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neonatal INTENSIVE CARE

The Journal of Perinatology-Neonatology

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RESPIRATORY SYNCYTIAL VIRUS (RSV): ARE WE DOING ALL WE CAN?

Enormous progress has been made in the fight against RSV disease, but there remains much more to do

Despite our best efforts:

- ***An estimated 125,000 infants and children are hospitalized each year in the United States as a result of RSV disease***[1,2]
- ***RSV continues to be the most frequent cause of lower respiratory tract infections such as bronchiolitis and pneumonia among infants less than 1 year of age***[2]

Premature lungs are more vulnerable to severe RSV disease

Compared to full-term infants, 34-week gestational age (GA) infants have:

- ***Only 52% of the calculated lung volume***[3]
- ***About 35% thicker airway walls***[3]

This means that the lungs of 34-week GA infants have less volume to accommodate gas exchange.

At 1 year, prematurity continues to impact lung function. Results from a study conducted in premature infants (<36 weeks' GA) who had no history of respiratory disease during the neonatal period demonstrated:

- ***<50% of predicted lung function compared to the normal predicted value***[4,5]

Therefore, even healthy-looking premature infants may be susceptible to infection.

RSV disease can affect all premature infants regardless of degree of prematurity[6]

A study of infants hospitalized with RSV disease compared 33–35 week GA infants with those ≤32 weeks' GA. Hospital outcomes were found to be at least as severe in the 33–35 week GA group. These late preterm infants (33–35 weeks' GA) had a(n)[7*]:

- ***24% longer hospital length of stay***
- ***33% longer ICU length of stay***
- ***81% greater rate of intubation***

*These endpoints were not analyzed for statistical significance between the ≤32 week GA and 33–35 week GA groups.

The need for RSV prevention is critical

Unfortunately, RSV is highly contagious. And because even healthy-looking 33–35 week GA infants face severe consequences from RSV disease,[7] it is important to consider preventive measures for all at-risk infants.[6†]

†Infants with bronchopulmonary dysplasia or a history of premature birth (≤35 weeks' GA) and children with hemodynamically significant congenital heart disease.

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Editorial

A Message to a Multiple Birth Mother

Julia Pippa, RN, BA

Julia Pippa is a school nurse with regular and special needs students.

Your premature infant has survived. Thanks to a strong NICU team, stellar equipment and four months in the hospital, your baby is coming home to join four siblings, who just recently completed their own stint in the NICU. Your joy at the homecoming is tainted somewhat by your exhaustion and worry. You can't allow yourself to think about what the next hour will bring for your family, much less the future. But, you say, I was a preemie and I'm fine. Yes, and you also were a single birth with a high enough weight to keep you in the hospital a mere week. Your babies had birth weights so low that they were not yet completely developed fetuses when they were born. They needed the simulated womb and the expertise of the NICU to continue their growth outside of your uterus. But they made it, you say, and now they are normal. Maybe not. Leaving the womb unavoidably causes physiological stress on a term baby. Think then, what trauma it is on an infant, born too soon. Your premature children, thanks to the multiple pregnancy brought on by in vitro fertilization, are at risk. This catch-all phrase means they may have defects. Mental retardation, cerebral palsy, respiratory problems, to name a few.

- What if you had accepted not having children, the way it was meant to be?
- You felt you had always wanted a family and besides, everyone you know has children and you were certain they looked down on you, or at the very least pitied you.
- What if you had realized that the amount of money you spent on years of unsuccessful in vitro fertilization depleted your funds so that now you don't have nearly enough to raise five children? What if the in vitro doctor had told you the nasty side of multiple births? All the risks. Or maybe he did and you didn't listen.
- What if you had opted, as the doctor suggested, to carry only two of the fetuses?
- This was not an option for you as your religious organization said that would be aborting three lives, and you are righteously against abortion.
- What if you had known that all the family and friends who had sworn to help you with the overwhelming task of caring for five children, suddenly straggled off, leaving you virtually alone? Your husband turning out to the most overwhelmed and useless of all.
- What if the littlest one, who already is showing spastic, uncontrolled movements, has cerebral palsy?
- What if number three, who is already slower than the others, turns out to be mentally retarded?
- What if you had asked for advice from a counselor, versed in the pros and cons of in vitro fertilization and its aftermath. Its consequences.
- What if you had contacted a financial adviser to review the cold, hard facts of your monetary position?
- What if you had insisted on the doctor telling you every single effect this multiple birth would have on your family, instead of refusing to allow him to tell you anything negative.
- What if there were laws governing the myriad, unresolved, multiple birth issues?

The government will now have to pay for keeping your family going and if any of your children have disabilities, the price will be that much higher.

And do you know, mom, who will be footing this outrageous bill? The rest of us.

Editor's note: Neonatal Intensive Care would be very interested in receiving your responses to this commentary. Please send your replies to s.gold4@verizon.net.

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Neonatal CMV Infection

Muhammad Aslam, MD

Cytomegalovirus (CMV) is a DNA virus of herpesviridae family. Humans are the only reservoir of infection with a life-long infection. It is found in all body secretions except tears. CMV infection is very common and the seroprevalence in the United States (US) reaches 50-85% by age 40 years. More than 40% of pregnant women are infected with congenital CMV infection representing 1% of all live births in US each year. 30 to 40% fetuses of infected women become infected with CMV and 15% of these develop significant disease. Infection early in the gestation is associated with higher risk of severe fetal disease. CMV infection is the leading cause of infectious sensory-neural hearing loss and developmental delay in US children.

Maternal infection is categorized as primary or latent. Primary infection presents with mononucleosis like symptoms whereas latent infection is usually asymptomatic. Vertical transmission of infection can occur anytime during pregnancy or in the perinatal period. Vertical infection is further categorized as congenital or perinatal. Congenital infection represents acquisition of infection in the first 3 weeks of life. It is usually transmitted to the fetus in utero and diagnosed by fetal imaging studies. Maternal primary infection carries a 50% transmission rate as compared to 0.5-2% in latent reactivated infection. Perinatal infection is usually seen after the first 3 weeks of life. It can result from intrapartum exposure to CMV within the maternal genital tract, postnatal exposure to infected breastmilk and infected blood products, and rarely nosocomial transmission.

Approximately 90% of infants with congenital CMV infection are asymptomatic and 15% of these develop sensory-neural hearing loss. Unilateral hearing loss is more common than bilateral. On the other hand 10% of infants with congenital CMV infection are symptomatic and two thirds of these develop sensory-neural hearing loss. The hearing loss is almost always progressive resulting in severe to profound hearing loss in the affected ear. Available data recommend evaluation of CMV infection on any infant failing hearing screen. Infants with CMV hearing loss should have serial hearing evaluations performed. Infants with CMV hearing loss may be cognitively normal or delayed. Symptomatic infants usually present with petechiae or purpura (79%), hepatosplenomegaly (74%) and jaundice (63%). Other findings include intrauterine growth restriction, seizures, feeding difficulties and blue-berry muffin spots. Visual problems include chorioretinits, optic atrophy, retinal scars and central vision loss. Laboratory findings include elevated hepatic transaminases, direct hyperbilirubinemia, anemia, thrombocytopenia, and elevated cerebrospinal fluid protein concentration. Brain imaging demonstrates periventricular calcifications and leukomalacia.

Tests to detect CMV infection can be performed on urine, blood, saliva and amniotic fluid. Recent data have focused on CMV PCR on the amniotic fluid or umbilical cord blood to determine fetal infection. Shell vial or spin enhanced culture of urine is a rapid way to detect CMV. CMV PCR has a high sensitivity and specificity for infection and is used for initial screening for infection. CMV antigen test is very sensitive but not specific and is therefore used for monitoring the efficacy of treatment. Studies have evaluated the detection of CMV infection from newborn screening (Guthrie) card samples. CMV IgG detection represents past infection and immunity, whereas presence of IgA, IgE and IgM indicates recent seroconversion and active viral replication with high risk of fetal and neonatal infection.

Fetal infection has been treated with maternal administration of antiviral drugs to achieve adequate antiviral concentrations in the amniotic fluid. Due to side effects of this therapy the intervention is not favored by most obstetricians. Newer data have focused on administration of CMV hyperimmune globulin into the fetal abdominal cavity. Studies are in trial phase for this intervention and are not performed in all centers in USA. Major side effects are abortion and fetal death.

Whether to treat infants with asymptomatic neonatal CMV infection is controversial. Those in favor quote well documented hearing loss in these infants and role of treatment in preventing the progression of the disease. Those against quote “side effects” of therapy with antiviral agents and limited efficacy of the drugs. Treatment of symptomatic infants with antiviral agents is less controversial with most physicians favoring treatment. Ganciclovir is an intravenous antiviral used in various clinical trials against CMV infection. Kimberlin DW et al have demonstrated the benefits of using ganciclovir on prevention of hearing loss in infants with CMV, but almost two thirds of patients in the treatment group developed neutropenia. Other reported side effects of ganciclovir include thrombocytopenia and reproductive toxicity. Valganciclovir is an oral medication which is converted in the body to ganciclovir. CMV hyperimmune globulin is used rarely in the treatment of fulminant CMV viremia. Aslam et al have documented successful treatment of CMV induced refractory neonatal thrombocytopenia with CMV hyperimune globulin.

Muhammad Aslam is Instructor in Pediatrics, Harvard Medical School.

Universal screening of all pregnant women for CMV infection is not recommended. This is based on the fact that overall risk of CMV infection is low (0.2%) and isolation of virus from the cervix or vagina of the pregnant women cannot be used to predict fetal infection. Also fetal diagnosis requires amniocentesis and available interventions (fetal therapy, abortion) which are harmful to the fetus. Center for Disease Control and prevention (CDC) published guidelines to prevent CMV infection in 2006. These are summarized as follows;

- Pregnant women should practice hand washing after contact with diapers or oral secretions.
- If there is mononucleosis like illness during pregnancy, evaluate the mother for CMV and counsel about risk to the unborn fetus.
- Antibody testing can confirm prior CMV infection.
- Recovery of CMV from the cervix or urine near delivery does not warrant a cesarean delivery.
- Benefits of breastfeeding outweigh the minimal risk of acquiring CMV.
- No need to screen for CMV or to exclude CMV excreting children from schools or institutions.

In conclusion, CMV infection is very common and available literature lack to provide specific guidelines for the prevention and management of the disease as a whole and especially in pregnant women. Trials on fetal interventions are in effect and the conclusion so far is the fatal nature of interventions directed at fetal treatment. Controversy exists regarding the use of antiviral agents in CMV infection and no clear guidelines have been defined to select a particular set of patients who may benefit from treatment. Prevention seems to be a key factor to limit the transmission of infection and universal precautions during pregnancy can prevent acquisition of CMV. Further studies are needed to determine an effective fetal and neonatal management against CMV infections.

News

☐ March-April 2008

MORBID?

Some parents have taken to having pictures taken of their dead infants, according to a recent article by Stephanie Simon in the Los Angeles Times. Bereavement photography is now offered by many hospitals, but it's a slapdash effort, and some parents wanted something more formal. So now there's a network of 3,000 professional photographers who can take posed pictures of parents with their deceased infants. They'll take pictures of pregnant moms, too, if an ultrasound reveals fatal fetal anomalies. The photog's network has a website where parents can talk to like-minded parents, called "Now I Lay Me Down to Sleep," and the photographers will retouch pictures to make the infants look like they're sleeping.

NEONATAL CONFERENCE

The 5th Advanced Practice Neonatal Nurses Conference presented by the Academy of Neonatal Nursing will be held April 24–26, in Miami, FL. The theme for this meeting was chosen in recognition of the need to build evidence to support neonatal practice, but also to support neonatal nursing practice where evidence is still being determined. A lineup of intriguing sessions is planned that includes: How Much Evidence? When to Treat?, Proteomics: The Wave of the Future, Workforce Issues for NNPs, and Chronic Lung Disease—The State of the Science. The conference will also feature posters, and, for the first time, Advanced Practice Nurses are invited to submit abstracts for podium presentations on ventilation and nutrition practices in their units. Guidelines for submission can be found on the Academy website. In

addition to a first-rate conference, participants are also treated to a great city. Miami is a wonderful destination with incredible food and ocean breezes. Register early and save by going to www.academyonline.org.

A CUT ABOVE

Doctors at Queen Charlotte's Hospital in London are pioneering "natural caesarean" births with the aim of making the surgery less traumatic for mother and baby. Normally, after the incision, babies are delivered rapidly behind a screen. But in a photo essay published by the BBC online, the parents, Sheri and Jason Tan, were able to watch the baby's head emerge. A full minute later the baby is shown still only half way out and only then waking up to announce its presence. It took three minutes for the baby - a boy - to be delivered - and he was immediately passed to his mother. The aim of "natural caesarean" is to make this invasive form of delivery as un-traumatic as possible for mother and baby. Queen Charlotte's says the natural caesarean is now becoming an established procedure at the hospital. To see the pictures of this birth visit http://news.bbc.co.uk/2/hi/in_pictures7154594.stm.

AGAINST THE ODDS

A pair of twins have beaten odds of 140,000-1 by being born with a shared birth sac and placenta, according to a report by the BBC. Emma Canning gave birth to Hannah and Sophie on 27 December by Caesarean section at Birmingham Women's Hospital. Scientists remain mystified as to how the rare type of pregnancy, known as monoamniotic, occurs. In about half of cases typically, one or both babies fails to survive. If the cords are pulled tight, then the babies can die inside the womb, said the consulting obstetrician. Monoamniotic pregnancies are dangerous because the twins' umbilical cords can become entwined around the babies. Only 10 monoamniotic pregnancies occur in the UK each year, the hospital said.

NO MORE ROOM

Neonatal units in England are having to close their doors to new admissions once a week on average because of staff shortages, according to a recent BBC report. The National Audit Office report said there were 459 vacancies for neonatal nurses, 9% of the total workforce. The Office warned that many of the 180 units in England were too full to give the best care to sick babies, and that a third of units were operating above the 70% capacity set out as a guideline by the British Association of Perinatal Medicine. Three units were operating above 100% capacity, meaning there were more babies in cots than there were trained staff to care for them. One in 10 English babies born, about 60,000 a year, need neonatal care. The NAO found that the networks had cut the need for long-distance transfers, but also warned only half had specialist transport 24 hours a day, seven days a week for those babies that needed moving. Wide variations were found in the death rates of babies. The South West Midlands network had the highest death rate at 4.8 babies per 1,000, while the figure was 1.8 in Surrey and Sussex. The differences were attributed to socioeconomic factors.

THERAPEUTIC NIHILISM

NICUniversity.org reports on the fit between evidence-based medicine and clinical research on its website, in an article by Malcolm Chiswick, MD, FRCP, Professor of Child Health and Paediatrics at the University of Manchester. Chiswick says, "Treatments we offer patients should be based on good scientific evidence" but that "although the analysis of evidence is important, it must be seen as part of a wider picture and become better integrated with everyday clinical practice." Chiswick noted, "Less seasoned physicians, and even some who are quite experienced, may respond with uncertainty and despair on rounds when they realize that the treatments offered do not meet the highest evidence-based standards. Often, the appropriate research studies have simply not been done, or the research has failed to demonstrate a strong conclusion... When confidence is undermined, it can result in therapeutic nihilism and a loss of direction in our approach toward patients. He notes that "the history of neonatology is punctuated by therapeutic disasters, where the risks of treatments were not fully appreciated at the time they were administered... When the highest level of evidence exists for or against a given treatment, it is easy to practice evidence-based medicine... However, there are a huge number of clinical problems for which there is no strong evidence base for their best management. The real challenge, therefore, is how we should be training and preparing doctors to practice medicine in these circumstances, without despair and without walking away from the problem. To put it starkly, how should we practice non-evidenced-based medicine?... We need to acknowledge the limitations as well as the strengths of EBM in everyday clinical practice... Working to policies, while acknowledging at the same time that what we do may not turn out to be the best approach, is an important element of training for doctors."

SHOW ME THE MONEY

The British government must look at how maternity leave is calculated to ease the financial load on parents of premature babies, a charity says. A survey by Bliss found on average, a sick baby cost parents £1,885 in lost earnings and extra spending. In the UK, the first six weeks of maternity pay is paid at a rate of 90% of the mother's regular salary, before switching to a statutory rate for the next 33 weeks. But some premature babies remain in hospital much of that time, which means many mothers have already used up most of their paid leave by the time their baby comes home. After surveying 169 parents, the charity found the most significant costs were run up by travel, buying food away from home, and lost earnings through taking time off work. Nearly half of parents lost money this way, with average lost earnings totalling £2,457.

Childcare for existing children while the parents were at hospital was also an extra expense, at an average of £552. Those on low incomes or families where one or both parents were self-employed were particularly hard-hit, the charity said. However it did note that many parents reported sympathetic employers, as well as the support of family and friends in terms of child-care, transport, and even loans. The Department for Business, Enterprise and Regulatory Reform noted that the government had just increased statutory maternity pay—£112.75 per week—from 26 weeks to 39 weeks, and said it hoped the extra paid leave would considerably extend the time that mothers can spend with their babies once they have returned home.

EAR TO THE GROUND

A study from The Children's Hospital and Regional Medical Center of Seattle, Washington, has found from health records of infants who died from SIDS a unique pattern of hearing loss as compared to infants who did not have SIDS. SIDS infants had a four-point hearing sensitivity in the right ear. Healthy infants typically have stronger hearing in the right ear. The author of the study, Dr. Daniel D. Rubens, proposed that "vestibular hair

cells transmit information to the brain regarding carbon dioxide levels in the blood. Injury to these cells may disrupt respiratory control, playing a critical role in predisposing infants to SIDS." Rubens hopes, with further study, it will be possible that a standard hearing test may identify babies at risk for SIDS and preventative measures taken. Reported in the Academy of Neonatal Nursing newsletter. For more, visit academyonline.org.

DOUBLE LATTE NON FAT IN A BABY BOTTLE, TO GO

Very premature babies who were given caffeine to regulate their breathing had a significantly lower incidence of disabilities at the age of two years, according to an international study led by researchers at McMaster University. Researchers studied more than 2,000 premature babies who were either treated with caffeine or given a placebo. Babies receiving the caffeine were less likely to develop cerebral palsy and cognitive delay. The study involved infants who weighed between 500 and 1,250 grams at birth, and who were at risk of apnea. The ongoing study will continue to follow the children until they reach the age of five. The latest results of the study showed that 46% of the infants receiving the placebo died or survived with a neuro-developmental disability. Among the babies receiving caffeine therapy, only 40% had an unfavorable outcome by the time they reached the end of their second year of life. Researchers noted that of all the drugs we use in the neonatal intensive care unit, caffeine is the first to have been shown conclusively to reduce long-term disability in very preterm babies. Caffeine reduced the rates of cerebral palsy and cognitive delay but had no significant effect on the rates of death, bilateral blindness and severe hearing loss. The Caffeine for Apnea of Prematurity (CAP) project enrolled 2,006 premature infants who were born between October 1999 and October 2004 in nine countries. The research project was designed to address long-standing concerns about possible adverse effects of caffeine therapy in pre-term infants. Earlier findings released last year by the same research team revealed that babies who received caffeine had a lower incidence of abnormal lung development than infants who were given a placebo.

WE'LL SUE

Dennis and Kimberley Quaid, whose twins were overdosed on heparin 1,000 times stronger than the proper dosage, are planning to sue the product's maker. The children were given the wrong dosage at LA's Cedars Sinai NICU. Subsequent tests indicated that there were no adverse effects on the patients. Three patients at the hospital each received vials containing 10,000 units per milliliter of heparin instead of vials with a concentration of 10 units per milliliter. Once the hospital staff realized the error, they did tests to measure the patients' blood clotting function. Quaid and his wife are the biological parents of the twins, who were born November 8 to a surrogate mother. The product liability lawsuit seeks more than $50,000 in damages and claims that the manufacturer, Baxter Healthcare, was negligent in packaging different doses of the product in similar vials with blue backgrounds. The lawsuit also says the company should have recalled the large-dosage vials after overdoses killed three children at an Indianapolis hospital last year. The Quaids didn't sue the hospital, which acknowledged its error. The patients were receiving intravenous medications and the heparin was used to flush the catheters to prevent clotting. Two of the patients needed a drug that reverses the effects of heparin, the hospital said at the time. In the suit, the Quaids said the heparin was unreasonably dangerous as it was packaged and sold because both the small and large dosage vials had labels with blue backgrounds when the vials should have been completely distinguishable (by) size and shape. Last February, Baxter Healthcare Corp. sent a letter warning health care workers to carefully read labels on the heparin packages to avoid a mix-up and added a red warning label. But the lawsuit argues that the company didn't do enough because it failed to recall the large-dosage vials after the infant deaths in Illinois and repackage the drug. CNN subsequently reported that the couple denounced the Cedars-Sinai Medical Center over a "lack of candor" about medical errors they believe caused their newborn twins to receive overdoses of a blood thinner. The Quaids said they were particularly upset to learn findings released by the California Department of Public Health conflicted with the hospital's initial report that the children each received one vial containing 10,000 units per milliliter of heparin instead of the common dosage of 10 units per milliliter. The report found that the children had received two 10,000 unit doses over an 8-hour period.

QUANTITY OF CARE

A report by the CDC noted that the US had more neonatologists and newborn intensive care beds per person than Australia, Canada and the United Kingdom but still has a higher rate of infant mortality than any of those nations. The report also said that the rate at which infants die in the United States has dropped substantially over the past half-century, but broad disparities remain among racial groups, and the country stacks up poorly next to other industrialized nations. In 2004, the most recent year for which statistics are available, roughly seven babies died for every 1,000 live births before reaching their first birthday, down from about 26 in 1960. Babies born to black mothers died at two and a half times the rate of those born to white mothers, according to the CDC figures. The United States ranks near the bottom for infant survival rates among modernized nations. A Save the Children report last year placed the United States ahead of only Latvia, and tied with Hungary, Malta, Poland and Slovakia. Doctors and analysts blame broad disparities in access to health care among racial and income groups in the United States.

ANOTHER MIRACLE

A Bolton, UK mother has given birth to a "miracle baby" following keyhole surgery to correct a prolapsed womb. Sarah Wiffen, 31, from Darcy Lever, Bolton, gave birth to daughter Natalya by cesarean section at the Royal Bolton Hospital. Weighing in at 6lb 15oz (3.15kg), she is thought to be the first baby in the world to be born after the procedure. Health professionals at the hospital hope they can use the procedure on women in the future. Miss Wiffen was diagnosed with the condition after the birth of her second son and was told she would need a hysterectomy with no chance of having another child. However, just two months after surgery she became pregnant. Consultant Obstetrician and Gynaecologist Jonathan Broome carried out the keyhole surgery and delivered the baby. He said "I felt that by doing this procedure it still gave her the chance of another baby. It is something we can learn from and hopefully repeat for other women." Reported by the BBC.

NO BRAINER

Indomethacin may be associated with brain damage and intestinal issues in premature babies, according to a new analysis by the University of Rochester Medical Center. Dozens of studies have been done, but none have had a large sample

size or a definitive outcome on the effects of indomethacin. The new meta-analysis pulls together enough data to conclude that there is an association between use of indomethacin and babies experiencing periventricular leukomalacia. The analysis also showed an association between indomethacin and necrotizing entercolitis. However, use of antenatal indomethacin is not associated with intraventricular hemorrhage, patent ductus arteriosus, respiratory distress syndrome, or death.

MEASELY

Children of HIV-infected mothers have a low persistence of antibodies to vaccines, making them suscetible to infections such as measles, according to a paper published online by PLS. The study describes the results of a cross-sectional study carried out amongst 18-36 month-old children born to HIV-infected mothers and living in Central Africa, and suggests that immuno-suppressed HIV-infected children have a low persistence of antibodies to the vaccines of the Expanded Program on Immunization. The researchers found that antibody levels to measles vaccine was particularly low among children who were HIV infected, and that antibody levels to vaccine amongst HIV-uninfected children born to HIV-infected mothers were lower than expected. This raises the possibility that HIV exposure during pregnancy might influence the response to EPI vaccines in the first weeks of life. The results suggest that children living with HIV may need an adapted EPI vaccine schedule.

BAD ADVICE?

YouTube's information about vaccination is one sided: against it, according to a study by NYU and the University of Toronto Department of Public Health. Researchers watched 153 YouTube videos about vaccination and immunization, and found that more than half the videos published childhood, flu and HPV vaccines in a negative or ambiguous light. Researchers said their study showed that a significant amount of immunization content on YouTube contradicts accepted vaccination standards. Also, videos that portray vaccinations in a negative light are getting significantly more viewing traffic than those that portray them in a positive light. For more, see the study, "YouTube breeding ground for anti-vaccination" at the University of Toronto website, or see "YouTube as a Source of Information on Immunization: A Content Analysis" Jennifer Keelan, PhD, et al, JAMA Vol. 298 No. 21, December 5, 2007.

SQUEAK!

Researchers from London's Imperial College have successfully implanted lung cells grown from embryonic stem cells into the lungs of mice. For their research, the Imperial College team decided to work with mouse ESCs that are capable of differentiating into any other type of cell. They had already succeeded in cultivating cells of this type in order for them to develop into specialized lung cells that expressed certain markers (epithelial, endothelial or adult stem cell markers). The researchers marked the stem cells using iron oxide nanoparticles containing a fluorescent green marker visible with the aid of a microscope. Then they injected them into the tail veins of two groups of mice. One group was made up of normal mice, while the other group had been treated with a toxin that damaged the pulmonary epithelium. Two days later, the mice had marked cells in their lungs, in the exact location where the researchers had expected to find them. In the main, the stem cells had colonized the areas of the pulmonary epithelium where gas exchange takes place. Better still, no fluorescent cells were found in any other organs. Researchers now need to determine the precise nature, functions and longevity of the grafted cells. It is also important to rule out any possible toxicity from this therapy, in particular the potential for accidental implantation of undifferentiated cells.

COMPROMISED

A new program in Israel is aimed at dealing with osteopenia of prematurity, which can cause bone fractures and rickets in the infant, and osteoporosis later in life. Tel Aviv University pediatric physicians are promoting a training program that aims to make preemie bones stronger through a protocol to prevent OPP. The researchers have shown that mild ten-minute exercises performed five times a day, five times a week for four weeks on the wrist, elbow, shoulder, ankle, knee, and hip joints, improved bone strength in preemies as measured using bone ultrasound. Daily interactive periods of holding and stroking the infant also influences bone growth and development, they conclude. The program involves extension and flexion exercises on preemies' arms and legs. Normally, doctors treat OPP with calcium and phosphorus supplements added to breast milk or IV fluids, but the treatments don't increase bone strength and preemies still wind up with fractures. The researchers reasoned that if exercise worked for strengthening the bones of older children and adults, there was no reason why it wouldn't work for preemies.

