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Table of Contents

DEPARTMENTS
6 Editorial
7 News

ARTICLES
14 Clinical Experience Using Inhaled Epoprostenol
16 Reducing Maternal and Neonatal Mortality
24 Early Feeding of Fortified Breast Milk
27 Intelligent Neonatal Monitoring
36 Preterm Birth By Vacuum Extraction

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Targeted Neonatal Echocardiography (TNE) in the Neonatal Intensive Care Unit

Azif Safarulla, MD, Ayysha Syed, MD, and Muhammad Aslam, MD

With advancements in neonatal care, the role of echocardiography has changed remarkably over the last few years. It has transitioned from echocardiograms being performed by pediatric cardiologists to diagnose and monitor congenital heart disease (CHD) and patent ductus arteriosus (PDA) to being used by neonatologists of late as a tool for assessment of hemodynamic instability. This wave of change has been spawned by an increasing awareness and desire to better manage neonates, as well as due to the unavailability of pediatric cardiology services in certain remote areas in the United States and Europe.

Dr. Mertens and associates published the following article in 2011, “Targeted Neonatal Echocardiography (TNE) in the Neonatal Intensive Care Unit—Practice guidelines and recommendations” in the European Journal of Echocardiography. This article examines the current trend of TNE being performed by non-cardiologists. It clearly defines what constitutes TNE and indications for the same, the practical applications, and more importantly establishes realistic guidelines on how to create and maintain quality in recording and interpreting data, which is in accordance with standards set by the American Society of Echocardiography, European Association of Echocardiography and Association for European Pediatric cardiologists. These guidelines include a training period of 4 to 6 months dedicated to pediatric echocardiography with performance of at least 150 neonatal echocardiograms. Following completion of the 4 to 6 months dedicated to pediatric echocardiography with performance of 150 neonatal echocardiograms, the next step is training by pediatric cardiologists to diagnose and manage neonates in an appropriate manner will enable clinicians to better understand and manage the changing hemodynamics in a neonate in the first few days of life, which often is the most critical time. In addition, it has other applications in terms of assessing organ blood flow, suspected effusion (pleural, pericardial), position of central line, ECMO cannulas, etc. As our clinical knowledge expands, the applications will continue to evolve. In case of patient with a strong clinical suspicion of CHD, significant PDA, systemic hypotension, the initial assessment should be done by a pediatrician having experience in performing TNE. Once ruled out, follow up studies can be performed by personnel sufficiently trained in performing and interpreting TNE.

In conclusion, TNE has arrived at the scene and it is here to stay. TNE is an extremely useful tool which if utilized in the appropriate manner will enable clinicians to better manage neonates in an array of clinical situations. It represents an opportunity for the Neonatology and Pediatric Cardiology to work together to improve clinical care and for cardiology to take a leadership role in properly training and maintaining quality of information obtained via TNE.

New Name Helps Chiesi Turn Corner
Cornerstone Therapeutics Inc., a specialty pharmaceutical company focused on commercializing products for the U.S. hospital and adjacent specialty markets, today announced an official name change to Chiesi USA Inc. following the completion of its acquisition by Chiesi Farmaceutici S.p.A. The acquisition, making Cornerstone a wholly-owned subsidiary of Chiesi, and this name change are the last steps in a process that began when Chiesi became Cornerstone’s majority shareholder in 2009. “As Chiesi USA, we look forward to offering our patients and providers more benefits than ever before,” said Ken McBean, President of Chiesi USA. “The additional resources made available by this merger will allow Chiesi USA to provide greater support for research and development initiatives while maintaining our commitment to the key therapeutic areas we serve. Being part of a global company also offers our employees additional opportunities for growth and additional support needed to build upon our success.” Chiesi USA will continue to market its existing portfolio of products to the hospital and adjacent specialty markets and will actively pursue licensing and acquisition activities in these areas. Chiesi USA’s headquarters will remain in Cary, N.C.

Complications Weigh on Mothers
New research suggests that jumps in maternal body mass index (BMI) are associated with increased risks of adverse perinatal and neonatal outcomes, according to the Journal of the American Medical Association. Dagshien Ann, of Imperial College London, and colleagues conducted a systematic review and meta-analysis of cohort studies examining maternal BMI and its association with risk of fetal death, stillbirth, and infant death. The researchers found that the summary relative risk (RR) per 5-unit increase in maternal BMI was 1.21 for fetal death (95% confidence interval [CI], 1.09-1.35), 1.24 for stillbirth (95% CI, 1.18-1.30), 1.16 for perinatal death (95% CI, 1.00-1.35), 1.15 for neonatal death (95% CI, 1.07-1.23), and 1.18 for infant death (95% CI, 1.09-1.28). Women who had a BMI of 20 (used as the reference standard), 25, and 30 kg/m², respectively, had absolute risks per 10,000 pregnancies of 76, 82, and 102 for fetal death, 48, 49, and 58 for stillbirth, 66, 73, and 86 for perinatal death, 20, 21, and 24 for neonatal death, and 33, 37, and 43, for infant death. “Even modest increases in maternal BMI were associated with increased risk of fetal death, stillbirth, and neonatal, perinatal, and infant death,” the authors write. “Weight management guidelines for women who plan pregnancies should take these findings into consideration to reduce the burden of fetal death, stillbirth, and infant death.”

That Awkward Moment After Birth
A new study has found that an awkward maneuver—in which doctors hold a wet, screaming infant at the level of the mother’s vagina for a crucial minute or longer so that gravity will help blood flow—is probably unnecessary. Babies who were placed on their mothers’ stomachs before clamping fared just as well as those who were held lower, the researchers found. Doctors in the delivery room are increasingly urged to hold off cutting the umbilical cord of a newborn. Delayed clamping, as it’s called, allows blood to continue flowing from the placenta to the iron stores in the baby. The study out of the National Institute of Child Health and Human Development found no difference whether the baby was at abdomen level on the chest, or the baby was held at the vagina—it made no difference in terms of extra blood the baby got. The authors hope their finding will convince doctors reluctant to delay cord clamping to start the practice. The study assigned 194 healthy full-term babies to be placed on their mother’s abdomen or chest for two minutes and 197 babies to be held at the level of the vagina for two minutes.

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Editorial

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babies, and better outcomes for mothers. San Francisco General with low rates of C-section have no difference in outcomes for single baby, normal presentation, full term. The comparable rate Angeles Community Hospital did C-sections in 62.7 per cent of is the most commonly performed surgery in America. Another 60 per cent more for a C-section than a vaginal delivery—and this works to improve birth outcomes, said commercial insurers pay California Maternal Quality Care Collaborative, a group that encourages private-practice doctors to do C-sections. One is doctors for their time removes the two most powerful incentives for the doctor’s convenience, and scheduled inductions of labor. Yet V.B.A.C. rates nationwide today are only a third of what they were in 1996. The scarcity of V.B.A.C. means that a first C-section puts a woman on track to have every child by California Medicaid program, Medi-Cal, wisely pays the same for all births, so doctors have no financial incentive to do a C-section with Medi-Cal patients. That’s not the case with commercial insurers, according to the Maternal Quality Care Collaborative. But this is not the most important way that the financial incentives push doctors in the wrong direction. Perhaps more important is the fact that most of what a private-practice Ob-Gyn doctor earns from taking care of a pregnant woman comes from the delivery. That means doctors have a strong financial incentive to deliver their patients’ babies themselves. How is this a problem? It leads to more C-sections scheduled for the doctor’s convenience, and scheduled inductions of labor that often end in C-sections. Even for unscheduled deliveries, it contributes to the most important syndrome behind unnecessary C-sections: failure to wait. Salaried doctors, nurses and midwives can help increase the rates of vaginal births. Information in this article is by Tina Rosenberg and first appeared in the New York Times.

Drugs Linked to Early Births New research showing a link between depression medication and early births highlights the need for women to talk with their doctors before taking one of the drugs during pregnancy, physicians say. The risk of preterm birth, defined as earlier than 37 weeks, was 55% higher in women who took an antidepressant while pregnant, according to a paper published in PLoS One. The risk was even higher, an increased 96%, among pregnant women who took an antidepressant during their final trimester. Taking an antidepressant during pregnancy “is not a decision to be taken lightly,” says Krista Huybrechts, a researcher at Harvard Medical School and Brigham and Women’s Hospital who led the study. The paper was a systematic review of 41 studies that looked at use of antidepressants by pregnant women. Overall, 11.6% of infants born in the U.S. in 2012 arrived in a preterm birth, and patients to try to avoid multiple pregnancies. Multiples have a greater risk of preterm birth, which is associated with an increased risk of death and many long-term health problems, including neurological disabilities, the article said. The analysis was funded by the March of Dimes, a nonprofit whose goals include reducing premature births. A new report recommends changes in fertility treatments to reduce risky outcomes including multiple births and preterm births.

Double Your Pleasure, Double Your Complications While many women who struggle with infertility say having twins is a blessing, medical experts are increasingly calling for measures to be taken to reduce the country’s rate of multiple births. In an analysis posted online in the journal Fertility and Sterility, researchers from the Hastings Center, an independent bioethics research institute, and the Yale Fertility Center called for a number of policy changes to encourage doctors and patients to try to avoid multiple pregnancies. Multiples have a greater risk of preterm birth, which is associated with an increased risk of death and many long-term health problems, including neurological disabilities, the article said. The analysis was funded by the March of Dimes, a nonprofit whose goals include reducing premature births. A new report recommends changes in fertility treatments to reduce risky outcomes including multiple births and preterm births.
article recommended encouraging single embryo transfers during IVF, expanding insurance coverage of IVF and improving patient education about the risks of multiple pregnancies. It also recommended limiting the use of controlled ovarian stimulation, a separate fertility treatment that is believed to account for more multiple births than IVF. Over the past two decades, the rate of twin births in the U.S. has increased by about 70%, fueled by older maternal age and increased use of fertility treatments. In 2012, 3.3% of births resulted in twins, according to the Centers for Disease Control and Prevention. A New England Journal of Medicine article last year estimated that by 2011 about 30% of twin births and 7% of triplet and higher births resulted from conception by assisted fertility treatments.

Infant Helmets Studied
New research says that a common remedy for the problem of flattened infant skulls—an expensive custom-made helmet—that most cases produces no more improvement in skull shape than doing nothing at all. Pediatricians have long urged parents to put newborns to sleep on their backs to help prevent sudden infant death syndrome. While the practice underdoubtedly has saved lives, it also has increased the numbers of babies with flattened skulls. Roughly one baby in five under the age of 6 months develops a skull deformation caused by lying in a supine position. A report in the journal BMJ, is the first randomized trial of the helmets.

Don't Blame the Doctors
A new report by a committee of experts in obstetrics, pediatrics, neurosurgery and maternal medicine has found that blaming doctors—especially through malpractice suits that have prompted many obstetrician-gynecologists to abandon the delivery room—for brain injuries in newborns via oxygen deprivation during labor or delivery might be misplaced. It turns out many conditions that occur during or even before pregnancy can lead to neural injury damage to full-term babies.

Skull flatness at back of the head may be accompanied by facial abnormalities, major bleeding during pregnancy, infection of the fetal membranes and a stroke in the baby around the time of birth.

