in the relatively more uniform circumstances set by the eligibility criteria for their particular trial; they may be best placed to consider bereavement practices which are tailored to fit the population and circumstances of a given trial. Research in this area is sensitive but it is essential that bereaved parents should also be consulted. Studies have demonstrated that bereavement-related research is feasible, and suggest that bereaved parents might be willing and helpful participants on this challenging and sensitive subject.

The task ahead is for those with relevant insight and expertise, to collaborate to find a range of approaches which are sensitive to the variety of parents seen by clinicians and applicable and adaptable to the specific circumstances addressed in individual trials. As a first step in this process the BRACELET Study includes a second qualitative component which aims to explore death, dying and bereavement in the context of neonatal RCTs from the perspectives of trial team members, clinicians and bereaved parents.

References
lower; and the infant is described as uniformly enlivened and strengthened after the bath. The stomach, it is remarkable, has never once given way; and this must be solely attributed to the extreme care observed in regulating the proportions of nourishment, whether by the breast or by the spoon; and it has been remarked that the little creature seems uncommonly happy after her doses of wine and gruel. When lifted for necessary purposes, she does not fail to testify by her crying the sense she entertains of the annoyance.

Of the benefits to be derived, in such cases, from the judicious use of wine, there can be but little doubt; and, without wine, it seems almost certain the other nourishment would have been of little avail; and the same may be said of the proper regulation of the temperature—in this case hitherto exclusively artificial, except during the short periods when applied to the nurse’s breast. At present all looks well, but the mother being dead, and the family arrangements requiring, at no distant period, the removal of the infant to the abode of the wetnurse, half a mile distant, the change is not to be viewed without suspicion as to its effects.
Determinants of Survival in Very Low Birth Weight Neonates in a Public Sector Hospital in Johannesburg

Daynia E. Ballot, Tobias F. Chirwa, Peter A. Cooper

Abstract
Background: Audit of disease and mortality patterns provides essential information for health budgeting and planning, as well as a benchmark for comparison. Neonatal mortality accounts for about 1/3 of deaths <5 years of age and very low birth weight (VLBW) mortality for approximately 1/3 of neonatal mortality. Intervention programs must be based on reliable statistics applicable to the local setting; First World data cannot be used in a Third World setting. Many neonatal units participate in the Vermont Oxford Network (VON); limited resources prevent a significant number of large neonatal units from developing countries taking part, hence data from such units is lacking. The purpose of this study was to provide reliable, recent statistics relevant to a developing African country, useful for guiding neonatal interventions in that setting.

Methods: This was a retrospective chart review of 474 VLBW infants admitted within 24 hours of birth, between 1 July 2006 and 30 June 2007, to the neonatal unit of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in Johannesburg, South Africa. Binary outcome logistic regression on individual variables and multiple logistic regression was done to identify those factors determining survival.

Results: Overall survival was 70.5%. Survival of infants below 1001 grams birth weight was 34.9% compared to 85.8% for those between 1001 and 1500 grams at birth. The main determinant of survival was birth weight with an adjusted survival odds ratio of 23.44 (95% CI: 11.22-49.00) for babies weighing between 1001 and 1500 grams compared to those weighing below 1001 grams. Other predictors of survival were gender (OR 3.21; 95% CI 1.6-6.3), birth before arrival at the hospital (BBA) (OR 0.23; 95% CI: 0.08-0.69), necrotising enterocolitis (NEC) (OR 0.06; 95% CI: 0.02-0.20), hypotension (OR 0.05; 95% CI 0.01-0.21) and nasal continuous positive airways pressure (NCPAP) (OR 4.58; 95% CI 1.58-13.31).

Conclusions: Survival rates compare favorably with other developing countries, but can be improved; especially in infants <1001 grams birth weight. Resources need to be allocated to preventing the birth of VLBW babies outside hospital, early neonatal resuscitation, provision of NCPAP and prevention of NEC.

Background
The fourth Millennium Development Goal is to reduce the mortality of children under the age of 5 years by two thirds, before the year 2015. Neonatal mortality accounts for 37% of deaths below the age of 5 years and “improved neonatal and maternal care could save the lives of countless newborns.”

In the Perinatal Problem Identification Program (PPIP) [ppip.co.za], a self reporting data base that covers about 40% of births in South Africa, the early neonatal mortality rate has been static over the past few years at about 9.5 per 1000 live births. However, the majority of neonatal deaths remain unaudited and the national figure is thus probably higher. Very low birth weight (VLBW) infants represent a vulnerable group of newborns with a high mortality rate. There are many reports of factors affecting early survival of VLBW infants; these are summarized in Table 1. The survival rate of VLBW infants worldwide ranges between 40% in developing countries such as Jamaica to more than 90% in developed countries, such as the Netherlands, with an average of about 73% (See Table 1). The mortality rate for VLBW infants in Soweto, Johannesburg, between 2000 and 2002 was reported at 71%, which corresponds to developed countries in the mid 1980’s (see Table 1).

There has been steady improvement in the overall early survival of VLBW infants over time (see Table 1) e.g. from 50% in 1977 to 81% in 1995 in Texas and from 81% in 1986 to 90.3% in 1998 in New Zealand. Malaysia, a developing country, showed a similar improvement from 62% in 1993 to 81.6% in 2003. The degree of improvement, however, is less marked in more recent years—the NICHD showed almost no improvement in early VLBW survival between 1995/6 (84%) and 1997-2002 (85%).

Audit of neonatal care by participating in a database such as the Vermont Oxford network (VON) assists quality control provides a benchmark for comparison and opportunities for research and collaboration with other neonatal units. In developing countries with busy, under-resourced neonatal units, participation in the VON is difficult as it requires appropriate information systems and additional dedicated staff members. There is therefore a lack of current, valid statistics from such units, even though large

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Table 1: Survival of Very Low Birth Weight infants

<table>
<thead>
<tr>
<th>Location</th>
<th>Weight (Main inclusion criteria)</th>
<th>Time Period</th>
<th>Number of babies</th>
<th>Survival</th>
<th>Factors associated with survival of babies</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Texas</td>
<td>VLBW</td>
<td>1977-1995</td>
<td>50%</td>
<td>81%</td>
<td>Number of babies offered mechanical ventilation; Black females survival advantage</td>
<td>[3]</td>
</tr>
<tr>
<td>Israel</td>
<td>VLBW</td>
<td>1985-87</td>
<td>69</td>
<td>70%</td>
<td></td>
<td>[4]</td>
</tr>
<tr>
<td>Italy</td>
<td>VLBW ELBW</td>
<td>1987-1988</td>
<td>634</td>
<td>77%</td>
<td>Lower Birth weight or gestational age, Gender, No antenatal steroids, 1 minute Apgar, No spontaneous respiration in delivery room, body temperature/pH on admission</td>
<td>[5]</td>
</tr>
<tr>
<td>Taiwan</td>
<td>VLBW</td>
<td>1995-1998</td>
<td>162</td>
<td>78.4%</td>
<td></td>
<td>[8]</td>
</tr>
<tr>
<td>South America</td>
<td>VLBW</td>
<td>1997-1998</td>
<td>385 (11 neonatal units)</td>
<td>73% (49-89%)</td>
<td>Birth weight, gestational age, No antenatal steroids, air leaks</td>
<td>[9]</td>
</tr>
<tr>
<td>Sofia (Bulgaria)</td>
<td>VLBW ELBW</td>
<td>1998-1999</td>
<td>122</td>
<td>86%</td>
<td>Birth weight, gestational age, low Apgar scores, Cord Ph &lt; 7.1, Need for cardiac compressions/ adrenaline in delivery room</td>
<td>[10]</td>
</tr>
<tr>
<td>Thailand</td>
<td>VLBW ELBW</td>
<td>1996</td>
<td>613</td>
<td>76%</td>
<td>Gestational age, birth weight, delivery room resuscitation, Pneumothorax</td>
<td>[12]</td>
</tr>
<tr>
<td>East Anglia (England)</td>
<td>VLBW ELBW</td>
<td>1993-1997</td>
<td>1244</td>
<td>75-79%</td>
<td>Gestational age, Birth weight, No antenatal steroids</td>
<td>[13]</td>
</tr>
<tr>
<td>USA (NICHD)</td>
<td>VLBW</td>
<td>1995-1996</td>
<td>84%</td>
<td>85%</td>
<td></td>
<td>[14]</td>
</tr>
<tr>
<td>Turkey</td>
<td>VLBW</td>
<td>1997-2002</td>
<td>122</td>
<td>84%</td>
<td>Birth Weight</td>
<td>[15]</td>
</tr>
<tr>
<td>Spain</td>
<td>VLBW</td>
<td>2002-2005</td>
<td>8942</td>
<td>80.6%</td>
<td>Outborn, birthweight</td>
<td>[16]</td>
</tr>
<tr>
<td>India</td>
<td>VLBW</td>
<td>3 years (not stated)</td>
<td>260</td>
<td>63%</td>
<td>Birth weight, gestational age, maternal bleed, 1 minute Apgar, apnoea, neonatal septicemia, shock, hypothermia, no antenatal steroids</td>
<td>[17]</td>
</tr>
<tr>
<td>Brazil</td>
<td>VLBW</td>
<td>2004/5</td>
<td>579 (16 tertiary units)</td>
<td>84% (69-95%)</td>
<td>Gestational age, maternal hypertensive, 5 minute Apgar, respiratory distress, place of birth</td>
<td>[18]</td>
</tr>
<tr>
<td>Malaysia</td>
<td>VLBW</td>
<td>1993-2003</td>
<td>69</td>
<td>62.3%</td>
<td>Birth weight, gestational age, No antenatal steroids, Caesarean delivery, gender</td>
<td>[19]</td>
</tr>
<tr>
<td>Thailand</td>
<td>VLBW ELBW</td>
<td>2002/3</td>
<td>78</td>
<td>81%</td>
<td>Birth weight, gestational age, No antenatal steroids, 5 minute Apgar, intubation in delivery room, respiratory distress, syndrome</td>
<td>[20]</td>
</tr>
<tr>
<td>Jamaica</td>
<td>ELBW</td>
<td>2002/3</td>
<td>47</td>
<td>43%</td>
<td>Gestational age, birth weight, gender, No antenatal steroids, Caesarean delivery</td>
<td>[21]</td>
</tr>
<tr>
<td>South Africa</td>
<td>VLBW ELBW</td>
<td>2000-2002</td>
<td>2164</td>
<td>71%</td>
<td>Birth weight, 1 &amp; 5 minute Apgars, Caesarean delivery, antenatal care, gender</td>
<td>[22]</td>
</tr>
</tbody>
</table>