CUT IT OUT

Despite continued reports in the medical literature of harm caused by cesarean surgery, the US cesarean section birth rate has increased to 31.1% for 2006, an historic high, according to a new report released by the Centers for Disease Control (CDC). As a result, Lamaze International is encouraging women to seek care providers and birth settings with low c-section rates in order to improve health outcomes for themselves and their babies. Research indicates that where and with whom a woman gives birth are two of the most important factors affecting her likelihood of having a cesarean. Therefore, a woman who chooses a provider or birth setting with a low cesarean rate is less likely to have a c-section. Research also has shown that providers and facilities can lower their cesarean section rates without compromising health outcomes. Lamaze International urges expectant parents to interview care providers and carefully select one based on criteria that will optimize the chance of a safe and satisfying outcome, including the frequency with which that provider uses interventions that carry risks. The organization noted, however, that the rates of cesarean surgeries for many care providers and hospitals are not readily available. As a result, Lamaze International is giving priority funding to projects that work toward improving public reporting and transparency in maternity care.

ROLLOVER

Can cosleeping be dangerous? A five-week-old infant died recently after apparently suffocating while sleeping in bed with her mother, who may have rolled on top of her daughter, Modesto, California police reported. The mother woke and saw that her baby wasn't breathing. In a nearby California town, a three-month-old girl was accidentally smothered by her ten-year-old brother after he rolled over the infant in his sleep. In 2004, eight accidental infant smothering deaths in 18 months led Philadelphia health officials to warn parents against bringing babies to bed with them. Some say cosleeping makes it too easy to suffocate a baby in thick covers or for an adult to roll on top

of the infant. Supporters say safe bed sharing encourages breastfeeding, makes it easier for infants to sleep, and promotes the bond between mother and baby. In 2005, the American Academy of Pediatrics issued a statement discouraging bed sharing. The academy acknowledged studies showing its effect in promoting breastfeeding and bonding. But, it cautioned, other studies showed that bed sharing "can be hazardous under certain conditions." These studies linked infant death by suffocation to other children or parents in the bed. Some studies only showed a significant link among mothers who smoked. One European study found SIDS, to be a significant risk of bed sharing for infants up to 8 weeks old. Bed sharing has become more common since the 1990s, according to a study in 2003 by the National Institutes of Health. The study, a telephone survey of more than 8,000 people, found that the proportion of infants usually sharing an adult bed at night increased from 5.5% to 12.8% from 1993 to 2000. Supporters of cosleeping say studies discouraging the practice are often skewed and that not enough research has been done to examine the results of healthy bed-sharing situations. Often, when infants die during cosleeping, she said, the baby is already sick or the bed sharing was a result of an impromptu, rather than established, decision.

STILL TOO SOON

The preterm birth rate rose again in 2005 and data for 2006 show a continued increase, underscoring the urgent need for a sustained, comprehensive plan to address this growing crisis. The National Center for Health Statistics has released final birth data for 2005 showing that the preterm birth rate, the percentage of babies born at less than 37 weeks gestation, is continuing its relentless rise, with more than 525,000 babies, or 12.7%, born prematurely. That's up from 12.5% in 2004. The rate has risen 20% since 2000. Prematurity is the leading cause of death in the first month of life. In 2005, preterm birth costs the nation more than $26.2 billion in medical and educational costs and lost productivity. Average first year medical costs were about 10 times greater for preterm than for term infants.

SOUNDS GOOD

GE Healthcare has licensed a technique patented by an Eastern Virginia Medical School (EVMS) obstetrician that can automate the acquisition of ultrasound images used by physicians to diagnose fetal heart defects. GE Healthcare has licensed the software for exclusive use in its 3D/4D ultrasound systems. Alfred Abuhamad, MD, chairman of obstetrics and gynecology at EVMS, recognized for his skills in using ultrasound to detect fetal heart defects, developed the automation protocol, called Sonography based Volume Computer Aided Diagnosis (SonoVCAD). "This is going to change the way ultrasound is practiced," said Abuhamad. GE has incorporated Abuhamad's automation protocol in the Voluson E8, the next generation of the GE Voluson ultrasound platform for women's healthcare. This new 3D/4D ultrasound system includes a number of new tools to help improve clinical workflow, including SonoVCAD.

GOTTA HAVE HEART

The American Heart Association reports that congenital heart defects rank as the most common birth defect and the number one cause of death during the first year of life. Nearly twice as many children die from congenital heart disease in the United States each year as die from all forms of childhood cancers combined. Abuhamad's protocol automates the acquisition of images to display the planes that are needed for a complete ultrasound evaluation of the fetal heart, a procedure that's difficult given the complexity of the organ. The proprietary SonoVCAD technology displays all of the 2D planes. This includes identification of the four-chamber, left outflow tract and right outflow tract views of the fetal heart. With the software, an ultrasound clinician identifies a standard starting point for the four-chamber view, and Abuhamad has created algorithms that allow the other planes to be generated from that view. Those views allow physicians to identify the type and severity of fetal heart defects.

RESPIRONICS PURCHASED

Royal Philips Electronics of The Netherlands said it is acquiring Respironics, according to the Wall Street Journal, for €3.6 billion ($5.1 billion) in cash. In joint statements, the companies said they had reached a definitive merger agreement under which Philips will acquire all of Respironics' outstanding shares for $66 a share. Over a 12-month period ending in September, 2007, Respironics reported sales of approximately $1.2 billion. It has around 5,300 employees world-wide. Royal Philips makes a wide range of products from shavers and televisions to medical scanners and light-emitting diodes, and has in recent years transformed itself from an electronics manufacturing company into a technology company focused on lifestyle and health. In September '07, the company launched its "Vision 2010" strategic plan, under which it will simplify its structure into three core sectors: Philips Healthcare, Philips Lighting, and Philips Consumer Lifestyle. Several divestments have left the company with a cash pile of several billion euros. The company said Tuesday it would buy back up to €5 billion of its own shares. The tender offer isn't subject to any financing contingency, though it requires US and European Union regulatory clearances. Respironics will become the headquarters for Philips Home Healthcare Solutions group within Philips Healthcare.

SLICE OF LIFE

To circumcise or not? Opponents argue that infant circumcision can cause both physical and psychological harm, while recent evidence shows that circumcision may be medically beneficial. Two doctors debate the issue recently in BMJ. There is now rarely a therapeutic indication for infant circumcision, yet ritual (non-therapeutic) male circumcision continues unchecked throughout the world, long after female circumcision, facial scarification, and other ritual forms of infant abuse have been made illegal, writes Geoff Hinchley, a consultant at Barnet & Chase Farm NHS Trust. He notes that the law and principles pertaining to child protection should apply equally to both sexes. As such, why do society and the medical profession collude with this unnecessary mutilating practice? In addition to religious justification, there have been many spurious claims for circumcision, including the prevention of penile cancer, masturbation, blindness, and insanity, most of which relate to adult sexual behavior and not to the genital anatomy or best interest of a child, Hinchley added. He conceded that male circumcision may reduce HIV risk in sexually active adults, but said the decision on whether an individual wishes to have this procedure should be left until they are old enough to make their own informed health care choices. He added that male genital mutilation is not a risk-free procedure. As far as legal protection, Hinchley said that both the US and the UK legal systems discriminate between the sexes when it comes to protecting boys and girls from damaging ritual genital mutilation. The counterpoint argument was provided by Kirsten Patrick from the BMJ, who said that male circumcision carries

little risk and cannot be compared with female circumcision. She said that while any surgical operation can be painful and do harm, the pain of circumcision, if done under local anaesthesia, is comparable to that from an injection for immunization. Patrick noted that in terms of evidence of benefit, male circumcision has been associated with a reduced risk of sexually transmitted infections, such as human papilloma virus, chancroid and syphilis. Although the complications rate from infant circumcision are essentially unknown, because most operations are unregistered, data suggest that it is between 0.2% and 3%, with most complications being minor. Furthermore, she said, no robust research exists examining the long term psychological effects. Male circumcision is not illegal anywhere in the world, she added. A clinical review in the same issue of BMJ noted that medical indications for male circumcision in both childhood and adulthood are rare, but that complications can be drastic. See Head to Head: Is infant male circumcision an abuse of the rights of the child? and Medical aspects of male circumcision. BMJ Volume 335 pp 1180-1 and 1206-9.

WORTH ITS SALT

Experts in iodine deficiency have urged renewed international commitment to help prevent loss of IQ due to fetal brain damage by facilitating access to iodized salt for the final 30% of world households that don't yet have it. Iodized salt now reaches 70% of world households, up from less than 20% in the early 1990s.

According to Unicef, thanks to successful production and marketing of iodized salt since the early 1990s, an additional 84 million annual births are now protected from the danger of significant brain damage due to iodine deficiency disorders (IDD). However, it's reported that progress towards universal iodine coverage has slowed since 2002 and an estimated 1.6 billion people remain at risk of IDD. According to Unicef, 38 million newborns worldwide remain unprotected and there are still 36 countries where fewer than half of households consume iodized salt. Poverty and associated health, nutrition, and social factors prevent at least 200 million children in developing countries from attaining their development potential. Among these factors the estimated impact of iodine deficiency is considered the largest and affects at least 20-25% of children in developing countries. Fetal brain function damage due to iodine deficiency ranges from loss of up to10 to 15 points of IQ to severe mental retardation. To avoid suffering IDD, a human requires in a life time a total just one teaspoon of iodine - this can be added to salt at a cost of about 10 cents worth per year. But it is necessary to ingest micro amounts of iodine on a regular basis. Consumption of iodized salt is the best form of IDD prevention and Universal Salt Iodization (USI) is the goal. The greatest need for micro amounts of iodine is in the mother's womb. The Network for Sustained Elimination of Iodine Deficiency noted rapid progress towards universal iodization of edible salt. Since 1990 more than two billion people have become users of iodized salt, a remarkable feat in dietary behavior change. At least 34 countries have reached the USI goal, with 90% of households consuming iodized salt. Households yet to be reached include the world's most marginalized areas.

SEEMS KIND OF OBVIOUS

Many premature babies face serious health challenges, not the least of which is breathing, according to a headline in Medical News Today. But current research suggests that even relatively healthy preemies confront deficits in lung function that last into their second year and longer. A recent study in Brazil, published in the American Journal of Respiratory and Critical Care Medicine, noted the common knowledge that healthy infants born prematurely may have smaller sized airways relative to the lung volume, but researchers wanted to find out if these preemies underwent a catch-up period. Researchers recruited 26 preterm infants born between 30 and 34 weeks' gestation and compared their lung development and function to that of full term infants at about 10 weeks of age, then again at an average age of 15 months. They found that lung capacity and development relative to body size was similar between the groups, but airway function was consistently lower in the premature infants at both evaluations. The researchers also found that premature infants who had more fully developed lungs faced *greater* respiratory problems than those who required prolonged supplemental oxygen. The researchers surmised that perhaps, in preterm infants, supplemental oxygen may be a marker of a less mature lung, which may have a better long term respiratory prognosis than infants with accelerated maturation due to prenatal events such as infection and inflammation. It was hypothesized that the preterm infants' reduced lung function may be due to airways that do not develop at the same rate as their lung volume.

A+

Johns Hopkins reports that vitamin A supplementation can reduce mortality caused by diarrhea, acute respiratory infection and fever. A Reuters Health Information report by C. Vidyashankar reports that the Johns Hopkins team assigned 5,786 neonates to receive 24,000 IU vitamin A orally twice within the first 48 hours after birth and 5,833 neonates to receive a placebo. All infants received 100,000 IU vitamin A orally at the end of the study period. Death rates due to diarrhea and fever were significantly lower among vitamin A-supplemented infants as compared to controls, while mortality due to acute respiratory illness also showed a lower trend among the vitamin A-supplemented infants. Researchers noted vitamin A supplementation studies done in low-income countries over the past 20 years reveals a decrease in mortality; however, morbidity is not affected.

SPLIT

University of Texas researchers recently reviewed the medical records and examined the placentas of 16 ELBW infants and reported a surprising finding of the presence of Candida albicans in the placentas of two SIP patients. Researchers also noted other differences between SIP patients and controls, including umbilical cord lesions indicating severe chorioamnionitis, maternal antibiotic treatment before or at delivery, systemic candidiasis, sepsis due to coagulase-negative Staphylococcus, and cerebral lesions. The researchers said caregivers should be especially on the lookout for danger signs in SIP patients, particularly in the case of an acute gasless abdomen in a very small infant. Reported by Reuters Health Information; study published in Pediatrics.

TYING THE CORD

Infants with LSDs like Hurler syndrome and Krabbe disease can be treated with umbilical cord blood taken from unrelated donors, according to a study by Duke University. Reuters Health reports that transfusions of selected stem cells can replace the enzymes that cause the organ failure that accompanies these diseases. Duke's study involved umbilical cord blood

transplantation received from unrelated donors by 159 patients whose performance status was below 80%,with approximately 20% of babies testing CMV-positive. The patients received pre-transplant conditioning and the cord blood was screened for the necessary enzyme.

Overall survival was 79% at 6 months. The five-year overall survival was 79.5%. Researchers noted that front-line caretakers need to be aware of the problem so they can refer management to a center that can perform a cord blood transplant.

DATA CAPTURE

A recent article in Respiratory Care concluded that wireless data capture provided a record of clinical events that could improve surveillance of ventilator use to the benefit of patients. The author noted that this method of data acquisition offered "a higher degree of surveillance with possibilities of producing error free information for research." It was noted that a previous inspection of more than two million ventilator events at the researcher's institution revealed 136,400 transcription errors, including disconnected alarms, inaccurate recordings of readings, and missing entries. For this study, information recorded detections of ventilator changes in the absence of the RT, when adjustments were made, if alarm settings were altered, event duration, and how the ventilator affected the patient. The study recorded data from a Puritan Bennett 840 Ventilator for several days, with frequency of recordings from two to three hours to 60 seconds. Tests were designed to monitor equipment functionality in the ICU using bluetooth wireless technology and a wi-fi network. See "Wireless On-Demand and Networking of Puritan Bennett 840 Ventilators for Direct Data Capture," William R. Howard, MBA, RRT, Respiratory Care, November 2007 Vol 52 No 11.

CLASSIFIED

A new classification system developed through research at Cincinnati Children's Hospital and Medical Center is improving diagnosis and treatment of rare lung diseases in infants. The system clears up confusion about how to classify and treat diseases that are rarely seen by most doctors and pathologists. Formerly, doctors used a number of different terms to label the same disease. In some cases, a disease with a favorable prognosis has been confused with a potentially lethal lung disease. The study, funded by the National Institutes of Health through its Rare Lung Diseases Consortium, included data from 11 medical centers in North America. Investigators reviewed 187 biopsies of children under the age of 2 who were being evaluated for diffuse lung diseases like interstitial lung disease (ILD). Children with ILD commonly have prolonged respiratory symptoms of fast breathing and low oxygen levels and exhibit diffuse changes on chest radiographs. When the cause of their symptoms is not identified with blood tests or x-rays, a surgical lung biopsy is often needed for diagnosis. In this study, the researchers were able to classify 88% of the 187 lung biopsy cases, and found a diverse spectrum of lung diseases that are largely unique to young children. One-quarter of the lung diseases studied were grouped together under the label "growth abnormalities." The best-known is pulmonary hypoplasia.. Another group of diseases was categorized as "surfactant dysfunction disorders," which refer to genetic abnormalities of surfactant. The new classification system is said to be helping pathologists diagnose children's lung disease more accurately, leading in some cases to more appropriate treatment. For instance, in the past, children with lung growth abnormalities might have been treated as though they had ILD and given steroids, which may not be an effective treatment for them. The new system also gives doctors more information about an infant's prognosis. In the past, children with ILD were thought to have a high rate of illness and death. The classification system can help doctors distinguish certain children who may appear very ill, but who have a high chance of recovery (such as children with pulmonary interstitial glycogenosis and neuroendocrine cell hyperplasia of infancy), from those with a particular genetic mutation, known as ABCA3, who are unlikely to recover on their own and may need a lung transplant.

UNINTENDED CONSEQUENCES

The BCG vaccine, which aims to prevent tuberculosis among children in developing countries, might be causing illness and death among some HIV-positive infants, researchers say. The findings are included in a report about the HIV/TB co-epidemic released by the Forum for Collaborative HIV Research. The report said that the benefits of potentially preventing severe TB among HIV-positive infants are outweighed by the risks associated with the use of BCG vaccine. The World Health Organization previously recommended that all healthy infants receive the BCG vaccine as soon as possible after birth. However, the agency released a report in May 2007 changing its position because of evidence that HIV-positive infants had an increased risk of developing BCG disease. The BCG vaccine is based on a weakened strain of the bacterium that causes TB in cattle. Many of the infants who receive the vaccine are born HIV-positive and subsequently have compromised immune systems that make them susceptible to BCG disease, which is caused by the bovine bacterium in the vaccine. One study found that the vaccine had a 75% mortality rate among children with BCG disease and that 70% of those children were HIV-positive. In that study, an estimated 400 of every 100,000 HIV-positive infants in South Africa's Western Cape province had become ill from the BCG vaccine, and it was unclear how widespread the problem might be across Africa. This story is copyrighted by the Kaiser Network, The Henry J. Kaiser Family Foundation, originally reprinted in Medical News Today.

PRODUCTS

HEART TO HEART

Masimo the inventor of Pulse CO-Oximetry and Read-Through Motion and Low Perfusion pulse oximetry, reported that a new independent and objective clinical study demonstrates the ability of Masimo SET Perfusion Index (PI) to improve detection of congenital heart defects (CHD) in newborns with duct-dependent systemic circulation. Even when routine neonatal physical examinations and saturation screenings fail, PI may help to accurately detect CHD. It has been documented that up to 30% of all deaths from CHD in the first year of life are due to unrecognized cases being discharged to the home.

PI is a measurement featured in the Masimo Rainbow SET technology platform that reflects the real-time changes in peripheral blood flow at the monitored site and the strength of the plethysmographic signal displayed on the pulse oximeter. In addition to improving the detection of CHD in infants, the ability to noninvasively and continuously measure PI could enable faster identification of clinically significant changes in a patient's physiologic status, including potentially hypothermia,

hypovolemia, shock and/or sepsis. In the study, entitled "Noninvasive Peripheral Perfusion Index as a Possible Tool for Screening for Critical Left Heart Obstruction," conducted at the Institute of Clinical Sciences, Gothenburg University, Sweden, the investigators observed whether PI was a dependable indicator in critically ill newborns to enable its use for congenital heart disease screening purposes. The researchers indicated that several studies have reported that babies with congenital heart disease are not detected by routine neonatal physical examinations and that neonatal screening fails mainly in children with duct-dependent systemic circulation. They conducted single pre- and postductal measurements of PI using the Masimo Radical SET Pulse Oximeter in a total of 10,000 healthy newborns (ranging in age from 1 hour to five days) and established PI reference values of healthy babies. In establishing reference values that validate possible PI indices for normal vs. disease state in newborns, researchers were able to show that low PI values may correspond to illness. Study results showed that combined neonatal examination and oxygen saturation screening detected only 78% of the newborns with LHOD, but when PI was added, 100% of all newborns with LHOD showed abnormalities, indicating that PI may reflect abnormal blood flow from the heart in CHD newborns. All LHOD newborns had either pre- or postductal PI values below the interquartile cut-off value of 1.18 and five had values below a potential cut-off of 0.70, leading researchers to conclude that "PI values lower than 0.70 may indicate illness and a value less than 0.50 indicates definite underperfusion." Study findings suggest that a combination of saturation screening cut-offs with PI value cut-offs may help improve the early detection of congenital heart defects that have duct-dependent systemic circulation. As a result, researchers concluded that PI is a "promising tool for improving the detection of critical congenital heart disease with duct-dependent systemic circulation.

TUBULAR

A new line of functional, comfortable, and attractive tracheostomy tube holders that are offered with designs for babies, kids, and teens is being introduced by Dale Medical Products, Inc of Plainville, MA. Dale PediPrints Tracheostomy Tube Holders feature the new PediDucks, PediStars, and Blue designs for babies, kids, and teens which are printed onto latex-free neckbands that are moisture repellent and ensure a snug fit without compromising security. Providing fastener tabs that are shaped to easily fit into the flange of any size trach tube, these family-friendly trach holders have rounded hook-and-loop back tab fasteners for sizing. Offering greater comfort, convenience, and security than twill ties, Dale PediPrints Tracheostomy Tube Holders assure a snug fit for necks from neonate to 19½ inches. PediDucks neckbands are 3/4-inch wide, Pedi-Stars and Blue are each 1-inch wide and they fit all brands of tracheostomy tubes to help prevent accidental dislodgment or displacement, trachesophogeal fistula, tracheal stenosis, or airway ganuloma. Dale PediPrints Tracheostomy Tube Holders are priced from $2.75 each, individually packaged 10 per box. Samples are provided upon request. Contact dalemed.com.

STREAMLINED SOARING

Siemens Medical Solutions helps hospitals and healthcare systems innovate their clinical and financial workflows through Soarian, its next-generation, workflow-engineered healthcare information system. Soarian combines clinical, financial and operational processes to support patient-centered care. By streamlining access to images and data from a variety of medical modalities in one location, Soarian helps facilitate more informed decision-making, leading to improved care delivery, increased staff satisfaction, and more efficient business practices. In addition to helping streamline critical information across clinical, financial and administrative functions, Soarian is assisting many healthcare organizations in improving workflow and patient safety. Currently, more than 100 Soarian-enabled workflows are live across the Siemens global customer base, demonstrating the ability to seamlessly connect clinical, operational, and financial processes in support of patient-centered care. Contact siemens-medical.com.

GO WITH THE FLOW

Vapotherm introduced Precision Flow, its new respiratory care device at the AARC annual conference in Orlando, FL at the AARC meeting. Precision Flow is the first high flow therapy device to integrate humidification, gas blending, flow control, and full alarm functionality into a single device for the delivery of nasal cannula inspired gases. The company has submitted and is awaiting 510(k) clearance for the new product from the FDA. The company's current device, the 2000i, is used in hundreds of hospitals throughout the US. With Precision Flow, the respiratory community will have a new option in high flow therapy that includes broader functionality, additional safety features and ease of use. Contact vtherm.com

GETTING BIGGER

Q-Core Ltd, a leading developer of Electronic Drug Delivery Systems (EDDS) for the medical devices market, announced the expansion of its sales coverage in Europe with the signing of strategic partnerships with leading distributor PMH. Under the agreement, PMH will distribute Q-Core's complete line of multi-therapy pumps, including administration sets and accessories. These products include a full range of pumps that merge hospital and homecare environments, improving patient quality of life. Q-Core multi-therapy and enteral feeding pumps fit comfortably in a pouch, and may be worn in virtually any patient's social environment. They are also easily transported to the hospital where they hook into existing cradles so hospital staff can monitor drug administration without inserting a new pump and using existing equipment. PMH will provide its customers with a full EDDS solution including Multi-Therapy Infusion Pumps, administration sets and accessories provided by Q-Core. Q-Core is a privately held company and PMH is certified in Portugal. Contact q-core.co.il.

READY FOR TAKEOFF

The US Food and Drug Administration has granted Hamilton Medical a 510(k) clearance to market the Hamilton-G5 ventilator. Designed expressly with patient safety in mind, the ICU ventilator features the unique Ventilation Cockpit. This intuitive user interface provides a graphic representation of the patient's lung mechanics and shows when the patient may be ready for separation from the ventilator. Like other Hamilton Medical ventilators, the Hamilton-G5 offers the proven closed-loop ventilation mode, ASV. ASV automatically applies lung-protective strategies, reducing the risk of operator error and promoting early weaning. The optional P/V Tool maneuver records a static/pressure curve at the bedside for safe determination of PEEP and tailored lung recruitment.
The Hamilton-G5 is designed to provide positive pressure ventilatory support to adult, pediatric, and optionally, infant patients. It is intended for use in a hospital and institutional environment where healthcare professionals provide patient

care, including use at the patient bedside for intra-facility transport. Contact hamiltonmedical.net.

GAS IT UP

Airgas Puritan Medical's National Oxygen Kit (NOK) is designed to supply hospitals with immediate access to emergency oxygen during natural disasters or security events. This self-contained product is the first oxygen delivery system designed for immediate large-scale treatment. A single NO is equipped with enough cylinders, regulators and masks to treat up to 40 people for a 24-hour period. Toggle valves allow instant access to oxygen without the need for an "e" key or other tools. NOKs have a guaranteed shelf life of five years for the oxygen and ten years for the cylinders, ensuring a low-maintenance supply for the long-term. For more contact airgas.com.

BEHRING STRAIGHT

Siemens is integrating Dade Behring into its existing business of Siemens Medical Solutions Diagnostics, a wholly owned subsidiary of Siemens Medical Solutions USA, Inc, with a transaction that took place this past November. The acquisition will allow Siemens to become the leader in the laboratory diagnostics market and enables Siemens to offer its customers a comprehensive portfolio of innovative solutions across the whole healthcare continuum - from prevention to diagnosis, to therapy and care. The company is bringing together the entire medical imaging, laboratory diagnostics and clinical IT value chain under one roof, offering opportunities for the integration of a comprehensive range of technology, workflows and information that will help deliver an improved quality of patient care at reduced costs. According to Siemens, together with Dade Behring, Siemens Medical Solutions Diagnostics is well-positioned to lead the way in bringing new capabilities to the diagnostics industry. Jim Reid-Anderson will lead the Siemens Medical Solutions Diagnostics global business that has nearly 15,000 employees. Jochen Schmitz will remain Chief Financial Officer (CFO). Primary offices of the company will be located in Deerfield, IL, the current headquarters of Dade Behring. Siemens has 475,000 employees. Contact siemens.com.

KEEPS SOARING

Siemens Medical Solutions helps hospitals and healthcare systems innovate their clinical and financial workflows through Soarian, its next-generation, workflow-engineered healthcare information system. Soarian combines clinical, financial and operational processes to support patient-centered care. By streamlining access to images and data from a variety of medical modalities in one location, Soarian helps facilitate more informed decision-making, leading to improved care delivery, increased staff satisfaction, and more efficient business practices. In addition to helping streamline critical information across clinical, financial and administrative functions, Soarian is assisting many healthcare organizations in improving workflow and patient safety. Currently, more than 100 Soarian-enabled workflows are live across the Siemens global customer base, demonstrating the ability to seamlessly connect clinical, operational, and financial processes in support of patient-centered care. Contact siemens-medical.com.

NOT FOR GRANTED

More than 10% of the nation's healthcare facilities are seeking grants from Cardinal Health through a $1 million fund set up by the company to help improve patient safety. More than 700 hospitals, health systems and community health clinics responded to Cardinal's announcement about the grant program, which is the largest and first of its kind in the private sector. To support initiatives that enhance patient safety and quality of care, Cardinal Health will grant up to $50,000 per facility to fund new and innovative programs that establish or implement creative and replicable methods to address challenges in providing quality patient care and to help drive improvements. The company expects to fund up to 40 of the 730 grant requests. In selecting grant recipients, Cardinal Health's selection committee is looking for: projects that respond to a clearly identified, high priority safety issue; projects that apply new thinking and approaches to development of solutions; collaborative programs; demonstrable and sustainable measures to assure that improvements hold up over time; and model programs that can be replicated at other organizations. Contact cardinalhealth.com.