Simulator Helps Re-create Emergencies
A team from Christiana Care Health System in Delaware is working with staff from local hospitals using a newborn simulator mannequin to help them anticipate and respond to emergency situations. The mannequin, known as HAL, mimics a full-term baby at birth. The interactive simulator looks and sounds like the real thing, from the way it cries, its heart beats and even the way its skin colors changing. It can be programmed to have the kind of problem a newborn might have at birth, such as an audible heart defect, breathing difficulties or requiring an IV insertion. Staff can identify and treat these issues in advance of an actual emergency, so they are prepared if one arises. Nurses, respiratory therapists, pediatricians and even emergency department staff are among those who are trained using the Newborn HALs programmable emergencies. The simulator lets staff run through different scenarios, such as a baby who is born not breathing. They have to know how to handle that. Then they are debriefed and taught how the situation could have gone better.

Twin-Twin Transfusion Syndrome Reduced
The number of children suffering severe disabilities after treatment for a deadly condition affecting just over 10% of all identical twin pregnancies could be significantly cut after University of Birmingham, UK, researchers developed a laser-based treatment, in collaboration with other experts in Europe. A team led by Birmingham’s Prof. Mark Kilby carried out a study into a modified laser treatment to reduce the number of babies born with a disability arising from Twin-Twin Transfusion Syndrome (TTTS). The study, published in medical journal The Lancet, says that the new technique, known as the "Solomon method", can reduce both the recurrence of TTTS and associated disabilities. Kilby, who is Professor of Fetal Medicine in the University’s College of Medical and Dental Science and Centre for Women’s & Children’s Health and director of the Fetal Medicine Centre at Birmingham Women’s NHS Foundation Trust, worked on a collaborative trial with experts from five centres in Europe, to compare the Solomon technique with a more conventional laser treatment. Although the number of babies that died was similar for both treatments, the incidence of TTTS fell from 7% to 2% in the Solomon treatment arm.

MISRIS Infection Risks
There is an increased risk for MISRSA infection during hospitalization if patients are colonized with MRSA on admission, according to recent study findings published in Pediatrics. “The development and implementation of molecular diagnostic methods, strict compliance with infection control policies, and establishment of decolonization policies with favorable results among pediatric patients seem to be the necessary next steps in this effort,” the researchers wrote. Fainareit N. Zervos, MD, and colleagues from the infectious diseases division at Rhode Island Hospital and Warren Alpert Medical School of Brown University, both in Providence, R.I., conducted a meta-analysis to determine the burden of colonization on admission, the time trends and the significance of colonization. The researchers evaluated 18 studies published from 2008 to 2013 that reported the prevalence of MRSA colonization on ICU admission.

Camera Offers NIC Access
Nationwide Children’s Hospital, one of the largest and most comprehensive pediatric hospitals in the United States, just finished installing NICVIEW, which supports their philosophy of family-centered care in a unit where the length of stay is longer. NICVIEW, the NICU camera system, helps extend family-centered care by giving parents a virtual window to their newborns. Many of the babies in the NICU, ICC and SCN are born prematurely and are released within a few days. However, the length of stay for some on this unit at Nationwide Children’s can be months. While not a replacement for visiting in person, this password-protected system allows parents and extended family members 24/7 access to the new bundle of joy.
A federal task force is recommending that some pregnant women take low-dose aspirin daily to avoid getting preeclampsia, a condition that complicates some pregnancies and can be dangerous for mother and baby. Aspirin in general isn’t recommended during pregnancy because it can contribute to maternal and fetal bleeding. However, low-dose aspirin has been found to help reduce the risk of preterm birth for pregnant women with certain health conditions. The recommendation by the U.S. Preventive Services Task Force comes after the nation’s senators voted to question the rationale behind the guideline. The task force said that women who have had preeclampsia during previous pregnancies should take a pill of 81 milligrams—often called “baby aspirin”—each day after the 12th week of pregnancy. The recommendation applies to pregnant women whose doctors consider them at high risk for the condition, as baseline risk alone may not have previous medical experiences with aspirin. Preeclampsia affects about 4% of pregnant women in the U.S., and is most often managed with drugs and other medical treatments. Medical researchers in Sweden, the investigators were able to account for almost all births and standardize their testing. Therefore, their results are not generalizable to a country such as the US, where accounts of births and lab testing are more variable.

Neonatal Abstinence Syndrome to Be Tracked
A bill sent to Indiana Governor Pence would force the state’s hospitals to report every time a baby was born with drugs in its system. The bill would help the state track what’s known as Neonatal Abstinence Syndrome (NAS), which is difficult right now since hospitals don’t have to keep track of when it takes place. “This is a program that for the first time allows us as a state to grasp the problem of NAS and understand it in our hospitals,” said Senator Jean Breaux (D, Indianapolis), a co-sponsor of the bill. If the governor signs it, several groups including the Indiana State Medical Association and the National Medical Association — will also be directed to better study the problem, based on the data gathered by hospitals. “It allows us to partner with hospitals so we can reduce the instance of babies born with drugs and allow them the opportunity of a better quality of life,” Breaux said during an appearance with Attorney General Greg Zoeller, who also supported the bill. State agencies would also begin a grant program to help reduce Indiana’s infant mortality rate under the bill.

Canada Not Hearing the Message
In Canada, only four provinces screen every child for hearing loss and fewer still have standards in place to ensure timely follow-up and treatment for children who do have auditory problems. Speech-Language and Audiology Canada (SAC), along with the Canadian Academy of Otolaryngology-Head and Neck Surgery, have issued a report card on the state of newborn screening. Eight of the 13 provinces and territories get a failing grade, four (Ontario, Nova Scotia, Prince Edward Island and New Brunswick) get a passing grade and one only (British Columbia) gets top marks. The grades are based on having a program with standardized procedures to detect hearing loss, and measures to ensure timely intervention, including diagnosis, treatment and monitoring. A Quebec study estimated that by increasing screening to 100% of newborns (25 per cent), the province would save $1.7 million a year. That’s because the cost of educating children whose hearing loss is detected later is considerably lower. Furthermore, it’s a godsend for families, who said they’d be relieved if their newborns were screened for hearing loss. Aspirin Recommended for Some Pregnant Women
A federal task force is recommending that some pregnant women are unwilling to perform V.B.A.C.s because of requirements that they receive pre-pregnancy counseling to optimize their health prior to pregnancy. They also say that strategies to predict those at greatest risk are needed.

Got Milk?
Prolacta Bioscience, the pioneer in human milk-based nutritional products, announced the introduction of Prolact CR, the world’s first and considerably milk calcium-based human milk replacement. Prolact CR is composed of approximately 60% fat, 2.5% protein and 2.5% lactose, three nutrients that are essential for maintaining bone health and for healthy growth. Prolact CR is used with either mother’s own breast milk or human donor milk to standardize milk at 20 Cal or less, which facilitates the study of bone mineralization in the NICU. Standardizing human milk helps these babies increase energy and weight while in the NICU. Prolact CR is available by prescription for infants undergoing feeding therapy at NICUs. The results of a randomized clinical study of 79 premature infants to evaluate the effects of adding human milk to the diet of preterm infants at the Neonatal and Pediatric Intensive Care Unit were outstanding. The purpose of this study was to determine if premature infants were presented at the Pediatric Academic Societies and Asian Societies for Pediatric Research conference (Feeding CAHPS on May 5, 2011). Prolact CR joins a complete line of human milk-based, nutritional products that are clinically proven to improve health outcomes of critically ill preemies.

Early Elective Deliveries Drop
The latest report on Utah’s policy of antenatal corticosteroid drop in the practice of early elective deliveries, according to a survey of hospitals released by The Leapfrog Group, an organization funded by businesses to improve the quality of health care work for quality and safety improvement. Last year the national average was down to 4.6 percent—a fall of 73 percent in three years. “During changes in the last 10 to 15 years we’ve become as spectacular—we’ve, wow, we’re really improved,” said Leah Binder, the president and chief executive of The Leapfrog Group. “I have never in my career seen anything like the progress we’re seeing on early elective deliveries.” The American College of Obstetricians and Gynecologists had been warning against early elective delivery since 1979. The March of Dimes, one of the most respected advocacy groups in America, had long campaigned to discourage the practice. Delivery at 37 or 38 weeks was widely considered benign— but infant mortality is at least 50% higher in the 36 to 37 week range. The Leapfrog group has suggested that the number of women having these procedures. The proscription raises many concerns for women who want to give birth vaginally—to cesareans—but find they have to travel considerable distances to get to cesareans—the shorthand is V.B.A.C.s are largely safe. Despite the ban, these procedures are commonly performed. A recent study in the US suggests the prevalence of V.B.A.C.s has increased. It’s not clear why. Dr. Jeanne A. Conry, president of the American College of Gynecologists and Obstetricians in 2010 said that vaginal births after cesarean—a low 5%, 7% and 10% respectively. These babies are also more prone to suffer sudden death, feeding and developmental problems. The reasons for the ban, according to Leapfrog, includes better reporting of the use of this practice, leading to more states educating hospitals about discouraging it, and payment reform. For example, Texas in 2011 banned Medicaid (the state’s program, Medicare is federal), which pays for 55 percent of births, from reimbursing hospitals for early elective deliveries.

VBACs Still Being Discouraged
Guidelines issued by the American Congress of Obstetricians and Gynecologists in 2010 said that vaginal births after cesarean—the shorthand is V.B.A.C.s—are largely safe. Despite this, many hospitals and doctors still do not perform them for fear of liability. The American College of Obstetricians and Gynecologists has been extraordinarily aggressive in pushing for cesarean. “The position of the study’s authors. Dr. Jeanne A. Conry, president of the National obstetricians group, said she was concerned and surprised that more hospitals had not made it easier for women to have V.B.A.C.s. “When the statement came out, we had hope that it was going to bring about changes. It hasn’t,” said Dr Conry, assistant physician in chief at the Permanente Medical Group in Rosaline, Calif. Dr. Conry said she and other doctors at her hospital strongly encouraged V.B.A.C.s because they are less invasive. Information in this article originally appeared in the New York Times.

Painkiller Use Surges for Pregnant Women
Doctors are prescribing opioid painkillers to pregnant women in astonishing numbers, new research shows, even though risks to the developing fetus are largely unknown. Of 1.1 million pregnant women enrolled in Medicaid nationally, nearly 23 per cent filled an opioid prescription in 2007, up from 18.5 per cent in 2000, according to a study published in the journal Obstetrics & Gynecology. That percentage is the largest to date of opioid prescriptions among pregnant women. Medicaid covers the medical expenses for 45 percent of births in the United States. The lead author, Rishi J. Desai, a researcher fellow at Brigham and Women’s Hospital, said he had expected to “see some increase in trend, but not this magnitude. One in five women using opioids during pregnancy is definitely surprising.” A study of 590,000 privately insured women found that 14 per cent were dispensed opioid painkillers at least once during pregnancy. From 2005 to 2011, the percentage of pregnant women prescribed opioids decreased slightly, but the figure exceeded 12 per cent in any given year, according to Dr Brian T. Bateman, an anesthesiologist at Massachusetts General Hospital, and his colleagues. Their research was published in Anesthesiology. Information in this article originally appeared in the New York Times.

Playing NICE With Infants
Neonates with suspected early onset sepsis are often treated aggressively with antibiotics, according to a recent paper from the National Institute for Health and Care Excellence (NICE) which has recommended a gentler approach. NICE (2012) recommends treating neonates who have risk factors for sepsis but are clinically well with only 36 hours of IV antibiotics provided that they remain well, inflammatory markers remain within normal limits and their microbiological tests are negative. This is supported by a recent audit study in which 236 term babies who were mildly unwell, positive for early onset sepsis, were safely discharged after 36 hours of antibiotic therapy; none of whom were readmitted with sepsis.
Clinical Experience Using Inhaled Epoprostenol (Flolan) in Neonatal and Pediatric Patients at Children’s Hospital Central California

Lawrence Nicol, AS, RRT

Prostacyclin (also known as prostaglandin E2 or PGE2), is an arachidonic acid metabolite formed by a prostacyclin synthase in the vascular endothelium. Prostacyclin stimulates adenylyl cyclase in vascular smooth muscle cells, which increases intracellular cAMP resulting in vasodilation. As a drug, it is also known as epoprostenol or Flolan. These terms are often used interchangeably.