VLBW = Very low birth weight (< 1501 grams) ELBW = extremely low birth weight (< 1001 grams)

The purpose of this study was to review the survival to hospital discharge and morbidity of VLBW infants at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), a busy neonatal unit in a developing country.

**Methods**

This was a retrospective record review of all neonates with a birth weight <1501 grams admitted to the neonatal unit of CMJAH within 24 hours of birth from 1 July 2006 to 31 June 2007. All inborn neonates were admitted directly to a labour ward nursery, so statistics included inborn babies who died shortly after birth. VLBW babies who were delivered at outlying primary level hospitals or clinics and those who were born before arrival in hospital (BBA) were also admitted to the neonatal unit. Data was entered from hospital records onto a Microsoft Access (2003) database.

Maternal information obtained from the delivery records included age, parity, gravidity, antenatal care, administration of antenatal steroids, syphilis screening and treatment, human immunodeficiency virus (HIV) screening and prophylaxis, place of delivery, fetal presentation and mode of delivery. HIV screening followed a protocol of voluntary counseling and testing; mothers could refuse to be tested. Prophylaxis was only given to infants where mothers were proven to be HIV positive. Polymerase chain reaction (PCR) testing to confirm HIV infection in the neonate was only done from 6 weeks of chronological age. Neonatal intensive care unit (NICU) admission was not determined by HIV exposure.

The baby's weight, Apgar scores and details of delivery room resuscitation were also obtained from the delivery records. Gestational age was determined from a combination of maternal history (expected date of delivery, height of fundus, first trimester ultrasound) and the Ballard score, which was done by attending clinical staff. The birth weight was plotted on Fenton23 growth charts to determine whether the baby was appropriate for gestational age numbers of patients are treated annually.

It is essential to have this information to guide forward planning for therapeutic interventions, budgeting and staffing, with the aim of improving outcome. Local data relevant to a developing country is essential to facilitate this planning; it is not possible to transpose data from one area to another.
The cause of death was reviewed by the primary author (DEB) and classified according to the PPIP classification. The PPIP was established in 1989 in South Africa as a national tool for perinatal death audit. In order to have manageable data, the single most likely cause of death is listed. Major categories include prematurity, asphyxia, infection and congenital anomaly. Each category is further subdivided into sub-categories; prematurity is subdivided into extreme immaturity, HMD, IVH, NEC and pulmonary hemorrhage. No postmortem examinations were done on the study patients. Details of ICU admissions include indication for ventilation, dates and type of ventilatory support, (IPPV or NCPAP) and surfactant therapy. Babies who received both NCPAP and IPPV were classified as needing ventilator assistance for the purposes of analysis.

Babies were managed according to the unit policies at the time. Ventilatory support was offered to babies above 900 grams birth weight, due to severely limited tertiary resources. Babies were not routinely intubated or given NCPAP in the delivery room; ventilatory support (including NCPAP) was commenced when the infant showed signs of respiratory failure. All babies, irrespective of birth weight, were provided with standard neonatal care (nursed in an incubator, given supplemental oxygen, intravenous fluids, antibiotic therapy, blood transfusion, phototherapy as needed and KMC). Surfactant therapy was only given as rescue therapy to babies on ventilatory support, usually to those patients who did not wean rapidly from supplementary oxygen. A second dose of surfactant could be given if the baby had responded to the initial dose and then deteriorated again. NCPAP was introduced to the neonatal unit March 2006. During the period of the study, there was no rooming in facility, so mothers could only do KMC intermittently during the day. KMC was introduced once a baby was in room air and tolerating full enteral feeds. Cranial ultrasound was done during the first week of life by a paediatric neurologist and, if indicated, repeated after 1 to 2 weeks and just prior to discharge. Babies who died within the first 72 hours may not have undergone a cranial ultrasound. Screening for retinopathy of prematurity was done by an ophthalmologist at 36 weeks post conceptional age. If babies were discharged prior to this age, an outpatient appointment was booked for the ophthalmology clinic. Babies were discharged home once they had established enteral feeds, were off supplemental oxygen, maintaining temperature and had achieved a weight of 1600 grams. Some babies were discharged to regional step down facilities for weight gain, close to the time of discharge home.

Statistical analysis: Statistical analysis was done on a personal computer using SPSS version 17 (SPSS Inc). Continuous variables were summarised using mean and 95% confidence intervals, while categorical variables were summarised as ratios and percentages. For the purposes of analysis, babies transferred out and those discharged home directly were combined as “survivors” and compared to those babies that died during their

Table 2: PPIP classification of mortality

<table>
<thead>
<tr>
<th>Cause of death</th>
<th>Cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extreme multisorgan immaturity</td>
<td>56</td>
<td>40</td>
</tr>
<tr>
<td>HMD</td>
<td>22</td>
<td>15.7</td>
</tr>
<tr>
<td>Asphyxia</td>
<td>17</td>
<td>12.1</td>
</tr>
<tr>
<td>NEC</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Nosocomial sepsis</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Septicaemia</td>
<td>3</td>
<td>2.1</td>
</tr>
<tr>
<td>Congenital infection</td>
<td>2</td>
<td>1.4</td>
</tr>
<tr>
<td>IVH</td>
<td>3</td>
<td>2.1</td>
</tr>
<tr>
<td>Congenital abnormality</td>
<td>4</td>
<td>2.8</td>
</tr>
<tr>
<td>Pulmonary Haemorrhage</td>
<td>2</td>
<td>1.4</td>
</tr>
<tr>
<td>Unspecified</td>
<td>3</td>
<td>2.1</td>
</tr>
</tbody>
</table>
hospital admission. Cross-tabulations of categorical variables with survival were produced and statistical associations between these categorical variables and survival outcome were done using the Chi-Square test of association. Normally distributed continuous variables were compared using the unpaired t test and the Mann-Whitney U test was used to compare discrete variables and those continuous variables that were not normally distributed. Binary outcome logistic regression was done on individual variables to predict survival. Those variables which were significant at the univariate analysis were entered into a multiple logistic regression using the backward selection procedure. All the statistical tests were conducted at 5% significance level.

### Results

Among the four hundred and eighty eight eligible VLBW babies who were admitted during the study period, 474 records (97.1%) of VLBW babies born to 448 mothers were retrieved and available for review. The overall survival was 334/474 (70.5%). The mean birth weight was 1133.5 grams (95% CI 1111.9-1155.0), mean gestational age was 29.9 weeks (95% CI 29.6-30.1) and mean duration of hospitalization was 25.8 days (95% CI 23.8-27.8). The mean age at time of death was 5.77 days (95% CI 3.66-7.88) and of discharge/transfer was 34.23 days (95% CI 32.13-36.32). The mean duration of supplemental oxygen was 8.2 days (95% CI 6.8-9.7) and mean duration of mechanical ventilation was 8.08 days (95% CI 6.15-10.01).