TIE ONE ON

The new Pepper Medical Inc Vent-Tie is a patented ventilator Anti-disconnect device coupled with a trach tube neckband. This unique combination device offers a margin of safety to ventilator dependent patients and clinicians alike. The easy to use Vent-Tie features a quick release Velcro strap that is compatible with all trach tubes, elbow connectors, and closed suction devices. The integral anti-disconnect strap eliminates the use of rubberbands, shoelaces and tape to secure the ventilator circuitry to the trach tube. The Vent-tie neckband is made of a soft, 100% cotton flannel that offers moisture wicking properties to keep skin dry and cool. This disposable, combination product saves time and money by offering an all-in-one device. The economical Vent-Tie is priced at $3.95 each, individually packaged in boxes of 20 each. Free samples available upon request. Contac (800) 647-0172, peppermedical.com.

HOME AND HOSPITAL

Q-Core Ltd, a leading developer of Electronic Drug Delivery Systems for the medical devices market, announced the latest version of multi-therapy pumps that merge hospital and homecare, improving patient quality of life and safety while decreasing cost of care. The Q-Core line of multi-therapy pumps, including infusion pumps, enteral feeding pumps and veterinary infusion pumps, can be worn comfortably in a pouch in virtually any social environment and easily transported to the hospital where it is hooked into a cradle so hospital staff can monitor drug administration. Q-Core's efc Technology (Electromagnetic Flow Control Technology), based on the principles of electromagnetic propulsion, dramatically improves flow accuracy and enhances the continuous nature of the IV flow, thereby increasing patient safety. With an exceptional infusion rate spanning from 0.1-1000 ml/hr, Q-Core pumps can be used for all patients, including infants, enabling hospitals to save on the extra costs typically required when purchasing various sized pumps and IV sets. As the first infusion pump on the market to employ this principle, Q-Core's efc Technology also has a unique ability to perform any linear or non-linear flow profile, in any physical orientation, increasing patient mobility and comfort. Q-Core's detachable touch screen with intuitive programming capabilities provides a new level of simplicity and ease of use for patients who lack medical training. The user-friendly interface reduces the chances of error in configuration, while the Q-core event log, storing up to 5,000 treatment-related events, allows hospital staff to precisely monitor out-patient activity. Q-Core's pumps include the uniquely designed

Magic Straw, a disposable module attached to the pump as part of the Administration Set, providing automatic anti-free flow protection and upstream/downstream occlusion protection. The Magic Straw is easy to install, and its design prevents incorrect installation of the tubing.

OVER THE RAINBOW

Masimo featured its Masimo Patient SafetyNet, a new remote monitoring and clinician notification system, along with its upgradeable Masimo Rainbow SET technology platform, at the AARC Congress. Patient SafetyNet combines the performance of Masimo Rainbow SET pulse oximetry with wireless clinician notification via a pager to provide safety to patients on general care floors where nurse-to-patient levels preclude the level of direct surveillance needed to preempt sentinel events. When a SafetyNet-monitored patient is in respiratory distress, meaningful and actionable alarms are generated by the Masimo bedside monitor and sent wirelessly to designated clinicians. The Masimo Patient SafetyNet instantly routes bedside-generated alarms through a server to a clinician's hand-held paging device in real time. The system also allows for escalation of the alarm to additional clinicians. The SafetyNet can support up to 40 bedside monitors and can be integrated into a hospital's IT infrastructure or operate as a standalone wireless network. Contact masimo.com.

HISTORY

Draeger recently celebrated its double centennial of medical safety and technology. The company arrived in the US in 1907, bringing the first mobile short-term respirator, the Pulmotor. Other highlights in the company's history: 1902: first anesthesia machine; 1904: first innovation in breathing developed by Bernhard Drager, the 1904/09 model respiratory protective device; 1907: first mobile short-term respirator, and the birth of the "Draegermen," who operated it; 1913 world altitude record of 6,120 m for airplanes set with Draeger high-altitude breathing apparatus; 1947: iron lung prototype developed; 1950: Draeger unveiled its Model G first integrated anesthesia and ventilator apparatus; 1952: Poliomat, the first long-term ventilator; 1959: Draeger intros its Assistor 640, the first pressure-controlled ventilator; 1989: Babylog debuts, the company's first neonatal ventilator; 2001: Savina is Draeger's first mobile ventilation system; 2006: SmartCare/PS, the first automated knowledge-based ventilation weaning system is launched in the US; 2007: Oxylog 3000 ICU-level performance emergency transport ventilator is launched. For more contact draegermed.com.

LINKING UP

MediServe and Theronyx today announced a partnership in which MediServe becomes the exclusive marketing, sales, and support provider for the Theronyx suite of software solutions for respiratory care in the United States. MediServe will continue to market its award-winning MediLinks solution and services to clients who require MediLinks industry-leading ability to adapt to a unique workflow and tightly integrate with hospital information systems. The company will market the Theronyx OPUS-RT solution to clients seeking a respiratory care solution that can be rapidly deployed with minimal integration. MediServe will also market the new Theronyx solution for ventilator management in critical-care settings, OPUS-CriticalCare, which targets efficient management of ventilator patients. Both companies will continue to enhance their current products and develop additional advanced products and services for the healthcare market.

INSPIRATION

Inspired Technologies, Inc announced it obtained FDA 510(k) clearance for its VIAspire Oxygen Portable, a component of its Personal Oxygen System. The lightweight, long duration and quick-to-fill portable provides a ready supply of liquid oxygen for patients requiring oxygen therapy. The VIAspire features the SmartDose technology, an algorithm that responds to a patient's breath rate. SmartDose delivers more oxygen when the patient needs it, supporting optimal oxygen saturation levels and thus promoting activity. Another part of VIAspire, the Liquefier, received 501(k) clearance in September. The VIAspire Oxygen Portable fills faster and lasts longer than transfilled gas portables and is available in three sizes. The company also announced the closing of its latest financing round. Birchmere Ventures, Cardinal Partners, Draper Triangle Ventures and Innovation Ventures have joined in funding the company's next stage of growth. For more about Inspired (formerly COPD Partners), contact inspiredtechnologies.com.

A MOUTHFUL

Children's Medical Ventures (ChMV), a subsidiary of Respironics, Inc, announced the addition of oral syringes to its line of safety solution products for the NICU and PICU. These specialty use syringes have been developed to help reduce feeding errors in the NICU and PICU, and to help professional healthcare providers avoid potential tubing misconnections. ChMV collaborated with NICU healthcare professionals in an effort to eliminate the potential error of infusing a newborn infant with breast milk or formula instead of the intended medication or intravenous solution. These errors pose a significant risk to the patient and hospital. The result is a complete line of oral syringes (1 ml, 5ml, 10 ml, 20 ml, 30 ml and 60 ml sizes) designed to reduce the possibility of feeding/medication errors. Safety design measures include a highly visible label that reads "ORAL DISPENSER," a bright orange tip that distinguishes it from medication syringes, and a connector that will not securely attach to a standard luer lock connector. Because standard 1 ml syringes are commonly used to administer medication in the hospital setting, ChMV's 1 ml syringe is a highly noticeable amber color and its labeling reads "FOR ORAL USE ONLY." The foundation of ChMV's new Oral Syringe is the Becton-Dickinson (BD) syringe and is compatible with the most commonly used hospital syringe pumps such as those manufactured by MedFusion and Baxter. Other significant features of the Children's Medical Ventures' Oral Syringes include individual product packaging that allows the clinician to see the syringe type and size before opening the package. Additionally, the body of the syringe is clear and allows clinicians to easily monitor feeding and check for residuals. Contact childmed.com.

IN THE BAG

B&B Medical Technologies now offers The Test Lung, a new, economical choice for providing high quality demonstration and testing applications on mechanical ventilators. The Test Lung simulates the respiratory system, providing nominal levels of resistance and compliance as well as a variable leak function to demonstrate patient-trigger function or the leak compensation of a respiratory system. The Test Lung is packaged with a 1 liter, Latex- free Silicone Ventilation Bag, Test Lung Connector Kit and Rp5 Resistance. The 1 liter Silicone Ventilation Bag is durable, easily removable and can be cleaned or sterilized as needed. The Test Lung Connector Kit adapts to all patient circuits and proximal airway flow sensors. The Test Lung

Connector Kit has three adapters, two with Luer Ports and Caps, providing easy ability to demonstrate the ventilator's leak compensation performance and patient-trigger function. The Test Lung is compact in design and lightweight. Each Test Lung is tested and validated for resistance and compliance in the application range and has a unique serial number to ensure its compliance with specification. A Precision Resistor Kit provides the precision adapters needed to simulate changes in airway resistance. The Kit contains three resistors: Rp5, Rp20 and Rp50. The Precision Resistor Kit can be cleaned and sterilized. The Test Lung and Precision Resistor Kit are the ideal tools for teaching and demonstration of mechanical ventilation in addition to performing ventilator verification testing in the respiratory care, biomedical labs and anesthesia departments. Contact bandb-medical.com.

EXECUTIVE PROFILE

GE Healthcare

Information provided by Mike Genau, Vice President, General Manager for GE Healthcare's Maternal -Infant Care business.

Describe your product(s) and its unique features:
2007 was a tremendous year for GE Healthcare's Maternal Infant Care business with three significant, new product introductions. We are continuing to create leading technologies and innovations to directly support caregiving, so clinicians can be ready for the unexpected. We're committed to helping hospitals be ready for the unique care these most fragile patients need and to improve outcomes and reduce stress for babies, families and clinicians. The newest technologies in our product family that highlight this commitment are:

• Giraffe Warmer: This product continues the innovation forged by our Giraffe OmniBed, with technologies still exclusive to GE such as the recessed heater head, and 360 degree rotating mattress. The Giraffe Warmer was designed specifically for the neonatal intensive care environment. Our customers tell us the most significant new features are the hands-free alarm silence and the integrated aimable procedure light.

• Panda Warmer: A new addition to our product portfolio, the Panda Warmer was designed for the unique needs of the labor and delivery environment. It shares some features with the Giraffe Warmer such as the recessed heater head and hands-free alarm silence. An exclusive, optional integrated resuscitation system requires minimal setup time for clinicians to standardize resuscitation protocols across the perinatal care area. GE designed this system with the American Academy of Pediatrics' (AAP) latest Neonatal Resuscitation Program Guidelines (NRPG) in mind. Another optional feature, advanced SpO_2 monitoring, captures the infant's pulse rate and oxygenation throughout the resuscitation process and displays data on the bed's full-color control panel. An alarm-free warm-up mode allows clinicians to maintain an appropriately warmed mattress so the bed is ready for the baby at admission.

• BiliSoft LED Phototherapy System: This phototherapy system is a revolutionary blue LED and fiber optic-based technology for treating newborn jaundice. This innovative product responds to clinical guidelines while at the same time promotes the developmental care of newborns. BiliSoft delivers phototherapy anywhere – in the NICU, well baby nursery or at home. Designed with the feedback of neonatal nurses around the world, BiliSoft provides distinct improvements over existing technologies. BiliSoft utilizes six blue LEDs with a "soft" large light pad, in two sizes, for use with premature infants or full-term babies meeting the American Academy of Pediatrics' (AAP) Guidelines on Jaundice Management.

How does your product directly affect patient care?
On our Giraffe Warmer and Panda Warmer, the recessed heater completely eliminates the traditional, often awkward overhead heater design. The sleek, modern design improves clinician and parent access to the infant, removing overhead obstacles while providing uniform heat across the entire mattress - even during procedures such as X-ray. The hands-free alarm silence on our Giraffe Warmer and Panda Warmer eliminates the need for additional help during procedures just to press the alarm-silence button. Even gloved persons can silence the alarm without touching the unit to press the alarm-silence button – which some studies suggest can be an area susceptible to contamination. For BiliSoft, a new soft, flexible fiber optic light pad allows the swaddling, or wrapping, of full-term babies to further enable feeding and holding during phototherapy. BiliSoft operates quietly, creating a soothing, comfortable environment for the newborn wherever it's needed—in the hospital or at home. Our goal is to provide maximum efficiency in intensive phototherapy, while also allowing for positioning, swaddling and other direct contact with the baby.

Tell us about the latest advances in the area your product serves.
Certainly, one of the most impactful changes has been the issuance of NRP and Phototherapy Guidelines by the AAP. These important guidelines have guided our product design. Guidelines and standards are an important voice in defining customer needs and requirements. Indeed, all our new products—Giraffe, Panda, BiliSoft—have benefited from these documents and are designed to meet them.

What sets your product apart from others in the field?
We are completely focused on Maternal-Infant Care, completely dedicated to the clinical needs of the NICU and L&D – dedicated to mothers and babies. We have a long-term vision of a platform of products incorporating significant advances to address challenges in the L&D and NICU. The two new warmers are the next step toward achieving that vision – with more on the horizon. They have all come from directly and passionately listening to our customer needs.

Discuss your R&D process, including end-user input.
Our new products are the result of five years of intensive research into customer, patient and clinical needs. We invested the time to make the new products reflect what the clinical user's requirements are in terms of patient care. We go through a number of iterations in our design process. Periodically, we may even extend product launch timelines to ensure that we have accurately designed the product to meet those needs.

By working closely with leading institutions and clinicians, we are developing new technologies that provide the caregiver with a comfortable working space that is flexible and applicable for

both L&D and the NICU. We continue to invest in ways to build upon platforms and improve the patient recovery cycle, clinical workflow and productivity.

What are your goals for R&D in the near future?
Our top R&D goals are high product quality, continuing to reduce costs and driving innovation. In the R&D realm, miniaturization is driving innovation—we're able to do things on smaller platforms that we've ever been able to do before. We take advantage of these advancements in miniaturization and computerizations to reduce device complexity so clinicians can spend more time on nursing and interacting with patients and families, as opposed to managing the machine. We have recently segmented our business to focus on the L&D and NICU. We recognize that NICU and L&D are fast paced and complex care areas. Our research with clinicians is driven to provide them with systems that can reduce medical errors, and thus improve outcomes. We will continue to integrate information from our products with other clinical information systems to aid in clinical decision-making. Low birth-weight infants offer new challenges for care. We must continually evaluate and improve all of our products as the environment and clinical needs in the NICU and L&D change, so that we can deliver and maintain products with clinical relevance and acceptance.

Discuss the educational services you offer for use of your product.
We have always provided clinical education on our products. A new area of focus is on providing a broader educational offering. These include new single, multi-day and even Web-based educational offerings so our customers will better understand how to use our product more effectively. We are continuously looking to offer educational services where we can add value.

Talk about how you test and evaluate your product in actual day-to-day use.
Of course all our products are designed and tested to meet applicable standards and requirements around the world. But, the final test is always customer acceptance. We take this very seriously – we have a full time clinical manger on staff to conduct clinical validation of our products both pre- and post-introduction.

What new technology do you see as having the greatest impact on your area of expertise?
In-vitro fertilization and births at advanced maternal age are leading to more pre-term, high-risk and low-birth-weight babies. The result is that smaller babies than ever are surviving. We continually examine and re-examine our product innovations to keep pace of advancements in related fields that impact NICU and L&D.

Discuss the international scope of your testing/marketing/development efforts.
We recognize that clinical practices and economic development differ around the world. The ability of a rural hospital in China, India or Africa to manage sophisticated technology may not be as well developed as hospitals in the U.S. Yet, the global unmet needs of mothers and infants are dramatic and under-served. The World Health Organization (WHO) reports half a million mothers die of complications in childbirth, and 4 million infants die each year in the neonatal period. Of the 136 million births recorded, 10 percent are premature. The world is focused on this pressing challenge through the Millennium Development Goals (MDG) published by the United Nations in 2000. GE saw a real need for better maternal and infant care around the world, and created this maternal and infant care business in 2004. We are focused on finding the right product type to improve access to care, and meet the need for affordable technology. We are using an "in-country-for-country" business model for R&D, engineering and manufacturing for products relevant to their society, economy and clinical practice. We are designing and developing new technology at GE's R&D center in India, as part of our "In India, for India" program to make technology more affordable, reliable and more accessible to larger sections of society. For example with our work in India, we know many of the birthing centers don't have effective phototherapy systems. Failure to treat infant jaundice can result in serious brain damage, and even death. Emphasis on earlier detection and treatment of jaundice in newborns is one way our GE Maternal-Infant Care business is making a difference in India. We hope to repeat this model in other countries in the coming years.

Tell us how you utilize conferences, seminars and such to promote your product.
Conferences, seminars and forums provide the best opportunity for a two-way conversation with clinicians on how our products solve their challenges. Conferences are important to us, as they are important to our nursing colleagues. We look forward to them as a place to engage in a dialog with clinicians, as well as an opportunity for us to support the hosting associations and organizations. It's a convenient opportunity for customers to look at our new products. As we're engaging in these dialogs with clinicians, it offers the opportunity to validate our marketing message and conduct limited user research about trends in the marketplace.

Imaging Case Book: Neonatal Marfan Syndrome

Jayendra R. Sharma, MD, FACC; Dieepika Thacker, MD

Imaging Casebook

A full term male baby was born to a 25-year-old primigravid mother by normal spontaneous vaginal delivery. The perinatal history was unremarkable.

On physical exam, the weight of the baby was 2.9 kg, length 51cm and head circumference was 35 cm. Heart rate was 146/minute, respiratory rate was 40/minute, and blood pressure was 52/32 mmHg. There was no significant blood pressure gradient between the upper and lower extremities. Oxygen saturation was 96%. The baby had an aged facial appearance (figure 1) and long fingers and toes (figure 2). He was found to have a grade 2/6 ejection systolic murmur at the left upper sternal border. Rest of the physical examination was unremarkable. Chest x-ray showed eventration of right dome of the diaphragm (figure 3). An echocardiogram showed mild proplapse of both, the mitral (figure 4) and tricuspid valves with mild AV valve regurgitation. There was no aortic root dilation. The complete eye evaluation by ophthalmologist was normal except for megalocornea.

Family history was significant for a recent diagnosis of lens dislocation in the father when he went to the ophthalmologist for a vision check. On cardiac referral, the father was found to have mitral valve prolapse with moderate to severe mitral regurgitation and mild aortic root dilation.

On follow up of the baby at 3 months age, there was no significant change in the degree of mitral regurgitation or aortic root dimensions.

The authors are with the Department of Pediatrics/ Division of Pediatric Cardiology, The Children's Hospital at Downstate/ SUNY, Brooklyn, NY. The authors wish to thank Dr Benamanahalli K. Rajegowda and Dr Muhammad Aslam for providing final peer-review of this article and recommendation for publication. Both are members of editorial advisory board of neonatal intensive care. Dr Rajegowda is chief of neonatology at Lincoln Medical and Mental Health Center and Professor of Clinical Pediatrics at Weill Medical College of Cornell University. Dr Aslam is clinical fellow in newborn medicine at Children's Hospital Boston and Instructor in Pediatrics at Harvard Medical School.

Discussion

Marfan Syndrome was first described by a French pediatrician Antoine Marfan in 1896. The syndrome is characterized by involvement of the skeletal, ocular, cardiovascular, cutaneous and pulmonary systems and specific criteria have been described for its diagnosis.[1] The diagnosis is usually made in late childhood or adolescence, however numerous cases have been described in early infancy and the neonatal period.

Neonatal cases are usually more severe and carry a worse prognosis. The cardiac findings and phenotypic features along with the family history led to a diagnosis of Neonatal Marfan syndrome (nMFS) in this baby. Eventration of the diaphragm is known to occur in babies with neonatal Marfan.[2]

Mutations in the gene for fibrillin-1(FBN1) on chromosome 15q21.1 cause Marfan syndrome. The inheritance is typically autosomal dominant though sporadic cases may account for up to 25% of the cases. The group of connective tissue disorders caused by FBN1 Mutations is collectively termed as type-1 fibrillinopathies which include severe neonatal marfan syndrome, dominant ectopia lentis, familial ascending aortic aneurysm, isolated skeletal features of Marfan syndrome and Shprintzen-Goldberg syndrome.[3] A remarkable degree of clinical variability both within and between families with Marfan syndrome is well known. All nMFS mutations reported to date lie in one of the two hot spots in region of FBN1 exons 24-32, comprising mainly missense mutations in exons 24-27 and mutations causing skipping of exons 31 or 32.[4]

In addition to the classic skeletal features of Marfan such as arachnodactyly and hyperextensible joints, the neonatal form may present with joint contractures, usually involving the elbows, digits and knees.[5] These often respond to physical therapy. Other orthopedic manifestations such as scoliosis and joint dislocations usually present later in life. Typical facial features include enophthalmos, malar hypoplasia and a prominent forehead, high arched palate, crumpled ears with loose skin, often described as a "worried" or an "aged" look. Cardiac findings may include a murmur of mitral or tricuspid regurgitation though often the murmur may be absent in the first few days of life. Echocardiography is more sensitive in detecting cardiovascular manifestations in the neonatal period.

Figure 1: Prominent forehead and crumpled ears with "aged" look

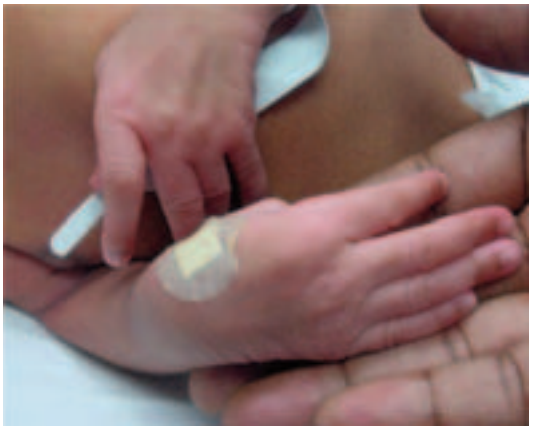

Figure 2: Long fingers

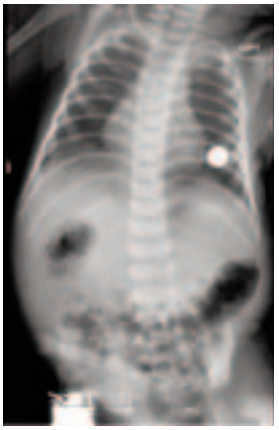

Figure 3: Eventration of right dome of diaphragm

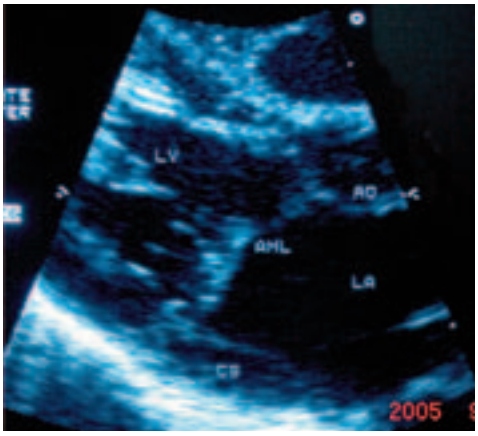

Figure 4: Flattening of both mitral leaflets with buckling of posterior leaflet in systole

Mitral valve prolapse and aortic root dilation are the most common findings, both of which may be progressive.[6,7,8] Tricuspid regurgitation and dilation of the main pulmonary artery may occur.[5] Ophthalmologic features in the newborn include megalocornea and iridodonesis.[6] Lens dislocation is unusual before 2 months and usually occurs between 2 and 4 years of age. Pulmonary involvement may present with neonatal emphysema.

The cause of death in neonatal Marfan is usually intractable congestive cardiac failure from mitral and tricuspid regurgitation,[6] as opposed to Marfan syndrome in older patients where the cause of death is often aortic dissection.[5,6] Prognosis is poor and most affected children die in the first year of life.[7,9]

Early recognition of neonatal Marfan syndrome is important in order to be able to anticipate and treat the cardiovascular complications associated with the diagnosis.

Newborn babies with congenital contractural arachnodactyly (Beals syndrome) should have an echocardiogram and ophthalmologic evaluation to look for features of Marfan syndrome. B-Blockers may be beneficial in patients with progressive aortic root dilation.[3] Infants with mitral or tricuspid regurgitation and congestive cardiac failure may require treatment with after load reducing agents, diuretics or digoxin. Mitral valve replacement or reconstruction, or even cardiac transplant may be required for severely affected babies.[8,10] Close ophthalmologic follow up can help prevent the development of visual loss. Orthopedic evaluation and frequent monitoring can help improve the quality of life in these patients.

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Patient Safety: It Starts With Training

Justin Tse, BS, RRT-NPS

Patient Safety is the number one goal on the minds of healthcare providers today. The Institute of Healthcare Improvement (IHI) and the Society of Critical Care Medicine (SCCM) are examples of organizations making strides at keeping our patients safe. There are many initiatives at work in hospitals to reduce medical errors. Ventilator bundles, sedation vacations and standardized medications are just a few ways hospitals are trying to improve healthcare. One area that is emerging in many institutions across the country is simulation based training.

Simulations have been used for many years to train men and women in various tasks. Commercial aviation and the military are just two of many areas spending millions of dollars in improving safety and reducing errors. An article written by Salas, Wilson, Burke, and Priest in the Joint Commission Journal on Quality and Patient Safety discusses using simulation-based training to improve patient safety. The main reasons simulations are used include "… it offers a realistic, safe, cost-effective, and flexible environment in which to learn requisite competencies for the job."[1]

Simulations can be used to provide healthcare workers with real life scenarios and allows them to use the skills they were taught before doing procedures on patients. The healthcare worker can then learn from any mistakes he/she may make during the simulation and not on an actual patient.

This article's purposes are as follows:[1]

- To highlight the key features needed so as to promote standardization of simulation-based training
- To make designers of health care simulation-based training aware of its possibilities
- To use research-based guidelines to promote dialogue and collaborations between learning, health care, and simulation experts

This article offers guidelines which can help educators design simulation based training:

Guideline 1. Understand the training needs and requirements
Guideline 2. Instructional features, such as performance measurement and feedback, must be embedded within the simulation
Guideline 3. Craft scenarios based on guidance from the learning outcomes
Guideline 4. Create opportunities for assessing and diagnosing individual and/or team performance within the simulation
Guideline 5. Guide the learning
Guideline 6. Focus on cognitive/psychological simulation fidelity
Guideline 7. Form a mutual partnership between subject matter experts and learning experts
Guideline 8. Ensure that the training program worked.