Intravenous epoprostenol (Flolan) is approved to treat Primary Pulmonary Hypertension (PPHN), but its use is limited by adverse effects including systemic hypertension and worsening of intrapulmonary shunting. When inhaled, epoprostenol (Flolan) may reduce pulmonary hypertension and improve oxygenation without decreasing systemic blood pressure. Aerosolized epoprostenol (Flolan) has been shown to be as effective as an inhaled nitric oxide in reducing pulmonary vascular resistance in heart transplant candidates, in decreasing pulmonary artery pressures, and improving right ventricular function in animals with hypoxic pulmonary vascular constriction. It has also been shown to be as effective as a selective pulmonary artery vasodilator with improvement in oxygenation in patients with Acute Respiratory Distress Syndrome (ARDS).

Inhaled prostacyclin was first used in humans in 1978.1 In 2004, based on the knowledge above and in journal articles written by Kelly in 2002, and Bindl in 1994, we started using inhaled epoprostenol or Flolan in the Neonatal Intensive Care Unit (NICU) at Children’s Hospital Central California. Based on the recommendations of our Cardiologists in collaboration with the Medical Director of the NICU we used it on a limited basis initially with success to treat pulmonary hypertension. The nebulizers (Mini Heart) we used then were efficient, but sometimes created problems associated with the extra flow of gas that was added to the ventilator circuit. In pressure modes of ventilation the peak pressures had to be adjusted down once the nebulizer was running. Tidal volumes increased and could not be measured accurately because of the extra flow of gas into the circuit from the nebulizer.

Nitric oxide has been the standard of care for treatment of pulmonary hypertension in infants greater than 34 weeks of gestation. In April 2010, because of the rising costs associated with the administration of nitric oxide along with our previous experience with inhaled Flolan, we started a program using inhaled Flolan as an adjunct or alternative to nitric oxide, first in the Pediatric Intensive Care Unit (PICU), and then the NICU. We contacted 16 centers across the country for their advice and expertise. Specifically for the NICU, we researched the articles of Zwissler, Sodiot, Lowson, DeLea, Olmsted and Konduri/Kim. We purchased the highly efficient vibrating mesh type of nebulizers made by Aerogen. The Aerogen nebulizers are efficient and they do not add any additional gas to the breathing circuit so that peak pressures and tidal volumes are not affected. We also purchased Aerogen’s proprietary syringes and tubing sets to further ensure patient safety. We used Medfusion IV pumps, and utilized a team approach with nursing in programming the pumps. Initially, we only introduced inhaled Flolan to the ventilator circuits after nitric oxide was already in use, and then tried to wean the nitric oxide if possible while closely assessing the patient. We have utilized inhaled Flolan successfully with patients on ventilators, NIPAP, high flow nasal cannulas, and oxygen masks.

To date in the PICU and NICU combined, we have used inhaled Flolan on fifty-six patients and have successfully weaned forty-two of them (75%) off of inhaled nitric oxide. The smallest patient was 870 grams.

We have used inhaled Flolan on twenty-two NICU patients. The majority were in the NICU itself but some were recovered and kept in the PICU after their cardiac surgery. Fifteen of these patients (68%) were successfully weaned off nitric oxide. Of the seven who were not, two of them had such an improvement in their oxygenation status after the initiation of inhaled Flolan (they were already receiving nitric oxide) that we were able to send them out for ECMO. One of the seven patients had hypotension that was thought to be caused by the Flolan so it was discontinued. Other than the one possible case of hypotension, we have not seen any untoward effects in using inhaled Flolan.

We use a high-efficiency expiratory filter to prevent moisture and drug from getting into our ventilator exhalation valves. We have not observed any problems with the viscosity of the diluent in endotracheal tubes or ventilator systems even on patients less than 1800 grams. We have not observed tracheitis from the Flolan pH.

We started this program to see if we could provide the same safe level of care to our patients and cut costs at the same time. We were able to successfully and safely wean some patients off of nitric oxide. We did see a cost savings in decreasing our nitric oxide use especially when we ran out of contract hours with Ikaria. What we found was the benefit of having another biochemical pathway to treat pulmonary hypertension. In two instances the patients were already receiving nitric oxide and not improving significantly. The addition of inhaled Flolan did make a significant difference in improving their oxygenation status. The other advantage we observed was that some patients on low doses of nitric oxide had rebound reactions when coming off nitric oxide. These patients could be successfully weaned off nitric oxide by the addition of inhaled Flolan. Weaning the Flolan was accomplished without rebound pulmonary hypertension. Therefore, we feel that we have been able to safely provide an additional pathway for pulmonary vasodilation for our neonatal and pediatric patients.

References
1 Lowson S. Inhaled alternatives to nitric oxide. Anesthesiology. 2002; 96: 1504-1513.
Abstract

Background: Birth Preparedness and Complication Readiness (BPCR) interventions are widely promoted by governments and international agencies to reduce maternal and neonatal health risks in developing countries; however, their overall impact is unknown. We aimed to determine whether BPCR at a community level can reduce maternal and neonatal mortality in developing countries. We also examined intervention impact on a variety of intermediate outcomes important for maternal and child survival.

Methods: We conducted a systematic review and meta-analysis of randomized trials of BPCR interventions in populations of pregnant women living in developing countries. To identify relevant studies, we searched the scientific literature in the PubMed, Embase. Cochrane library, Reproductive health library. CINAHL and Popline databases. We also undertook manual searches of article bibliographies and web sites. Study inclusion was based on pre-specified criteria. We assessed bias by computing pooled relative risks (RR) using the Cochrane Handbook for Systematic Reviews of Interventions. For dichotomous outcomes, we determined the percentage of patients assigned to each intervention. The Additional file 2 provides an overview of the included studies.

Results: Fourteen randomized studies (282,562 live births) met the inclusion criteria. Meta-analyses showed that exposure to BPCR interventions was associated with a statistically significant reduction of 18% in neonatal mortality risk (twelve studies, RR = 0.82, 95% CI 0.74, 0.91) and a non-significant reduction of 28% in maternal mortality risk (seven studies, RR = 0.72, 95% CI 0.63, 0.84) and a 53% significant reduction in maternal mortality risk (four studies, RR = 0.47, 95% CI 0.26, 0.87). Pooled results revealed that BPCR interventions were also associated with increased likelihood of use of care in the event of newborn illness, early setting of the umbilical cord and initiation of breastfeeding in the first hour of life.

Conclusions: With adequate population coverage, BPCR interventions are effective in reducing maternal and neonatal mortality in low-resource settings.

Background

In spite of important progress towards attaining the Millennium Development Goals (MDGs), maternal and neonatal mortality remains a major public health problem in developing countries (1,2). Improvements in maternal health and reductions in maternal mortality have been slower than anticipated and – despite randomized evidence – remain out of reach for the MDG target of a 75% reduction in the maternal mortality ratio (MMR) from 1990 to 2015 (3). Although child survival progress is accelerating (4), only 31 countries are on track to achieve the MDG target to reduce child mortality by two-thirds between 1990 and 2015 (2). Moreover, over the period 2000–2010 decreases in mortality have been rapid in the age group 1–59 months, such that the neonatal fraction of deaths has increased from 38.2% to 40.9% (4). To achieve MDG 4 and 5, the global community will need to focus attention and resources on effective strategies to reduce maternal and neonatal deaths, particularly in poor and underserved communities (5).

Developing countries have recently invested in behavior change and community mobilization interventions to reduce maternal and neonatal mortality (6). BPCR programs generally involve counseling for women and their families to: 1) encourage them to make decisions before the onset of labour and potential occurrence of obstetric complications; 2) inform them about the signs of complications so they will know and be able to act promptly if needed; 3) inform them about the locations of emergency services to make the care-seeking process more efficient; and 4) encourage them to save the money needed to pay for services and to plan their transportation to a health facility during labour and in case of emergency (6-9).

To aid in BPCR implementation, the Johns Hopkins Program For International Education in Gynecology and Obstetrics (JHPIEGO) has developed a BPCR matrix (6) that delineates the roles of policymakers, facility managers, providers, communities, families, and women in ensuring that newborns and women receive appropriate, effective, and timely care. The BPCR matrix outlines plans and actions that can be implemented by each group of stakeholders to build an enabling environment for normal and emergency care.

BPCR is a broad and integrative strategy; evidence related to its comprehensive implementation is scarce. However, components of the BPCR matrix have been implemented and evaluated in many settings (10-14). BPCR components are included in the new World Health Organization (WHO) model for antenatal care as part of antenatal education – a key part of the MDG target (15). On critical primary research in India (16) and elsewhere, WHO and UNICEF (17) also now recommend antenatal and postnatal home visits to counsel mothers, provide newborn care and facilitate referral (18). In addition to making use of formal health services, BPCR requires making effective use of community health workers and health promotion groups. A 2010 systematic review and meta-analysis of community-based intervention packages found a significant reduction in neonatal mortality (twelve studies, risk ratio 0.76, 95% CI 0.68, 0.84), but inconclusive evidence of reduction in maternal mortality (ten studies, risk ratio 0.77, 0.99, 1.02) (19). Community mobilization through stakeholders such community health workers, or through participation in women’s groups also forms part of the BPCR concept (20). This component was recently evaluated in a Lancet analysis focusing on trials involving women’s groups practising participatory learning and action (21). Meta-analyses of seven trials showed that exposure to women’s groups was associated with a 28% reduction in maternal mortality (odds ratio 0.73, 95% CI 0.58, 0.93), a 49% reduction in maternal mortality (odds ratio 0.51, 95% CI 0.35, 0.74), and a 28% reduction in neonatal mortality (odds ratio 0.77, 0.65, 0.90).

This systematic review and metaanalysis provides the first assessment of the full range of BPCR strategies on maternal mortality, neonatal mortality, and a variety of intermediate outcomes critical for maternal and child survival. It also aims to assess which components of the BPCR concept are most effective.

Objective of the review

The primary aim of this review was to evaluate the impact BPCR interventions in reducing maternal and neonatal mortality in developing country settings. We also examined the impact of BPCR interventions on process outcomes such as use of skilled health care services, and hygiene practices in the home. Stratified analyses were used to examine program impact in relation to types of interventions and background neonatal mortality level.

Methods

Criteria for including studies in the review

Types of studies

These were intervention packages that included any component of the BPCR concept, individually or in combination. Interventions could take place in antenatal, intrapartum, postpartum and neonatal care periods, and at different levels of care (primary, facility, home community). Specific approaches were measured including counselling of women in prenatal clinics, home visit strategies, and community mobilization activities.

Comparator group

Women who received no experimental BPCR intervention defined by studied trial.

Outcome measures

Primary outcomes are maternal mortality and neonatal mortality. Recurrent maternal deaths are institutional delivery, home delivery with skilled birth attendant, use of skilled care for neonatal illness, use of postpartum care, clean cutting of the umbilical cord, initiation of breastfeeding within the first hour of birth, knowledge of maternal and neonatal danger signs, and birth preparedness and complication readiness behaviours.