### Table 3: Obstetric related risk factors and prediction of mortality

<table>
<thead>
<tr>
<th>Variable (Valid cases)</th>
<th>Category total</th>
<th>Survived (%)</th>
<th>Died (%)</th>
<th>P value</th>
<th>Odds ratio 95% CI of OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>SGA (461)</td>
<td>Yes 178</td>
<td>143 (80)</td>
<td>35 (20)</td>
<td>0.001</td>
<td>2.07 1.32 - 3.22</td>
</tr>
<tr>
<td></td>
<td>No 283</td>
<td>188 (66)</td>
<td>95 (34)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender (470)</td>
<td>Female 251</td>
<td>192 (76.5)</td>
<td>59 (23.5)</td>
<td>0.004</td>
<td>1.8 1.24 - 2.69</td>
</tr>
<tr>
<td></td>
<td>Male 219</td>
<td>141 (64.4)</td>
<td>78 (35.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antenatal care (474)</td>
<td>Yes 256</td>
<td>197 (77)</td>
<td>59 (23)</td>
<td>0.001</td>
<td>1.97 1.32 - 2.95</td>
</tr>
<tr>
<td></td>
<td>No 218</td>
<td>137 (63)</td>
<td>81 (37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antenatal corticosteroids (474)</td>
<td>No 218</td>
<td>137 (63)</td>
<td>81 (37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV exposed (328)</td>
<td>Not given 301</td>
<td>203 (67.4)</td>
<td>98 (32.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes 120</td>
<td>84 (70)</td>
<td>36 (30)</td>
<td>0.057</td>
<td>0.61 0.36 - 1.02</td>
</tr>
<tr>
<td>Syphilis Exposed (474)</td>
<td>No 208</td>
<td>165 (80)</td>
<td>43 (21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes 12</td>
<td>7 (58.4)</td>
<td>5 (42)</td>
<td>0.351</td>
<td>0.58 0.18 - 1.85</td>
</tr>
<tr>
<td>Place of birth (470)</td>
<td>Inborn 383</td>
<td>286 (74.7)</td>
<td>97 (25.3)</td>
<td>&lt; 0.001</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>BBA 51</td>
<td>20 (39)</td>
<td>31 (61)</td>
<td>0.22</td>
<td>0.12 - 0.40</td>
</tr>
<tr>
<td></td>
<td>Out born 36</td>
<td>24 (66)</td>
<td>12 (33)</td>
<td>0.68</td>
<td>0.33 - 1.41</td>
</tr>
<tr>
<td>Mode of delivery (464)</td>
<td>NVD 197</td>
<td>123 (62.4)</td>
<td>74 (37.6)</td>
<td>&lt; 0.001</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Vaginal Breech</td>
<td>25 (32)</td>
<td>12 (48)</td>
<td>0.65</td>
<td>0.28 - 1.50</td>
</tr>
<tr>
<td></td>
<td>Elective CS</td>
<td>12 (9)</td>
<td>3 (25)</td>
<td>1.80</td>
<td>0.47 - 6.88</td>
</tr>
<tr>
<td></td>
<td>Emergency CS</td>
<td>229 (182.79.5)</td>
<td>47 (20.5)</td>
<td>2.33</td>
<td>1.51 - 3.59</td>
</tr>
<tr>
<td>Presentation (448)</td>
<td>Vertex 401</td>
<td>290 (72.3)</td>
<td>111 (27.7)</td>
<td>0.541</td>
<td>0.82 0.43 - 1.57</td>
</tr>
<tr>
<td></td>
<td>Breech 47</td>
<td>32 (68.11)</td>
<td>15 (31.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resuscitation at birth (474)</td>
<td>Yes 154</td>
<td>91 (59.1)</td>
<td>63 (40.9)</td>
<td>&lt; 0.001</td>
<td>0.46 0.30 - 0.69</td>
</tr>
<tr>
<td></td>
<td>No 320</td>
<td>243 (75.9)</td>
<td>77 (24.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypothermia at birth (474)</td>
<td>Yes 13</td>
<td>5 (38.5)</td>
<td>8 (61.5)</td>
<td>0.01</td>
<td>0.25 0.08 - 0.78</td>
</tr>
<tr>
<td></td>
<td>No 461</td>
<td>329 (71.4)</td>
<td>132 (28.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 minute APGAR Score (409)</td>
<td>Score &gt;= 6</td>
<td>304</td>
<td>231 (76)</td>
<td>73 (24)</td>
<td>0.093 1.52 0.93 - 2.46</td>
</tr>
<tr>
<td></td>
<td>Score &lt; 6</td>
<td>105 (67.6)</td>
<td>71 (32.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Valid cases = those with no missing data, thus, a complete case analysis
Percentages are reported for rows
Birth weight and gestational age: The mean birth weight of survivors (1213 grams; 95% CI: 1192.5-1234.1) was significantly greater (p<0.001) than that for babies that died (942.5 grams; 95% CI: 904.5-980.5). The mean gestation period for survivors (30.7 weeks, 95% CI: 30.4-31.0) was significantly more advanced than that of those who died (27.6 weeks, 95% CI: 27.2-28.1). The median 5 minute Apgar score of those babies that survived, 8 (IQR: 1-9) was significantly higher than the non-survivors, 6 (IQR: 1-10) with p=0.005. Mortality by birth weight category is shown in figure 1. As survival seem to increase with birth weight, an association between a quadratic term was fitted which also showed significant association (p=0.010) with survival. Survival was closely related to birth weight category, ranging from zero below 601 grams to 62% (32/52) from 901 to 1000 grams and 93% (317/331) from 1301 to 1500 grams. The survival of extremely low birth weight infants (<1001 grams) was 34.9% (50/143) compared to 85.8% (284/331) for babies with a birth weight from 1001 to 1500 grams. The adjusted survival odds ratio was 23.44 (95% CI: 11.22-49.00) for babies weighing from 1001 to 1500 grams compared to those weighing below 1001 grams. The main cause of death according to the PIPP classification is shown in Table 2. The single most common cause of death was extreme multi-organ immaturity, in 40% of cases, followed by HMD in 15% of cases.

Maternal and delivery period: The mean maternal age was 26.5 years (95% CI: 25.8-27.1) and 37.3% (152/407) were primiparous. Risk factors for mortality related to antenatal care, labour and delivery are presented in Table 3. Emergency Caesarean section (CS) was done for fetal distress in 63/229 (27.5%) of cases. Where emergency CS was done for maternal indications, the most common reasons were pregnancy induced hypertension 45.6% (63/138) followed by antepartum hemorrhage in 13% (18/138). No CS was done for HIV infection alone. Odds ratios with 95% confidence intervals are presented for each risk factor. Significant predictors of survival on univariate analysis were weight for gestational age, gender, antenatal care, place of delivery, mode of delivery, the need for delivery room resuscitation and hypothermia at birth. Maternal HIV exposure, maternal infection with syphilis, the administration of antenatal interventions such as ensuring preterm infants are delivered in hospital, improved neonatal resuscitation and provision of NCPAP. A provincial neonatal resuscitation programme has recently been introduced to improve the resuscitation skill of birth attendants. Patient education as to when to seek help during labour and improved emergency transport will be required to prevent preterm infant BBA. Although provision of antenatal steroids did not achieve statistical significance in this study, the number of women receiving antenatal steroids is unacceptably low (36%). This is a specific obstetric intervention that needs to be addressed and will improve neonatal outcome. Delivery by CS was advantageous, but may reflect those patients who have received antenatal care, including antenatal steroids and who delivered in hospital. It is not feasible to do elective CS on all preterm deliveries in our resource constrained setting.