Simulation-based training has been an effective training tool. In an article in Chest by Rosenthal et al, competence was evaluated in emergency airway management. Forty-nine starting internal medicine interns were tested after having completed ACLS the year before. All the interns were tested and scored using a CPS and then given individualized instruction. They were then retested with the same scenario after 6 weeks and were also evaluated during actual patient contact. "All starting medical interns demonstrated poor initial airway management skills. SST was effective in improving these skills, both on retesting with the patient simulator and in actual patient situations. Interns trained by a house staff team professional performed as well as interns trained by the attending."[2]

Simulation-based training can help improve patient safety by providing a safe learning environment and reduce potential errors. The healthcare community can reduce errors and learn much from simulation-based training. "Simulation-based training offers a flexible architecture that provides trainees with opportunities to practice the learned competencies in a safe environment, allows for the collection of performance data, and provides feedback regarding performance."[1]

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Justin Tse is with Hamilton Medical

The Clinical Utility of Lactic Acid Testing with ABGs in the Neonatal Setting — A Case Study

Doug Wilder, RRT

Case

A 19 year old female presented to the hospital with increasing labor pains and delivered an otherwise normal 3 lbs. neonate. The neonate was placed under an infant warmer with an Oxyhood at 100% O_2.

After a period of one hour the patient's respiratory rate increased to 60 with mild retractions noted.

A blood gas was ordered and run on the Roche **cobas b** 221 < 6 > blood gas system.

The following results were reported:

Parameter	Reported Value	Neonatal Normal Ranges
pH	7.331	7.35 – 7.50
PCO_2	44.3	35 – 45
PO_2	225.0	50 – 80
HCO_3	22.9	22 – 26
tHb	20.5	13 – 22
SO_2	99.5%	< 90
Glu	60	80 – 120
Lac	6.2	< 2.0

Assessment

The patient has a normal SO_2 of 99.5% normal PCO2, normal HCO_3, and all electrolytes were in normal range. Based on ABG values and physical appearance, the patient appeared normal with increased respirations attributed to its premature condition. Upon closer review of the ABG results along with the lactic acid level of 6.2 mmol which is three times the upper limits of the normal range, the patient was diagnosed with Infant Respiratory Distress Syndrome. This syndrome increases the breathing rate in response to incomplete lung development characterized by reduced amounts of lung surfactant, cyanosis, the formation of a glassy membrane over the alveoli and pulmonary collapse. As respiration increases inspiratory muscles work harder to provide oxygen. The increased muscle activity results in utilization of glucose and increase in lactic acid in the bloodstream due to the inefficiency of the neonatal liver to convert the lactic acid to pyruvic acid.

Treatment

The patient was transferred to the NICU administered Bicarbonate, Glucose, Surfactant and placed on nasal CPAP overnight. The nasal CPAP was removed the next day.

Conclusion

Lactic acid and glucose as part of a neonatal ABG panel provides greater diagnostic capabilities in assessing and treating Infant Respiratory Distress Syndrome and related conditions.

Recommendation

All NICU blood gas analyzers should have the ability to run lactic acid and glucose like the Roche cobas b 221 < 6 > system. All neonatal blood gas panel should include lactic acid and glucose as a standard of care in the neonatal setting.

Doug Wilder, RRT, is Manager of Respiratory Services, Memorial Medical Center, Livingston, TX. This article was provided by Roche.

Midline Neck Skin Polyp in a Newborn Poses Diagnostic Dilemma

Benamanahalli K. Rajegowda, MD; Suja Vinod, MD; Zehra Panjvani, MD; Marilyn Guerrero, MD

Introduction

Congenital malformations that occur in the midline of the neck in newborn infants are mainly thyroglossal duct cysts and dermoid cysts. These occur as a result of defective closure or persistence of remnants of the thyroid gland migration or defects in closure and poses important diagnostic challenges to infant care providers. They present in the healthy newborn with a polypoid like lesion at the center of the front of the neck just above the suprasternal area. These malformations are not life threatening but their diagnosis is important to guide management. They can be excised for cosmetic purposes or to prevent complications. We present the case of an infant with a skin tag in front of the neck diagnosed as acrochordon or fibroepithelial polyp. A brief review of the relevant literature is also provided.

Case Report

A full term appropriate for gestational age male infant was born by normal spontaneous vaginal delivery. Maternal prenatal screen was negative except for positive group B streptococcus status for which she received intrapartum antibiotic prophylaxis. Fetal sonogram done at 16 and 26 weeks gestation revealed no evident fetal anomalies. APGAR was 9 and 9 at one and five minutes respectively. His weight 3,455 grams, head circumference 35 cm and length 49 cm were appropriate for gestational age. Physical examination was essentially normal except for a polypoid, pedunculous and fleshy skin tag on the front midline of the neck just above the suprasternal area (Picture 1). There was no redness, hair, pit, or pores. It was non-tender and covered by skin with no discharge. No movements were noted with respiration or swallowing. It measured 1 x 0.9 x 0.7 cm. In view of the location of this pedunculated skin polyp a tentative diagnosis of thyroglossal duct remnant cyst was made. A sonogram of the neck demonstrated the skin tag with a hypoechogenic base extending to the trachea with no inner connection (Figure 1). A CT scan of the neck demonstrated a normal thyroid gland with very superficial skin lesion on the neck measuring approximately 7mm in diameter (Figure 2).

Pediatric surgery evaluated the infant and reviewed the diagnostic radiologic studies. A decision was made to surgically excise the lesion at 12-16 weeks of life. Infant continued to do well and at 12 weeks of age underwent surgical excision without complications. At surgery there was no tract or fistula. The surgical specimen was sent for histopathology (Figure 3).

Discussion

Thyroglossal and bronchial anomalies are the most common anomalies in the newborns and the infants. They manifest at birth or later as a cyst, duct, dimple, fistula, abscess or remnant. A midline neck anomaly usually occupies a triangular area in the front of the neck above the suprasternal notch and on either side of the sternocleidomastoid muscle. The most common cause of midline neck mass is thyroglossal duct cyst which represents more than 50% of the malformations followed by epidermal/ dermal cysts, ectopic thyroid, lymphadenitis, hamartomas, and enlargement of thyroid gland from thyrotoxicosis or Hashimoto's disease. Rarely papillomas, teratomas and fibroepithelial polyps can arise in the same place. In our case the skin tag was initially believed to be thyroglossal cyst based on clinical and diagnostic imaging but the surgical excision and histopathology demonstrated no inner connection and no thyroid tissue. A retrospective diagnosis of fibroepithelial polyp was made.

Fibroepithelial polyp is also called a skin tag or acrochordon. It is a benign, soft and fleshy mass mainly composed of hyperplastic epidermal tissue overlying a dermal connective tissue stalk. Although it can occur anywhere in the body, location in front of the neck is very uncommon and very few such cases have been reported in literature. The anterior neck location causes a diagnostic dilemma as clinicians are more concerned about thyroglossal cyst or thyroid anomalies in such cases. Whatever the etiology such a mass has to be excised for diagnostic and cosmetic purposes in addition to avoiding long

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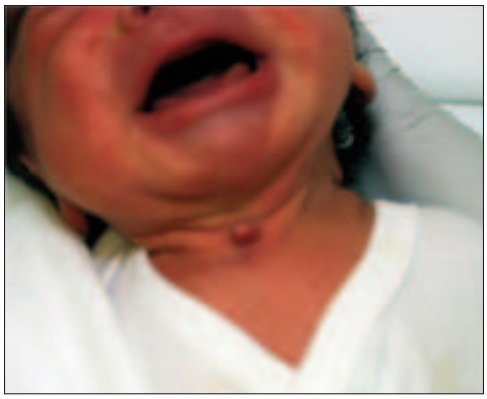
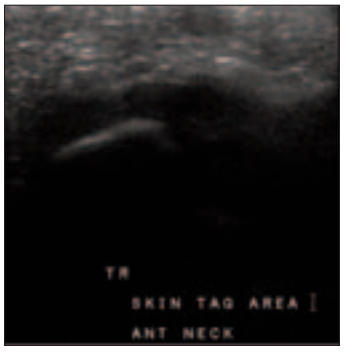
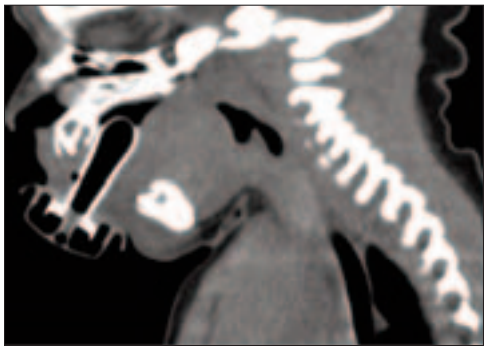


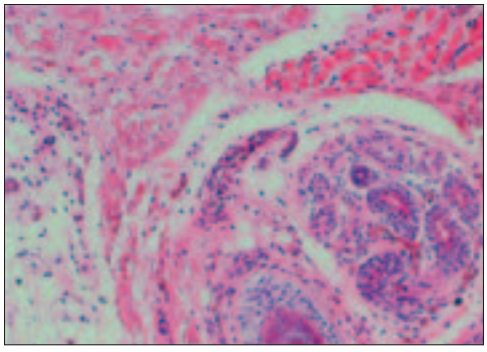
Picture 1. A & B: Anterior and lateral view of the skin tag in front midline of the neck.





(left) Figure 1. Ultrasound of the anterior neck demonstrating skin tag measuring 3 x 2 mm with a hypoehoic base.

(right) Figure 2. CT scan of the neck demonstrating a superficial lesion in the anterior neck measuring 7mm in diameter with no underlying connection to inner structures.



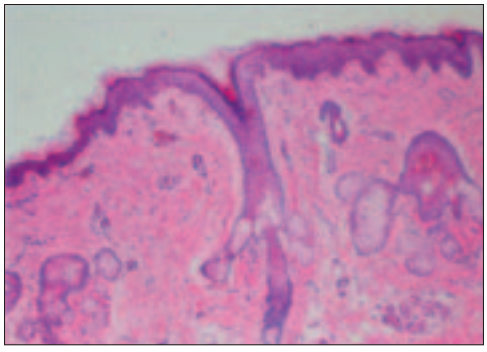


Figure 3. Microscopic examination under low and high power fields demonstrate a polypoid exophytic mass covered with keratinizing squamous epithelium, possessing numerous hair follicles and associated sebaceous glands.

term complications. In our case the mass was confirmed to be acrochordon or fibroepithelial polyp based on the histopathological diagnosis. An association with carbohydrate intolerance has been described in the literature, most commonly impaired glucose tolerance test and diabetes mellitus. There are also case reports of occurrence of basal cell skin carcinoma in association with acrochordon and this is another reason for their removal. Due to these potential complications they should not only be removed but serial follow up of the patient should also be ensured.

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Prone Positioning of Extremely Low Birth Weight Neonates During Mechanical Ventilation Results in Slightly Higher pCO_2 and Slightly Lower pH

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Abstract

Introduction: In general, the Newborn Intensive Care Unit (NICU) bedside nurses and/or respiratory therapists change the body-position of each mechanically ventilated premature infant every three to four hours. We postulated that in the prone position, the chest wall of small preterm infants is less mobile, which can lead to reduced chest ventilatory excursions and decreased ventilation.

Methods: We conducted an historic cohort study, tabulating all blood gas values of mechanically ventilated neonates with gestational ages of 23 to 30 weeks, at McKay-Dee Hospital during the past five years. Data were categorized according to three weight groups; ≤1000 grams; 1001-1500 grams; and >1500 grams.

Results: Ninety-six patients that required mechanical ventilation for more than three days, had multiple arterial blood gasses in multiple positions, were not transferred to another hospital, and survived to discharge, constituted this study. No position-associated differences were seen in neonates >1000 grams. Fifty-two weighed ≤1000 grams and received high-frequency ventilation. While in the prone position, their pH was lower (7.29±0.09; mean±SD) than while supine, right-down, or left-down (7.34±0.09, $P<0.0001$). The 95% confidence interval (CI) for decrease in pH while prone was 0.03-0.05 pH units. Also, while in the prone position, their pCO_2 was higher (53.8±13.6 torr) than while in the other three positions (47.4±11.6; $P<0.0001$; 95% CI 5.2-8.4 torr). Similar findings were observed for 53 neonates ≤1000 grams on conventional ventilation; the pH while prone was 7.30±0.08 *vs.* 7.32±0.07 in the other three positions ($P<0.0001$, 95% CI 0.02-0.04 units), and the pCO_2 while prone was 53.2±8.6 *vs.*49.7±9.9 in the other three positions ($P<0.0001$, 95% CI 1.7-5.3 torr).

Conclusions: When providing care to mechanically ventilated ELBW neonates, one can anticipate slightly lower pH values and slightly higher PCO_2 values in the prone position.

Introduction

Periodically changing the body-position of a critically ill, mechanically ventilated, neonate is a common component of pulmonary and developmental support.[1-4] It seems that most NICUs advocate changing the position of such patients about every three to four hours, and four positions are typically used – supine, right side down, left side down, and prone. We postulated that among very low birth weight neonates (VLBW; <1500 grams birth weight), the prone position can render the chest wall less mobile, which might lead to reduced chest ventilatory excursions and decreased ventilation. If this is so, it might be manifested by an increase in the pCO_2 and a decrease in the pH. We postulated that any consistent trends toward reduced ventilation in the prone position would be worth knowing about, so this could be anticipated when arterial blood gasses from such patients are interpreted. Our hospital records include the position of the neonate when the blood gas was obtained; therefore we conducted an historic cohort study to assess any association between body position of mechanically ventilated preterm neonates and arterial blood gas results.

Methods

Data were collected from patient flow-sheets of neonates ≤30 weeks gestation mechanically ventilated during the years of 2002 to 2006. Patients were included only if they required mechanical ventilation for more than three days, had arterial blood gasses measured in multiple positions, were not transferred to another hospital, and survived to discharge. Data from all such patients were tabulated into three groups based on weight; ≤1000 grams; 1001-1500 grams; and >1500 grams. Data collected included date of birth; gestational age; birth weight; infant weight for each day while on mechanical ventilation; ventilator mode, infant position; and arterial blood pH and pCO_2 while in the various positions. The pH and pCO_2 values while in various body positions were compared using an unpaired Student t test. The McKay-Dee Hospital Institutional Review Board approved the study.

Results

During the years 2002 through 2006, 94 patients required mechanical ventilation for more than three days, had arterial blood gasses in all four positions, were not transferred to another hospital, and survived to discharge. The records of these 94 were reviewed for this study.

Patients weighing >1000 grams had no position-associated differences in pH or pCO_2. However, among those weighing ≤1000 grams, consistent differences were observed (Table).

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Positioning	Conventional Ventilation		95% CI *vs.* prone	*P* Value *vs.* prone	High Frequency Ventilation		95% CI *vs.* prone	*P* Value *vs.* prone
	Mean	S.D.			Mean	S.D.		
Right Side pCO_2	49.7	9.7	1.6-5.4	0.0004	47.3	11.9	4.6-8.6	0.0001
Left Side pCO_2	48.8	9.0	2.6-6.3	0.0001	47.8	10.2	4.2-8.0	0.0001
Supine pCO_2	48.2	10.1	3.0-6.9	0.0001	46.0	10.7	6.1-9.7	0.0001
Prone pCO_2	53.2	8.6			53.8	13.6		
Right Side pH	7.34	0.08	-0.06 -0.03	0.0001	7.33	0.09	-0.05 -0.03	0.0001
Left Side pH	7.32	0.06	-0.04 -0.02	0.0001	7.32	0.08	-0.05 -0.02	0.0001
Supine pH	7.33	0.08	-0.05 -0.02	0.0001	7.34	0.09	-0.07 -0.04	0.0001
Prone pH	7.30	0.08			7.29	0.09		

Table. The effect of body-positioning on pCO2 (torr) and pH (U) of arterial blood of neonates weighing <1000 g while on conventional ventilation (n=52) or high-frequency ventilation (n=53).

These differences were seen whether the patients were ventilated using a high frequency ventilator (n=52) or using a conventional ventilator (n=53) (11 were in both groups, because data were obtained before and after they changed from high-frequency to conventional ventilation).

When ELBW neonates on high frequency ventilation were in the prone position, their pH was lower (7.29±0.09; mean±SD) than in the supine, right-down, or left-down positions (7.34±0.09, $P<0.0001$). The 95% confidence interval (CI) for decrease in pH while prone was 0.03-0.05 units. Also, while in the prone position, their pCO_2 was higher (53.8±13.6 torr) than while in the other three positions (47.4±11.6; $P<0.0001$; 95% CI 5.2-8.4 torr). Similar findings were observed for 53 neonates ≤1000 grams treated with conventional ventilation; the pH while prone was 7.30±0.08 *vs*. 7.32±0.07 in the other three positions ($P<0.0001$, 95% CI 0.02-0.04 units, and the pCO_2 while prone was 53.2±8.6 *vs*. 49.7±9.9 in the other three positions ($P<0.0001$, 95% CI 1.7-5.3 torr).

Discussion

Mechanically ventilated preterm infants are routinely subjected to periodic changes in position. Our study suggests that among those weighting >1000 grams, such positioning has no consistent effect on pH or pCO_2. However, in ELBW neonates, prone positioning results in a small but consistent increase in pCO_2 and decrease in pH. We do not interpret this finding as contraindicating prone positioning of ELBW neonates. In fact, these changes, which are probably clinically insignificant, could be outweighed by benefits to periodic prone positioning. Such benefits might include better pulmonary toilet, better oxygenation, and better neurodevelopment.[1,2,5,6]

The effect of position on ventilation and oxygenation of ELBW neonates is a complex matter involving many variables. For instance, the compliant chest wall of an ELBW neonate might be better stabilized by prone positioning,[6] and such stabilization might provide for better synchrony with the ventilator, and with an increase in tidal volume and minute ventilation.[7-9] However, this benefit has not been observed in all studies,[10,11] but rather an increase work of breathing is generally reported. Another issue affected by position might be ventilation/perfusion mismatch. In some neonates prone positioning might serve to improve this parameter while in others it might be worsened. Another issue complicating the interpretation of position and ventilation was reported by Heinrich et al, who observed that when an infant was prone with the head turned to the left, ventilation in the left lung decreased, while no difference was noted if the head was turned to the right.[12] We were unable to assess any association of head position with arterial blood gas results, because the head position was not recorded in our data. Another complicating issue is whether the abdomen is relatively free or relatively restricted while in the prone position. However, Wagaman et al reported no such effect on lung compliance, tidal volume, or minute ventilation.[5]

Two previous studies, using transcutaneous CO_2 measurements, are consistent with our present observations. Namely, Schwartz *et al*[13] studying VLBW infants, and Bozynski et al studying neonates 570 to 1360 grams, found higher transcutaneous CO_2 measurements while in the prone position.[14]

We recognize many shortcomings and pitfalls in the present study. Among these, the retrospective nature of the study leaves us uncertain about the timing of the observed changes. Specifically, we are uncertain how soon to expect changes in pH and pCO_2 after making a position change, and we are uncertain if these effects are relatively transient or persist until the position is changed. Also, we are not clear regarding the relevance of head position (to the right *vs.* to the left) on pCO_2 and pH of prone ELBW neonates. Moreover, we are uncertain regarding whether the relative freedom of the abdomen has an effect on the results. Despite these problems and uncertainties, we maintain that our overall finding can be of value to those

who interpret arterial blood gasses of mechanically ventilated ELBW neonates, giving them the anticipation of a minor increase in pCO_2 and decrease in pH, in the prone position.

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Theory of Obstetrics: An Epidemiologic Framework for Justifying Medically Indicated Early Delivery

K.S. Joseph

Abstract

Background: Modern obstetrics is faced with a serious paradox. Obstetric practice is becoming increasingly interventionist based on empirical evidence but without a theoretical basis for such intervention. Whereas obstetric models of perinatal death show that mortality declines exponentially with increasing gestational duration, temporal increases in medically indicated labor induction and cesarean delivery have resulted in rising rates of preterm birth and declining rates of post-term birth. Other problems include a disconnection between patterns of gestational age-specific growth restriction (constant across gestation) and gestational age-specific perinatal mortality (exponential decline with increasing duration) and the paradox of intersecting perinatal mortality curves (low birth weight infants of smokers have lower neonatal mortality rates than the low birth weight infants of non-smokers).

Discussion: The fetuses at risk approach is a causal model that brings coherence to the various perinatal phenomena. Under this formulation, pregnancy complications (such as preeclampsia), labor induction/cesarean delivery, birth, revealed small-for-gestational age and death show coherent patterns of incidence. The fetuses at risk formulation also provides a theoretical justification for medically indicated early delivery, the cornerstone of modern obstetrics. It permits a conceptualization of the number needed to treat (e.g., as low as 2 for emergency cesarean delivery in preventing perinatal death given placental abruption and fetal bradycardia) and a calculation of the marginal number needed to treat (i.e., the number of additional medically indicated labor inductions/cesarean deliveries required to prevent one perinatal death). Data from the United States showed that between 1995–96 and 1999–2000 rates of labor induction/cesarean delivery increased by 45.1 per 1,000 and perinatal mortality decreased by 0.31 per 1,000 total births among singleton pregnancies at ≥ 28 weeks of gestation. The marginal number needed to treat was 145 (45.1/0.31), showing that 145 excess labor inductions/cesarean deliveries in 1999–2000 (relative to 1995–96) were responsible for preventing 1 perinatal death among singleton pregnancies at ≥ 28 weeks gestation.

Summary: The fetuses at risk approach, with its focus on incidence measures, provides a coherent view of perinatal phenomena. It also provides a theoretical justification for medically indicated early delivery and reconciles the contemporary divide between obstetric theory and obstetric practice.

Background

Increases in medically indicated labor induction and cesarean delivery in recent decades have resulted in increases in preterm (< 37 weeks) birth rates, while births at term (37–41 weeks) and postterm (≥ 42 weeks) gestation are also being delivered much earlier than previously. However, such changes in obstetric practice are not consistent with obstetric theory since traditional obstetric models of perinatal death show that perinatal mortality rates decrease exponentially as gestational age increases. This paper examines the 'paradox of modern obstetrics' and various other conundrums within perinatology and discusses the 'fetuses at risk approach' as a potential solution. The latter approach is an epidemiologic formulation that identifies fetuses as the candidates for perinatal events (as opposed to the traditional obstetric and epidemiologic models that typically focus on newborns as the candidates for perinatal events). The fetuses at risk approach provides a coherent framework for reconciling the diverse set of problems facing perinatology and for developing a coherent epidemiologic framework for justifying medically indicated early delivery.

The paradox of modern obstetrics: The cornerstone of modern obstetrics is selective, carefully timed early delivery given fetal compromise (maternal indications sometimes necessitate early delivery as well). Medically indicated labor induction and cesarean delivery are typically employed when the balance of risks and benefits indicate that birth and supportive neonatal care are preferable to an intrauterine environment that is adversely affecting fetal well-being.

Induction of labor to effect early delivery was introduced in the mid-18th century as a management option for contracted pelvis. In the 1950s, early delivery after 35 weeks gestation was routinely used to prevent stillbirth in severe cases of Rh hemolytic disease. More recently, with advances in the diagnosis of fetal compromise (biophysical profile, umbilical artery Doppler velocimetry, etc) and in neonatal care (antenatal corticosteroids, surfactant, assisted ventilation, etc), rates of medically indicated labor induction and cesarean delivery have

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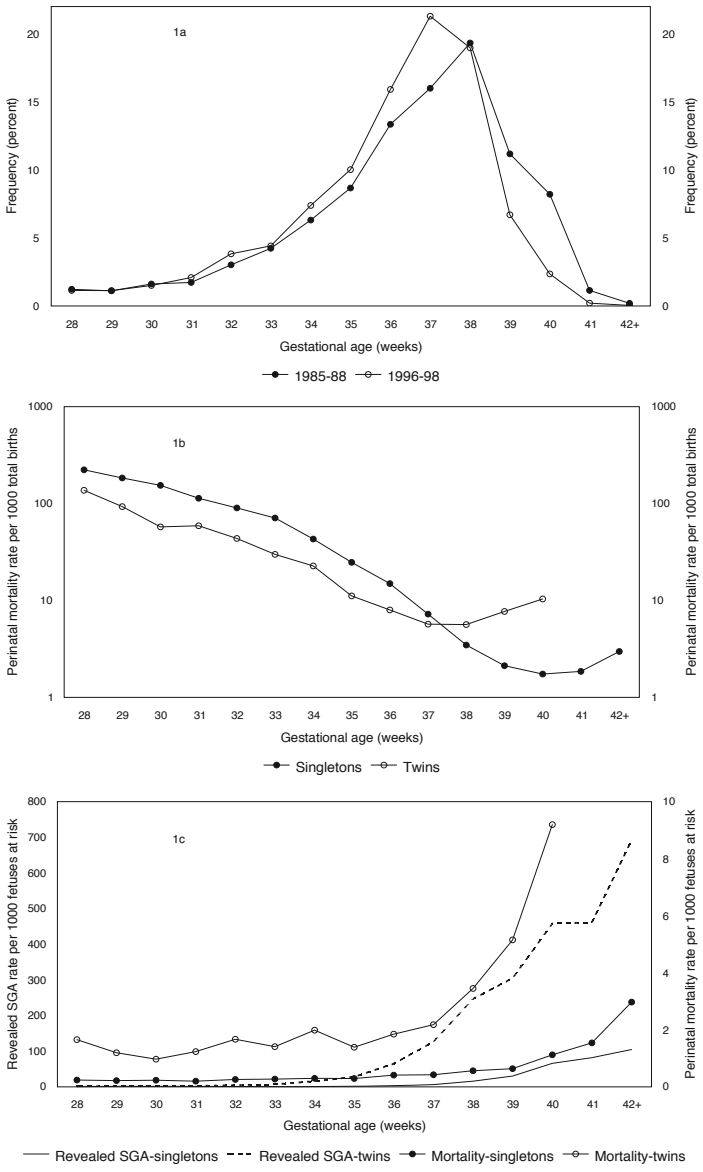

Figure 1: Gestational age distribution (1a) and gestational age-specific perinatal mortality (1b and 1c) rates, Canada.
Gestational age distribution of twin live births in Canada 1985–88 versus 1996–98 (Figure 1a), conventional calculation of ges•tational age-specific perinatal mortality rates per 1,000 total births among singletons and twins, Canada 1991–97 (Figure 1b), and gestational age-specific rates of revealed small-for-gestation age (SGA, primary Y-axis) and perinatal death (secondary Y-axis) per 1,000 fetuses at risk among singletons and twins, Canada 1991–97 (Figure 1c). Reprinted with permission [16].

increased substantially in industrialized countries at preterm, term and postterm gestation. The consequent "left-shift" in the population distribution of gestational age at birth (Figure 1a) has been responsible for the well-recognized phenomenon of rising preterm birth rates and declining postterm birth rates in industrialized countries. In Canada, preterm birth rates among twins and higher order multiple births have increased monotonically from approximately 30% in the 1970s, to 40% in the early 1980s, to 50% in the 1990s and to approximately 55% currently. Substantial changes have occurred in the gestational age distribution of singletons as well, with increases in preterm birth rates from 5.6 percent in 1981–83 to 6.4 percent in 2000, and declines in postterm birth rates from 6.0 percent in 1981–83 to 1.2 percent in 2000. Most of the latter decline in postterm births has occurred due to the introduction of a policy of routine labor induction for postterm pregnancies (although changes in the modality of gestational age ascertainment, from menstrual dating to ultrasound dating, have contributed as well).