Language of publication

Only studies published in English or French were considered.

Search methods to identify studies

The search strategy was designed in conjunction with an information retrieval specialist and followed Cochrane collaboration guidelines (22). We searched the PubMed, Embase, Cochrane library, Reproductive Health library, PLOLINE and HINARI databases. The search was updated through December 5th 2013. The search strategy combined the terms “birth preparedness”, “antenatal education”, “home visits”, “antenatal care”, “maternal morbidity”, “maternal mortality”, “facility-based childbirth” and “developing countries” (Additional file 1 presents a sample search strategy). To supplement the electronic searches, we also hand-checked bibliographies of review papers and related articles (21), international agency websites (WHO, UNFPA, BRFSS, USAID and CARE) and two scientific journals specialized in maternal and neonatal health: BMC Pregnancy and Childbirth and International Journal of Gynaecology & Obstetrics.

Selection of studies

Two authors (DS and MJ) reviewed titles, abstracts and full texts for eligibility. Disagreements were resolved by consensus. Included studies were of randomized design or non-randomized comparative option 2. The authors are associated with The Department of Health Administration, Faculty of Medicine, University of Montreal, The Department of Social and Preventive Medicine Faculty of Medicine, University of Montreal, and The Division of Global Health, University of Montreal Hospital Research Centre (CIRUM). This is an Open Access article distributed under the terms of the Creative Commons Attribution License which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited.
Quality assessments did not influence inclusion of studies in the meta-analyses. However, these assessments later served as criteria for subgroup analyses, and were used in interpreting results.

Data synthesis

We performed random-effects analyses to combine relative risks (RR) comparing intervention groups with control groups. Meta-analyses were conducted using the random-effects model due to important variations in populations and in interventions. In combinations of RRs and/or 95% confidence intervals (CIs), we calculated for outcomes measured in the same way by at least two studies. All were binary variables. Studies contributing to the meta-analyses ranged from two to 12. Data were re-analyzed based on the ITT principle and baseline differences in outcomes were assumed to have little influence. Combinations were carried out using the Mantel-Haenszel method in the Cochrane Review Manager software [27]. For results reported as cluster averages, the number of events for each group was estimated using the formula n=cluster average/100.

To adjust for cluster effects, for each study randomized we divided the original number of participants by the cluster effect, whose value was 1 (1-M*1/C), where M was the average cluster size and C the intraclass correlation coefficient [24].

Finally, we prepared a description of the reported results for outcomes not included in the meta-analyses, such as knowledge of maternal and neonatal danger signs and birth preparation behaviors.

Investigation of heterogeneities and subgroup analyses

To investigate heterogeneities we calculated the I² statistic, which describes the percentage of variation among studies due to heterogeneity rather than to chance [25]. An I² value of 50% or more indicated significant heterogeneity among studies.

Subgroup analyses were planned on the basis of the following factors identified as potential sources of heterogeneity: these were: methodological quality of the trials, the method of allocation of intervention (i.e., prenatal clinic, home or community); intervention approach (i.e., clinic-based counselling, home visits, community promotion led by stakeholders and women groups [participatory sessions], participants’ living environment (i.e., rural or urban), baseline or control group neonatal mortality rate.

![Figure 5](Image 613x416 to 954x750)

**Figure 5** Community-based group sessions

- **A)** 2010, 517 15203 540 11695 53.6 0.058 [0.023, 0.147]
- **B)** 2010, 56 1271 91 1125 0.48 0.04 [0.009, 0.143]
- **C)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **D)** 2010, 55 3074 95 3264 0.68 0.029 [0.010, 0.076]
- **E)** 2010, 57 2969 110 3295 0.86 0.017 [0.010, 0.076]
- **F)** 2012, 53 17404 66 7759 12.5 0.17 [0.150, 0.200]

**Table 1.2.1** Community-based group sessions

- **A)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **B)** 2010, 56 1271 91 1125 0.48 0.04 [0.009, 0.143]
- **C)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **D)** 2010, 55 3074 95 3264 0.68 0.029 [0.010, 0.076]
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- **F)** 2012, 53 17404 66 7759 12.5 0.17 [0.150, 0.200]

**Table 1.2.2** Community-based group sessions

- **A)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **B)** 2010, 56 1271 91 1125 0.48 0.04 [0.009, 0.143]
- **C)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **D)** 2010, 55 3074 95 3264 0.68 0.029 [0.010, 0.076]
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**Table 1.2.3** Community-based group sessions

- **A)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **B)** 2010, 56 1271 91 1125 0.48 0.04 [0.009, 0.143]
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- **D)** 2010, 55 3074 95 3264 0.68 0.029 [0.010, 0.076]
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- **F)** 2012, 53 17404 66 7759 12.5 0.17 [0.150, 0.200]

**Table 1.2.4** Community-based group sessions

- **A)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **B)** 2010, 56 1271 91 1125 0.48 0.04 [0.009, 0.143]
- **C)** 2010, 515 1565 547 13703 17.8 0.031 [0.008, 0.082]
- **D)** 2010, 55 3074 95 3264 0.68 0.029 [0.010, 0.076]
- **E)** 2010, 57 2969 110 3295 0.86 0.017 [0.010, 0.076]
- **F)** 2012, 53 17404 66 7759 12.5 0.17 [0.150, 0.200]
problems, planning strategies, implementing strategies and phases of the action-learning cycle: identifying and prioritizing meetings, the facilitators guided the women through the four in action-learning cycles. Two studies combined community purely prenatal. Three studies considered a home visit strategy. Only in the two individual trials assessing evaluated a whole series of interventions including prenatal and postnatal components. For all interventions, the target population utilization [30].

Objectives
Characteristics of the interventions
Description of studies included in the review
Methodological quality of the retained studies
Outcomes measured
Study settings were Indi, Nepal, Bangladesh, Ghana, Malawi, Pakistan and four Latin American cities (Rosario in Argentina, Pelotas in Brazil, Havana in Cuba, and Mexico City in Mexico).

Participants
Type of interventions
Discussion
Limitations of the review

We included 28 studies. Five of the included studies were conducted in adolescent populations, investigating interventions in the early period after birth (i.e., ≤ 30‰; > 30‰ to < 40‰; ≥ 40‰); baseline or control group (see Figure 5). In four trials in which the group participated in interventions showed a statistically significant increase in the probability of facility-based delivery that was not statistically significant (RR = 1.16; 95% CI: 0.92, 1.45).

Home delivery with skilled birth attendance. Four studies measured the use of skilled birth attendance in home deliveries (28, 30, 32, 33). The combined effect of the interventions on this outcome was not statistically significant (RR = 1.06; 95% CI: 0.61, 1.85).

Use of postpartum care. This process outcome was measured in the two individual trials [20, 30] conducted in urban settings. The effect of intervention was not significant.

Conditional use of care in newborn illness. Four studies evaluated this outcome. The combined results indicated a substantial improvement in the probability of using skilled services among the reported cases of newborn illness (RR = 2.30; 95% CI: 1.70, 3.11). Stratified analysis revealed no significant difference in relation to the educational strategy used.

Clean cutting of the umbilical cord. The use of sterile materials to cut the umbilical cord was measured for home deliveries in six studies [18, 20, 31-33]. The combined result showed a moderately statistically significant positive impact on this endpoint (RR = 1.35; 95% CI: 1.14, 1.55).

Initiation of breastfeeding within one hour after birth. This process outcome was assessed for home deliveries in four studies [18, 31-33]. The aggregate effect of the interventions was positive, statistically significant and substantial in size (RR = 1.79; 95% CI: 1.47, 2.14).

Knowledge of maternal and neonatal danger signs / birth preparedness and complications readiness. We did not combine results for these two outcomes, because they were measured differently in the studies. Knowledge of danger signs was measured by two trials [20, 31], and birth preparedness and complication readiness behaviours were also measured in two trials [20, 32]. All studies showed improvements in measured outcomes.

Discussion
We undertook a systematic review and meta-analysis to investigate the effectiveness of Birth Preparedness and Complications Readiness interventions in reducing maternal and newborn mortality and morbidity and in improving some process outcomes contributing to maternal and newborn survival. Fourteen randomized studies were selected for synthesis. The methodological quality of the studies was generally adequate except for criteria related to blinded of evaluators, since only three studies used evaluators who were blinded to the intervention.

Key results of the review
The three randomized controlled trials showed that BPRC interventions were associated with significant reductions in neonatal mortality. Positive but statistically non-significant effects were shown for maternal mortality. Significant improvements in some process outcomes associated with child survival (i.e., use of care in the event of newborn illness, clean cutting of the umbilical cord, breastfeeding within the first hour after birth) were also shown.

In addition, two trials reported improvements in knowledge about danger signs, and two others [30, 34] indicated that women in intervention groups were more likely to carry out birth preparation activities and engagement in readiness activities than women in their peers in the control groups.

Interventions coverage of target population
Variation in the proportion of women reached by the interventions was an important factor in explaining heterogeneity of findings [21].

Home visits versus women's group sessions
Home visits to women and community-based women’s group sessions are both strategies that can potentially reduce the risk of neonatal mortality. However, subgroup analyses suggested that combining the two strategies would have a greater impact than would either one alone. While the number of studies may be insufficient to draw definitive conclusions, this observed tendency is logical as the two strategies may complement each other. Individual counselling is more personalized and appropriate for developing the mothers’ personal skills related to sanitary care practices. Community-based activities are still needed to support decision-making, because in traditional settings, decisions are more often taken by the community than by the individual. In practice, the choice of one strategy or another will depend on the social context and the available resource availability. Future studies that take into account cost parameters will be useful for comparing the different options.

Regions with very high neonatal mortality rates
Subgroup analyses showed that reductions in neonatal mortality occurred significantly depending on the neonatal mortality rate in the control group. The neonatal mortality risk decreased by 25% (RR = 0.75; 95% CI: 0.63, 0.88) in trials where the mortality rate in the control group was greater than 10 per 1000. However, the decrease was not statistically significant in studies where the control group mortality rate was below 40 per 1000. This result confirmed earlier findings that educational interventions are more useful for preventing and managing infections [35]. In regions with high neonatal mortality (more than 40 per 1000), the cause of death structure is dominated by infections diseases due to poor sanitation [16,35]. These conditions can be improved by implementing appropriate educational interventions that promote essential preventive measures [36]. On the other hand, in contexts where the neonatal epidemiological structure is dominated by non-infections diseases (e.g. premature death), educational interventions would seem to be less effective [38].
Effectiveness analyses are also needed to provide direction to those preparing health care interventions for countries to adopt. In addition, WHO has published prenatal standards of care, including prenatual education, with updates regarding delivery. We are calling on health care providers to ensure that prenatal services in developing countries are adequate. It would be important to understand the effectiveness of birth preparation programs offered in prenatal care, including the role of nutrition and support for women during labor and delivery, and the impact on the outcomes of neonatal death and mortality, providing insights into underlying mechanisms of disease causation and intervention effect. Together, these three systematic reviews underscore the potential value of several BPCR components in reducing maternal and neonatal mortality.

Conclusions for practice

There is evidence to support implementation of BPCR components such as home visits, community mobilisation, and combined strategies. Third, our review is the first to examine results by level of neonatal mortality, providing insights into underlying mechanisms of disease causation and intervention effect. Together, these three systematic reviews underscore the potential value of several BPCR components in reducing maternal and neonatal mortality.