### Table 4: Risk factors for mortality related to disease/treatment in the neonatal period

<table>
<thead>
<tr>
<th>Risk factor (Valid cases)</th>
<th>Total</th>
<th>Survived (%)</th>
<th>Died (%)</th>
<th>P Value</th>
<th>Odds ratio</th>
<th>95% CI of Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>HMD (437)</td>
<td>Yes</td>
<td>299</td>
<td>190 (63.5)</td>
<td>109 (36.5)</td>
<td>&lt; 0.001</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>138</td>
<td>116 (84.1)</td>
<td>22 (15.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical ventilation (474)</td>
<td>Yes</td>
<td>99</td>
<td>71 (71.7)</td>
<td>28 (28.3)</td>
<td>0.76</td>
<td>1.08</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>375</td>
<td>263 (70.1)</td>
<td>112 (29.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal CPAP (474)</td>
<td>Yes</td>
<td>96</td>
<td>80 (83.3)</td>
<td>16 (16.7)</td>
<td>0.002</td>
<td>2.44</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>378</td>
<td>254 (67.2)</td>
<td>124 (32.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surfactant therapy (474)</td>
<td>Yes</td>
<td>90</td>
<td>73 (81)</td>
<td>17 (19)</td>
<td>0.014</td>
<td>2.02</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>384</td>
<td>261 (68)</td>
<td>123 (32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sepsis (445)</td>
<td>Yes</td>
<td>62</td>
<td>40 (64.5)</td>
<td>22 (35.5)</td>
<td>0.085</td>
<td>0.61</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>383</td>
<td>287 (74.9)</td>
<td>96 (25.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gram Negative (474)</td>
<td>Yes</td>
<td>37</td>
<td>21 (56.8)</td>
<td>16 (43.2)</td>
<td>0.057</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>437</td>
<td>313 (71.6)</td>
<td>124 (28.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gram Positive (474)</td>
<td>Yes</td>
<td>28</td>
<td>23 (82.1)</td>
<td>5 (17.9)</td>
<td>0.163</td>
<td>1.99</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>446</td>
<td>311 (69.7)</td>
<td>135 (30.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDA (474)</td>
<td>Yes</td>
<td>26</td>
<td>18 (69)</td>
<td>8 (31)</td>
<td>0.887</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>448</td>
<td>316 (71)</td>
<td>132 (29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypotension (474)</td>
<td>Yes</td>
<td>23</td>
<td>7 (30)</td>
<td>16 (70)</td>
<td>&lt; 0.001</td>
<td>0.166</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>451</td>
<td>327 (73)</td>
<td>124 (27)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEC grade 2/3 (474)</td>
<td>Yes</td>
<td>26</td>
<td>9 (35)</td>
<td>17 (65)</td>
<td>&lt; 0.001</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>448</td>
<td>325 (73)</td>
<td>123 (27)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVH (328)</td>
<td>No</td>
<td>253</td>
<td>209 (83)</td>
<td>44 (17)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gr 1</td>
<td>11</td>
<td>8 (72.7)</td>
<td>3 (27.3)</td>
<td>0.56</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>Gr 2</td>
<td>40</td>
<td>25 (62.5)</td>
<td>15 (37.5)</td>
<td>0.35</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>Gr 3</td>
<td>16</td>
<td>12 (75)</td>
<td>4 (25)</td>
<td>0.63</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>Gr 4</td>
<td>4</td>
<td>1 (25)</td>
<td>3 (75)</td>
<td>0.07</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>PVL</td>
<td>4</td>
<td>2 (50)</td>
<td>2 (50)</td>
<td>0.21</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Note: Valid cases = those with no missing data
Percentages are reported for rows
steroids and the presenting part at delivery did not predict survival. Only 69% of mothers had known HIV status and 36.5% of mothers had received antenatal steroids.

Neonatal period: Air leak was recorded in 3 patients (0.6%) and high frequency ventilation was used in 3 patients (0.6%). These variables were not included in the analysis due to small numbers. Bronchopulmonary dysplasia (BPD) (defined as oxygen requirement >28 days) was present in 42 (8.8%) of babies. Nevirapine prophylaxis was given to 97/120 (80.8%) of the HIV exposed infants; 25/354 (7%) of mothers offered HIV testing refused consent. 11/474 (2.3%) of the babies were put up for adoption. Only 87 (18.3%) of the babies were screened for ROP prior to discharge. Only two babies had ROP, both of which were stage 1. KMC was done by 211/474 (44.5%) of mothers.

Odds ratios and 95% confidence intervals for each risk factor related to the neonatal period (both disease and treatment) are shown in Table 4. HMD, NCPAP, surfactant therapy, hypotension, NEC and IVH were all predictive of survival. The need for mechanical ventilation, PDA and the presence of sepsis did not predict survival.

Multivariate analysis: Multivariate logistic regression is shown in Table 5 for complete cases, ie a complete case analysis with the entered variables defining a complete case. Variables entered into the model included birth weight, SGA, gender, antenatal care, place of birth, mode of delivery, NEC grade 2/3, hypotension, HMD, resuscitation at birth, hypothermia, surfactant therapy and NCPAP. Gestational age was not included in the model as it is highly correlated with birth weight (correlation coefficient 0.717 p<0.001) and birth weight is more accurate in our setting than estimation of gestational age. IVH was not included due to the large number of missing variables. The final model showed that birth weight, gender, resuscitation at birth, BBA, hypotension, definite NEC and provision of NCPAP were significant predictors of mortality in this population. The model predicted mortality correctly in 87% of cases. Birth weight was the single most important predictor of mortality, correctly predicting mortality in 82.9% of cases. The odds ratio for death for birth weight ≤1001 grams was 10.41 (95% CI 6.62 to 16.6) and for gestational age <28 weeks was 11.97 (95% CI 7.1 to 20.1).

Discussion

This retrospective review provides current survival rates and indicates where resources should be channeled in order to improve survival of VLBW infants in South Africa. The overall survival rate was 70.5% for VLBW infants at CMJAH 2006/2007. This is almost exactly the same as that reported from CH Baragwanath for 2000-2002 (71%), which reflects the similarity in practice and disease profile between the two units, which form part of a single academic complex. This survival rate also compares favorably with the global average of 73% (see Table 1), but is substantially below that of developed countries.

The survival of ELBW infants in the present review of 35% was less than that in other developing countries, such as Jamaica and Thailand but once again very similar to that of CH Baragwanath (32%). The most significant cause of death in this study was extremely low birth weight/extreme multi-organ immaturity. This is in close agreement with national data for South Africa from the same time period—46% of all neonatal deaths were immaturity related, of which 44.9% were due to extreme immaturity and 35.6% due to HMD.

The main determinants of survival in the present study, birth weight, gender, being born before arrival in the hospital, resuscitation at birth, NEC, hypotension and NCPAP, are not surprising and very similar to other reports on VLBW outcome. However, the study shows that, despite great improvements in neonatal care, the VLBW survival in South Africa is below that in other developing countries and can improve.
substantially. This can be achieved by simple interventions such as ensuring preterm infants are delivered in hospital, improved neonatal resuscitation and provision of NCPAP. A provincial neonatal resuscitation program has recently been introduced to improve the resuscitation skill of birth attendants. Patient education as to when to seek help during labor and improved emergency transport will be required to prevent preterm infant BBA. Although provision of antenatal steroids did not achieve statistical significance in this study, the number of women receiving antenatal steroids is unacceptably low (36%). This is a specific obstetric intervention that needs to be addressed and will improve neonatal outcome. Delivery by CS was advantageous, but may reflect those patients who have received antenatal care, including antenatal steroids and who delivered in hospital. It is not feasible to do elective CS on all preterm deliveries in our resource constrained setting.

South Africa is a developing country with limited health resources and high patient numbers; it is not possible to provide full tertiary support to every VLBW infant. For many years this problem has been addressed by limiting ventilatory support, including the administration of surfactant and NCPAP, to those neonates above a specified birth weight cutoff. Prior to the widespread use of NCPAP, this cutoff was 1000 grams. The ventilation cutoff was reduced to 900 grams just before the study period, with the introduction of NCPAP to the unit. The poor survival or our ELBW infants is undoubtedly influenced by this policy and NCPAP with surfactant should be provided to babies from 750 grams in order to bring our ELBW survival rate up to that in other developing countries.12,20,21

NEC and hypotension were the other significant predictors of mortality. The overall rate of NEC was 5.5%, which accounted for 10% of the deaths. Interestingly the rate of NEC was comparable to that in the VON in 2005, which represents well resourced settings. Prevention of NEC should also be a priority, including promotion of breastfeeding. Our rate of breastfeeding at the time of the study was extremely low, mainly due to the HIV epidemic. Only 69% of mothers were tested for HIV, but 36% were positive. The protocol during the study period was to formula feed HIV exposed babies. Of concern, is the high rate of untested mothers, the relatively high rate of refusal to be tested and failure to administer HIV prophylaxis in 16.4% of exposed mothers; this may reflect the mothers who were diagnosed after the early neonatal period. Ensuring that all mothers are counseled and tested for HIV is essential to prevent mother to child transmission and, in turn, facilitate the promotion of breastfeeding and reduction of NEC. Although 36% of screened mothers were HIV positive, HIV status did not predict neonatal outcome. This is in agreement with a study from Durban27 which found that HIV exposed babies were not different from HIV unexposed neonates with regard to birth weight, gestational age, need for ICU admission, complications of ventilation, sepsis, IVH or death. Furthermore, most HIV exposed neonates are subsequently uninfected. HIV exposure is not a major determinant of neonatal survival and is not used as a criterion for ICU admission.

CMJAH represents a high risk obstetric population with many referrals for obstetric complications, the most frequent of which is pregnancy induced hypertension. Improved management of this obstetric complication may reduce the number of VLBW infants. There are also significant social problems with 2.6% of the babies delivered as a result of illegal termination of pregnancy and 2.3% being given up for adoption. The whole issue of preventing unwanted pregnancy is also pertinent in our population.

The low rate of in hospital screening for ROP is also an area of concern and needs to be improved. A significant number of babies are referred to the ophthalmologist at the time of their first follow up visit for ROP screening, but this may be too late in terms of adequate intervention.

Conclusion

Although the overall survival of VLBW infants in our unit compares with the global average (see Table 1), the survival of our ELBW infants can be significantly improved. NCPAP and surfactant should be provided to ELBW infants >750 grams birth weight. Prevention of VLBW deliveries outside the hospital, improved administration of antenatal steroids, universal screening for HIV, improved neonatal resuscitation and strategies to prevent NEC, will also improve the VLBW survival rate.