However, traditional epidemiologic and obstetric models of perinatal death do not support this iatrogenic increase in early delivery. Such models show that the rate of gestational age-specific perinatal mortality (calculated by dividing the number of perinatal deaths at any gestation by the number of total births at that gestation) decreases exponentially as gestational age advances (Figure 1b). Although such models provide a justification for early delivery at ≥ 41 weeks for singletons and at ≥ 39 weeks for twins (Figure 1b), they suggests that a left-shift in the gestational distribution in the preterm or term gestational age range will lead to increases in overall perinatal mortality rates. For instance, early delivery at 34 weeks instead of 36 weeks gestation (or early delivery of singletons at 38 instead of 40 weeks) implies a substantially higher perinatal mortality rate (note log scale, Figure 1b). In fact, the recent left-shift in the gestational age distribution in Canada and in the United States (due to increases in labor induction and cesarean delivery) was accompanied by a decline in perinatal mortality.

Apparently contradictory phenomena: The paradox of modern obstetrics is also evident in relation to cerebral palsy. Although preterm birth is highly associated with cerebral palsy and deemed to be an important cause of cerebral palsy, the rising rate of preterm birth (especially among twins) has not resulted in an epidemic of cerebral palsy. Related conundrums are evident in the literature on fetal growth restriction. The methods used to identify small-for-gestational age (SGA) live births (< 3rd or < 10th percentile of birth weight for gestational age) suggest that a fixed fraction of births (approximately 3% or 10% depending on the cut-off used) are growth restricted at each gestation. Such an implied constancy of the growth restriction rate across gestation is at odds with an exponentially declining rate of gestational age-specific perinatal mortality. Clearly, this incongruence between patterns of in utero growth faltering and death needs to be reconciled, given the known relationship between fetal growth restriction and perinatal death.

Other problems in the fetal growth literature relate to fetal growth standards. Some fetal growth standards provide unisex reference values, several are sex-specific and yet others provide both sex-specific and unisex reference values. Of equal concern is the fact that several fetal growth standards are customized for different races, parity, plurality and other characteristics, while others are not.

Perhaps the most intriguing of the paradoxes in the perinatal literature is presented by intersecting birth weight- and gestational age-specific perinatal mortality curves. Birth weight- and gestational age-specific perinatal mortality curves intersect when contrasts are made by smoking status, plurality (Figure 1b), race, parity, infant sex, country, etc. This phenomenon was first identified by Yerushalmy who showed that whereas, at low birth weight, infants of smokers have a lower neonatal mortality rate than infants of non-smokers, the reverse is true at higher birth weight. Are the low birth weight or preterm infants of smokers more healthy than the low birth weight or preterm infants of nonsmokers? Addressing the paradox of intersecting perinatal mortality curves is important because the resolution of

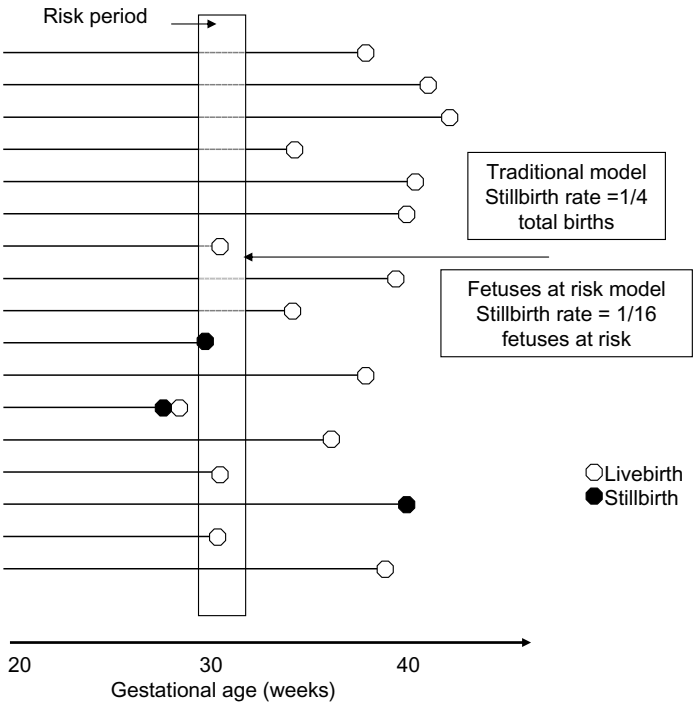

Figure 2: Schematic depiction of pregnancy course and options for calculating the gestational age-specific stillbirth rate.
Traditional calculation: Number of stillbirth at any gestational week/Number of total births at that gestational week = 1/4 = 250 per 1,000 total births. Fetuses at risk calculation: Number of stillbirths at any gestational week/Number of fetuses at risk of still-birth at that gestational week = 1/16 = 63 per 1,000 fetuses at risk.

scientific paradoxes often leads to greater substantive insights. The contemporary appeal of traditional models notwithstanding, intersecting perinatal mortality curves (and the other above-mentioned conundrums) suggest that there may be a more compelling perspective on perinatal events.

Discussion

The conundrums and paradoxes evident in contemporary perinatology are, at least partly, a consequence of the manner in which time related concepts are addressed in traditional models.

Two time scales are commonly used in perinatology and these measure the duration of life in utero (gestational age, which is anchored to the first day of the last menstrual period) and the duration of life after birth (chronologic age, which is anchored to birth). The clinical problems caused by these dual overlapping scales are generally recognized, especially by clinicians in neonatology, who resort to a single scale for expressing age, namely, post-menstrual age or corrected gestational age. Such recognition is also reflected in the evolution of Bronchopulmonary Dysplasia, which was historically defined as a requirement for oxygen at more than 28 days after birth but now refers to a requirement for oxygen or ventilatory support at 36 weeks of post-menstrual age. An important aspect of the use of dual time scales that is not related to duration issues is the qualitative label that is assigned to death depending on whether death occurs before or after the second time scale becomes operational. Thus, a fetus who dies in utero at 38 weeks is a stillbirth but another who dies at 2 weeks of chronologic age after birth at 36 weeks is a neonatal death. Birth has a preeminent position in qualifying life events for reasons that appear to be more sociologic than biologic.

Gestational age is often treated as a determinant in perinatal epidemiologic studies. As a determinant, gestational age at birth (and birth weight, which is closely correlated with gestational age) serves as a powerful predictor of death and other adverse perinatal outcomes. However, from an epidemiologic perspective, gestational age is in fact follow up (survival) time and should be treated as such in causal models.

The problem inherent in calculating traditional gestational age-specific stillbirth rates (eg, using the number of stillbirths and live births at 32 weeks as the denominator for the stillbirth rate at 32 weeks) and equating these estimates with gestational age-specific stillbirth risk was first identified over 15 years ago.

Table 1: Numbers and rates of perinatal death, live birth and small for gestational age (SGA) live birth among singletons births, Canada (excluding Ontario), 1991 to 1997.

Gestational age	Stillbirths	Neonatal deaths	Live births	SGA live births	Rates (Conventional)		Fetuses at risk†	Rates (Fetuses at risk)		
					SGA (%)	Perinatal mortality per 1,000		Births per 1,000	R-SGA per 1,000	Perinatal mortality per 1,000
34	329	175	10661	1011	9.5	45.9	1583286	6.9	0.6	0.32
35	318	172	18128	1822	10.1	26.6	1572296	11.7	1.2	0.31
36	439	249	41962	4226	10.1	16.2	1553850	27.3	2.7	0.44
37	451	269	87566	9104	10.4	8.2	1511449	58.2	6.1	0.48
38	552	364	232039	22163	9.6	3.9	1423432	163.4	15.6	0.64
39	522	359	356922	35792	10.1	2.5	1190841	300.2	30.2	0.74
40	601	464	536302	54709	10.2	2.0	833397	644.2	65.9	1.28
41	304	219	245665	24104	9.8	2.1	296494	829.6	81.7	1.76
≥ 42	92	77	50433	5250	10.5	3.3	50525	1000.0	104.8	3.34
Total‡	8694	5562	1614531	160429	10.0	8.8	1623225	1000.0	100.0	8.70

Note: Perinatal mortality includes stillbirths and neonatal deaths. Live births at each gestation served as the denominator for the conventional SGA rate and total births at each gestational week served as the denominator for conventional perinatal mortality rate. Under the fetuses at risk approach, birth, revealed SGA (R-SGA) and perinatal mortality rates were calculated using the number of fetuses at risk at that gestation as the denominator for the rate.
† Calculated by summing the number of fetuses who delivered at that and subsequent gestational weeks.
‡ All gestational ages, including those < 34 weeks and those with missing gestational age.

Table 2: Numbers and rates of perinatal death, live birth and small for gestational age (SGA) live birth among twin births, Canada (excluding Ontario), 1991 to 1997.

Gestational age	Stillbirths	Neonatal deaths	Live births	SGA live births	Rates (Conventional)		Fetuses at risk†	Rates (Fetuses at risk)		
					SGA (%)	Perinatal mortality per 1,000		Births per 1,000	R-SGA per 1,000	Perinatal mortality per 1,000
34	42	23	2513	447	17.9	25.4	29170	87.6	15.5	1.99
35	28	14	3302	740	22.5	12.6	26615	125.1	28.0	1.39
36	28	23	5372	1491	27.8	9.4	23285	231.9	64.5	1.85
37	29	15	6835	2249	33.0	6.4	17885	383.8	126.7	2.18
38	30	11	6720	2695	40.2	6.1	11021	612.5	246.5	3.45
39	15	7	2843	1291	45.5	7.7	4271	669.2	304.8	5.15
40	11	2	1246	641	51.5	10.3	1413	889.6	458.2	9.20
41	1	0	129	71	55.5	7.7	156	833.3	461.0	6.41
≥ 42	0	0	26	18	69.2	0.0	26	1000.0	692.3	0.00
Total‡	703	869	34944	10325	29.9	44.1	35647	1000.0	298.8	44.1

Note: Perinatal mortality includes stillbirths and neonatal deaths. Live births at each gestation served as the denominator for the conventional SGA rate and total births at each gestational week served as the denominator for conventional perinatal mortality rate. Under the fetuses at risk approach, birth, revealed SGA (R-SGA) and perinatal mortality rates were calculated using the number of fetuses at risk at that gestation as the denominator for the rate.

† Calculated by summing the number of fetuses who delivered at that and subsequent gestational weeks.

‡ All gestational ages, including those < 34 weeks and those with missing gestational age.

Yudkin et al proposed that all fetuses delivered and undelivered at the gestational age of interest are at risk of fetal death at that gestation and constitute the denominator for calculating the risk of stillbirth at that gestational age (Figure 2). This 'fetuses at risk' formulation for stillbirth is widely recognized and accepted in the literature, although the traditional formulation has numerous adherents as well. More recently, Yudkin's formulation has been extended beyond stillbirth to include the estimation of incidence rates for various perinatal phenomena including birth, growth restriction, and perinatal death.

The incidence rate of any pregnancy related event at any gestation is defined as the number of new cases of the event that occur within that gestational week divided by the number of candidates at risk for the event at that gestation. Thus, the incidence of birth (Tables 1,2) is calculated by dividing the number of births at any gestation by the number of fetuses at risk of birth at that gestation. The concept is appropriately extended to all relevant perinatal phenomena including the incidence of labor induction, cesarean delivery and pregnancy complications (such as hyperemesis gravidarum preeclampsia and chorioamnionitis, (Figure 3). In fact, documenting the incidence pattern of most pregnancy complications over the course of pregnancy has not been undertaken seriously. Although the exact time when a pregnancy complication occurs may sometimes be difficult to ascertain, this is not a sufficient reason for abandoning the study of the incidence patterns of pregnancy complications.

The incidence of growth restriction is a good example of an index whose estimation presents a challenge. Although routine obstetric practice includes screening for and diagnosis of growth restriction, the technology is insufficiently advanced to permit valid and complete ascertainment of all new cases at each gestation. Given this limitation, an alternative index, namely, the incidence of revealed SGA (Tables 1, 2, Figure 1c, Figure 3) may be calculated by dividing the number of SGA births at any gestation by the number of fetuses at risk of SGA birth at that gestation. The primary utility in estimating this proxy incidence rate is in order to approximate the incidence pattern of growth restriction with increasing gestational duration i.e., to estimate whether it increases, decreases or remains constant. The measure cannot provide the absolute rate of SGA at any gestation since the numerator of the index is dependant on birth (hence the term "revealed"). Improvements in technology will permit quantification of the absolute rate (incidence) of growth restriction at each gestation in the future.

The fetuses at risk approach for stillbirth is a survival analysis model with censoring of subjects (fetuses) at birth. This gestational age-specific stillbirth calculation provides estimates of the cumulative incidence of fetal death at each week of gestation and approximates the incidence density (hazard) of stillbirth. The extended fetuses at risk model integrates perinatal death and serious neonatal morbidity (e.g., severe respiratory distress syndrome, severe intraventricular hemorrhage, etc) into a single framework (Figure 4) since these events all have their origins in pregnancy, labor or birth. This is consistent with principles ingrained in routine obstetric practice and state-of-the-art clinical trials where the definitive obstetric outcome embraces perinatal mortality and serious neonatal morbidity. Similarly, with recent literature suggesting that cerebral palsy has a predominantly prenatal origin (i.e., critical neurologic injury occurs before birth), this outcome is also assigned to the point of birth, despite being diagnosed years later. Combining stillbirth, neonatal death and serious neonatal morbidity into a single composite outcome is consistent with traditions in obstetrics and is justified by the broadly overlapping multifactorial etiology that characterizes these distinct entities.

As mentioned, the extended fetuses at risk model most deviates from traditional models with respect to events that occur after birth and yet have a prenatal etiology. Under the traditional model of perinatal death, neonatal deaths occur among infants in the first month after birth and the unborn fetus is not a candidate for neonatal death. However from a broad biological, obstetric and ultimately epidemiologic point of view, a fetus at

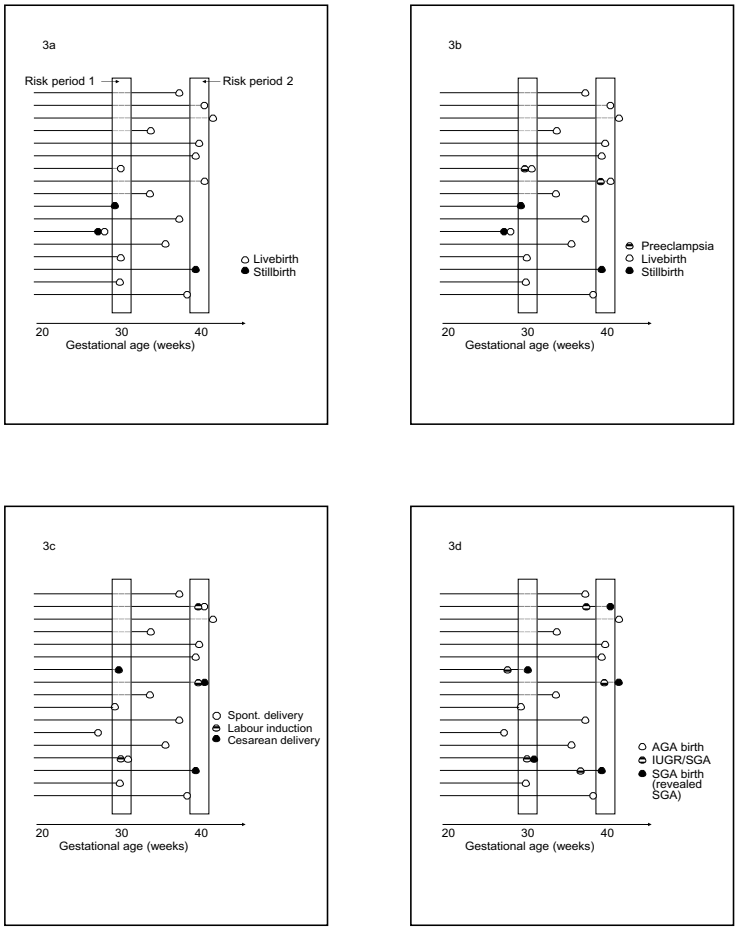

Figure 3: Schematic depiction of pregnancy course and options for calculating the incidence of various perinatal phenomena. Schematic depiction of the course of several pregnancies illustrating the options for calculating the gestational age-specific rate (incidence) of stillbirth (Figure 3a), preeclampsia (Figure 3b), obstetric intervention (Figure 3c), and revealed small•for-gestational age (figure 3d). Figure 3a: Traditional calculation: Number of stillbirths at any gestational week/Number of total births at that gestational week = 1/4 = 250 per 1,000 total births in the first risk period and 1/5 = 200 per 1,000 total births in the second period. Fetuses at risk calculation: Number of stillbirths at any gestational week/Number of fetuses at risk of stillbirth at that gestational week = 1/16 = 63 per 1,000 fetuses at risk in the first risk period and 1/6 = 167 per 1,000 fetuses at risk in the second period. Figure 3b: Traditional calculation: Number of deliveries with preeclampsia at any gestational week/Number of deliveries at that gestational week = 1/4 = 250 per 1,000 deliveries for the first period and 1/5 = 200 per 1,000 deliveries for the second period.Fetuses at risk calculation: Number of new cases of preeclampsia at any gestational week/Number of pregnan•cies at risk of preeclampsia at that gestational week = 1/16 = 63 per 1,000 pregnancies at risk in the first period and 1/6 = 167 per 1,000 fetuses at risk in the second period. Figure 3c: Traditional calculation: Number of deliveries following labour induc•tion or cesarean delivery at any gestational week/Number of deliveries at that gestational week = 2/4 = 500 per 1,000 deliver•ies for the first risk period and 3/5 = 600 per 1,000 deliveries for the second period. Fetuses at risk calculation: Number of deliveries following labour induction or cesarean delivery at any gestational week/Number of pregnancies at risk of labour induction or cesarean delivery at that gestational week = 2/16 = 125 per 1,000 pregnancies at risk for the first period and 3/6 = 500 per 1,000 pregnancies at risk for the second period.Figure 3d: Traditional calculation: SGA rate assumed to be uniform 10% or 3% at each gestation depending on cutoff used (10th percentile or 3rd percentile). Fetuses at risk calculation: Number of new SGA cases at any gestational week/Number of fetuses at risk of SGA at that gestational week = 1/15 = 67 per 1,000 fetuses at risk for the first risk period and 1/4 = 250 per 1,000 fetuses at risk for the second risk period. Fetuses at risk calculation for revealed SGA rate: Number of revealed SGA cases at any gestational week/Number of fetuses at risk of SGA birth at that gestational week = 2/16 = 125 per 1,000 fetuses at risk in the first risk period and 2/6 = 333 per 1,000 fetuses at risk in the second period.

any gestation is at risk of stillbirth and neonatal death at that gestation. If one considers a woman at 28 weeks gestation with severe preeclampsia and fetal compromise, the risk of stillbirth is easy to conceptualize. The risk of neonatal death is substantial as well and can follow either premature labor or medically indicated delivery. The same risks apply in concept to a woman with a healthy pregnancy at 28 weeks gestation, despite the magnitude of the risks being considerably smaller. Thus, although neonatal deaths literally occur among infants, fetuses can be considered candidates for neonatal death as well. This is analogous to the calculation of age-specific rates of death from breast cancer. Such rates are calculated using all women in the population as the denominator (ie, as candidates for death from breast cancer), although one could argue that death from breast cancer can only occur among women with breast cancer.

The extended fetuses at risk formulation of death provides two alternative models that treat time per epidemiologic principles (as survival time and on a single time scale). In the first model, namely, the comprehensive model of death, time is measured on the scale of post-menstrual (or post conceptional) age with fetuses/infants censored at death. Birth is ignored as an event (for truncating the original time scale) and no distinction is made between deaths that occur before and after birth. The epidemiologic risk set at any point in post-menstrual time is constituted by the fetuses/infants at risk of death at that point in time. When this framework is integrated into a proportional hazards model, birth may be introduced as a time-dependant covariate with time-varying effects. In the second model, namely, the obstetric model of death, time is measured on the scale of gestational age with fetuses censored at birth or death. All deaths that have their origins in prenatal or labor and delivery events are deemed relevant to obstetrics. Thus, as per traditions in obstetrics, stillbirths and neonatal deaths (and serious neonatal morbidity) are assigned to the point of birth. The epidemiologic risk set for such obstetric outcomes is constituted by the fetuses at risk for such events, namely, all unborn fetuses at the gestational age in question (Figure 4).

The fetuses at risk formulation brings coherence to the study of perinatal phenomena. It shows that the incidence of pregnancy complications such as preeclampsia and chorioamnionitis increases as gestational age advances. Revealed SGA rates also increase with increasing gestational age (Figure 1c) and presage the rise in perinatal mortality rates. Gestational age-specific perinatal mortality curves do not intersect in comparisons by smoking status, plurality (Figure 1c), race, parity, infant sex, etc. Smokers have higher rates of revealed SGA and perinatal death than non-smokers at all gestational ages and twins have higher rates of revealed SGA and perinatal death than singletons at all gestational ages (Figure 1c). Similarly, the incidence of birth, labor induction and cesarean delivery show patterns that are congruent with patterns of revealed SGA and death. The rising patterns of gestational age-specific revealed SGA and perinatal death also offer a preliminary justification for medically-indicated early delivery. Finally, the fetuses at risk approach provides insights into issues as diverse as the etiology of cerebral palsy and the need for customized fetal growth standards. Specifically, it shows that the rate of critical

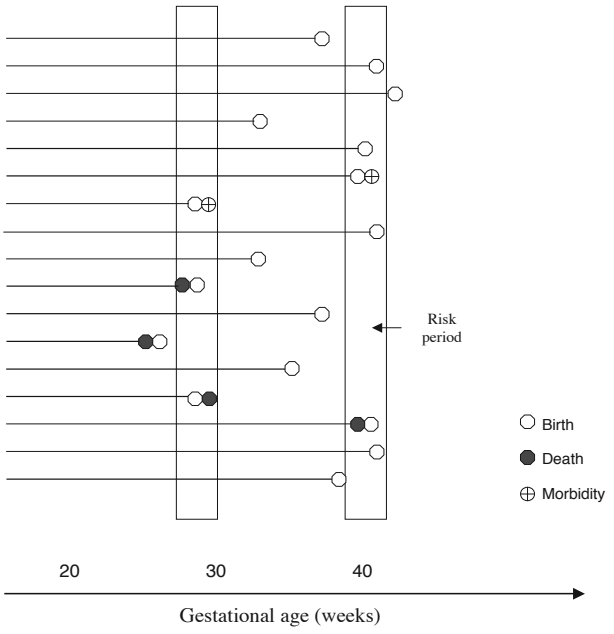

Figure 4. Schematic depiction of the survival analysis (obstetric) model for perinatal death or serious neonatal morbid•ity. Schematic depiction of survival analysis model for perinatal death or serious neonatal morbidity with censoring at death or birth (whichever occurs earlier). Perinatal death and serious neonatal morbidity are assigned to the point of birth. In the first risk period, there are 16 fetuses at risk of perinatal death or serious neonatal morbidity, 3 births, 1 stillbirth, 1 neonatal death and 1 case of serious neonatal morbidity. In the second risk period, there are 7 fetuses at risk, 6 births, 1 stillbirth and 1 case of severe neonatal morbidity. Under the conventional calculation, with perinatal mortality defined as the number of perinatal deaths within any period divided by the number of total births in that period, the perinatal mortality/morbidity rate is 3/3 in the first risk period and 2/6 in the second. Note increase in denominator and decrease in rate from the first risk period to the sec•ond risk period (from 100% to 33%). Under the fetuses at risk formulation, with perinatal mortality defined as the number of perinatal deaths in any period divided by the number of fetuses at risk of perinatal death in that period, the perinatal mortality/ morbidity rate is 3/16 in the first risk period and 2/7 in the second risk period. Note decrease in denominator and increase in rate from the first to the second risk period (from 19% to 29%).

neurologic injury that causes cerebral palsy increases with advancing gestational age and suggests that the pregnancy complications (which precede preterm birth) are the cause of cerebral palsy (and not preterm birth itself). With regards to fetal growth standards, the fetuses at risk formulation shows that perinatal mortality patterns are consistent with separate fetal growth standards for males and females but not with the available separate standards for blacks and whites in the United States.

The fetuses at risk formulation faces its most serious challenge from the traditional idea that perinatal mortality declines as gestational age increases. Indeed, this latter inference appears intuitive and is corroborated by the readily apparent relationship between birth weight and perinatal mortality. Despite the socially important prognostic purpose served by the traditional model of perinatal death, it is not appropriate as a causal model. The use of dual overlapping time scales for life in utero (gestational age) and after birth (chronologic age) and the truncation of the full biologic continuum (as in the calculation of neonatal mortality rates using live births at a particular gestational age as the denominator) is problematic on the level of first principles and also because it is responsible for numerous paradoxes and conundrums. The entire mortality experience of a cohort of fetuses (as documented on single time scale) is of interest, irrespective of whether death precedes or follows birth (see Figure 4).

As for explaining the rise in growth restriction and perinatal mortality rates with increasing gestation, one can speculate that the ability of the utero-placental system to support the fetus declines with increasing gestational age. Rising rates of growth restriction (as reflected in rising rates of revealed SGA) and perinatal death with increasing gestational duration reflect increases in the incidence of pregnancy complications such as preeclampsia and chorioamnionitis and also other stochastic processes that adversely affect vascular function within the utero-placental system.

The above-mentioned arguments suggest that the traditional and fetuses at risk models serve vastly different purposes. The distinction between descriptive versus causal models is particularly relevant in this context; traditional models which truncate the biologic continuum are better viewed as descriptive (noncausal) models which are ideal for setting prognosis at birth, while the fetuses at risk formulation represents a causal model that yields biologic insights and provides the basis for obstetric intervention.

Developing an explicit epidemiologic framework for justifying medically indicated early delivery is important in order to avoid conflicts between obstetric theory and practice. Thus, in the absence of appropriate obstetric theory, population increases in preterm birth (occurring secondary to increases in medically indicated preterm birth) may be viewed as adverse developments under the traditional theoretical framework. This would lead to a discounting of the perinatal mortality reductions that are a consequence of recent changes in the management of compromised fetuses at preterm gestation. Also, the obstetric literature needs to be more articulate with respect to the number of labor inductions and cesarean deliveries that are needed to prevent one perinatal death or serious neonatal morbidity (given a particular domain/indication). The proposed epidemiologic framework based on the fetuses at risk model is illustrated below using live births and stillbirths in the United States between 1995–1996 and 1999–2000 (National Center for Health Statistics perinatal mortality data file for all states and the District of Columbia). Perinatal mortality was defined to include stillbirths and neonatal deaths but excluded perinatal deaths due to congenital anomalies (in order to eliminate the potential effect of temporal increases in prenatal diagnosis and pregnancy termination for major congenital anomalies).