Implications for research

Additional primary studies are needed to consolidate the results of our review. In particular, it will be important to conduct randomized trials of interventions in settings with high maternal and high maternal neonatal mortality. This is particularly important in francophone West and Central Africa, where no similar studies have been conducted. The role of neonatal and maternal mortality are among the highest in the world. It would be interesting to conduct trials of educational programs in areas where the methods are sufficiently available but underused by the population [37]. The main methodological weakness that should be corrected in future trials relates to the blinding of evaluators. Blinding introduces special considerations in the context of cluster-randomized trials to the participation of the intervention of implementers who cannot generally be blinded to these types of intervention in cluster-randomized trials, it is important to independent investigators to evaluate the outcomes.
Early Feeding of Fortified Breast Milk and In-Hospital Growth in Very Premature Infants: A Retrospective Cohort Analysis

Christoph Maas, Cornelia Wiechers, Wolfgang Bernhard, Christian F Poets and Axel R Franz

Abstract
Background: Fortified human milk may not meet all nutritional needs of very preterm infants. Early transition from complementary parental nutrition to full enteral feeds might further impair in-hospital growth. We aimed to investigate the impact of the cumulative intake of fortified human milk on early postnatal growth in a cohort of very low birth weight infants after early transition to full enteral feeds.

Methods: Retrospective single-centre observational study. Data are presented as median (interquartile range).

Results: N = 206 very preterm infants were analysed (gestational age at birth 27.6 (25.6-29.6) weeks, birth weight 915 (668-1170) g). Full enteral feeds were established at postnatal day 8 (6-10) and adequate postnatal milk feed intake (difference in standard deviation score for weight from birth to discharge -0.105 (0.603 - -0.323)). Standard deviation score for weight from birth to day 28 decreased more in infants with a cumulative human milk intake >75% of all enteral feeds (-0.664 (-1.083 - -0.341)) than to those with <25% human milk intake (-0.41 (-0.76 - -0.17); p = 0.017). At discharge, a trend towards poorer weight gain with higher proportions of human milk intake persisted. In contrast, we observed no significant difference for head circumference growth.

Conclusions: Our current standardized fortification of human milk may not adequately support early postnatal growth.

Background
Human milk feeding reduces the risk of necrotising enterocolitis [1,2] and is associated with improved long-term outcome in very preterm infants [3,4]. On the other hand, several reports show an association of maternal nutrition with early postnatal growth restriction in very preterm infants even if human milk was fortified [5,6]. This is most probably caused by intra- and inter-individual variability of human milk composition resulting in deficits in macro- and micronutrient supply in some infants [7]. These negative effects on growth may be particularly relevant to very preterm infants receiving expressed breast milk early on.

We consequently investigated the relationship between the proportion of cumulative total enteral feeding volume administered as breast milk and early postnatal growth in a cohort of very preterm infants after early transition to full enteral feeds.

Methods
This retrospective, non-consecutive three-year cohort analysis was performed at Tübingen University Children’s Hospital. The ethics committee at the University of Tübingen, Faculty of Medicine, approved this retrospective evaluation and waived the need for parental consent, hence parental consent was not asked for.

Study population
We evaluated all inborn infants with a gestational age (GA) <32 weeks at birth and a birth weight (BW) <1500 g, born in 2006, 2007 and 2009. The initial study [8] aimed at evaluating the effect of accelerated enteral feeding advancement on the time to full enteral feeds. As there was a transitional period (2008/09) after implementation of the new feeding guidelines, data was collected for two cohorts: infants born in 2006/07 and in 2010.

Data collection
Exact nutritional intakes and anthropometric data were determined daily by detailed chart review for the first 28 days of life, then weekly, until discharge.

Nutrition policy
A standardized feeding protocol was applied that defined feeding increments, handling of feeding difficulties, and complementary parental nutrition. Feeding of expressed breast milk of the infant’s own mother was encouraged. Because donor milk was not available, supplemented breast milk was complemented with preterm formula (Beba preterm formula, Nestlé) if necessary to meet the prescribed enteral feeding volume.

The feeding policy in 2006/07 was to start enteral feeds on the fourth day of life with 10-15 ml/kg of preterm formula (Beba preterm formula, Nestlé) as soon as possible. Preterm formula was replaced by breast milk. Daily feeding advancements were scheduled at increments of 15-20 ml/kg. Supplementation with a multicomponent fortifier (FM 95, Nestlé; 1.0-1.5 g protein and 18-27 kcal per 100 ml) was started when enteral feeds reached 150 ml/kg.

In contrast, in 2010, enteral feeds were initiated with 20 ml/kg/d and advanced to 25-30 ml/kg. Breast milk fortification was started at a feeding volume of 100 ml/kg.

In cases of fluid restriction (total fluid intake <150 ml/kg/d), the dosages of a monocomponent fortifier was increased up to 7.5% (equal to 1.5 g protein and 27 kcal per 100 ml) in both periods. At discretion of the attending neonatologist, the dosage of multicomponent fortifier was also augmented in infants showing persistently faltering growth.

Assumptions and definitions
For calculation of macronutrient supply, we assumed a protein and energy content of 1.4 g/100 ml and 67 kcal/100 ml in human milk.

Full enteral feeding was defined as ≥140 ml/kg/day of milk feeds actually administered for more than 24 h.

Further details of the study population, exclusion criteria, nutrition policy and macronutrient supply have been reported previously [8].

Measures of growth
From birth to discharge, weight was measured daily with electronic scales and frontooccipital head circumference (HC) weekly with a measuring tape.

Standard deviation scores (SDS) for weight and HC were computed using LMgrowth (version 2.14, http://www.healthforallchildren.com/?product=lmgrowth). The reference population was the British 1990 growth reference [9,10] fitted by maximum penalized likelihood as described before [10]. To account for the impact of intrauterine growth restriction, SDS differences (SDS_column - SDS_ref) and (SDS_ref - SDS_column) were calculated to illustrate in-hospital postnatal growth.

Data on linear growth were not reported due to the poor reliability of length measurements in the routine neonatal intensive care.

Statistical analyses
Data are presented as median (interquartile range). Comparison of feeding and nutrition policy was performed using the Wilcoxon/Kruskal-Wallis test or Fischers exact test. Statistical significance was assumed at p < 0.05.

Results
206 of 240 inborn infants with a GA <32 weeks and a BW <1500 g had complete data sets and were analysed. GA at birth was 27.6 (25.6-28.6) weeks and BW 915 (668-1170) g. Full enteral feeds were established at postnatal d8 (6-10). A total of 107/206 infants (52.2%) received at least some breast milk. The proportion of cumulative total enteral feeding volume provided as breast milk was 86% (41%-95%) at d28 and 81% (33%-94%) at discharge.

122/206 (62%) and 112/206 (55%) infants received >75% human milk, whereas the proportion of human milk was <25% in 57/206 (28%) and 40/206 (19%) infants, respectively. SDS-difference for weight from birth to discharge was significantly more negative with >75% cumulative human milk intake in comparison to the group receiving <25% human milk (Figure 1, p = 0.017). Comparing infants with >75% cumulative human milk intake versus those with <25% human milk intake, GA, BW, SDS for weight at birth (0.906 (-1.64 - -0.27) vs. 1.28 (-2.11 - -0.64), p = 0.17), proportion of infants with SDS for weight at birth < -2 (39/252, p = 0.65), gender distribution, Clinical Risk Index for Babies (CRIB) and cumulative energy intake were similar (see Table 1). There were however, a slightly lower calculated cumulative protein intake until d28 in the group receiving >75% human milk (3.38 (3.67-4.02) vs. 3.08 (3.77-4.26) g/kg/d; p = 0.023). The incidence of necrotizing enterocolitis was 3.6% in the group receiving >75% human milk and 5% in the group receiving <25% human milk (difference not significant, p = 0.53).

SDS-difference for weight persistently tended to be lower until discharge with >75% vs. <25% cumulative human milk intake (SDS-difference for weight -0.29 (-0.74 -0.02) vs. -0.56 (-0.67 - -0.001); p = 0.07). SDS-differences for weight during hospitalisation for all study infants and the two subgroups are displayed in Figure 1.

Discussion
Following early transition to full enteral feeds with predominantly fortified human milk, we observed a significant drop in SDS for weight and a non-significant trend towards lower HC in the first four postnatal weeks, with the majority of infants returning to their growth trajectories until discharge (Figure 1). The latter was most true notably for infants receiving a cumulative human milk intake <25%. During the first four weeks of life a cumulative human milk intake >75% was associated with a significantly more severe decline in SDS for weight compared to children receiving <25% human milk (Figure 1). This difference persisted as a trend until discharge. These results are in line with previous reports [5,6] yet with remarkably better feeding outcomes than median SDS difference for weight of 0.28 at discharge with >75% human milk in this study, compared with 0.45 in the study by Colai et al. [6].

In contrast to the observed differences in weight gain, no significant difference was observed in HC growth with different proportions of cumulative human milk intake, both as a difference in SDS column HC and the better HC growth than overall weight gain in predominantly human milk fed preterm infants is consistent with the previously delineated “feeding paradox” in very preterm infants describing better neurodevelopmental outcome in spite of suboptimal initial weight gain [4].

Most likely the differences in weight gain can be attributed to intra- and inter-individual variability of human milk composition, most likely the early decline in protein content of human milk fed preterm infants even if human milk was fortified by 25-30 ml/kg/d. Breast milk fortification was started at a feeding volume of 100 ml/kg.

The authors are with Department of Neonatology, University Children’s Hospital Tübingen, Germany. This is an Open Access article distributed under the terms of the Creative Commons Attribution License.
supply in some infants predominantly receiving human milk if current standardized fortification is applied [7]. The variability in nutrient content of human milk is reflected in the wider (interquartile range) requirements for fat, protein and other nutrients at discharge and discharged infants observed in receiving >75% human milk compared with those receiving <25% (Figure 1).

Future studies are required to show whether this potential protein deficit is best prevented by standardized supplementation with more protein given to all infants fed human milk, or via individual fortification of human milk after milk analysis.

Furthermore, optimization of the micronutrient content of human milk and formula to the needs of very preterm infants may be required for further improvement of growth [12].

Strengths of this study include the meticulous documentation of exact nutrient intakes along with anthropometric data expressed as SDS-changes during hospitalization in early enteraly fed very preterm infants. Additionally, the cohort included a high proportion of extremely immature infants who are at the highest risk of faltering postnatal growth. Limitations consist in the retrospective, observational, and single-center design of the study. The fact that we do not report linear growth data because of potential poor follow-up. This study may be required for further improvement of growth [12].

**Conclusions**

Although adequate early postnatal growth can be achieved in early enteraly fed very preterm infants, our current standardized fortification of human milk does not meet the needs of all infants to prevent persistent growth deficit in predominantly human milk fed very preterm infants. Special attention to intra- and inter-individual variability of protein content in human milk may be required.

**References**


Thermal imaging

Radiation in the long wave infrared (LWIR) bands (8-14 µm) is important because the human body emits most of its thermal radiation, which encodes valuable physiological principles, in this region of electromagnetic spectrum. This vital information, if properly processed and analyzed, may be used in many noninvasive applications such as temperature mapping and arterial pulse measurements [6,9,10]. A solid base that includes an understanding of the physics of image formation principles, the choice of an IR band, and instrumentation is crucial for successful biometrics signature processing. Such signatures include superficial vessel blood flow [11], forehead mean temperature, and nostril thermal patterns [4,12-14].