References


The HFNC was then increased to 8 L/min a few hours later. The peak Edi was below the 25 microvolt level (average 24 microvolts) at 8 L/min of HFNC. The patient physically appeared to exhibit less use of accessory muscles and had fewer intercostal and sternal retractions.

Monitoring the electrical activity of the diaphragm following mechanical ventilation and extubation helped avert re-intubation in this infant. He appeared to be resting comfortably on 8 L/min of HFNC and vital signs were stable.

The Edi catheter was valuable in monitoring the infant's drive to breath.

Tom Noblet commented, “Use of the Edi to evaluate post-extubation therapy helped determine optimum settings for this infant. This resulted in reduced work of breathing and helped avoid re-intubation and re-institution of ventilation of this infant, with their accompanying potential complications such as ventilator-associated pneumonia.”

References


Cesarean Section Rate...continued from page 32

change their lifestyle, must receive a good prenatal care, which is available to all, must attend natural childbirth classes, and in this way they will have a very positive decision in delivering their babies vaginally. If they have doubts they should question their obstetrician, although they may not have time to get a second opinion, but they should demand natural childbirth as much as possible. Women are the ones who can make a major decision in bringing down the CS rate in this country by taking control of their fetal health by delivering in a family-centered child-birthing institution, and definitely not at home. CS for known maternal complications will still continue to be a life saving option for those where such risk factors are identified.

[Editorial comment by Les Plesko: While there's no question that cesareans are on the rise, I wonder, re the authors' comments, how much of the onus can really be placed on mothers, as per the concluding comments. Most moms get advice from their obstetricians, who often recommend CS, for whatever reason. The medico-legal complex has a vested interest in pushing c-sections. The edifice of healthcare provision has become daunting, increasingly complex, and confusing for many moms-to-be. While moms obviously want the best possible birth experience, they are of course reliant on their caregivers in such a coercive environment. Also, the claim that prenatal care is available to all is spurious. It is not. Finally, I would add that insurance companies play a major role in the increase in C-sections, with some providers denying vaginal birth coverage for moms who have had a previous CS.]
Analysis of Preterm Deliveries Below 35 Weeks’ Gestation

Wei Yuan, Anne M. Duffner, Lina Chen, Linda P. Hunt, Susan M. Sellers, Andrés López Bernal

**Background:** Preterm birth remains a major public health problem and its incidence worldwide is increasing. Epidemiological risk factors have been investigated in the past, but there is a need for a better understanding of the causes of preterm birth in well-defined obstetric populations in tertiary referral centres; it is important to repeat surveillance and identify possible changes in clinical and socioeconomic factors associated with preterm delivery. The aim of this study was to identify current risk factors associated with preterm delivery and highlight areas for further research.

**Findings:** We studied women with singleton deliveries at St Michael’s Hospital, Bristol during 2002 and 2003. Two hundred seventy-four deliveries between 23-35 weeks’ gestation (preterm group), were compared to 559 randomly selected control deliveries at term (37-42 weeks) using standard statistical procedures. Both groups were >80% Caucasian. Previous preterm deliveries, high maternal age (>39 years), socioeconomic problems, smoking during pregnancy, hypertension, psychiatric disorders and uterine abnormalities were significantly associated with preterm deliveries. Both lean and obese mothers were more common in the preterm group. Women with depression/psychiatric disease were significantly more likely to have social problems, to have smoked during pregnancy and to have had previous preterm deliveries; when adjustments for these three factors were made the relationship between psychiatric disease and pregnancy outcome was no longer significant. 53% of preterm deliveries were spontaneous, and were strongly associated with episodes of threatened preterm labor. Medically indicated preterm deliveries were associated with hypertension and fetal growth restriction. Preterm premature rupture of the membranes, vaginal bleeding, anaemia and oligohydramnios were significantly increased in both spontaneous and indicated preterm deliveries compared to term controls.

**Conclusions:** More than 50% of preterm births are potentially preventable, but remain associated with risk factors such as increased uterine contractility, preterm premature rupture of the membranes and uterine bleeding whose aetiology is unknown. Despite remarkable advances in perinatal care, preterm birth continues to cause neonatal deaths and long-term morbidity. Significant breakthroughs in the management of preterm birth are likely to come from research into the mechanisms of human parturition and the pathophysiology of preterm labor using multidisciplinary clinical and laboratory approaches.

**Methods**
Study population: This survey was done at St Michael’s Hospital, Bristol. This is a tertiary referral maternity center with approximately 5,500 deliveries a year; preterm deliveries (under 37 weeks’ gestation) accounted for approximately 8% of all births during 2002 and 2003. In this survey we have focused on deliveries between 23-35 weeks’ gestation (3% of all births) because these account for most of the perinatal mortality and
Table 1: General characteristics of the study groups.

<table>
<thead>
<tr>
<th></th>
<th>Control (≥ 37 weeks’ gestation)</th>
<th>Preterm (&lt;35 weeks’ gestation)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of deliveries</td>
<td>559</td>
<td>274</td>
<td></td>
</tr>
<tr>
<td>Gestational age at delivery (completed weeks)</td>
<td>Median 40 (Range 37 - 42)</td>
<td>Median 33 (Range 23 - 34)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>464 (83.0%)</td>
<td>229 (83.6%)</td>
<td>0.46</td>
</tr>
<tr>
<td>Asian</td>
<td>45 (8.1%)</td>
<td>17 (6.2%)</td>
<td></td>
</tr>
<tr>
<td>African</td>
<td>33 (5.9%)</td>
<td>22 (8.0%)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>17 (3.0%)</td>
<td>6 (2.2%)</td>
<td></td>
</tr>
<tr>
<td>Mean maternal age (years)</td>
<td>28.8 (SD 6.04) (Range 15-44)</td>
<td>29.7 (SD 6.46) (Range 16-46)</td>
<td>0.045</td>
</tr>
<tr>
<td><strong>Distribution of births</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singletons</td>
<td>553 (98.9%)</td>
<td>228 (83.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Twins</td>
<td>6 (1.1%)</td>
<td>44 (16.1%)</td>
<td></td>
</tr>
<tr>
<td>Triplets</td>
<td>0</td>
<td>2 (0.7%)</td>
<td></td>
</tr>
</tbody>
</table>

morbidity and so improvements in management are likely to have a strong impact on neonatal outcome. We obtained lists of all deliveries below 35 weeks gestation from the hospital database for two complete years 2002 and 2003 (n=274). We used computer generated random numbers to draw separate samples from lists of all term babies delivered within each of the 2 years, using term; preterm ratios of 2:1 to increase power; 559 out of 8,204 term babies were included. Gestational age was based either on certain dates or a dating scan. Antenatal care was undertaken by an obstetrician or community midwife or a combination of the two professionals and followed standard UK practice.

This study was approved by the Central & South Bristol Research Ethics Committee.

Statistical analysis: Initial maternal and newborn information was taken from the hospital computer databases (STORK and Vermont Oxford Network). The hospital medical records of each delivery were retrieved and analysed in detail by a trained research midwife (AMD) using a structured proforma. Information recorded was anonymized by assigning a unique project number to each delivery. Data on maternal and fetal characteristics at birth were recorded, including maternal age and gestational age at delivery, ethnicity, gestational age at booking, complications of pregnancy and delivery, birth weight, Apgar score and baby gender. A wide range of potential risk factors—smoking and drinking status before and during pregnancy, history of drug use, socioeconomic status, past obstetric history (including previous history of termination, miscarriage and preterm birth) were recorded. Maternal body mass index (BMI at booking was calculated using weight (kg)/height (m)^2. The definition of lean was BMI <20 kg/m^2 and obese BMI ≥30 kg/m^2. Data was entered into a Microsoft excel 2003 database and imported into STXTA version 10 for analysis.

Comparisons between cases and controls were made using standard statistical procedures. Continuous variables were summarized by mean (SD) except for gestational age, which was not normally distributed, where the median (range) was used instead. Means were compared using unpaired Student’s t-tests. For categorical variables Chi-squared tests were used and two-tailed Fisher’s Exact tests for 2 × 2 tables where expected frequencies were small. A 5% level of significance was used throughout. Multiple logistic regression was used to adjust for confounding factors and compute odd-ratios.

Results: The control and preterm groups had very similar ethnicity and maternal age but, as expected, multiple births were more common in the preterm group (Table 1). Eight of the multiple pregnancies were the result of assisted reproduction treatment (IVF). Since the obstetric management of multiple pregnancies differs from that of singleton pregnancies, we excluded all the multiple pregnancies from further analysis.

