Overwhelming scientific and clinical data proves that High Frequency Oscillatory Ventilation provides both lung protection and lung recruitment. It’s the right tool for your treatment decisions for neonates, pediatrics and adults.

VIASYS Healthcare is the only company that offers a full range of Lung Protection Ventilation: High Frequency Oscillatory Ventilation, Automatic PV Curves, SiPAP, Heliox Ventilation and LPV Strategy Assistance.

Only the SensorMedics 3100 HFOV manages the most delicate balance in mechanical ventilation—Recruitment AND Protection.

Viasys Healthcare has a full line of invasive and non-invasive ventilators for critical care, acute, sub-acute and home care applications.

For more information on SensorMedics 3100 HFOV please visit www.viasyshealthcare.com/HFOV
Every day clinicians are faced with meeting the challenge of critical care. Fortunately, MAQUET is there, providing continuous innovation and assistance to empower clinical performance.

From the latest technologies, such as NAVA*, that improves patient ventilation synchrony, to the Open Lung Tool, which assists lung protection strategies, the SERVO platform delivers outstanding ventilation support for all patient types, from the ICU to transport to the MRI* suite.

Whether it’s our clinical applications team, which delivers the highest level of in-service training, or our worldwide symposia on critical care ventilation, MAQUET’s global commitment to clinical performance is clear.

To find out about local clinical education seminars and to receive the latest information on SERVO innovations, visit www.maquet.com/us or call 1-888-MAQUET-3.

SERVO-i from MAQUET.

MAQUET - The Gold Standard.

* These products are pending 510(k) review and are not yet commercially available in the U.S.
HELP PROTECT HIGH-RISK INFANTS FROM SEVERE RSV* DISEASE...

Premature infants born near the start of or during the RSV season may be at especially high risk for RSV.

...TAKE PREVENTATIVE MEASURES IN THE NICU

*Respiratory syncytial virus.

Editorial

Your Death and Theirs

Are neonatologists’ decisions about life sustaining/end of life decisions affected by their take on their own mortality? An interesting question. Medical News Today reports that doctors who fear their own death say they are more prepared than other doctors to hasten death in sick newborns for whom further medical treatment is considered futile. The findings are based on a survey of 138 neonatologists across Australia and New Zealand, to be published in an upcoming issue of Archives of Disease in Childhood Fetal & Neonatal Edition. The doctors were asked questions about their ethical practice and to complete the Multidimensional Fear of Death Scale (MFODS), which measures different facets of personal fear of death.

According to Medical News Today, “Of the 138 doctors contacted, 78 (56%) completed the questionnaire. Virtually all of them said they sometimes withheld or withdrew life-sustaining treatment in newborns with severe mental and/or physical disability and those for whom further medical treatment was considered to be overly burdensome or futile.” The respondents said they used painkillers or sedatives in both situations to alleviate pain and suffering, but without intending to hasten death. However, one in three specialists was prepared to use painkillers or sedatives to relieve pain and suffering by intentionally hastening death in newborns with severe disability, and more than three out of four were prepared to hasten death for this purpose in babies for whom further treatment was considered futile. According to Medical News Today, “In this situation, they preferred to use painkillers or sedatives to hasten death rather than withhold minimal treatment, such as tube feeds or oxygen, in a bid to prevent unnecessary pain and suffering. One in five neonatologists said that hastening death in this context was unacceptable by either means. The study also reported a link between the neonatologists’ personal fear of death and their ethical practice. Doctors who said they were not prepared to hasten death had significantly less fear of the dying process and of premature death than those prepared to hasten death with painkillers or sedatives. But they had significantly more ‘fear of being destroyed.’ The author suggests that doctors’ fear of the dying process or of premature death may unconsciously motivate them to hasten a newborn’s death in order to relieve their own death anxiety. Similarly, those who fear being ‘destroyed’ may not be prepared to hasten death, because of their own fears, even though this may be the most humane way to relieve a newborn’s suffering.” Of course, the study doesn’t really suggest that neonatal physicians are condoning euthanasia, or that it’s even happening in neonatal intensive care units. Still, it demonstrates how personal views definitely impact treatment modalities and options. It’s certainly something to think about.