Methods

All measurements were performed using a VaristCAM IR head (InfraTec GmbH, Germany) IR camera (LWIR, 7 µm to 14 µm). The camera transmits the thermal map to a PC via the IEEE 1394 FireWire interface. The neonate’s thermal images were taken inside a convective incubator (Caleo, Draeger AG, Germany) and converted to a 2D array containing temperature information within the LabVIEW software platform. Additionally, a geometric correction was applied to the acquired thermograms showing the effect of geometric correction of the neonate’s skin and an alternative layout of the neonate prior to NIRT imaging.

Thermography imaging experiment design

Only ten newborn infants were selected to participate in the clinical study, five of them were under radiant warmer therapy and the rest are placed inside convective incubator. A referential ground truth measurement was implemented by using skin temperature electrodes as gold standards. The accuracy of these clinical skin electrodes is within ± 0.1 °C. The NIRT imaging and measurement was performed at the Department of Neonatology (RWTH Aachen University Hospital), and this has been approved by the medical ethics committee of the RWTH Aachen University Hospital, issued on 19 August 2009 with reference CE032/009. The acquired thermography data were used for testing the tracking algorithm. Each dataset contained one measurement scene consisting of a newborn infant undergoing thermography inside a convective incubator or under a radiant warmer. The tracking time was approximately 20 minutes for each subject with a frame rate of 25 fps, and the measurements were conducted as a real-time imaging operation. In principle, a higher frame rate (up to 50 fps) could be achieved; however, a higher frame rate would increase the size of the thermography data to an out-of-memory level in many PCs.

Thermography acquisitions began after IR camera calibration and the transmission of IR radiation through the foil is between 0.92 and 0.94. Moreover, the data were registered against an emissivity equal to unity (considering neonatal skin as a typical blackbody radiator), although the actual value of emissivity was equal to 0.972 [22,23]. This correction strategy plays a vital role in accurate temperature mapping because any slight difference in the emissivity value will tend to add inaccuracies to the temperature reading from the IR camera.

Virtual sensor architecture

The term “Virtual InfraRed SENsor” (VIBENS) relates to a sensing method based on augmented visual or physical measurements. In this work, a virtual temperature sensor was developed wherein contactless temperature measurements essentially replace the clinical gold standards. Furthermore, a virtual sensor tracking software was developed using LabVIEW Vision Assistant (National Instruments) as an integrated toolkit. This software allowed the skin to be connected directly to the LabVIEW console by using a native interface file provided by the manufacturer (Figure 6).

Thermography acquisitions began after IR camera calibration and were followed by the extraction of the thermal data from the color space of the image; this task formed the initial step of the VIBENS concept. Moreover, the selection of the ROI array was initiated afterward to set the tracking coordinates of the neonate’s body to be implemented in the image-processing loop and architecture (Figure 7).
Abbas and Leonhardt

For the matching process, the normalized correlation (NC) is adopted in the similarity measurement. Therefore, we consider pixel values along a concentric circle within the template $S \rightarrow P$.

The parametric vector approach for template matching

The mathematical process of image cross-correlation is simple; the RPT is overlaid on the source thermogram image, and the correlation matrix $C$ is multiplied individually. Additionally, all of the matched templates are summed to produce a single correlation value.

The correlation value matrix is then scanned for its peak value. This position generally conforms to the position in the source image that most closely matches the template [22,34,35].

The correlation value matrix is then scanned for its peak value. This position generally conforms to the position in the source image that most closely matches the template [22,34,35].

Scale (shift)-and rotation-invariant technique

One of the greatest flaws in cross-correlation is its inability to match objects in a source image that are either of different size or rotated compared to the reference template. These two template-matching mechanisms are used in the ROI descriptor (corresponding to the projected template) in the frame matrix. The mathematical approximation of such a template inside a rectangular window $T(x,y)$ is as follows:

$$P_i = \frac{1}{S} \sum_{x, y} T(x,y)$$

where $s$, for $0 \leq s \leq N$, denotes the different scaling values generated by scaling the template image. The approach enables fast matching in the ROI tracking algorithm. The computational efficiency is significantly increased because the RPT process reduces a 2D thermography image array into a 1D vector. Additionally, the correlation matrix $C$ can be determined in the training phase while the optimal parameters $s^*$, the scaling value obtained directly from the correlation vector $F_{xx}$ and the correlation matrix $C$, are determined in the matching phase [38].

In fact, there is no iteration step involved in this tracking template-matching-based algorithm. Therefore, the computational time is considerably reduced.

Generally, this data description is appended to the input template image. During the matching phase, the template descriptor (the ROI descriptor, $P_{ROI}(x,y)$) is extracted from the template image and used to search the template in the inspection image [31-33].

The mathematical process of image cross-correlation is simple; the RPT is overlaid on the source thermogram image, and the intensity values for each corresponding pixel are multiplied individually. Additionally, all of the matched templates are summed to produce a single correlation value [32,33].

Essentially, the Lagrangian multiplier (LM) method can solve this problem of difference optimization. The solution of $\omega$ is given by

$$\omega = \frac{L^T F}{[L^T \cdot L]^{1/2}}$$

where

$$\omega = \frac{\omega_1 \ldots \omega_L}{L}$$

and

$$\omega = \frac{\omega_1 \ldots \omega_L}{L}$$

The next step of the algorithm is producing the scaling value $s^*$ estimation of the scene subimage, which initiates in terms of the following equation

$$s^* = \frac{1}{N} \sum_{i=1}^{N} \omega_i s_i$$

which should accurately monitor the motion of the target surface even in the presence of partial occlusion or deformation [24]. This tracking system is applied to follow the motion of the target’s outline (and not only superficial features) [25-28]. Generally, motion tracking in not a straightforward process, it depends on the proper definition of the tracked anatomical geometry and the ability to follow-up and mark the defined ROI over multiple thermography frames (Figures 7 and 8).

Primarily, the tracking algorithm can be divided into five main stages, as illustrated in Figure 8: IR thermography acquisition, ROI geometry profile definition, object coordinate tracking, information extraction, and sensor display. The manner in which the active ROI moves through the image frames is illustrated in Figure 9, where the yellow rectangle moves with the relative motion of the baby inside the camera’s field of view (FOV).

When template matching, the ring projection template (RPT) process was used to address rotational variations within the thermography-image scene. The RPT reduces a 2D thermogram image into a 1D vector. In general, this task is used as a preprocessing step in the VIRESSENS approach.
The flexibility to perform stress-test infrared thermography, motions initiated by the patient. The VIRSENS approach offers loss of the ROI due to unexpected movements or involuntary motions initiated by the patient. Table 1 illustrates the correlation of the tracked ROI descriptor over the measurement scene with respect to a newly chosen position of the ROI descriptor.

In summary, the results obtained from the virtual sensor demonstrate its ability to accurately track different geometric profiles over the external anatomy of a neonate. Only a small percentage of the motion detection trials failed to track due to the lack of a properly matching matrix for the ROI descriptor under study (see Table 1).

The main clinical application of the presented virtual sensor approach is the continuous monitoring of patients without loss of the ROI due to unexpected movements or involuntary motions imitated by the patient. The VIRSENS approach offers the flexibility to perform stress-test infrared thermography.

Table 1: Comparison of scoring rate success for VIRSENS in NIRT imaging

<table>
<thead>
<tr>
<th>Frame no.</th>
<th>Success rate (%)</th>
<th>Data-over flow time (ms)</th>
<th>Tracked anatomical region</th>
<th>Correlation coeff.</th>
<th>Error rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>82</td>
<td>1.200</td>
<td>Face-hand/belly</td>
<td>0.0005</td>
<td>0.125</td>
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<tr>
<td>7</td>
<td>74</td>
<td>1.403</td>
<td>Face-hand/belly</td>
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<tr>
<td>3</td>
<td>80</td>
<td>1.227</td>
<td>Face-hand</td>
<td>0.0015</td>
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</tr>
<tr>
<td>79</td>
<td>79</td>
<td>1.296</td>
<td>Face-hand/belly</td>
<td>0.0023</td>
<td>0.182</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>1.372</td>
<td>Face-hand</td>
<td>0.0012</td>
<td>0.302</td>
</tr>
<tr>
<td>6</td>
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<td>1.214</td>
<td>Face-hand/belly</td>
<td>0.0031</td>
<td>0.319</td>
</tr>
<tr>
<td>7</td>
<td>87.2</td>
<td>1.306</td>
<td>Face-hand</td>
<td>0.0024</td>
<td>0.470</td>
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<tr>
<td>8</td>
<td>82</td>
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</tr>
<tr>
<td>9</td>
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<tr>
<td>10</td>
<td>88.5</td>
<td>1.307</td>
<td>Face-hand</td>
<td>0.0023</td>
<td>0.412</td>
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</table>

Table 2: Comparison of different desired ROI locations of virtual temperature sensor

<table>
<thead>
<tr>
<th>NIRT datasets/infant</th>
<th>Tracked regions</th>
<th>Desired ROI region</th>
<th>Desired ROI (fitting and tracked)</th>
<th>False ROI (misallocated)</th>
<th>Scoring percentage %</th>
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</thead>
<tbody>
<tr>
<td>Infant 1</td>
<td>Facial</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>75</td>
</tr>
<tr>
<td>Abdominal</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>66.6</td>
<td></td>
</tr>
<tr>
<td>Upper limb</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Infant 2 (radiant warmer)</td>
<td>Facial</td>
<td>4</td>
<td>2</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Abdominal</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>66.6</td>
<td></td>
</tr>
<tr>
<td>Upper limb</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Infant 3 (radiant warmer)</td>
<td>Facial</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Abdominal</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>83.3</td>
<td></td>
</tr>
<tr>
<td>Upper limb</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Infant 4 (radiant warmer)</td>
<td>Facial</td>
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<td>3</td>
<td>1</td>
<td>75</td>
</tr>
<tr>
<td>Abdominal</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>83.3</td>
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<tr>
<td>Upper limb</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Infant 5</td>
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<td>4</td>
<td>5</td>
<td>2</td>
<td>75</td>
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<tr>
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<td>6</td>
<td>5</td>
<td>2</td>
<td>66.6</td>
<td></td>
</tr>
<tr>
<td>Upper limb</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>80</td>
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<tr>
<td>Lower limb</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>80</td>
<td></td>
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<tr>
<td>Infant 6</td>
<td>Facial</td>
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<tr>
<td>Abdominal</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>83.3</td>
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</tr>
<tr>
<td>Upper limb</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Infant 7</td>
<td>Facial</td>
<td>4</td>
<td>2</td>
<td>5</td>
<td>75</td>
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<tr>
<td>Abdominal</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Upper limb</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

Table 2 provides some quantitative analysis for performance measurement in different thermography datasets within NIRT study. This table showing the scoring of matches of tracked ROI per anatomical regions for seven infants participating in the study. As we can see from Table 2 that the higher success rate of this scoring occurs, in the facial, plane where there is a prominent landmark such as nose, orbital, forehead and maxillofacial regions. Therefore, this is highly discriminated from other anatomy such as hand, arms, legs and trunk can be use the facial tracking as referential template for tracking accuracy and validation procedure of virtual thermal sensor.

Conclusion

In this study, a thermal imaging tracking method was proposed and tested based on a template-matching algorithm. The developed method uses a spatially trained ROI tracker whose interactions are modeled using cross-correlations of the ROI template and a searchable IR image. The method’s output provides pixel-level tracking accuracy even in the presence of multidimensional target transformation. The proposed tracking method was effectively tested in thermal and visual datasets featuring facial regions and other anatomical objects.