Maternal age and BMI: Previous reports have indicated that extremes of maternal age and low maternal weight predispose to preterm birth and we have confirmed that the incidence of preterm birth in women over 39 years of age remains significantly higher than in younger women (Table 2); however the proportion of teenage mothers in the two groups was similar. Both lean and obese mothers were more common in the preterm group (odds ratios 1.75 (95%CI 1.02 to 3.01) and 1.41 (95% 0.92-2.15) respectively; reference category was the normal BMI group), but the overall difference did not reach statistical significance (Table 2).
Socioeconomic factors: The proportion of women with at least one social problem (low income; poor housing; unsupported or single parent) was significantly higher in the preterm than in the control group (Table 2). Smoking before conception was not associated with preterm birth (data not shown); however the proportion of women who smoked during pregnancy was significantly higher in the preterm than in the control group. The proportion of smokers in women with and without social problems was 58.2% and 19.6%, respectively. The proportions of women who consumed alcohol or admitted using any recreational drugs (cannabis, amphetamines, barbiturate, crack, cocaine, heroin, methadone, ecstasy) during pregnancy were similar in the control and preterm groups.

History of previous pregnancies: About 70% of women in both groups had been pregnant previously and more than 56% had had previous deliveries (Table 3). The proportion of women with a previous preterm delivery (between 20 and 37 weeks’ gestation) in the preterm group was significantly higher than in the control group. Analysis of previous pregnancies under 20 weeks’ gestation revealed that terminations of pregnancy were significantly more common in the preterm group; however the proportion of spontaneous miscarriages in the two groups was similar.

Pre-existing medical conditions: The most common pre-existing medical conditions in the control and preterm deliveries are listed in Table 4. Hypertension (blood pressure >140/90 mmHg), psychiatric disorders and uterine abnormalities were significantly associated with preterm delivery. A history of cervical incompetence was found only in the preterm group. Multivariable analysis revealed that women with psychiatric disorders were significantly more likely to have social problems (P<0.001), to have smoked during pregnancy (P<0.001) and to have had previous preterm deliveries (P=0.007). When adjustments were made for the effect of these three factors the

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**Table 2: Demographic and socioeconomic parameters in singleton pregnancies.**

<table>
<thead>
<tr>
<th></th>
<th>Control (≥ 37 weeks’ gestation)</th>
<th>Preterm (&lt;35 weeks’ gestation)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of deliveries</td>
<td>533</td>
<td>228</td>
<td></td>
</tr>
<tr>
<td>Median gestational age at delivery (completed weeks) and range</td>
<td>40 (Range 37-42)</td>
<td>33 (Range 23 - 34)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Maternal age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean maternal age at delivery (years)</td>
<td>28.8 (SD 6.04)</td>
<td>29.4 (SD 6.69)</td>
<td>0.24</td>
</tr>
<tr>
<td>≤ 18 years</td>
<td>33 (6.0%)</td>
<td>13 (5.7%)</td>
<td>0.002</td>
</tr>
<tr>
<td>19-39 years</td>
<td>509 (92.0%)</td>
<td>199 (87.3%)</td>
<td></td>
</tr>
<tr>
<td>&gt;39 years</td>
<td>11 (2.0%)</td>
<td>16 (7.0%)</td>
<td>(Comparison of proportions of mothers &gt;39 years P &lt; 0.001)</td>
</tr>
<tr>
<td>Body mass index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean BMI at booking (kg/m²)</td>
<td>25.03 (SD 5.29)</td>
<td>25.8 (SD 6.71)</td>
<td>0.10</td>
</tr>
<tr>
<td>Lean &lt;20</td>
<td>42 (7.9%)</td>
<td>24 (12.3%)</td>
<td>0.054</td>
</tr>
<tr>
<td>Normal 20 - 29.9</td>
<td>402 (75.7%)</td>
<td>131 (67.2%)</td>
<td></td>
</tr>
<tr>
<td>Obese ≥30</td>
<td>87 (16.4%)</td>
<td>40 (20.5%)</td>
<td></td>
</tr>
<tr>
<td>Socioeconomic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With social problems</td>
<td>60/548 (10.9%)</td>
<td>50/218 (22.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Smoking during pregnancy</td>
<td>114/553 (20.6%)</td>
<td>83/226 (36.7%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Drinking Alcohol during pregnancy</td>
<td>180/550 (32.7%)</td>
<td>75/228 (32.9%)</td>
<td>0.96</td>
</tr>
<tr>
<td>Using drugs during pregnancy</td>
<td>20/553 (3.6%)</td>
<td>12/226 (5.3%)</td>
<td>0.28</td>
</tr>
</tbody>
</table>
relationship between psychiatric disorders and preterm birth was no longer significant (odds-ratio [95%CI] reduced from 1.6 [1.1-2.4] to 1.2 [0.8-1.8]).

Complications of pregnancy: The incidence of maternal, fetal and other complications of pregnancy is shown in Table 5. Episodes of threatened preterm labor were the most common maternal complication in preterm deliveries, and occurred almost exclusively in the preterm group. Vaginal bleeding, anaemia (haemoglobin <10.5 g/dl) and proteinuria (1+ or more on dipstick, excluding urinary tract infection) occurred in both control and preterm pregnancies, but were significantly increased in the latter. Hypertension with proteinuria (pre-eclampsia) was significantly increased in the preterm group. Hypertension without proteinuria (pregnancy induced hypertension) was low in both groups. Raised alpha fetoprotein (AFP) levels were more common in preterm pregnancies, but the incidence was low. Other common complications such as urinary tract infection (UTI), the presence of pathogens in high vaginal swabs (HVS) and the observation of reduced fetal movements were similar in both groups (Table 5).

Fetal complications were more frequent in the preterm group, especially oligohydramnios, followed by fetal growth restriction and fetal abnormalities (including both structural and chromosomal abnormalities) (Table 5). Preterm premature rupture of the membranes (PPROM) and prolonged rupture (>48 hours) of the membranes were significantly more common in the preterm group.

Multivariable analysis indicated that women with pre-eclampsia were more likely to have fetal growth restriction; moreover each of the two factors was an effect modifier for the other (supported by significant interaction in logistic regression P=0.026). For example, the association of fetal growth restriction with preterm birth was much greater in the presence of pre-eclampsia than in its absence (OR 45.4 [95% CI 5.8-354.6] versus 3.71 [1.65-8.33], respectively). Women with both premature and prolonged rupture of the membranes were the most likely to have oligohydramnios (P<0.001). Finally, women with vaginal bleeding were more likely to have PPROM or episodes of threatened preterm labor (P<0.001 for both).

Labor and delivery: 65% of women in the control group went into spontaneous labor and 35% had an elective delivery (cesarean section or induction of labor) indicated for medical or obstetric reasons. In the preterm group 53% of women had spontaneous labor and 47% were delivered electively (P=0.002). When the incidence of complications of pregnancy is presented separately in spontaneous and elective deliveries (Figure 1) very different patterns can be observed. Spontaneous preterm deliveries were clearly associated with threatened preterm labor, PPROM and vaginal bleeding. The occurrence of one or more episodes of vaginal bleeding at any stage of pregnancy was relatively common in both term and preterm spontaneous deliveries, but the incidence was significantly higher in the preterm group. By contrast, elective preterm deliveries were strongly associated with anaemia, hypertension and fetal growth restriction (Figure 1). Interestingly, vaginal bleeding, oligohydramnios, PPROM and, to a lesser extent, threatened preterm labor were significantly increased in both spontaneous and elective preterm deliveries.

Neonatal outcome: Metabolic complications including jaundice, hypoglycemia and hypothermia were relatively common in both control and preterm groups, although the incidence was significantly higher in the latter (data not shown). Severe complications of prematurity such as respiratory distress (56%), patent ductus arteriosus (11%), intracerebral damage (9%) and necrotising enterocolitis (4.5%) were diagnosed almost exclusively in the preterm group. There were 15 stillbirths, 21 neonatal deaths (deaths within 28 days of birth) and 6 postneonatal deaths (after 28 days) in the preterm group compared to only 2 stillbirths, 2 neonatal deaths and 1 postneonatal death in the control group. The main causes of death in the preterm group were severe prematurity, infection and congenital abnormalities; in the control group deaths were associated with congenital abnormalities.

Discussion
This manuscript provides information on clinical factors
associated with preterm delivery in a tertiary referral hospital in the UK. The study benefits from its relatively homogeneous ethnic population and its setting in a maternity hospital with unified management guidelines in the central delivery suite. Moreover, it highlights the main risk factors that remain associated with preterm birth, and emphasizes the need to promote research into the basic mechanisms of parturition as the best way to develop effective management for spontaneous preterm labor.

In our predominantly Caucasian population, teenage pregnancies were not significantly associated with preterm birth; however, our data confirm that older mothers have an increased risk of preterm delivery. A low BMI is associated with increased risk of spontaneous preterm birth and this was reflected in our population. Previous preterm delivery is a strong risk factor for subsequent preterm birth and is the basis for most risk scoring systems. Moreover, our data confirm that hypertension and fetal growth restriction are major predisposing factors for elective preterm delivery.

Episodes of threatened preterm labor were strongly associated with spontaneous preterm deliveries. Thus, spontaneous preterm labor is characterized by remarkable uterine hyperactivity. The mechanism requires further investigation but it probably results from increased sensitivity of the uterus to stimulatory agonists such as oxytocin, prostaglandins or other endogenous mediators, as well as a premature loss of inhibitory pathways involving myometrial ion channels. We have recently shown that spontaneous preterm labor is associated with increased GTP bound RHO proteins in myometrial tissue, a pathway for enhanced uterine contractility through calcium sensitization.