Les Plesko, Editor
Big news from the little guy:
The Vapotherm® 2000i is back.

It’s the news clinicians, patients and families have been waiting for. The Vapotherm® 2000i is back.

We sincerely regret the inconvenience of the recall. The 2000i has an outstanding record over the past four years, treating thousands of patients worldwide. Our first responsibility, however, was to fully investigate, and ensure that the 2000i could be used safely.

We return the 2000i to our users with a revised Operating Instruction Manual that includes a new Disinfection Procedure and instructions for use of the device with sterile water.

Vapotherm would like to thank everyone in the neonatology, infection control and respiratory communities for your guidance and support. We’re glad to be back.
So far, 115 hospitals across the nation have increased reimbursement for INOmax® (nitric oxide) for inhalation. Is your hospital one of them?

Our team can help you identify the information you need to seek and obtain appropriate payment. To learn more, please contact INO Therapeutics and the INOtherapy Reimbursement Service at 1-877-KNOW-INO (1-877-566-9466) or visit www.inotherapeutics.com.
RENT-A-UTERUS
Rob Stein, writing in the Washington Post, reports on plans for the first US uterus transplant. Researchers in Manhattan have begun screening women left barren by cancer, injuries or other problems who want a chance to bear their own children. The planned operation, Stein reports, is stirring objections among some transplant experts, fertility specialists and medical ethicists, who question whether the procedure has been tested sufficiently and whether the benefit of being able to carry a pregnancy outweighs the risks for the woman and fetus. Others said having a childbearing experience had little to do with actual parenting and shouldn’t be so important. But defenders of the transplant effort said that thousands of women cannot bear children because they were born with a malfunctioning uterus or their wombs were damaged, and said women should make the choice to have the transplant, not doctors or ethicists.

Doctors in Saudi Arabia reported the first human uterus transplant, in 2002, on a 26-year-old woman whose womb had been removed six years earlier because of hemorrhaging after the birth of her first child. The donor was a 46-year-old woman with an ovarian condition that required removal of her ovaries and uterus. Although blood clots forced surgeons to remove the organ after 99 days, doctors called the procedure a technical success.

US researchers have practiced on rats, pigs, rabbits and a monkey, and said problems that occurred in Saudi Arabia could be avoided. To perform the transplant, doctors would wait to make sure the organ was working properly. An embryo created through in vitro fertilization would then be placed in the womb. If the pregnancy went well, the baby would be delivered by Caesarean section, and the doctors would remove the uterus.

BIG BABY
A huge baby has been born in Cancun, Mexico. He’s been nicknamed Super Tonio and weighs in at 6.6 kilograms. Cancun residents crowded the nursery ward’s window to see Antonio Vasconcelos, who was born early on Monday by a C-section at Jesus Kumate Rodriguez Hospital. The baby drank 5 ounces of milk every three hours, and measured 55 centimeters in length. “We haven’t found any abnormality in the child, there are some signs of high blood sugar, and a slight blood infection,” said the hospital’s director.

In Brazil, a baby born in January 2005 in the city of Salvador weighed 7.6 kilograms at birth. According to Guinness World Records, the heaviest baby born to a healthy mother was a boy weighing 10.2 kilograms, born in Aversa, Italy in September 1955. Antonio’s mother, Teresa Alejandra Cruz, 23, and father, Luis Vasconcelos, 38, said they were proud of the boy, and noted that Cruz had given birth to a baby girl seven years ago who weighed 5.2 kilograms. “It’s good, because now with this one, we’ll have a pair” of big babies, said Vasconcelos.