Incidence of medically indicated early delivery, birth, revealed SGA, and death

The rate of labor induction and/or cesarean delivery increased with increasing gestational age (Figure 5a), being lowest among pregnancies with no medical risk factors and higher among pregnancies with complications. The incidence of birth showed a similar pattern. The incidence of revealed SGA rose with increasing gestational age and was highest among twins and lowest among uncomplicated pregnancies (Figure 5b). Rates of perinatal death also increased with increasing gestational age and patterns were generally consistent with clinical expectation and patterns of revealed SGA (Figure 5c).

Number needed to treat

The number needed to treat (NNT), an index widely used in therapeutics as part of risk-benefit equations, is insufficiently

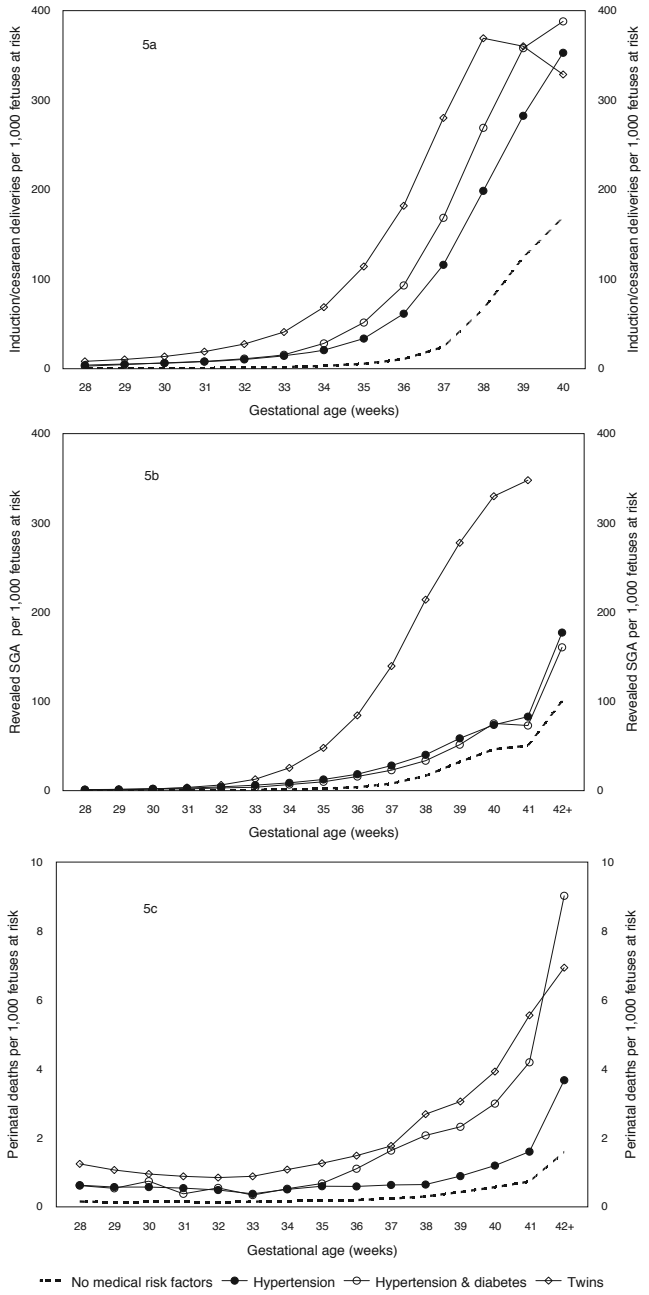

Figure 5. Incidence of labor induction/cesarean delivery, revealed small-for-gestation age (SGA) and perinatal death, United States 1999–2000. Incidence of labor induction and/or cesarean delivery (Figure 5a), incidence of revealed SGA (Fig•ure 5b) and incidence of perinatal death (Figure 5c) at 28 weeks gestation and over, among pregnancies with no medical risk factors, hypertension, hypertension and diabetes and twins, United States 1999–2000. Hypertension includes chronic and preg•nancy-associated hypertension and eclampsia (National Center for Health Statistics definitions).

articulated in connection with medically indicated early delivery. This is in part because conventional models of perinatal mortality imply that early delivery is associated with an increased rate of perinatal death (Figure 1b). Nevertheless, the concept of the NNT remains as relevant and critical in the context of medically indicated early delivery as elsewhere in medicine. The NNT for medically indicated early delivery (given a specific indication) may be defined as the reciprocal of the difference between the rate of perinatal mortality or serious neonatal morbidity given no obstetric intervention and the rate of perinatal mortality or serious neonatal morbidity given medically indicated early delivery.

The clinical scenarios described below are characterized by varying background rates of perinatal mortality (which substantially modify the NNT). The first scenario involves an obstetric emergency (e.g., placental abruption with fetal bradycardia) where a rapid absolute increase in the (incidence density) rate of perinatal death is anticipated over a short time span (minutes). It is expected that an emergency cesarean delivery carried out within 15–30 minutes will prevent perinatal death in more than half the fetuses. This implies an NNT of approximately 2 or less. Similarly, in a second scenario involving a serious pregnancy complication and fetal compromise (e.g., severe preeclampsia with fetal growth restriction), an expected perinatal mortality reduction due to labor induction and/or cesarean delivery (as opposed to no intervention) of about 100 to 200 per 1,000 fetuses implies an NNT of 5 to 10. A third scenario involves routine delivery of twin pregnancy at 38 weeks gestation. If routine delivery at 38 weeks (relative to no obstetric intervention) reduces the rate of perinatal mortality by about 5 per 1,000 fetuses, this implies an NNT of 200. The final scenario involves routine delivery at 41 weeks gestation given an uncomplicated singleton pregnancy. If the difference between perinatal mortality given routine delivery at 41 weeks versus spontaneous delivery without obstetric intervention is approximately 1 per 1,000 fetuses at risk, this implies an NNT of 1,000. In other words, 1,000 routine early deliveries at 41 weeks gestation (through labor induction and/or cesarean delivery) would prevent one perinatal death.

Virtually all estimates used in the NNT calculations above are speculative even if they represent more or less reasonable approximations. In fact, most inputs into the NNT calculation cannot be estimated given current standards of care since the decision not to intervene in such situations (eg, severe preeclampsia with fetal compromise) would constitute a breach of ethical standards.

The marginal NNT, which measures the effect of increases in medically indicated early delivery (beyond standard rates of medically indicated early delivery), is an alternative measure that is directly pertinent to obstetric practice. In this calculation, a temporal increase in medically indicated early delivery is set against the change in perinatal mortality in any particular domain.

Table 3 shows temporal changes in the incidence of obstetric intervention and perinatal death in the United States between 1995–96 and 1999–2000. The rate of labor induction and/or cesarean delivery among singleton pregnancies ≥ 28 weeks of gestation increased by 45.1 per 1,000 fetuses, from 339.4 per 1,000 fetuses in 1995–96 to 384.5 per 1,000 fetuses in 1999–2000 ($P < 0.0001$, Table 3). During the same period, the rate of perinatal death (excluding deaths due to congenital anomalies) decreased by 0.31 per 1,000 fetuses from 3.95 to 3.64 per 1,000 fetuses at ≥ 28 weeks of gestation ($P < 0.0001$). This yielded a marginal NNT rate of (45.1/0.31) or 145. Thus, 145 additional labor inductions/cesarean deliveries in 1999–2000 (relative to 1995–96) were responsible for preventing 1 perinatal death among singletons ≥ 28 weeks gestation. Marginal NNT estimates for specific subpopulations differed from those obtained for all singletons, being as low as 32 among twins ≥ 28 weeks and as high 927 among singletons ≥ 34 weeks with hypertension (Table 3).

Such marginal NNT calculations are analogous to calculations

Table 3: Rates of labor induction and/or cesarean delivery, perinatal mortality (excluding congenital malformations) and the marginal number needed to treat in order to prevent one perinatal death in various subpopulations, United States, 1995–96 and 1999–2000.

Population	Labor induction/cesarean deliveries per 1,000 fetuses			Perinatal deaths*/1,000 fetuses			Number needed to treat (marginal)
	1995–96	1999–00	Change†	1995–96	1999–00	Change	
Singletons ≥ 28 weeks, all	339.4	384.5	45.1	3.95	3.64	0.31‡	145
≥ 28 weeks, no medical risk factors	294.6	337.7	43.0	2.98	2.68	0.29‡	146
≥ 28 weeks, with hypertension	662.4	697.6	35.2	6.96	6.76	0.20	180
≥ 28 weeks, with diabetes	532.4	578.4	46.0	6.67	6.49	0.18	257
≥ 28 weeks, with hyp. and diabetes	744.6	779.3	34.7	8.83	9.96	-1.13	-31
Twins ≥ 28 weeks, all	636.5	685.3	48.8	12.13	10.63	1.50‡	32
Singletons ≥ 34 weeks, all	338.3	383.2	44.8	2.66	2.42	0.24‡	188
≥ 34 weeks, no medical risk factors	294.5	337.5	42.0	2.09	1.86	0.23‡	181
≥ 34 weeks, with hypertension	654.1	689.5	35.1	3.91	3.87	0.04	927
≥ 34 weeks, with diabetes	533.3	579.8	45.7	5.25	5.14	0.11	403
≥ 34 weeks, with hyp. and diabetes	740.9	776.6	35.0	6.86	7.29	-0.43	-81
Twins ≥ 34 weeks, all	634.8	685.9	48.7	6.68	6.16	0.53	92

* excluding perinatal deaths due to congenital malformations
† All temporal changes in labor induction/cesarean delivery rates were statistically significant P < 0.0001.
‡ Temporal changes in perinatal death rates statistically significant P < 0.0001.
Hypertension includes chronic and pregnancy-associated hypertension and eclampsia (National Center for Health Statistics definitions).

based on randomized trials which contrast routine induction of labor vs selective induction of labor at or beyond term or those which contrast aggressive vs expectant management given severe preeclampsia before term gestation. A meta-analysis of studies on the former issue showed that routine induction of labor reduced perinatal death rates several-fold (odds ratio of 0.20, 95% confidence interval 0.06 to 0.70). This implies an NNT of 1,250 for routine induction of labor at or beyond term gestation, assuming a perinatal mortality rate of 1.0 per 1,000 fetuses at risk following selective labor induction.

The proposed framework is based on two important assumptions. First, medically indicated early delivery is considered the final pathway for obstetric intervention. Thus, increases in labor induction and cesarean delivery are credited with preventing perinatal death even though such early delivery was facilitated by improved methods for assessing fetal well-being and supportive neonatal care. Early delivery is thus viewed as a therapeutic package which subsumes antenatal monitoring, diagnosis of fetal well-being, supportive neonatal care and other interventions that permit higher rates of early delivery to rescue compromised fetuses from a hostile intrauterine environment.

A second assumption is that temporal increases in labor induction and cesarean delivery rates and declines in perinatal mortality rates reflect true changes in obstetric practice (rather than changes in population characteristics). It is possible that changes in maternal characteristics (such as increases in older maternal age and pre-pregnancy obesity) may have been partly responsible for changes in labor induction, cesarean delivery and perinatal mortality rates in the United States between 1995–96 and 1999–2000. Although such changes are unlikely to have affected the results substantially (since the study interval was only 4 years), regression adjustment can be used to address this issue where necessary.

Current limitations of the fetuses at risk approach include an inability to precisely document the incidence of fetal growth restriction. This is because diagnosis of growth faltering in utero, although much facilitated in recent decades through ultrasonographic means, remains inaccurate and essentially unavailable at the population level. The alternative index of revealed SGA is useful but limited by its relationship to birth rate patterns. Further developments in ultrasound technology are needed so that incidence rates can be estimated more accurately based on an identification of all new cases of growth restriction (in utero). Another approximation in the fetuses at risk approach relates to the timing of the pathologic process or event. Assigning events such as neonatal death and serious neonatal morbidity to the moment of birth often involves a systematic overestimation of the timing of the critical pathologic process or event. The systematic nature of the problem means that the incidence patterns of perinatal mortality and morbidity are not seriously affected, however.

Summary

The cornerstone of modern obstetrics, namely, early delivery given fetal compromise, cannot be reconciled with traditional models of perinatal mortality which show that perinatal death rates decline exponentially as gestational duration increases. On the other hand, the fetuses at risk approach, which shows that pregnancy complications, revealed SGA and perinatal death rates increase with increasing gestational age, provides a justification for medically indicated early delivery and also resolves several prevailing conundrums in the perinatal field. Although inputs for estimating therapeutic indices related to medically indicated early delivery (such as the NNT) cannot be obtained for ethical reasons, it is possible to retrospectively estimate the marginal NNT associated with medically indicated early delivery. This provides an estimate of the number of additional medically indicated early deliveries that were required to prevent one perinatal death. On a more general level, the traditional model of perinatal death and the fetuses at risk approach are best viewed as serving different purposes; the former is suited for setting prognosis at birth while the latter provides a causal framework and the basis for obstetric intervention.

Effect of Intervention on the Rates of Breastfeeding of Very Low Birth Weight Newborns

Walter Santoro Júnior, Francisco Eulógio Martinez

Abstract

Objective: To describe an intervention to provide support and encouragement to mothers of preterm newborns and to evaluate its effect on breastfeeding rates in the first 6 months after hospital discharge.

Methods: One hundred newborns and their mothers were selected consecutively and prospectively according to order of birth. The mother-infant dyads were alternately assigned to one of two groups: one group received routine care (routine group), and the other group received the intervention (intervention group). The intervention consisted of individualized support in addition to the routine support provided in the Neonatology Service. Before delivery, one of the researchers was introduced to the mother and offered her information about the delivery. The researcher was also present at delivery, made an early visit to the infant in the intensive care unit, provided constant support for the mother to express breast milk and to maintain lactation, gave the mother information about maternal and infant hospital discharge, and provided outpatient follow-up after discharge.

Results: Thirty-six dyads completed the study. The characteristics of mothers and infants, as well as causes of exclusion, were similar in the two groups. In the routine group, 38.9% of the infants were being breastfed at hospital discharge, and median breastfeeding duration was 54 days. In the intervention group, 80.5% were being breastfed at discharge, and median breastfeeding duration was 91 days ($p<0.01$).

Conclusions: Simple support measures offered to mothers during hospitalization and outpatient follow-up had a very positive effect on breastfeeding rates.

Introduction

Establishing breastfeeding of preterm newborns is a great challenge. Several factors make it difficult, and the most evident are physiological limitations. Preterm newborns only achieve maturation to suck and swallow between the 32nd and 35th week postmenstrual age, which complicates the determination of an ideal time to initiate breastfeeding.[1,2]

In addition to the infant's immaturity, maternal factors may also make breastfeeding difficult. Early separation of mothers from infants is frequent because of the need to care for the infants in a neonatal intensive care unit. The postpartum period is a time of maximum maternal sensitivity, and mothers may fail to establish an affective bond with their infant at the most appropriate time because of the separation of the dyad.[3] Moreover, mothers are worried about the separation from their infants and their survival and growth, and may feel incompetent to perform their role, which generates further anxiety.[4,5] Studies in the literature emphasize that the creation of an affective bond between mother and infant and a low level of anxiety are important to establish breastfeeding.[6-8]

The difficulties to breastfeed a preterm infant continue after hospital discharge. Many infants being breastfed at discharge are weaned earlier than desired.[9]

Some studies describe programs to promote breastfeeding among mothers of preterm infants.[10] They stress the importance of providing support to mothers by qualified professionals,[11-14] and the benefits of support offered by the community and the family.[15-18]

The purpose of this study was to describe a breastfeeding intervention to provide support and information to mothers of preterm newborns and to evaluate its effects on breastfeeding rates in the first 6 months after hospital discharge.

Methods

This study was conducted in the Neonatology Service of Hospital das Clínicas, School of Medicine of Ribeirão Preto, Universidade de São Paulo, from February to November 2001. Infants included in the study weighed less than 1,500 g at birth. Preterm newborns and their mothers were assigned to one of two groups: one group received routine care (routine group), and the other group received the intervention (intervention group). The groups were formed simultaneously, and allocation

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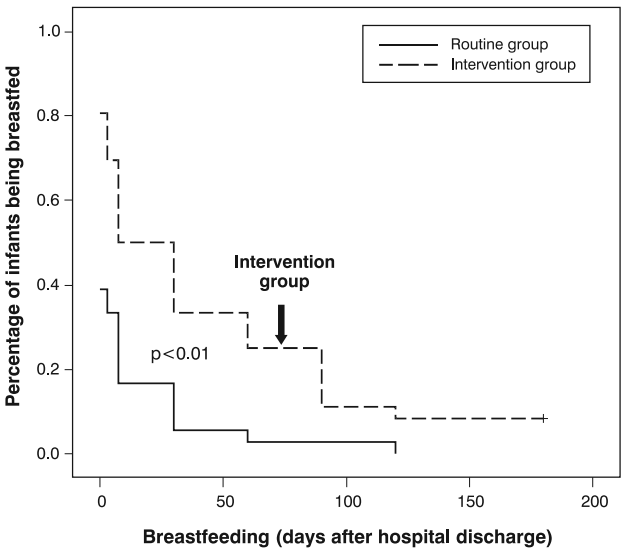
Table 1 - Characteristics of mothers and very low birth weight preterm newborns included in the study.

	Study groups		
	Routine group	**Intervention group**	**p**
Maternal age (years)*	24.5±7.7	27.7±6.4	0.06
Primipara, n (%)	16 (44.4)	15 (41.6)	1†
Experience in breastfeeding, n (%)	20 (55.5)	13 (36.1)	0.15†
Elementary school education, n (%)	29 (80.5)	21 (58.3)	0.07†
Secondary or college education, n (%)	7 (19.4)	15 (41.6)	0.07†
Birth weight (g)*	1.193±219	1.208±188	0.76
Gestational age (weeks)*	31.7±1.8	31.9±1.9	0.78
Small for gestational age, n (%)	13 (36.1)	16 (44.4)	0.63†
5-minute Apgar ≥ 7 n (%)	34 (94.4)	35 (97.2)	1†
SNAPPE-II‡	5 (0-34)	12 (0-38)	0.67
Hospitalization (days)*	49.4±17.2	46.5±16.2	0.47
Weight at discharge (g)‡	1.970 (1.900-2.885)	1.940 (1.870-2.700)	0.23
Postmenstrual age at discharge (weeks)*	38.9±1.7	38.5±2.2	0.34

SNAPPE-II = Score for Neonatal Acute Physiology Perinatal Extension II.
* Mean ± standard deviation - unpaired *t* test.
† Fisher exact test.
‡ Median (range) Mann-Whitney test.

followed the consecutive and alternate order of birth of the infants. By drawing lots, it was determined that the first infant would be assigned to the routine group. A sample size of at least 27 infants in each group was calculated according to previous data about breastfeeding in the first week after discharge detected in our Service[9,19] (about 40%) and the expectation of an increase of 40% due to the intervention (to over 80%) based on a two-tailed alpha value of 0.05 and beta value of 0.10.

Exclusion criteria were all situations that prevented breastfeeding due to the infant's or the mother's conditions. Therefore, the following exclusion criteria were established: severe neurologic problems or facial malformation that made breast sucking difficult; digestive tract malformations; hospitalization for longer than 4 months; HIV+ mother; and death. Twins were included, but multiple births were excluded.



Solid line = routine group; dashed line = intervention group.

Figure 1 - Kaplan-Meier survival curve: breastfeeding according to study group

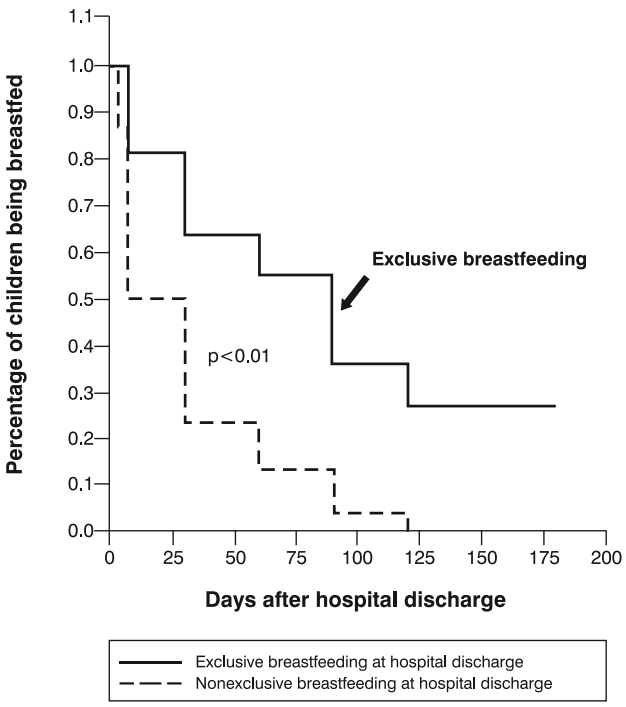
When the mother of a preterm infant was in labor, she received an explanation about the study and, in case she agreed to participate and signed an informed consent term, previous randomization was checked. If the infant belonged to the intervention group, the researcher was called and stayed with the mother in the labor room. In case the infant was assigned to the routine group, the researcher was only informed that a mother had been included in the routine group.

This study was approved by the Ethics in Research Committee of the Hospital de Clínicas de Ribeirão Preto, School of Medicine, Universidade de São Paulo, according to HCRP approval number 5899/2001.

The birth of a high-risk newborn is routinely assisted by a team whose basic concern is to support the infant's life. No healthcare worker is assigned to give the mother information about the infant's clinical conditions or treatment in the first hours of life.

Whenever possible, the preterm newborn should have physical contact with the mother in the delivery room. The mother's first visit to the infant in the intensive care unit is organized by the nursing team, but, due to the nurses' time availability, the mother may be separated from the infant for hours.

All puerperal mothers receive instructions about how to express milk, empty the breasts and increase liquid ingestion. Milk expression every 2-4 hours is suggested, and sterile containers are provided by the Milk Bank. Milk expression should begin as early as possible, and the duration of milk expression depends basically on the mother's well being.



Solid line = exclusive breastfeeding at hospital discharge; dashed line = nonexclusive breastfeeding at hospital discharge.

Figure 2 - Kaplan-Meier survival curves of breastfeeding from hospital discharge to the end of outpatient follow-up for 11 infants exclusively breastfed at hospital discharge and for 33 infants that were receiving nonexclusive breastfeeding at hospital discharge

During hospitalization, the mother should have unrestricted access to her infant, but many times she is discharged from the hospital earlier than her infant. After discharge, the mothers receive instructions and are encouraged to visit their infants without restrictions of time or duration.

When the infant is ready for hospital discharge, the pediatrician reinforces the importance of continuing breastfeeding. The mother receives instructions to offer the breast first, and to offer complements with artificial milk only when prescribed by the pediatrician. The first visit to the prematurity outpatient service is scheduled one week after hospital discharge.

This study's intervention began before delivery, when the researcher was formally introduced to the mother and answered her questions about delivery. At that time, it was made clear that the researcher would provide information about the infant's conditions to the mother but would not be directly involved in the infant's care. The purpose of the physical presence of the researcher was to offer support at a critical moment and to establish a relationship of trust with the patient.

The mother's visit to the infant in the intensive care unit was encouraged and occurred as early as possible to promote the creation of an affective bond between mother and infant. It took place as soon as the newborn was taken to the intensive care unit if the infant was clinically stable and the mother was ready to understand the information that she was going to receive. When a longer time was necessary to define the newborn's conditions, waiting time was up to 4 hours. When the mother's condition did not allow her to make an early visit, information was taken to her by the researcher while she was still in the post-anesthesia care unit. At the time of the visit, the mother received a simple description of what was going on, of the invasive or noninvasive monitoring system, of the infant's conditions, and of treatment in the next hours. Information was repeated to the mother as many times as necessary.

The initiation and continuation of the mother's milk production followed our Service's routine procedures. In the intervention group, however, the researcher individually reinforced previous instructions about the techniques to express milk, empty the breast, and increase liquid intake.

Mothers in the intervention group were encouraged to personalize their infant's crib or incubator. They could place identification labels where they wished, and were encouraged to bring small gifts that expressed their affection and their fast recovery wishes. Mothers other than those included in the study and who also chose to personalize their infants' cribs were not stopped by the healthcare team.

At the mother's hospital discharge, support was offered again and instructions about the continuation of milk production and treatment were repeated. The importance of visiting the infant, or making phone calls when visits were not possible, was also reinforced. The researcher was present during the visits whenever possible or when requested by the parents by phone. The parents' access to the unit was unrestricted.

When an infant of the intervention group was discharged, the researcher gave the parents a cell phone number for contact. The first visit was scheduled one week after discharge. However, depending on the case and when problems could not be solved over the phone, an extra visit was scheduled before that date.

Outpatient follow-up visits in both groups were monthly for 6 months after hospital discharge or until weaning. In the routine group, residents assisted by professors or other physicians provided care to the infants, but the infants in the intervention group were seen by the researcher. After leaving the intervention study, routine neonatology outpatient follow-up was ensured for the children not in the intervention group.

Data about the two groups were recorded and reviewed by the researcher; therefore, the study was not blinded. Exclusive breastfeeding was defined as feeding the infant with only the mother's milk, and breastfeeding was any situation in which the infant received the mother's milk, regardless of whether exclusively or not.

The Fisher exact or the chi-square test was used for the analysis of tables. The unpaired t test was used for the comparison of normally distributed data, the Mann-Whitney test, for nonnormally distributed data. Kaplan-Meier survival curves were compared using a log rank test. The EpiInfo 6.02 software was used for statistical analysis of data, and the level of significance was set at $p<0.05$.

Results

In 10 months, 100 consecutive mothers of preterm newborns in the Neonatology Service of Hospital de Clínicas de Ribeirão Preto, Universidade de São Paulo, agreed to participate in the study. Fifty-one were assigned to the routine group, and 49, to the intervention group. Thirty-six infants in each group

completed the study, that is, 15 were excluded in the routine group and 13 in the intervention group. All infants participating in the study were followed up in the outpatient service and there was no loss to follow-up up to the sixth month after hospital discharge or up to weaning.

The causes of exclusion were similar in the two groups, and the main causes were prolonged hospitalization (32%) and death (43%).

The characteristics of mothers and newborns included in the study are shown in Table 1. Mothers and infants in the two groups had similar characteristics. Maternal age in both groups ranged from 14 to 43 years, and mean age was 26.1 years. Most mothers lived in the city of Ribeirão Preto (61.1%), were multiparas (57%), had previous experience in breastfeeding (54.2%), studied up to the end of elementary school (69.4%), and had a cesarean delivery (72.2%).

The infants had a mean weight of 1,200 g at birth and a mean gestational age of almost 32 weeks; about 60% had adequate weight for gestational age, and over 95% had good vital signs at 5 minutes of life. Mean hospitalization time was 47 days; at hospital discharge, median weight was 1955 g and mean postmenstrual age was 38.7 weeks.