Table 4: Pre-existing medical conditions.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Control (≥37 weeks’ gestation)</th>
<th>Preterm (&lt;35 weeks’ gestation)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of deliveries</td>
<td>553</td>
<td>228</td>
<td></td>
</tr>
<tr>
<td>Anaemia</td>
<td>103 (18.6%)</td>
<td>45 (19.7%)</td>
<td>0.72</td>
</tr>
<tr>
<td>Respiratory problems</td>
<td>89 (16.1%)</td>
<td>39 (17.1%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Depression/Psychiatric Disease</td>
<td>83 (15.0%)</td>
<td>50 (21.9%)</td>
<td>0.019</td>
</tr>
<tr>
<td>Hypertension</td>
<td>51 (9.2%)</td>
<td>34 (14.9%)</td>
<td>0.020</td>
</tr>
<tr>
<td>Renal Disease</td>
<td>34 (6.1%)</td>
<td>18 (7.9%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Sexually transmitted diseases</td>
<td>33 (6.0%)</td>
<td>16 (7.0%)</td>
<td>0.58</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>24 (4.3%)</td>
<td>9 (3.9%)</td>
<td>0.80</td>
</tr>
<tr>
<td>Thyroid Disease</td>
<td>14 (2.5%)</td>
<td>3 (1.3%)</td>
<td>0.29</td>
</tr>
<tr>
<td>IVF</td>
<td>12 (2.2%)</td>
<td>6 (2.6%)</td>
<td>0.70</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11 (2.0%)</td>
<td>3 (1.3%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>10 (1.8%)</td>
<td>5 (2.2%)</td>
<td>0.72</td>
</tr>
<tr>
<td>Bleeding disorders</td>
<td>8 (1.4%)</td>
<td>3 (1.3%)</td>
<td>&gt;0.99*</td>
</tr>
<tr>
<td>Uterine abnormalities</td>
<td>10 (1.8%)</td>
<td>14 (6.1%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Cervical incompetence/cervical suture</td>
<td>0</td>
<td>5 (2.2%)</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

*Two-tailed Fisher’s Exact test
Separating imminent spontaneous preterm labor from recurrent but transient episodes of uterine contractions remains a major clinical challenge.

Bleeding in pregnancy was strongly associated with both spontaneous and elective preterm deliveries. Women with vaginal bleeding have an increased risk of induction of labor and cesarean section and the condition is associated with other pregnancy complications such as PPROM, oligohydramnios and fetal growth restriction. The mechanism by which intrauterine bleeding may lead to spontaneous preterm labor is not known, but it has been proposed that thrombin activation in the decidua leads to uterine contractions. Moreover thrombin increases matrix metalloproteinase activity in the fetal membranes providing a link between intrauterine bleeding and rupture of the membranes.

Anemia is one of the most common nutritional problems in pregnant women throughout the world and, after smoking, is the most important preventable risk factor for preterm birth. Our data show that even moderate anemia (<10.5 g/dl) in pregnancy is associated with preterm birth and this agrees with observations in other tertiary referral hospitals. Ascending intrauterine infection is often quoted as a pathogenic mechanism for preterm labor, however in our survey the proportion of women with bacterial pathogens in high vaginal swabs was similar in the control and preterm groups.

Preterm babies continue to die in the perinatal period or have severe neonatal complications which predispose to a high incidence of neurodevelopmental impairments and sensory deficits. The early administration of glucocorticoids to the mother and impressive advances in neonatal care have steadily...

Table 5: Complications of pregnancy.

<table>
<thead>
<tr>
<th></th>
<th>Control (≥37 weeks’ gestation)</th>
<th>Preterm (&lt;35 weeks’ gestation)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of deliveries</td>
<td>553</td>
<td>228</td>
<td></td>
</tr>
<tr>
<td>Maternal complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Threatened preterm labour</td>
<td>17/553 (3.1%)</td>
<td>126/228 (55.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vaginal bleeding</td>
<td>130/553 (23.5%)</td>
<td>117/228 (51.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anaemia</td>
<td>53/513 (10.3%)</td>
<td>76/224 (33.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension with proteinuria</td>
<td>43/514 (8.4%)</td>
<td>52/224 (23.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension without proteinuria</td>
<td>13/514 (2.5%)</td>
<td>4/224 (1.8%)</td>
<td>0.54</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>56/514 (10.9%)</td>
<td>35/224 (15.6%)</td>
<td>0.072</td>
</tr>
<tr>
<td>HVS B Strep.</td>
<td>26/514 (5.1%)</td>
<td>12/224 (5.4%)</td>
<td>0.87</td>
</tr>
<tr>
<td>HVS Other organisms</td>
<td>70/514 (13.6%)</td>
<td>35/224 (15.6%)</td>
<td>0.47</td>
</tr>
<tr>
<td>Hyperemesis</td>
<td>16/514 (3.1%)</td>
<td>3/224 (1.3%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Gestational Diabetes</td>
<td>14/514 (2.7%)</td>
<td>4/224 (1.8%)</td>
<td>0.45</td>
</tr>
<tr>
<td>Late booker</td>
<td>16/513 (3.1%)</td>
<td>8/223 (3.6%)</td>
<td>0.74</td>
</tr>
<tr>
<td>High Down’s Risk</td>
<td>16/513 (3.1%)</td>
<td>7/224 (3.1%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Raised AFP</td>
<td>4/513 (0.8%)</td>
<td>6/224 (2.7%)</td>
<td>0.075*</td>
</tr>
<tr>
<td>Fetal complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduced fetal movements</td>
<td>140/514 (27.2%)</td>
<td>76/224 (33.9%)</td>
<td>0.066</td>
</tr>
<tr>
<td>Oligohydramnios</td>
<td>49/514 (9.5%)</td>
<td>65/224 (29.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fetal growth restriction</td>
<td>12/514 (2.3%)</td>
<td>41/224 (18.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Large for dates</td>
<td>27/514 (5.3%)</td>
<td>8/224 (3.6%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Fetal abnormalities</td>
<td>14/553 (2.5%)</td>
<td>15/228 (6.6%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Other complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm premature rupture of membranes</td>
<td>5/553 (0.9%)</td>
<td>100/228 (43.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prolonged rupture of membranes</td>
<td>49/553 (8.9%)</td>
<td>49/228 (21.5%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Two-tailed Fisher’s Exact test
improved neonatal survival rates over the past three decades; however it is unrealistic to expect that improvements in neonatal intensive care will decrease neonatal mortality and the sequelae of prematurity much further. The onus is now on understanding the causes and mechanisms of parturition, so that spontaneous preterm labor can be prevented and preterm birth is only allowed to happen electively for the benefit of the mother and her baby. The proportion of elective preterm deliveries in our survey is considerably higher than in similar UK and European hospital populations in the 1970s and 1980s. This reflects a growing confidence among young obstetricians that justified intervention in preterm pregnancies results in good obstetric and neonatal outcome, but significant morbidity should not be forgotten.

This study has limitations because it has surveyed a population of several hundred women in a single tertiary hospital. The factors associated with preterm birth would be better addressed through prospective study of a very large geographical cohort. Furthermore, we believe that over the next decade epidemiological data will be supplemented by advances in uterine physiology and materno-fetal endocrinology which will improve our understanding of human parturition and help devise successful strategies to prevent preterm labor.

Figure 1. Complications of pregnancy in spontaneous and medically indicated elective preterm deliveries (23-35 weeks’ gestation) compared with spontaneous and elective term controls (≥37 weeks’ gestation). HVS: high vaginal swab. PPROM: preterm premature rupture of the membranes. Significant differences: * p < 0.001; ** p < 0.05.
Conclusions
The data from this study show that more than 50% of preterm births follow spontaneous preterm labor and further research to clarify the mechanism by which risk factors such as increased uterine contractility, premature rupture of the membranes and uterine bleeding result in preterm labor will be clearly beneficial. Moreover, it is important to address the major causes of elective preterm delivery, namely hypertensive disorders and intrauterine growth restriction. This may be achieved through the discovery of the etiology of pre-eclampsia and a better understanding of the control of fetal growth and placental function. The reduction of spontaneous preterm labor is a realistic aim; however our lack of knowledge of the process of labor is a major handicap in devising effective strategies. It is essential to promote research into the physiological and physiopathological pathways that increase uterine activity during pregnancy. The combination of laboratory and clinical research will provide the necessary breakthroughs to improve the prevention of preterm birth.

References
Anesthesia for Cesarean Section in the Presence of Multivalvular Heart Disease and Severe Pulmonary Hypertension

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Abstract

Introduction: Pulmonary hypertension is a rare condition and in combination with pregnancy, it can result in high maternal mortality. Mitral stenosis is one of the complicated cardiac diseases that may occur during pregnancy. In this report, we describe our management of such a case, which was even more difficult in combination with pulmonary hypertension, mitral stenosis, and aortic and tricuspid valve insufficiency requiring emergency cesarean section under general anesthesia.