The thermography tracking system for neonatal monitoring was implemented and tested for clinical monitoring inside NICU unit. The main conclusion from this experiment is that the tracking can be robust over well-calibrated thermography frames and for lesser jerky movements of the neonate. In fact, thermography measurements performed at a distance are beneficial from a psychological viewpoint for both staff and the patient’s relatives but produce challenges from the medical perspective. The tracking problem, which is pivotal in this study, was particularly challenging due to the functional nature of thermal IR imaging and its application in real-time operation.

Moreover, NIRT imaging depicts physiological changes; therefore, it is highly dynamic, non-linear, unpredictable in its uncertainties, and difficult to model. In addition, the estimation...
of the emissivity value at certain tracking points requires further optimization and development before it can be included in prospective NRT applications, such as the detection of respiratory signatures with the IRRTHM method or evaluation of superficial blood perfusion over active metabolic regions (e.g. at liver and brain). Because these applications would appear to be difficult tasks due to the slow hemodynamic activities of the superficial vessels, the method requires further development and improvement for clinical application in contactless blood perfusion and hemodynamics parameters.

Furthermore, this physiological tracking application based on thermography might consider a good candidate for running on smartphone and other mobile computing devices. These applications can be a part of the widespread adoption and use of mobile and computing vision technologies is opening new and innovative ways to improve health care delivery. Thus in turn can transform a mobile platform into a regulated medical monitoring system.

References

Preterm Birth By Vacuum Extraction and Neonatal Outcome: A Population-Based Cohort Study

Katarina Åberg, Mikael Norman and Cecilia Ekéus

Abstract

Background: Very few studies have investigated the neonatal outcomes after vacuum extraction delivery (VE) in the preterm period and the results of these studies are inconclusive. The objective of this study was to describe the use of VE for preterm delivery and to compare rates of neonatal complications after preterm delivery by VE to those found after cesarean section during labor (CS) or unassisted vaginal delivery (VD).

Methods: Data was obtained from Swedish national registers. In a population-based cohort from 1999 to 2010, all live-born, singleton preterm infants in a non-breech presentation at birth, born after onset of labor (either spontaneously, by induction, or by rupture of membranes) by VD, CS, or VE were included, leaving a study population of 40,754 infants. Logistic regression analyses were used to calculate adjusted odds ratios (AOR), using unassisted vaginal delivery as reference group.

Results: VE was used in 5.7% of the preterm deliveries, with lower rates in earlier gestations. Overall, intracranial hemorrhage (ICH) occurred in 0.64%, and brachial plexus injury in 0.13% of infants. Infants delivered by VE had higher risks for ICH (AOR = 1.84 [95% CI 1.09-3.22]), NEC (AOR = 4.48 [95% CI 2.84-7.07]) and brachial plexus injury (AOR = 6.21 [95% CI 2.22-17.4]), while infants delivered by CS during labor had no increased risk for these complications, as compared to VD.

Conclusion: While rates of neonatal complications after VE are generally low, higher odds ratios for intra- and extracranial hemorrhages and brachial plexus injuries after VE, compared with other modes of delivery, support a continued cautious use of VE for preterm delivery.

Background

Perterm birth is common [1] but still, the optimal mode of delivery of preterm infants is not known. Although neonatal outcomes in preterm infants delivered vaginally or by cesarean section (CS) [2-5] have been compared, there is no evidence to provide clear guidance on the method of choice [6]. Given the widespread assumption that assisted vaginal delivery could be harmful for fragile infants that are underweight and preterm, very few studies have addressed the use of vacuum extraction (VE) for preterm birth.

Delivery by VE is a common obstetrical procedure, and in many countries it has replaced the use of forceps. VE is used to terminate a protracted second stage of labor and as an intervention for fetal or maternal distress. VE requires vertex presentation, a fully dilated cervix and ruptured membranes [7]. A cesarean section, on the other hand, can be performed at any stage of labor and does not require prerequisites of this kind. Most clinical guidelines do not recommend VE before 34 gestational weeks [8-10]. These recommendations are not based on results of randomized controlled trials, but rely on the observation that preterm infants are more likely than term infants to develop ICH, and on extrapolations from studies of term infants showing that VE is associated with an increased risk of ICH and other neonatal complications [11-17]. Only three studies have previously investigated the use and outcomes of VE in preterm births. The first was undertaken over 40 years ago and showed increased mortality and morbidity among preterm infants delivered by VE as compared with term infants delivered by VE [18]. The second study compared neonatal morbidity in preterm infants delivered vaginally with (n = 61) or without VE (n = 122), and found no differences in neonatal morbidity between the two groups [19]. The last study compared VE and forceps for preterm delivery (n = 64) [20]; the neonatal outcomes were similar in both groups. The available data are clearly unlikely and hampered by limitations in power and, therefore, current knowledge on safety of preterm vacuum-assisted birth is unsatisfactory.

The aim of this study was to 1) describe the use of VE and compare it to rates of CS during labor in preterm deliveries in Sweden from 1999-2010, 2) characterize the distribution of perinatal risk factors associated with each mode of delivery, and 3) compare rates of neonatal intra- and extracranial hemorrhages, as well as occurrence of brachial plexus injury after preterm delivery by VE or CS during labor, using unassisted vaginal birth as a reference.

Methods

This study was based on data from national data bases held by the Swedish National Board of Health and Welfare. The national registration number, assigned to each Swedish resident at birth, was used for individual record linkage. We used two registers: the Swedish Medical Birth Register (SMBR) that covers 99% of all births in Sweden, and The Swedish National Inpatient Register (IPR) that covers all public inpatient care. The SMBR includes prospectively collected information on maternal characteristics, reproductive history, and complications during pregnancy, delivery, and the neonatal period. The IPR includes data on each hospital admission and discharge.

Table 1 Neonatal outcomes studied in 40,764 preterm infants

<table>
<thead>
<tr>
<th>Outcome</th>
<th>ICD-code</th>
<th>ICD-subgroup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intracranial bleeding</td>
<td>P10</td>
<td>Intracranial laceration and hemorrhage due to birth injury</td>
</tr>
<tr>
<td>Intraventricular hemorrhage due to birth injury</td>
<td>101</td>
<td>Subdural hemorrhage due to birth injury</td>
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<td>Intraventricular hemorrhage due to birth injury</td>
<td>102</td>
<td>Cerebral hemorrhage due to birth injury</td>
</tr>
<tr>
<td>Subarachnoid hemorrhage due to birth injury</td>
<td>103</td>
<td>Intraventricular hemorrhage due to birth injury</td>
</tr>
<tr>
<td>T entorial tear due to birth injury</td>
<td>104</td>
<td></td>
</tr>
<tr>
<td>Other intracranial lacerations and hematomas due to birth injury</td>
<td>108</td>
<td></td>
</tr>
<tr>
<td>Unspecified intracranial laceration and hemorrhage due to birth injury</td>
<td>109</td>
<td></td>
</tr>
<tr>
<td>Intraventricular (non-traumatic) hemorrhage of fetus and newborn</td>
<td>P52</td>
<td>Intraventricular (non-traumatic) hemorrhage of fetus and newborn</td>
</tr>
<tr>
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<td>Subependymal hemorrhage (without intraventricular extension)</td>
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<td>Neonatal cerebral dysfuncion</td>
<td>P90</td>
<td>Convulsions of newborn</td>
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<td>Neonatal cerebral ischemia</td>
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</table>

The Swedish Medical Birth Register (SMBR) that covers 99% of all births in Sweden, and The Swedish National Inpatient Register (IPR) that covers all public inpatient care. The SMBR includes prospectively collected information on maternal characteristics, reproductive history, and complications during pregnancy, delivery, and the neonatal period. The IPR includes data on each hospital admission and discharge.

Study population

During the period of 1999-2010 there were 75,296 (6.2%) preterm births in Sweden. We excluded deliveries by CS before the onset of labor (n = 17,306), forceps (n = 257), or performed with both VE and CS (n = 125). We also excluded stillbirths (fetal deaths occurring before labor or intra partum) (n = 1,839), multiple births (n = 11,088), and births in breech presentation (n = 3,917). Thus, the final study population was restricted to all live-born, preterm singleton infants with a non-breech presentation at birth, delivered after a spontaneous or induced onset of labor followed by CS, vacuum extraction (VE), or by unassisted vaginal delivery (VD) before gestational week 37 + 0 days (n = 40,764). CS during labor was defined as abdominal delivery after the onset of labor, either spontaneously, by rupture of membranes, or by induction.

A number of independent variables were collected; the maternal anthropometrics included: age, height, and body

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extremely preterm (before 28 weeks), very preterm (28-31 weeks), and moderately preterm (32-36 weeks). In a further step, we also divided the preterm gestational period according to guidelines on instrumental delivery into either: less than 34 weeks (VE not recommended), and ≥34 weeks (VE may be used). GA was recorded in completed weeks, and was based on routine ultrasound during performed at 17 to 18 postmenstrual weeks in 97.48% of all pregnant women. Infants that were lost to follow-up was categorized as less than 1,590 grams, 1,500-2,000 grams, 2,001-2,500 grams, 2,501-3,000 grams, and ≥3,000 grams.

Outcome variables
Neonatal diagnoses were classified according to the International Classification of Diseases (ICD) Tenth Revision (1997 and onwards), and identified/collated in the SMHR or in the IPR. The following neonatal outcomes (ICD codes) were assessed: intracranial hemorrhage and hematoma due to birth injury (P10), intracranial non-traumatic hemorrhage of fetus and newborn (P52), convulsions of newborn (P98), other disturbances of cerebral status of newborn (P11), subgaleal hematoma (P12), cephalohematoma (P19), and brachial plexus injury (P140-3).

The definitions of outcomes are described in detail in Table 1.

Neonatal diagnoses of intracranial hemorrhages in preterm infants were mainly based on imaging of the brain using ultrasonography, however, some assessments of the brain at term-equivalent age were alternatively performed with CT and/or MRI. Imaging of the brain was performed on clinical indications only in cases born moderately or late preterm, whereas all very premature infants (born before 32 weeks of gestation) were screened for intracranial lesions, even in asymptomatic infants. A diagnosis of convulsions included infants with clinical signs of convulsion and/or convulsion recorded by ICD codes P90, P91. Statistical analysis was performed using proportions and odds ratios (OR) with a 95% confidence interval (CI) for neonatal complications in relation to mode of delivery, unadjusted and adjusted for GA, parity, and for the most unadjusted (reference group SPSS 20.0 for Windows software package).

Three models were used to assess the relationship between the different modes of delivery and the risk for neonatal complications: one crude, and two adjusted (Models 1 and 2). The included covariates have been shown previously to be related to instrumental deliveries, and were related to the outcomes in cross tabulations. In Model 1, we adjusted for the following confounders or covariates: maternal age, height, BMI, parity, as well as infant year of birth, birthweight and GA. In Model 2, we added the indication for operative delivery and preeclampsia. The year of birth was entered as a continuous variable in accordance with a linear secular trend, and all other variables were entered as categorical. Furthermore, a separate logistic regression analysis was performed to investigate severe ICH in relation to mode of delivery. Here, intraventricular hemorrhages grades 1-2 were excluded and the analysis was adjusted for GA only. We also conducted separated analyses on potential relationships between sex and ICH in relation to mode of delivery. Missing data were entered as a separate category in the analyses. The study was approved by the Regional Ethical Review Board in Stockholm, Dnr 2008/1322-31.