The rate of weaning and no breastfeeding in the routine group at the time of hospital discharge was 61.1%. This value was significantly higher than the 19.5% found in the intervention group. This value remained statistically different between groups at 3 months of outpatient follow-up. In the routine group, the rates of exclusive breastfeeding and breastfeeding were 8.4% and 38.9% at hospital discharge and 5.6% and 36.1% at the time of the first visit. In the intervention group, these rates were 19.5% and 80.5% at hospital discharge and 16.6% and 75% in the first visit. Half of the infants receiving artificial milk at hospital discharge (11 in the routine group and 3 in the intervention group) did not have access to the maternal breast at any moment in their lives. Median breastfeeding duration in the group of infants that were breastfed, excluding, therefore, those that were never breastfed, was 54 days in the routine group and 91 days in the intervention day ($p<0.001$).

Figure 1 shows the Kaplan-Meier survival curves of continuation of breastfeeding according to study group. The intervention group had better breastfeeding indices during all the study, and the curves were statistically different ($p<0.01$).

Only 4 infants in the routine group and 7 in the intervention group were being exclusively breastfed at hospital discharge. Figure 2 shows the Kaplan-Meier survival curve of breastfeeding for these 11 infants, from hospital discharge to the end of outpatient follow-up, compared with the 33 infants that were receiving nonexclusive breastfeeding at hospital discharge. The curves are statistically different ($p<0.01$).

Discussion

The benefits of breastfeeding for preterm newborns are undeniable, but the rates of breastfeeding among these infants are still low.[9,10] Therefore, methods to improve these rates should be studied for preterm newborns.

Few studies in the literature specifically investigate breastfeeding of very low birth weight infants. There are few intervention models to provide support to mothers and to encourage breastfeeding of preterm newborns, and few evaluations of the development of these infants. Moreover, study results are conflicting. Therefore, studies should investigate models of interventions to encourage and sustain breastfeeding of preterm newborns.[10,20-24]

This study evaluated the impact of a very simple intervention offered to the mothers of preterm newborns from the delivery room to outpatient follow-up. This intervention consisted of having the researcher close to the mother to offer support and information and to answer her questions.

Despite the significant rate of exclusion of mother-infant dyads recruited for the study, the sample size was large enough to detect the beneficial effects of this intervention. Randomization was adequate in that there were no differences in the characteristics of the dyads studied. The support offered had a very important effect on improving breastfeeding rates at hospital discharge.

At hospital discharge, 38.9% of the children in the routine group were being breastfed: 8.4% were exclusively breastfed, and 30.5%, nonexclusively. These results are similar to previously described preterm newborn breastfeeding rates in our Service.[16,17] In contrast, 80.5% of the children in the intervention group were being breastfed at hospital discharge: 19.5% were exclusively breastfed, and 61%, nonexclusively. This very substantial and significant increase of breastfeeding rates at hospital discharge confirmed the positive effect of the support offered to mothers. The effects of providing support to mothers, by the presence of doulas or specialized professionals, have been known to improve breastfeeding rates for a long time.[15,25-27] This study confirmed those previous findings for mothers of preterm infants in a prospective randomized study. The breastfeeding rates at hospital discharge found after the intervention were similar to those reported for services with the best rates.[10]

The progression of breastfeeding at outpatient follow-up also provided important information that is rarely available in the literature. Median breastfeeding duration in the group of infants that were being breastfed at hospital discharge, excluding, therefore, those that were not breastfed, was 54 days in the routine group and 91 days in the intervention day ($p<0.01$). Once more, the data of the routine group were similar to those previously found in studies conducted in our Service.[9,19] The weaning rate was greater in the routine group, and the difference from the intervention group was observed up to the third month of outpatient follow-up of premature infants.

Despite the improvement of breastfeeding rates in the intervention group during all outpatient follow-up, the analysis of the survival curves showed that the rate of weaning during outpatient follow-up, indicated by the curve slope, was similar in the two groups (Figure 1). Similarly to other findings in the literature,[28] the intervention during outpatient follow-up was not enough to reduce weaning rates.

Another important aspect, the effect of type of breastfeeding at hospital discharge, may be observed in Figure 2. The weaning rate of infants that were being exclusively breastfed at hospital discharge was lower than that of children receiving nonexclusive breastfeeding, regardless of study group.

Exclusive breastfeeding has been described as an important factor in the continuation of breastfeeding in preterm infants.[29]

Some of the limitations of this study should be discussed. Although randomized, this study was not blinded, that is, data about the two groups were recorded and reviewed by the researcher. Despite the significant exclusion of mother-infant dyads recruited for the study, the sample size was large enough to detect the beneficial effects of the intervention. The number of children being exclusively breastfed at hospital discharge in each study group was small, which precluded the separate analysis of this variable.

In conclusion, this study demonstrated the importance of support and encouragement offered to the mother during the preterm infant's hospital stay. Simple measures, such as presence, support and frequent information from the researcher, had clear effects on breastfeeding rates at hospital discharge. Nonexclusive breastfeeding, which had a high incidence in this study, may indicate a failure in effectively establishing milk production, or in creating a good mother-infant bond. Therefore, future studies should improve the efficacy of this model and focus efforts on effective and exclusive breastfeeding at hospital discharge.

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Why the Way We Consider the Body Matters—Reflections on Four Bioethical Perspectives on the Human Body

Silke Schicktanz

Abstract

Background: Within the context of applied bioethical reasoning, various conceptions of the human body are focused upon by the author in relation to normative notions of autonomy.

Results: The author begins by descriptively exploring some main positions in bioethics from which the "body" is conceptualized. Such positions conflict: the body is that which is constitutive of the individual's experience and perception, or it is conceived of materially or mechanistically; or as a constructed locus, always historically and culturally transformed. The author goes on to suggest a methodological approach that dialectically considers embodiment from four different perspectives: as bodily self-determination, as respect for the bodily unavailability of the other, as care for bodily individuality; and lastly, as acknowledgement of bodily-constituted communities. These four perspectives encompass autonomy in two of its main interpretations: as the capability of a person to act independent of external forces, and as the moral ideal of pursuing individual wishes by means of role distance, self-limitation and universalization. Various bioethical cases are utilized to show how the four perspectives on the body can complement one another.

Conclusions: The way we consider the body matters. The author's dialectical method allows a premise-critical identification and exploration of bioethical problems concerning the body. The method is potentially applicable to other bioethical problems.

Introduction

During the 1970s, a number of performance artists shocked the public by making their bodies the subject of artistic performances. By being thus displayed, the body itself becomes both the medium of the artistic work and the scene on which it takes place.

The author is with the University of Göttingen, Department of Medical Ethics and History of Medicine, Gottingen, Germany. The author would like to thank Annett Lösch and especially Benjamin Waters for their help in translation and language. I would like to thank the four reviewers for helpful comments. This theoretical research is part of the EU-Research Project "Challenges of Biomedicine – socio-cultural contexts, European Governance and Bioethics" funded by EU Commission. Reprinted from BioMed Central, Philosophy, Ethics, and Humanities in Medicine,

In the performance Zerreißprobe (1970) the Austrian artist Günter Brus injured himself by cutting his head and thigh with a razor blade. The vulnerability of the flesh was to be shown by means of the extreme display of a body disfigured by pain and by interventions from the outside. Brus' performance at the same time was intended to demonstrate limits and extremes. The American artist Chris Burden had his left arm shot by a friend in the course of the performance, Shoot (1971), though the focus here was less on the vulnerability of the body than on the examination of ideals of masculinity and insensitiveness to pain as a test of courage. The French artist Orlan has been causing sensations since the 1990s by describing her body as "software" and declaring surgical operations on her face to be "art made of flesh and blood." In the course of these operations she regards herself as a living sculpture and "takes the liberty to experiment with her own body."[1]

In the 1970s, the liberty to be in charge of one's own body was discussed in another, quite different context as well: under the slogan "My body belongs to me!" thousands of women took to the streets in Germany, Britain, and the United States to demand a liberalization of the then existing abortion laws. These concerns and procedures—different as they may appear at first glance—point to the same important problem, namely the unclear or questionable relationships between the body, the self-determination of one and the same person, and its public articulation: What am I allowed to do with my own body, and to what extent can I permit others to do whatever they like with their bodies?

Emerging from these public discussions of the 1970s, we may ask whether these concerns and questions are still relevant for recent bioethical debates. Both examples, modern performance art and political demonstrations, have pointed to the political and social dimension of these questions, as especially 'external' power over the body was criticized. However, in the early 1970s many people did not understand these primarily as ethical questions. It was for many deemed as self-evident that the body is an object of self-determination and action. Bioethics itself, understood as the systematic consideration of ethical problems and ethical judgments on the basis of rational argumentation, was in its infancy at this time.[2] It was only in the 1990s that many scholars started to criticize the neglect of the body in academic bioethics.[e.g. 3,4,5] Additionally, in recent years, a "body boom" in media studies, history and social science has occurred. According to Anne Witz[6] the "corporeal turn" in sociology and feminism has emerged from a critique of the

exclusion of certain bodies (such as women, disabled persons or elderly people) from the academic discourse. These should now no longer be neglected.

Additionally, one can call into question the tendencies of both analytical metaethics and also moral philosophy, as both center around notions of personhood, rationality, preferences and self-determination, which are mainly conceptualized without any relation to the body, although bioethics often deals with problematic cases in which entities lack rationality and specific mental capacities, for example embryos, brain-dead patients, animals and so on. Thus, Margrit Shildrick[7] critically remarks that "bioethics is out of touch... with bodies themselves, in the phenomenological sense in which the being, or rather the becoming, of the self is always intricately interwoven with the fabric of the body." Of course, international academic bioethics has itself developed into a multifaceted discipline, with mutual relationships between moral philosophy, sociology of science and clinical ethics. Thus, generalizations are always problematic. Nevertheless, I think it is not totally wrong to state that many scholars in applied ethics and bioethics still tend toward—as Shildrick calls them—"conventional" positions, which stress "fixed standards of judgement."[7] One of these standards is the value of autonomy and self-determination. Another common strand often favored by partisans of liberal self-determination sees the human body as an "object" and as "property" subject to personal, self-determined disposal. For example, the moral claim that "every person should decide for themselves whether they want to donate their organs" is built upon the assumption that organ donation should be decided on by the donor, seeing the body as property or as a material object. In contrast, postmodernism, or as Shildrick[7] puts it, postconventional ethics, sees the body as "leaky, uncontained, and uncontainable." From this vantage, the body is neither separable from the self nor from other embodied selves. Many postmodernists also criticize the idea of thinking about the body as property, as an economic value, or as an instrument.[eg, 8,9]

Precisely in the field of body modification and bioethics we observe a clash of perspectives—in two ways. In the first place, there is a serious difference in the normative way of ethical judgment; secondly, there is a difference in how the body and embodiment are addressed. This distinction between mainstream bioethics and postconventional sociology and ethics could be difficult to overcome as long as both insist upon their "rightness."

However, in order to understand bioethics in a broader sense, as an academic discipline, sweeping aside for the moment social and political power plays in the academic world, it should be a basic interest for each and every one to hear and to understand what the others are saying. This could be partly achieved by choosing a method of ethical reasoning which is open to various and sometimes conflicting views, and this paper is a first attempt at presenting such a method. It is hereby necessary to state that according to my understanding, normative bioethics is systematic, processual method of ethical judgment.[10] It includes the description of an ethical problem, the analysis of underlying terms and opinions in the light of theories and practical experience and, finally, presents an ethical evaluation or a recommendation on how to act. (Whether this is only true for problem-solving ethics or also for moral philosophy in a general sense I cannot discuss here). In this paper I focus mainly on the issue of "problem definition," an issue that is necessarily crucial for all kinds of moral analyses and for final evaluation. This understanding of bioethics is applicable to conventional deontological, utilitarian and postconventional (such as care-ethics) perspectives. (What matters for each distinct position are the following decisions: Who do we identify as the relevant actors? What are the relevant values? And finally: what is our justification for them?) Thus, the aim of this paper is not to discuss postmodernism itself. Instead, I intend to critically reflect on mainstream medical ethics (which I see myself as a part of) and I want to show why and where some of the postmodern observations are very important and helpful.

In the first section, I want to show that the socio-historical and phenomenological approach on the one hand and conventional bioethics on the other cross each other (not only, but most prominently) in the debate about bodily limits and transgressing body borders. Conventional bioethics especially could profit from socio-historical and empirical-phenomenological investigations of these phenomena because they help clarify descriptive or anthropological premises about the body. Hence, I want to argue that—independently of the way in which the body is described in bioethics, whether as material and distinct from mind or as dynamic and socially interconnected—we must always deal with a value-laden phenomenon. Instead of seeking to avoid hidden moral assumptions, I suggest a methodological approach of making them explicit. By relating the contrary positions to one another dialectically, heuristic use can be made of the central conceptions of contemporary US and Mid-European bioethics. A "conception" means here an abstract notion or system of thoughts which is bundled in a term. However, such a term could be conceptualized in various ways. Thus, "autonomy" covers several aspects of self-determination, such as the opportunity for free decision, but also the capacity of voluntary self-limitation.[11] I develop four different normative perspectives of how autonomy and embodiment could be interlinked. I suggest that these recent conceptions of bodily autonomy could complement one another, instead of our presupposing only 'one' right view. This allows, in my understanding, an improvement to bioethical normative reasoning, and also helps ethicists interested in concrete problem-solving to start right from the beginning with a critical sensitivity to their own premises on what autonomy and the body mean. In a third step, I want to provide an outlook on how my suggested method broadens our way of asking ethical questions by discussing briefly three examples chosen from the fields of transplantation medicine, neuroprosthesis and cosmetic surgery. The chosen examples should also show that the way we consider the body in bioethics is not only an issue relevant for women's health or reproductive medicine,[12] but for all topics in bioethics. The aim of the approach is to be open to multi-dimensional categories in order to advance the identification and description of bioethical problems.

Results

The Body in ethical, social and historical considerations of medicine

The body is more than the locus: Of course, the body has always been and will always be the physical object of medical interventions and biomedical innovations, and it is therefore already included in bioethical thought.[3] Within the medico-ethical canon of non-maleficience, of risk aversion, of health and care, the body as some/the body as physicality is always involved as a locus (where the intervention or the action takes

place). Eventually, the bioethical discussion's primary focus on the body happens in the context of the veto right to bodily integrity or as moral concerns about suffering, often understood as a physical state. Both foci feature a predominantly instrumental relation to the body, because the body is regarded as a carrier of, or vehicle for, the decisive wishes, preferences or interests of a person. The understanding of the body as socially or culturally constructed or negotiated plays no role either for the justification of veto rights or for the situation of physical suffering. For example, in the case of suffering, the search for physiological parameters and quasi-objective criteria to measure it (as is a hot topic in animal ethics) refers to the natural, materialistically-conceived body. This conception, which has been described as the absent body,[5] is based on the assumption that the generation and validity of wishes and interests can be analyzed on the basis of the physical body alone without reference to the body in its social and phenomenological meaning. According to Leder,[13] this is due to the after-effects of Cartesian dualism and its materialist conception of the body as a machine. The human being and its personality were located exclusively within the bodiless spirit. But further contexts are also important. On the one hand, many writers mention the individual "constitutions of meaning qua the body."[14] Embodiment is regarded as experienced body sensation, whereby the body is understood as the scene of the immediate, of the pre-reflexive or of life's taking place, in the context of individual actions, perceptions and experiences in the role for human self-understanding.[15,13] (The idea of embodiment must not be used interchangeably with the idea of naturalness, as especially the boundaries between nature and culture remain unclear with respect to the body.) According to the early phenomenological tradition of Max Scheler (1913),[16] the German language allows for a distinction between "Korper" and "Leib," which relates to the difference between "thing body" (or "flesh") and "lived body." This distinction highlights some Cartesian presumptions, but is not identical with the body-mind distinction. Later, Merleau-Ponty[11] pointed rather to the ambiguity of the lived body as "corps propre"—an intermediate between flesh and the body as it is subjectively experienced by the mind.

On the other hand, scholars from history and social science stress the "historicity of the body." In this stance, we should pay more attention to the social and historical contingency and flexibility of the localization of perception, and of the description and disciplining of the body. The understanding of the body as socially constructed corporality is interpreted as a historically and culturally relative variable.[17,18] Following Donna Haraway[19] body images are of linguistic nature and do not represent the real body but are in fact 'objects of knowledge.' However, a very radical socio-constructivist approach would eliminate this perspective on the body as well. The conception of a (totally) flexible and ambivalent body reduces the body to nothing, or a mere space for projection. In postmodern transhumanism the body is often not ascribed a value of its own. Within the phenomenological approach, embodiment as an entity in its own right is seen as giving immediacy and materiality to individuals and societies, and as thus constitutive for human self-understanding.

With this approach, the precarious nature of conceptualizing the body becomes obvious. Phenomenology points to the already implicit normative significance of the body and the discussions about what should be done with, and made of it.[14]

Although one could fear that the loss of certainty concerning our body may result in a new form of absence of the body, the socio-cultural and poststructural criticism allows us to open our reasoning in further directions, such that we can now reflect on the one hand on the phenomenological perspective of perception and experience of embodiment and on the other hand on the perspective on the body as corporality that sees it as formed by culture, socialization or the history of science.

Since the goal of this article is to develop an approach which is open for different premises and perspectives regarding the body, I do not want to restrict my definition to one theoretical strand. Therefore, I suggest using the term "embodiment" to encompass the different perspectives.

Body limits as moral and epistemic uncertainties

What is of interest here is that both of the last mentioned approaches question the certainty of the claim that the body is only the physical locus of medical interventions on a theoretical level, while medicine and biotechnology question this certainty on a practical, everyday level. I suggest that the "body boom" continues because the time we live in chooses transgressions between bodies and also categories (in the sense of playing with limits) as a focal point for technical innovations and social designs of life.[7] The body boom is a result of the experienced and conscious play with the limits of the body.

However, the reactions to this are quite ambivalent. Whereas some free such transgressions from taboos by describing them as a logical consequence of technological development,[20] or even demand them, as the so called transhumanists do, others lament the (often hidden) increasing danger for both society and the individual posed by the new technical domination of the body and its perfection towards the elimination of finiteness.[21]

From an ethical point of view it remains to be analyzed whether, for instance, our intuition is morally wrong that certain forms of utilization of the body are not permitted, and whether certain practices must necessarily be judged as a morally problematic instrumentalisation of the body. It is my thesis, though, that such an ethical analysis will have to consider the anthropological and epistemological premises that form the basis for the relationships between embodiment and normative values. The following three observations shall serve as an introduction to my considerations of the intertwining of ethical, anthropological and epistemological dimensions:

1. Certain biomedical procedures (among others transplantations and implantations) activate moral intuitions or discomfort more strongly than others do, and thus raise questions concerning the normative relevance of the body;
2. At the same time, technologies that transgress both borders and 'limits' question the traditional categories of order of the Western culture (influenced by the Judeo-Christian Tradition, the Enlightenment and scientific ideas since the nineteenth century).[22] This pertains above all to the following binary categories:
   - Nature-culture: this basic distinction, based on Aristotelian thinking, is blurred for example, in the case of the cultivation of cells or artificially produced organisms.
   - Human person-machine: this distinction is challenged by manipulation of the mind through brain-implanted chips and brain-computer interfaces.
   - Human being-animal: this Aristotelian and also Judeo-

Christian distinction between humans and animal is questioned by, for example, the creation of human-animal chimeras.
   - Internal - external: the nineteenth century idea of physical and social boundaries is challenged for instance by questioning the ownership of an explanted organ or of an embryo created in vitro.
   - Body-mind: the Cartesian distinction between the body as a machine and the mind as the *ratio* is challenged for instance through the transplantations of brain tissue.
3. There are different reactions to the questioning of these conventional orders:
   - There is the naturalist argument, where the body is understood in a materialist way as irrelevant for the formation of norms. A value of the body can only be established by referring to the interests or values of the 'users' of this particular body;
   - This is a constructivist-relativist discussion about the variety of body conceptions, which either refuses all universally applicable claims to truth or, in a radical form, denies the body's materiality;
   - A normative, prescriptive relevance of the body is postulated, making of it something resistant and unavailable, with a value of its own—and end in itself.

Let us consider the first observation. Research in the history of medicine and culture suggests that the development of modern medicine (starting with anatomy, physiology, cellular pathology, bacteriology and hygiene, human genetics) has successively turned the human body into an object, and then dissected, regionalized, localized and standardized it.[23,24] As a consequence, the body and its parts tend to be regarded through a view known as "empiricist materialism"[3:300] and is seen as exchangeable and open to modification. Transplantation medicine, for instance, is historically clearly based on the localization theory of illness that dates from the mid-nineteenth century.[25] However, the practice of transplantation medicine could only be established on the basis of insights resulting from systemic immunology in the second half of the twentieth century, including the knowledge of how to understand and manipulate several pathways of immunological rejection. For a long time, the ethical discussion of transplantation medicine neglected consideration of the transfer of organs with respect to its integration into the body image and the union of body and spirit, although there were many sociological and anthropological publications on these issues.[26, 27]

The premise of interchangeability as regards physicality and personal identity was only questioned in ethics against the background of discussions about the transplantation of neuronal tissue or even entire heads,[28,29] whereas other body parts were not regarded as constitutive of identity. Such scientific and technological objectification and fragmentation has been criticized as "de-bodiment of reality" and "ousting from perception the body itself,'[30] and opposed as an attitude that exclusively focuses on control over the body. This criticism appears to contain the vague (and predominantly implicit) assumption that there exists a true or authentic perspective on the body-identity-relationship which one just needs to capture differently, in a new way.[21]

Even if one cannot fully agree with this criticism, it nevertheless hints at a situation that I would classify as paradoxical: the mutual relationship between, on the one hand, still very prominent theoretical premises of objectification, fragmentation and blindness towards the (lived) body within everybody medical practice; and, on the other hand, socially and politically powerful critiques of increasingly dominating biotechnologies, which stress that the body is unique, must be perceived subjectively, and has independence and resistance.

The second observation concerns the ways in which such paradoxes or ambivalences are triggered. Traditional Western Occidental culture distinguishes very clearly between human being and machine. It characterizes the human being as a hybrid being that can be located between the two poles of nature and culture, and it aims at the separation of the "own" from the "other" through individuation. According to my thesis, these poles are not only becoming blurred in the course of the biotechnological revolution, they are increasingly being dissolved. Certainly in our perception and language, mechanization, rationalization and instrumentalization of the body or of living things increasingly moves the balance of the traditional order in one particular direction, predominantly towards materialization.[30] According to the sociologist Gesa Lindemann,[31] certain medical technologies shake the hitherto common distinctions of relationships, namely the differentiation between the social interaction of two human agents on the one hand, and the relation of a personal agent and a non-personal object on the other. Lindemann demonstrates this by reference to her anthropological investigation of the ambivalent and sometimes contradictory attitudes of doctors, nurses and relatives to brain-dead patients in intensive care. Many bioethical problems result from this kind of situation: the question of how to treat and care for a brain-dead pregnant woman so that the baby may grow and be brought to term. Conceptual difficulties, already present in identifying and evaluating the distinction between two human agents or a personal agent and non-personal object, became obvious in discussions about the moral status of entities that transgress borders, for instance hybrid beings such as so-called chimeras. Such transitions from a loss of order towards normative evaluations lead to the third observation concerning reactions to such loss. The philosopher Hilge Landweer[32] has asserted that there are three very different and partly opposing strategies to place basic anthropological assumptions within contemporary images of the world:

a) Through the naturalist approach, the human being is reduced to a body and understood as a creature that is determined by physico-chemical processes beyond its control. Consequently, a person's self-relation would be nothing more than a complex neurophysiological process which could be changed and manipulated accordingly.

b) In the constructivist or postconventionalist approach, the essence of the human being can only be explained through historical and cultural discourses and contexts. Objective descriptions of the 'body' are no longer possible. There are only provisional truths, and their analysis is reduced to the description of a series of conflicting and dispersed discourses. At last, the materiality of the body could be understood as a discourse, itself, depending on narrations of the body.

c) In the "transformation" approach, the materiality of the body is assumed, yet embodiment is seen as inaccessible for and through science. The body (as the sensual access/interface to the world) is understood as a precondition of all experience and

knowledge. The body's independence and autonomy are defended. Despite all historical and cultural qualifications, this approach does not entirely neglect universally- applicable statements. However, the ways in which the body precedes all experience and knowledge cannot be captured by the terms 'nature' or 'biology', but escape any direct analysis. My first interim conclusion is that all three positions are needed to explain how the normative relevance of the body (eg seeing body parts as mechanistic spare parts) is related to other values (eg liberty, justice, self-development). I hereby distinguish between normativity (prescriptive; as rational ethical justification) and morality (descriptive; an analysis of values and socio-cultural attitudes in a group of people or society of what is right and wrong).[33]

Within the naturalist and constructivist positions, the modification of the body relates to the normative framework of personal interests, social obligations or reciprocal relational structures as determined for instance by post-conventional or feminist views. Of all three, the "transformation" position is most supportive of the independent development of the idea of the body as an essentially unavailable entity, with a specific inherent value. The terms "unavailable entity" and "unavailability" are used as *termini technici* to characterize normative limitations with respect to the body. The body must not be objectified and is never totally disposable for instrumentalisation. This value in its own right nevertheless needs to enter into some kind of relation with other norms and values, in order for positions to be taken from a bioethical perspective on the various forms of modification of the body.

According to a rather common point of view, whether an intervention into bodily intactness is morally permissible depends on the agreement of the person in question to suffer such an operation, be it the removal of a kidney or an artistic act as described in the introduction.

I thus want to focus on and discuss the relation of autonomy (as one prominent value in bioethics) and embodiment in the next step. This relationship is, in my opinion, a crucial issue, precisely because one cannot understand the various positions about the body and its meaning for the self without some consideration of liberalism, social conformism and the question of when a human act or decision is authentic, free and autonomous.

More than one relation: embodiment and autonomy

Let me give a short overview of two philosophers who have specifically investigated the relationship of embodiment and autonomy, by criticizing (radical) liberal tendencies in bioethics.

According to Richard Shusterman,[34] recent forms of conformism as well as individualism encourage somatisation; that is, practical attention paid to the body (through, for instance, cosmetic surgery, body building, medical operations, and piercing). There is an explanation for the positive co-existence of both the cult and the negation of the body: both trends are rooted in disrespect for the body, as concentration on the mere exterior materiality of the body does not acknowledge the body's independence. The body is no longer perceived as a given fate, but as raw material at the disposal of individual creativity. There are, however, some indications as to the dialectics of these practices: at least in their origins, many aesthetic body techniques such as tattooing or piercing can be seen as an individual's expression of resistance against standards and societal body norms. Similar to sports, they can also represent a positive body experience which is obtained through pain. Modifications of the body apparently promise liberties, yet at the same time there is a fear of the enslavement of the body. Shusterman distinguishes a "somatic of presentation" (a manipulation of outward appearance) and a "somatic of experience" (new breathing techniques, psychotherapy etc). With Shusterman, the former is especially criticized. This is due to a critical attitude which interprets attention paid to the body as an already alienated interest in an outward representation, which would therefore inevitably serve the corrupt aims of advertising and propaganda.[34] In contrast, Shusterman recognizes the somatic of the experience as an option that can have constitutive potential for identity and harmony.