Case presentation: A 29-year-old primipara was presented to the anaesthetic department for an urgent cesarean section with a diagnosis of severe pulmonary hypertension in combination with mitral stenosis. The patient was hospitalized prepartum and received oxygen therapy and anticoagulation with heparin. The patient was monitored during labor and delivery with oximetry and arterial and central venous pressure line. Pulmonary arterial lines were not used due to an increased risk and questionable usefulness. Echocardiography revealed a systolic pulmonary arterial pressure of 75 mmHg, and mitral stenosis, aortic and tricuspid valve insufficiency.

We decided to proceed under general anesthesia. Anesthesia was induced with etomidate, and succinylcholine. Dopamine and nitroglycerin infusion was preoperatively started and infusion was also preoperatively continued. Hemodynamic parameters were stable during delivery. Neonatal weight and apgar score were satisfactory. After the delivery of a healthy baby, oxytocin was administered. Surgery was completed uneventfully. During the postoperative period, the patient received furosemide and morphine. As the arterial blood gas analyses were stable and the hemodynamic parameters were within normal limits except an Hb value of 9,42 gr.L⁻¹, she was extubated postoperatively in the second hour in ICU.

Conclusion: Patients with significant multivalvular heart disease require careful preoperative, multidisciplinary assessment and anesthetic planning before delivery in order to optimize cardiac function during the peripartum period and make informed decisions regarding the mode of delivery and anesthetic technique.

Introduction

Pulmonary hypertension is a rare condition and in combination with pregnancy, it can result in high maternal mortality. Mitral stenosis is one of the complicated cardiac diseases that may occur during pregnancy. Furthermore, despite the improvements in medical, obstetric, anaesthetic, and intensive care, mortality rates still remain disappointingly high.

In this report, we describe our management of such a case, which was even more difficult in combination with pulmonary hypertension, mitral stenosis, and aortic and tricuspid valve insufficiency requiring urgent Cesarean section under general anesthesia.

Case Report

A 29-year-old Turkish primigavrid parturient with a height of 160 cm and a weight of 80 kg was presented to the anesthetic department for an urgent cesarean section with a diagnosis of severe pulmonary hypertension and associated multivalvular disease. At 35 weeks' gestation, she experienced palpitations, shortness of breath, dizziness, and dyspnea so she was referred for cardiology consultation. During examination, a systolic murmur (grade 2/6) was present in all auscultation areas.

There was some evidence of pulmonary edema in the chest X-ray; although she did not have hepatomegaly, there was 1+/1+ peripheral edema. The electrocardiogram showed a sinus rhythm of 95 beats.min⁻¹ with a normal axis, borderline right ventricular hypertrophy and an arterial blood pressure of 118/62 mmHg. She underwent echocardiography that revealed severe pulmonary hypertension with a systolic pulmonary artery pressure of 75 mmHg and an associated mitral stenosis with a mitral valve area of 1.3 cm². The right ventricle was dilated; the echocardiography demonstrated a mild mitral regurgitation, moderate-severe aortic regurgitation and moderate tricuspid regurgitation. Hematological and biochemical investigations were within normal limits except an Hb value of 9,42 gr.L⁻¹. She was hospitalized in coronary intensive care unit and treated with diuretics. At home, she was anticoagulated with low molecular heparin (Clexane), whereas cardiologists started heparin infusion at a rate of 1000 U.hr⁻¹ when she was hospitalized. Serial ultrasound and cardiocography tracings confirmed that fetal growth was normal. At 36 weeks' gestation when active labour began, it was decided that she should undergo cesarean section because induction of labor was considered inappropriate.

In the operating room, non-invasive arterial pressure monitoring, 6-lead ECG with ST-segment analysis, and pulse oximetry were applied. She was tachycardic and tachypneic. Preoperative and
perioperatively. Central venous pressure was maintained at two minutes perioperatively. Infusions of glyceryl trinitrate were started preoperatively and continued perioperatively. Central venous pressure was maintained at 5-10 mmHg throughout the operation. After a healthy 2,450 g baby was delivered with an Apgar score of 9 at the 1st and 5th minutes and an infusion of oxytocin (20 U for more than 2 hours) was started. Anesthesia was maintained with isoflurane, and 50% nitrous oxide in oxygen and 0.05 mg kg⁻¹ vecuronium, and 100 µg IV fentanyl were administered. During delivery, the patient’s pulmonary edema increased, and a decrease in oxygen saturation was observed. Pulmonary edema during delivery was rapidly resolved after diuretic administration. Surgery was completed uneventfully. After the operation, the patient was admitted to the intensive care unit where artificial ventilation and continuous monitorization were continued. During the postoperative period, the patient was sedated using an infusion of propofol and received morphine, furosemide, and glyceryl trinitrate at adequate doses. When the arterial blood gas analyses and the chest-X-ray were normal, the patient was extubated postoperatively in the second hour in the intensive care unit. She was discharged home in good condition after one week following the operation and was advised to undergo cardiac surgery.

Discussion
Cardiovascular stress owing to pregnancy, labor, delivery, and the postdelivery period induce different degrees of cardiac failure in every cardiac patient, and concomitant cardiac medication and therapeutic anticoagulation interfere with the anesthetic management. Adequate cardiovascular invasive monitoring is essential and should be administered and maintained in the postpartum period with the same criteria that reduce morbidity and mortality in cardiac patients undergoing general surgery.

In our case, standard vascular access included a radial artery catheter, an internal jugular central venous line, and a large venous catheter for rapid fluid infusion. We preferred not to attempt to insert central venous and arterial catheters until the patient was intubated as we considered that this procedure would be too stressful for this anxious patient and was likely to result in a further increase in heart rate.

This patient received her diagnosis late in pregnancy, beyond the time at which a therapeutic termination could have been performed. She was managed with a multidisciplinary approach, and her care included cardiologists and obstetricians but she was not consulted to anesthesiologists until delivery. But still, general anesthesia and cesarean section were successfully performed. She received aggressive anticoagulation as deep venous thrombosis and pulmonary embolism are important causes of postpartum mortality in patients with pulmonary arterial hypertension. Cesarean delivery was planned at 36 weeks’ gestation to maximize fetal lung maturation and to avoid deterioration in maternal cardiac status.

There are no controlled studies examining the best type of anesthetic technique in these patients, and guidelines and standards are lacking. Although no curative agent has been identified, the practitioners’ knowledge of the existing treatment options, pathophysiology, and the implications of various anaesthetic agents and techniques is required to ensure the highest level of patient safety and care. Experts recommend individualizing the anaesthetic management according to the parturient’s cardiovascular status and general pathophysiological concepts. Some authors have described the use of general anesthesia with good maternal outcome. However, others have reported increased pulmonary arterial pressure during laryngoscopy and tracheal intubation; moreover, adverse effects of positive-pressure ventilation on venous return may ultimately lead to cardiac failure.

As this patient was anticoagulated aggressively, general anesthesia was preferred. Opioid-based techniques are recommended for anesthesia in patients with valvular disease as they have a minimally depressive action on the cardiovascular system and provide excellent analgesia. But we were concerned that use of opioids in induction could result in respiratory depression of neonate, so fentanyl was not administered until delivery. However, to avoid an increase in systemic and pulmonary pressures resulting from laryngoscopy and tracheal intubation, lidocaine was administered and glyceryl trinitrate infusion was started preoperatively and continued postoperatively. Also, depths of analgesia and anesthesia levels were maintained adequately throughout the surgery in order to avoid tachycardia and hypertension. We tried to provide lower peak inspiratory pressures to avoid these adverse effects of artificial ventilation.

A systolic pulmonary artery pressure of above 50 mmHg is associated with cardiac complications during pregnancy as functional status worsens more rapidly in pregnant than in non-pregnant patients with mitral valve stenosis. Cardiac decompensation and pulmonary edema may occur in pregnant women with overt or silent mitral valve stenosis during the second or third trimester. Fluid restriction, diuretics, and control of atrial fibrillation are basic measures that can prevent pulmonary congestion.

The postpartum period is the most critical period for acute pulmonary hypertension decompensations. Symptomatic therapy during the postpartum period may include inhaled nitric oxide and epoprostenol infusion or inhaled iloprost. For women with unexpected primary pulmonary hypertension who need emergency cesarean section, inhaled nitric oxide is used. In this case, pulmonary edema that occurred after delivery was resolved with diuretics with no need of using inhaled nitric oxide or other pulmonary vasodilators.

Conclusion
Patients with significant multivalvular heart disease require careful preoperative, multidisciplinary assessment and anaesthetic planning before delivery in order to optimize cardiac function during the peripartum period and make informed decisions regarding the mode of delivery and anesthetic technique. Particularly the period after delivery carries a high risk of maternal death. Therefore, prolonged intensive care for both pre and postpartum periods is essential.
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