Table 2 shows rates (per 1000), crude and adjusted odds ratios for the outcomes by mode of delivery, and uses in-sample weights.

The ORs for convulsions were almost doubled in both neonatal outcome in relation to gestational age
Neonatal outcome in relation to gestational age
The proportion of preterm infants diagnosed with an ICH varied more than hundred-fold in relation to GA. It decreased from 21.5% among preterm infants born at 22–25 weeks of GA to 0.1% among those born after 36 weeks of gestation. The rates of neonatal convulsions among preterm infants decreased from 2.0% at 22–25 weeks to 0.25% among those born after 36 weeks of gestation. Figure 2. The proportion of preterm infants diagnosed with other disturbances of cerebral status (encephalopathy) decreased with GA, while proportion of infants with brachial plexus injuries or ICH increased slightly with GA. Figure 3.

Neonatal outcome in relation to mode of delivery
To report outcome in relation to gestational age, the study cohort was divided according to the current guidelines on the use of VE as either preterm births occurring between 24-25 weeks of gestation (VE may be used), and the occurrences before 24 weeks of gestation (VE not recommended). In our cohort, 35,192 (84.1%) of all preterm births occurred at 24-36 gestational weeks, and 7,562 (15.8%) before 34 weeks of GA.

In Table 3, neonatal outcomes before and after 34 + 0 weeks of gestation are presented in relation to mode of delivery. Overall, seven preterm infants were classified as having an ICH due to

Distribution of risk factors or covariates in relation to mode of delivery
Table 2 shows maternal and perinatal characteristics of the study population in relation to mode of delivery. The VE rate decreased with maternal height and 80% of the women who delivered by VE were primiparous, compared with 48% of those who underwent CS during labor (not in table). More than 45% of the women who delivered by VE had received epidurals analgesia during labor compared with 22% of women with VD, and 12% with CS during labor (not in table). Given the association between GA and VE, infants delivered with VE had higher birthweights.

The most common indication for VE was fetal distress (42%), followed by prolonged labor (25%). Having a large (≥30 cm) and occipitooanterior position (25%) or fetal distress (17%) were the most common indications for CS during labor, while only 3% in this group had a diagnosis of prolonged labor.

Neonatal outcome in relation to gestational age
The proportion of preterm infants diagnosed with an ICH varied more than hundred-fold in relation to GA. It decreased from 21.5% among preterm infants born at 22–25 weeks of GA to 0.1% among those born after 36 weeks of gestation. The rates of neonatal convulsions among preterm infants decreased from 2.0% at 22–25 weeks to 0.25% among those born after 36 weeks of gestation. Figure 2. The proportion of preterm infants diagnosed with other disturbances of cerebral status (encephalopathy) decreased with GA, while proportion of infants with brachial plexus injuries or ICH increased slightly with GA. Figure 3.

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In Table 3, neonatal outcomes before and after 34 + 0 weeks of gestation are presented in relation to mode of delivery. Overall, seven preterm infants were classified as having an ICH due to...
In this large cohort study of singleton, non-breech preterm births after onset of labor, we identified three clinically important findings related to mode of delivery. First, VE was used in 5.7% of preterm births, and despite recommendations of no use, 3.3% of preterm infants born before 34 gestational weeks were delivered by VE.

Secondly, VE for preterm birth was used more frequently in shorter mothers, primiparous and among women treated with EA as pain relief during labor. Finally, and adjusting for potential confounders and co-variables, preterm infants delivered by VE had almost double OR for ICH, four times higher OR for extracranial hemorrhage, as well as a 6-fold risk for brachial plexus palsy compared with VE delivery, indicating that the risk of intraventricular hemorrhage grades III-IV (the most common form of ICH in preterm infants) from the analysis ICH for VE, indicating that severe bleedings were more common among preterm infants delivered by VE.

Although VE was related to significantly increased rates of ICH, it is not clear whether the extraction as such causes the injury, or if there is an underlying common pathway for both VE-assisted delivery and ICH, i.e., that the relationship is confounded by indication. Since the ORs for ICH were significantly higher in the VE group compared with both the CS and unassisted VD groups, the ORs for other disorders of cerebral status were slightly higher in both the VE and CS groups as compared with VD, different mechanisms may be involved in the development of these two complications. The forces by vacuum extraction could lead to significant vertical stress, which might be avoided with CS. In a case report of MRI findings after birth injuries among infants delivered by VE [21], it was suggested that vertical traction on the skull and brain may produce atrophic lacerations and rupture of intracranial veins. Another explanation for our findings of different outcomes after VE and CS could be that infants delivered by VE may have been exposed to contractions for a longer time than those delivered by CS. A protective effect of CS delivered by lower ORs for ICH, however, the exposure to contractions as the sole explanation for the increased risks for ICH after VE is less likely, as the VE group—presumably the group exposed to the largest forces of labor—exhibited significantly lower odds for hemorrhagic complications compared with infants delivered with VE.

During the study period, the overall rate of ICH increased from 0% originally, up to 12% at the end of the period, most likely reflecting the increased access and use of ultrasonography among Swedish neonatologists in recent years. Improved ultrasound technology and image resolution may also have contributed to this development. Finally, we cannot exclude a contribution from misclassification: a large but normal choroid plexus could have been classified as a small subependymal hemorrhage by less experienced investigators. The findings of the diagnosis of small subependymal hemorrhage (without intraventricular extension, PS2¢) increased most compared to other types of ICH during the study period (from 0.5% to 2.6%), supports these interpretations.

The overrepresentation of subgaleal hemorrhage and cephalhematoma after VE is less surprising, since earlier studies have stated the relation between these diagnoses and the use of VE. The risk of subgaleal hemorrhage seems to be unrelated to GA, as this study demonstrates rates similar to those in previous studies of infants born at term [12,13].

The present study showed that preterm infants delivered by VE had a 6- to 7-fold risk increase for injury to the plexus brachialis compared with unassisted CS, and that this risk seems to be unrelated to GA, as this study demonstrates rates similar to those in previous studies of infants born at term [12,13]. The major strengths of this study were the large study population covering all preterm deliveries in Sweden during a period of twelve years, and the high quality of the registers, making it possible to analyze rare diagnoses and unusual events such as ICH in preterm infants delivered by VE. We were able to include data on risk factors, potential confounders, and outcomes collected independently from one another and without involving the study subjects, thus minimizing various types of bias (e.g., selection and recall bias). Moreover, antenatal and obstetric care is free of charge in Sweden, management routines as well as GA

### Table 3 Neonatal outcomes in preterm infants by mode of delivery and gestational age

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Intraventricular hemorrhage</th>
<th>Subgaleal- and/or cephalhematoma</th>
<th>Brachial plexus injury</th>
<th>Intracranial hemorrhage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gestational age</strong></td>
<td><strong>n = 47,154</strong></td>
<td><strong>n = 4,143</strong></td>
<td><strong>n = 2,602</strong></td>
<td><strong>n = 14,717</strong></td>
</tr>
<tr>
<td><strong>&lt;34 weeks</strong></td>
<td>617 (15.1)</td>
<td>486 (14.8)</td>
<td>105 (19.1)</td>
<td>26 (11.2)</td>
</tr>
<tr>
<td><strong>34-36 weeks</strong></td>
<td>164 (74.6)</td>
<td>415 (71.0)</td>
<td>95 (59.4)</td>
<td>18 (71.7)</td>
</tr>
<tr>
<td><strong>≥37 weeks</strong></td>
<td>53 (1.6)</td>
<td>35 (1.3)</td>
<td>10 (3.6)</td>
<td>8 (3.9)</td>
</tr>
</tbody>
</table>

### Table 4 Logistic regression (odds ratios) for intra- and extracranial hemorrhages, convulsions and other cerebral complications, and brachial plexus injury in preterm infants exposed to different modes of delivery

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Crude OR</th>
<th>AOR model 1</th>
<th>AOR model 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICH</strong></td>
<td><strong>Vaginal</strong></td>
<td><strong>CS during labor</strong></td>
<td><strong>VE</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,064</strong></td>
<td><strong>167</strong></td>
<td><strong>16.1</strong></td>
</tr>
<tr>
<td><strong>&lt;34 weeks</strong></td>
<td><strong>564</strong></td>
<td><strong>74</strong></td>
<td><strong>1.5</strong></td>
</tr>
<tr>
<td><strong>34-36 weeks</strong></td>
<td><strong>196</strong></td>
<td><strong>45</strong></td>
<td><strong>1.0</strong></td>
</tr>
<tr>
<td><strong>≥37 weeks</strong></td>
<td><strong>54</strong></td>
<td><strong>18</strong></td>
<td><strong>0.7</strong></td>
</tr>
</tbody>
</table>

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neonatal INTENSIVE CARE Vol. 27 No. 4 • July-August 2014
determinations are standardized, and 99% of births are delivered in public hospitals. This minimizes the risk for confounding by unmeasured socio-demographic factors. Another advantage was the inclusion of the main indications for VE and CS, enabling us to address the question of confounding by indication.

A major limitation of this study is that the registers do not contain detailed information about many important factors during the VE deliveries. For instance the registry does not provide specific information about the type of VE instrument used, level, position, and attitude of the fetal head in the pelvis when applying VE, location of placement of the vacuum cup, traction work, skill of the obstetrician, pressure exposure (duration and force), and cup detachments. The register does not provide information about confounders such as use of oxytocin and application of fundal pressure.

There is a general recommendation not to use VE before a GA of 34 weeks. According to the Royal College of Obstetricians and Gynaecologists, there is insufficient evidence to establish the safety on VE deliveries in gestations between 34 weeks. According to the Royal College of Obstetricians and Gynaecologists, there is insufficient evidence to establish the safety on VE deliveries in gestations between 34 weeks + 0 days and 36 weeks + 0 days [9]. Our results show that the use of VE is related to rare, but serious complications also between gestational weeks 34-36.

Conclusion

The rates of serious birth injuries and complications are generally low, but preterm infants delivered by VE have higher odds ratios for intra- and extracranial hemorraghes and brachial plexus injuries than those delivered by CS during labor or by unassisted vaginal delivery. We therefore support a longer and more detailed discussion about the indications for VE during labor and delivery, the need for greater standardization of the technique, and the importance of better documentation of the technique used and the complications seen.

References


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# 6 of the Top 10 NICU’s Use the Penguin® Nutritional Warmer

## Comparison of Hospital-Grade Nutritional Warmers

<table>
<thead>
<tr>
<th>Feature</th>
<th>Single Well &amp; Quad Penguin® Warmers</th>
<th>Waterless Milk Warmer™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy to clean with common hospital disinfectant</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Plastic feeding containers are never exposed to heat greater than 120°F to warm and/or thaw feedings</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Plastic feeding containers are exposed to heat greater than 150°F to warm and/or thaw feedings</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Warmer is able to warm feedings from the refrigerator to feeding temperature</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Silent operation for optimal protection of cognitive development</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>One step frozen to feeding cycle</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Device gently mixes to keep lipids and fortifiers in solution</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Device is intuitive and warm based on the milk’s starting temperature not based on a countdown system</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Thaws in less than 20 minutes</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Quad device is optimized for use in pods or nutritional preparation areas/rooms</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Device is optimized for all makes, models and sizes of breast milk storage bags, syringes and bottles</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Warmer compensates for environmental variables that affect the milk and delivers a consistent result every time</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Feedings are warmed in a waterless environment</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Feedings are protected in a “closed system” within a “sterile inner pocket”</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Accomodates feeding containers to 270 ml and syringes from 1 ml to 100 ml</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

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