In libertarian ethics, autonomy is, as already shown, the normative touchstone for many kinds of body modification. However, as Christman has shown in depth, there are various conceptions and interpretations of autonomy.[35,36] In general terms, autonomy is seen as a basic condition for liberty.[37] Following Carter, the crucial question is—in order to distinguish between negative and positive liberty—whether someone is primarily interested in the degree of external interferences and controls such as the state or other persons (negative liberty) or whether someone advocates the importance of internal factors such as self-commitments or shared social opinions (positive liberty). Both ideas of liberty focus attention on the way desires and interest are formed and put into practice,[38] while the content is not considered.[37] This observation points precisely to the debate over bodily autonomy, a term coined by Catriona Mackenzie.[39] Mackenzie develops an account of the theoretical relationships between choice, bodily capacities and autonomy in order to discuss the content of arguments concerning wishes and acts that interfere with embodiment and body modifications. She criticizes the notion of maximal libertarian autonomy that underpins the expansion of available body modifications, rights for body property and the instrumentalisation of the body for personal autonomy[39] because she rejects the idea that maximizing choices autonomatically increases a person's autonomy. In addition, she rejects the straight liberal maximal choice conception because it provides no normative criteria to assess which choices are autonomy-enhancing and which are impairing. Here, Mackenzie seems to refer to a radical libertarian interpretation of 'liberal ethics,' while there are liberal ethicists, most prominently John Rawls,[40] who also see self-restriction, fairness and paternalism as parts of a reasonable social morality and as protecting us from unreasonable first-order wishes which endanger our second-order wishes.

Referring to a relational conception of autonomy, and following Ricoeur's phenomenological approach, namely that human corporeality is the invariant condition of human selfhood, Mackenzie suggests understanding the body as part of our identity, such that her favored notion of bodily autonomy—also as a normative theory—always implies critical reflection on changes of bodily integrity and accepting the "givens of human embodiment."[39]

The attraction of Mackenzie's idea lies in its productive critique of a radical libertarian conception of bodily autonomy, as described above. It helps to detect the weak point of under-

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complex premises regarding the meaning and condition of the human body as an instrumental means. But again, her ambitious conception of bodily autonomy is itself built upon normative and anthropological premises which are taken for granted. Instead of the phenomenological position she seems to take as given, I would suggest that normative reflections on bodily autonomy should be grounded on several premises, including non-phenomenological positions, as they are also prominent in medical practice or radical postmodern thinking.

What follows for my argumentation? Now only conventional liberal bioethics, but also the critiques of these positions are in need of clarification and justification of their premises regarding embodiment. I understand this critique as a fruitful starting point for re-thinking our initial problem: How do we interpret and conceptualize the body in bioethics? And, secondly, the current international discourse in bioethics has to acknowledge its own diversity in its use of body conceptions. It is scientifically unsatisfactory to stick to some views and reject others as ideologies. The several, conflicting assumptions of what the human body "is" may result in conflicting ethical judgments. The aim is not so much to overcome all conflicts, but rather to have an explicit discussion on what the body means to bioethics and not only in theoretical papers but also in applied problem-solving ethics. There, I suggest an analytical matrix which allows a self-critical test of various premises by way of a dialectical composition of the various views. It is built upon the idea of a critical reflection of normative and anthropological premises by contrasting them with alternative or even antagonistic conceptions of body-autonomy-relationships. This multidimensional approach functions as a heuristic tool to identify and test bioethical assumptions with respect to different epistemic and anthropological premises regarding the body. At the same time the approach sustains tension between different notions of autonomy.

To achieve this, I start from a summary of the two polarized main lines concerning the interpretation of autonomy. According to Christman[35,36] autonomy refers, on the one hand, to the potential or actual capability of a person to act and decide independently of external influence and power. This avenue is often stressed in liberal argumentation, where self-determination is conceptualized without considering the social influence on norms and preferences. Its main pursuit would be negative liberty. I prefer to talk of self-determination in this understanding of autonomy, because the term stresses the "self" instead of external determination. On the other hand, autonomy could mean the moral ideal of developing values and normative standpoints by means of criteria of role distance, self-limitation and universalization. This avenue leads in the direction of the above mentioned 'relational autonomy' in which social responsibility and social relationships are the main entrance into understanding autonomy. I call it here "moral autonomy" to stress the capacity for moral self-reflection, as Mackenzie does: Moral (bodily) autonomy connects to the imagining of the good life through critical and creative self-reflection and the integration of biological, socio-cultural and biographical dimensions of bodily self-representation. This notion of autonomy also appears to be linked to the idea of a successful establishment of a coherent identity, despite fashionable trends and socio-cultural conformity. Both conceptions of autonomy do not necessarily preclude each other from a normative point of view. While the liberal 'minimum' conception of autonomy is understood as a capability to develop and formulate individual preferences despite or precisely because of social influences, the second 'maximum' one is understood as the capability to question and prioritize one's own preferences and to use them for orientation with respect of others' interests and needs.

According to my analysis in part 1, there are also at least two main polarized perspectives on the body. These also may enrich the bioethical debate. On the one hand, there is the phenomenological perspective which combines both the perception of the individuals' material and anthropological limitations (the physical dimension) and the lived-body phenomena such as sensual perceptions or pain. The other view understands embodiment as a textually or culturally inscribed exterior (such as categorization into specific anesthetic, social, gender or medical-scientific classes would be). As a result, we now have four different specific perspectives for the relationship. Each is based upon one of the specific interpretations of embodiment and autonomy that I have worked out above. The four perspectives are not hierarchically understood; one could start reading the matrix from the conventional, liberal materialistic perspective and end at the communitarian-deconstructivistic position, but also vice versa (I will illustrate this for concrete cases in the next section). But in order to avoid misunderstandings, I choose more adequate labels to describe these four perspectives:

I) "Bodily self-determination": Autonomy as the right to bodily self-determination refers in this view to the defense of one's own body against direct and indirect interventions by third parties. The body represents the immediate access to one's own personality (ie to express one's own opinion by a body modification), and at the same time can be regarded materialistically as a transformable entity. Autonomy remains fixed to the somatic/bodily-conveyed capabilities of personal identity (ie to communication, to coping with pain, to the conscious realization of personal characteristics). However, this view does not have to lead to the conclusion that an instrumentalisation of the body always means an instrumentalisation of the person, provided that the interventions in question are agreed to by this person, and the natural basis for this person's identity remains intact.

II) "Respect for the bodily unavailability of the other": Moral autonomy, as part of the self-restriction that I have discussed above, includes the respect for another person's bodily integrity, even if it conflicts with one's own preferences and aims of action. This necessitates a critical reflection on the ways in which one deals with the body of others and one's own within the social and cultural space. This respect is more than a negative right to repel claims of others. It understands respect for others as reciprocity for the wish to be respected. First and foremost, this respect for the bodily unavailability of others allows critical reflection of own needs for other bodies. But it also includes considerations about one's own body images, bodily integrity and desires for body modifications. Can one rightfully deduce certain demands to maintain or form bodily integrity on this basis, particularly so if this has implications for third parties? A self-critical view on body images and ideals could be required if one cannot be sufficiently sure of avoiding implicit or explicit discrimination of those who diverge from this ideal. In addition, moral autonomy can involve taking political-normative initiative for the bodily integrity of others even if one is not affected personally. This could be done through advocacy, esp. for those who cannot articulate their own interests and

views. This includes the commitment to political discussions about the unavailability of the body of third parties.

III) "Care for bodily individuality": Autonomy as self-critical reflection includes the fulfillment of individual interpretations of what a good life is for me, including a form of care and concern for my body. Therefore, an understanding of the body can be regarded as part of a conception of the good life: one's own interests and desires are linked to imaginations of bodily perception and expression, and to bodily-mediated actions such as communication, love and sensations. Visions of the good life include the striving for aesthetic values, and the development and stabilization of an identity as conveyed through sexuality, appearance as bodily characteristic and bodily techniques (such as in the acts of eating or moving etc.). Such bodily features are always situated within a complex understanding of individual normality, of political and social standardization, and of historical and cultural difference. Embodiment is critically investigated as socially constructed and discursively negotiable. This emphasizes and makes comprehensible the role of individual care for bodily characteristics: the central normative element of this care may well be the recognition of a difference rather than of a norm or normality. Care for bodily individuality goes further than having a maximal choice for body modification: It also includes the idea that the self and personhood are built upon individual appearance and individual body language and styling. Care includes the protection of bodily individuality by maintaining one's own identity even if one's body appears different and 'strange' to others. Recognition of bodily individuality could be understood as recognition of being different (to others). Therefore this need not lead to an exclusion of the other but can support the fortification of one's own self-determination through dialogue and a creative approach to the other. The background to this is the idea that there exist several ways of dealing with embodiment (and its weaknesses) which serve as a source of ideas for the conduct of life, and hence of ideas of the good life.

IV) "Recognition of bodily cooperation": Autonomy as the opportunity and capacity to develop a self as an autonomous person may at the very least require the right to one's own social identity within the framework of group membership. This group is assumed to express itself by means of specific forms of embodiment, of bodily interaction and of bodily-constituted communities; and to build a harmonic cooperation, here called 'bodily cooperation.' This recognition is built upon the care for bodily individuality but refers to forms of bodily expression in which the body is constitutive for specific social interactions. The building of stable social relationships such as parenthood, partnerships or friendship could not easily be thought without having bodily contact through touching or sharing bodily experience. For instance, most forms of sexuality are constitutively bodily social interactions, as are maternity or the social handling of dead human beings. Recognition of such bodily interaction leads to political and social recognition of those communities which are different in sexual preferences, eg homosexual communities.

Discussion

What conclusions can be drawn once we open up these four perspectives instead of the common narrowing to only one favored perspective? In the last section, I want to use the approach developed in part 2 for an improved, premise-critical description of ethical problems in recent biomedicine. The chosen examples of issues in transplantation medicine, neuroprosthesis or cosmetic surgery present serious cases of transgressing borders. Because of limitations of space, I will restrict the final discussion to the aim of showing the increased sensitivity to the various perspectives of normative judgments through different ways of formulating the starting problem.

I therefore start again from a liberal conception in which the argument of bodily self-determination is vehemently used to justify the right to body modification as long as informed consent is given by the affected person. As long as biomedical technologies are perceived as means to achieve emancipation from bodily limitations (through illness, pain or death) their legitimacy does not seem to be in doubt. But it is decisive whether new options secure, impair or increase the preservation of a person's interests and autonomy through body

modifications. For instance in the case of the transplantation of organs, how is the freedom of a patient to choose between options as provided through the medical system safeguarded within the framework of information, availability of medical treatments and agreement procedures? A special case is the possible commercialization of the donation of organs. The argument of bodily self-determination seems to support a liberalization of the trade in organs as long as it is guaranteed that possible medical risks are reliably assessed and made clear to the agent, and that injustice through possible exploitation is avoided.[41] But in the same field, we have to consider the understanding of what constitutes a person, as exemplified by the question whether self-determination continues beyond a person's heart death or total or part brain death. Here, the anticipated relationship of self-determination and embodiment (in the sense of an understanding of the body that has to be interpreted individually) is decisive. Is it a truly personal affair to decide on what should happen to one's dead body, or does one need to respect the piety of relatives and therefore accept certain limits? The former distinction between human being and machine, mind and body, is blurred by the technology itself (as "dead" persons are kept "quasi-alive" by heart-lung-machines). If a person's autonomy is linked only to current bodily self-determination and constructs the body as a physical instrument, further-reaching claims such as the social obligation to help other patients with organs eventually succeed, even if the dead person refused the explanation of organs whilst alive.

But further interesting perspectives appear when bodily self-determination is complemented with concerns about the respect for the bodily unavailability of another person. The constructed case of an individual decision-making process often cuts out medical and social reality: This includes questions about the person who serves as an organ donor or who carries out an operation, for instance as a doctor. For example, in the case of a living donation one needs to raise the question as to whether the living donor of a kidney considers the act of donation as a voluntary, autonomous decision, but also whether the potential organ receiver has a right to ask for the donation. The transgression of the internal-external-borders ("My kidney in your body?") opens the new field for the moral assessment of identity and bodily integrity. Taking serious the moral respect for others' bodily integrity opens as such a new perspective: Doctors, as well as any potential recipient of the organ have to acknowledge the moral dimension of their decision (to conduct the operation, and to receive the organ) and to take responsibility for their respective roles within the decision-making process. The critical reflection on the respect for the bodily integrity of the other also allows for a consideration of the impacts of modern biomedicine on people who are not directly affected, in terms of a possible discrimination of third parties. Discriminating with regard to others means to disadvantage them on the basis of their membership in a specific group although this specificity does not justify such inequality in treatment. While the focus on bodily self-determination neglects the dimension of future social developments, the respect for bodily unavailability opens the door for critical social impacts, even if they are indirect and only a future possibility. Such problems could be approached by considering slippery-slope arguments. Cosmetic surgery could hereby be seen as a challenge to the border between what is seen as natural and what is artificial. While this 'border' is not said to be a distinction between morally right or wrong, its transgression implies important questions of authenticity and cultural standards. For instance cosmetic surgery on an adult woman very often seems to be legitimated with reference to bodily self-determination. Taking influential pop cultural shifts in body images as possible and likely, this may result in a successive, implicit social compulsion for next generations to undergo similar modification of the body. The moral dimension of such individually legitimate decisions unveils ethical problems for those who are rather dependent on cultural standards (such as adolescents).

The conception of self-determination is related to a conception of the good life insofar as the fulfilling of single preferences and second-order interests could be seen as embedded in the 'whole' perspective of what a person should be, of what is part of his/her self and identity. The stabilizing effect of the exclusion of a separation from others on personal identity should not be underestimated.[42] This new idea of individual care leads to a positive effect that stabilizes identity. The role of care for bodily individuality and its characteristics, for the development of identity and thus for self-determination is further supported by the process of individualization and the deconstruction of fixed socially constructed categories such as healthy and ill, ugly and beautiful or natural and artificial. For instance, it allows a more open discussion of how to assess neuroprosthesis and brain implants to cope with certain disabilities (such as deafness), Parkinson disease (e.g. treated with xenotransplants) or patients with the Tourette-syndome (a disorder, which is characterized by uncontrollable vocalizations and movement and treated with deep brain stimulation).[see e.g. 43] These biomedical technologies could question the border between human being and machine or animal. If the body is seen only as a material basis or as depending on individual perception, the bioethical discourse is then poised on the (empirical) question of whether the prostheses or xenotransplants are able to change personal identity. Instead, realizing that the border itself is questionable, on the one hand, and that normative recognition of bodily cooperation, on the other hand, may count, alternative solutions such as the improvement of care and the reduction of barriers on the social, structural or town-planning for elderly or mentally ill people will be seriously discussed. Additionally, this directly opens up issues of distributive justice: We have to the face the problem that excessive use of biomedical solutions could forget all those disabled people and patients who—for personal or structural reasons—do not have access to biomedicine.

Finally, the consideration of the recognition of bodily-constituted communities and bodily cooperation allows us to question whether some biomedical practices could destroy cultural identities, for instance as signified by a loss of sign language due to the use of cochlea implants,[44] or whether it also contributes to the gestation of new ones (through the development of new collectives of patients, for instance). The normative tension between bodily self-determination and care for one's bodily individuality gives rise to a discourse over the extent to which the acceptance or refusal of an intervention into the body is rooted in a comprehensible insecurity or desired unavailability with respect to one's own body. Adding the perspective of the possible value of bodily-constituted communities allows new forms of assessing social actions and communication. Since the debate about race, sexuality, ethnicity and disability, we have seen by way of the negative effects of embodiments its crucial role in the perception of other 'cultural' identities. For instance, the social and political dimension of

patients' self-help groups could be better discussed as part of a socio-political dimension in the medical system than by focusing on individual decision-making. Patients support and advise each other; they share something which not only separates them from others, but also strengthens them: the existential experience of illness or of the long process of therapy and recovery.[45]

Conclusions

The opening for various relationships between autonomy and embodiment provides a central interface for the ethical reflection about who can decide when and how about one's own body. What elements of a person can be regarded as available or unavailable at which points in time during the process of this person's life or dying? Some liberal ethicists criticize the body boom in ethics as a "neo-heathen body cult,"[46] because they view it as inappropriate to refer to the body as morally relevant. However, as I argued above, this assumption could be self-contradictory if proponents of the liberal conception of self-determination recognize the principle of nonmaleficience as a moral duty to act in a responsible way—as many scholars do. Nonmaleficience and the obligation to reduce suffering are linked to a specific concept of the body—a body which is able to 'suffer' and 'feel pain' and can be 'harmed.' Instead of neglecting one's own anthropological and epistemic premises about this suffering body I suggest to be aware of them. I conclude therefore that the bioethical procedure of detecting and describing ethical dilemmas should also take into account the ways and limits of perceiving one's own body and those of others. From here, it should not be concluded that any kind of biotechnology is morally problematic just because it annihilates difference (for instance through the idea of making an "ill" person "healthy") nor is it generally justified just because patients gave their 'free' informed consent.

The body is a challenge for bioethics, because autonomy as the idea of the 'unavailability' of the body relies on various premises regarding the manner in which cultural and personal identity is built upon bodily practices, bodily constitutions and body images. Within the liberal bioethical context, bodily self-determination is often understood as a minimal moral consensus based on a legitimate resistance against medical (or state) paternalism. But as I showed so far, bioethics provides more than insisting on this minimal consensus; ethical reflection also serves a fruitful idea of a reflective self-relation of the moral agent. This reflection makes it necessary to think about the normative meaning of specific bodily related interactions with others and the respect and care for others' bodily integrity.

However, the categories for the cultural and natural order of the body as described above are not regarded as having a moral value in their own right, but as being very value-laden. Thus, the suggested matrix is open to various interpretations and offers both linguistic and argumentative access to critical inquiry and to the different ways of being a lived body or a thing body.[30] One should also note that the loss of order, as I described the moral epistemic uncertainties towards human bodies in Part 1, is constantly discussed within the bioethical debate, but is labeled in a different way: as the conflict about the so-called moral status of various entities, e.g. of a human embryo, of animals, or of brain-dead persons.

The loss of self-evident truths may often be regarded as a specifically modern phenomenon or even as the tragedy of modernity. Particularly the wider bioethical perspective shows to which extent epistemological and normative views are intertwined. However, in the course of self-reflection this loss can also be seen as something positive: as an opportunity for self-re-interpretations.

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Proximity Morality in Medical School – Medical Students Forming Physician Morality "On The Job"

Hans O. Thulesius, Karl Sallin, Niels Lynoe, Rurik Löfmark

Background

Medical ethics education differs from other subjects and the importance of formal courses in ethics has been questioned. Some medical schools combine instruction in bioethical principles with teaching of humanities programs. The teaching of ethics varies in Swedish medical schools from interspersed lectures to formal ethics courses. Lately, teachers are developing a common national curriculum in the view of a new Swedish university regulation in 2007 to align with European higher education in the Bologna Process. One of three main outcomes of medical education according to the new regulation is ability to understand and assess values and attitudes. Thus, there is a change process underway regarding medical ethics education in Sweden.

We designed a questionnaire survey in order to elucidate how medical students view the ethics education in medical schools. Many students gave input on the ethics course curriculum: Should ethics be taught in lectures or learned through group discussions? Should the ethics course be a separate course among others, or should it be part of other courses with lectures and group discussions interspersed? Should it come early or late in the medical school curriculum? Should the literature be specific ethics literature or novels and short stories with relevant ethical content? From multiple-choice responses we found that strong ethics interest was associated with frequent experiences of physician teachers as good role-models and an absence of poor role models. In the present study we wanted to explore what was going on in medical schools regarding the medical ethics education by analyzing open-ended survey responses together with response data from multiple-choice items.

Results

In this study we analyzed student attitudes and "what was going on" in the medical ethics education based on survey data. The medical students argued for a proximity morality stance, or forming morality "on the job." This morality forming is ideally done in comprehensive ethics courses with tutored small groups. Forming physician morality requires "ethics grammar" provided by selected high quality lectures, and impulses from attitude exercises and vignette reflections in "ethics labs". Patient cases and clinical issues are thus discussed in interactive groups that help to deal with emotionally difficult clinical situations. To desist negative role modeling is another function of the ethics courses where reflected professionalism is developed for diverse medical students in a heterogeneous world.

Proximity morality in medical school – How?: On the job morality forming in medical school is typically done in interactive discussion groups. These groups have a support network function where medical students are allowed professional role growth within a permissive context where ethical and value-laden issues are discussed and tried. The structure ideally consists of tutored groups that repeatedly work with case study approaches, discuss ethical principles, and continue during internship. Within a frame resembling the clinical setting students grow their own ethical attitudes and shape their individual physician morality. Group discussions provide good training for handling ethical difficulties since real world medical ethics consist of unique complex situations often involving several people. One goal of interactive ethics group discussions is to understand what appropriate physician behavior is.

Forming physician morality also includes quality lectures on ethics, preferably by professional ethicists. These lectures provide students with a basic "ethics grammar" about ethical principles and concepts. This feeds the interactive group discussions and improves their quality concerning ethical issues.

In the ethics lab, students work with practical, sometimes challenging attitude exercises and vignette reflections. These stimulate critical thinking about current ethical problems in clinical training. It requires that participants position themselves ideologically, and for some attitude exercises also physically. Attitude exercises are often done in case studies.

Proximity morality in medical school -Why?: Why would medical students want to form physician morality on the job?

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The deliberate forming of a physician morality is necessary for several reasons. A number of student responses dealt with arguments for ethics education in general and forming physician morality on the job in particular:

The professional identity of future physicians requires moral reflection. Medical students are different. Some are ethically naive, or not interested in ethics, and others even described as socially "autistic." The importance of ethics education is obvious for these groups.

A group discussion format of ethics education helps in processing tough experiences from the clinical setting.

Desisting negative role modeling. By defying ethics suppression and politically corrected ethics the influences of physicians/teachers as poor role models may be addressed and negative role modeling dealt with in the interactive groups. Some teachers and physicians were described as being "masters of opinion control" trying to neutralize discussions about ethically sensitive topics by putting the lid on discussions, and defending politically correct opinions.

In a statistical analysis of the survey presented elsewhere we saw a significant relationship between a low interest in ethics and frequent experiences of poor role models and the absence of good ones in all three terms. For final-term students, there was a significant association between a high interest in ethics and experiences of good role models and a preference for discussions in small groups.

Discussion

We propose that medical students by a proximity morality stance want ethics education on the job to help them in the learning process of becoming physicians. In this process they form their own physician morality rather than being taught ethics. This ideally takes place in comprehensive ethics courses where tutored groups openly discuss and reflect on difficult ethical topics and moral dilemmas. High quality lectures are interwoven to give an ethics grammar. These lectures provide default ethical principles nurturing group discussions together with attitude exercises and vignette reflections in ethics labs. These interactive discussion groups also have a support network function. Here students process ethical problems in an environment where physician morality is allowed to form and grow on the job. Hence, rather than being served ideologically stained opinions students prefer to reflect and discuss different ethical attitudes. As an example of their proximity morality one could say they want to bake their own moral cakes instead of being served ethical cookies.

Medical education could be seen as a form of moral training of which formal instruction in ethics constitutes only a small piece. In a study investigating the effect of ethics education on physician morality it was concluded that moral development and ethical confidence were unaffected by ethics education. The goals of ethics education was conceptualized as having cognitive, behavior and attitudinal dimensions. Ethics was supposedly studied for its own sake contributing to "one's all around character". We agree with this author's conclusions, and our analysis suggests that instead of an emphasis on teaching, ethics and morality has to be learned on the job as discovered in a neonatal unit study of proximity ethics. As a reference to oneself's morality Levinas talks about "the other." Similarly "the others" (fellow students and teachers/physicians) are necessary for understanding the suggested "on the job" morality development in our study.

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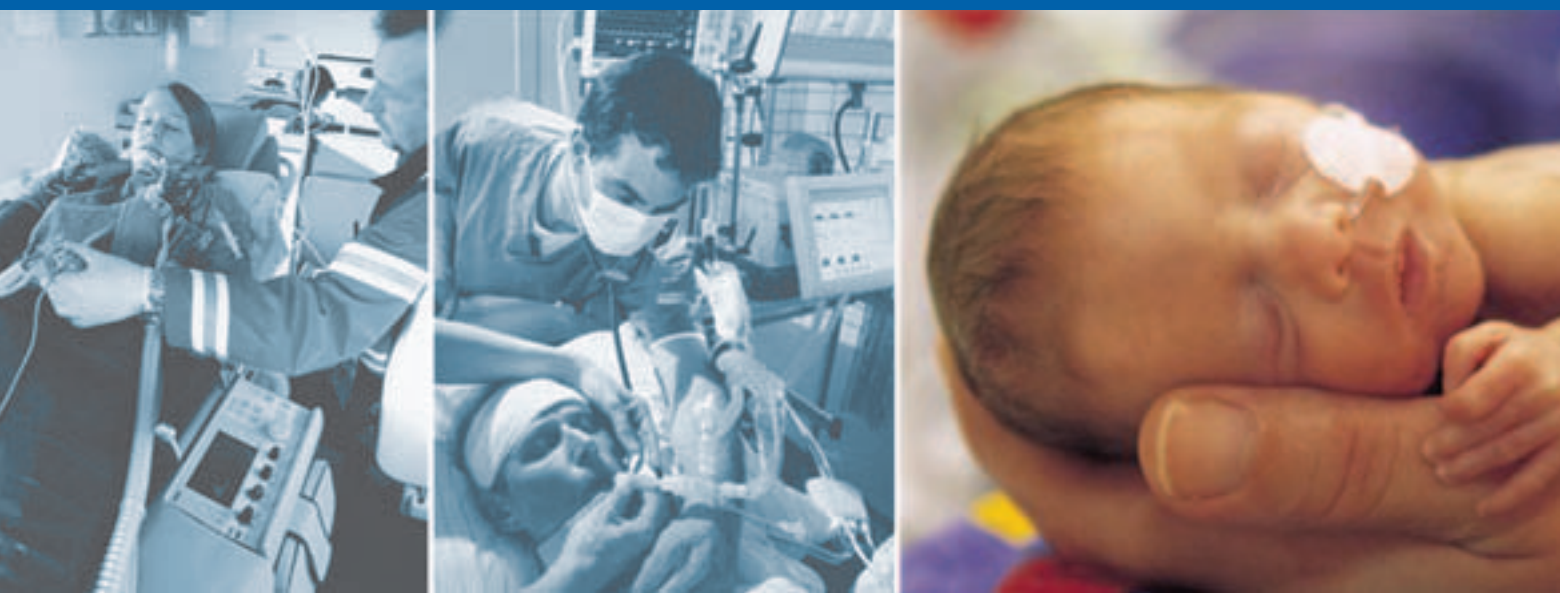

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