LITTLE BABY
Agence France Press reports that the world’s most premature living baby, born at 21 weeks and six days, has headed home after spending four months in a neonatal intensive care unit at Baptist Children’s Hospital in Miami. No baby born at less than 23 weeks was previously known to have survived, according to the University of Iowa, which keeps a record. When she was released from the NICU, the girl was four pounds. At birth, she weighed only 280 grams and measured 9.5 inches. Doctors said that at the time of her release, the baby girl was thriving and well enough to be cared for by her parents at home. The baby was delivered via C-section after attempts to delay a premature delivery failed. She was breathing without assistance at birth and even made several attempts to cry.

KICKING IT
Paediatric Anaesthesia presented a paper on severe withdrawal syndrome in three newborns subjected to continuous opioid infusion and seizure activity dependent on brain hypoxia-ischemia. Authors Bachiocco, et al with the Department of Anesthesia-Analgesia and ICU at S. Ortolan Hospital, Bologna, Italy, investigated whether brain hypoxia represented a risk factor for the occurrence and severity of opioid abstinence syndrome. Three newborns who manifested seizure activity as a result of hypoxia, focal brain ischemia, and hypoxia and sepsis, respectively, were compared with 17 neonates who suffered from hypoxia without developing seizure activity. The first three neonates suffered a severe withdrawal syndrome (a rating on the neonatal abstinence score >17), the others did not. The authors hypothesized that brain hypoxia facilitated the occurrence and severity of the withdrawal syndrome because some key neurochemical processes (such as N-methyl-D-aspartate activation, protein kinase C activation and nitric oxide production) are common to both phenomena. For the full article see Paediatr Anaesth. 2006 Oct;16(10):1057-62.

BRAIN GROWTH
Medical News Today reports that the regions of the brain that control vision and other sensory information grow dramatically in the first few months following birth, while the area that controls abstract thought experiences very little growth during the same period. University of North Carolina at Chapel Hill researchers have found that the back regions of the brain, which control vision and sensory integration, grew significantly faster than the prefrontal region, which controls abstract reasoning. In addition, the type of brain tissue called gray matter, which contains most of the neurons or nerve cells, grew much more robustly than another type of tissue called white matter, which contains the connecting fibers between neurons in different brain regions. Gray matter size grew by roughly 40 percent in the first months after birth, while white matter grew very little. The study was the first to systematically obtain very high resolution magnetic resonance imaging (MRI) scans on a large group of newborns. The results appear in the Journal of Neuroscience. Another key finding by the UNC team is that boys, on average, are born with brains about 10 percent larger than the brains of girls. This is consistent with the pattern seen in adults, Gilmore said in so far as men typically have a brain about 10 percent larger than that seen in women. However, the scans revealed that brain asymmetry was opposite in newborns and adults. In adults, the right side of the brain is usually slightly larger than the left side. Gilmore and his collaborators found the left side was slightly larger in the newborns who were included in the study. For the study, 74 newborns at the University of
North Carolina Hospitals were given high-resolution magnetic resonance imaging (MRI) scans in the first few weeks after birth. In terms of brain volume, the researchers found newborn male brains were 7.8 percent larger than females. In addition, males had 10.2 percent more gray matter and 6.4 percent more white matter than females. No significant difference in brain asymmetry was observed between males and females; the left side of the brain was on average 4.3 percent larger than the right side.

The researchers noted that the dramatic growth in gray matter, the part of the brain that contains most of the neurons, or nerve cells, may have implications for autism research. Children with autism have larger brains and more gray matter than average. The study suggests that in autistic children, something may go awry during gray matter growth in the first year of life.

GIVE IT A SHOT
A group of Portuguese researchers at the Institut Pasteur and the Institute for Biomedical Sciences - Abel Salazar - in Porto have identified a protein in a micro-organism which allows it to colonize a host by modulating its immune system. According to these scientists, who have published this study in the Journal of Immunology, the protein thus identified is a possible candidate for the development of a vaccine against Group B Streptococci. Some 800 cases of invasive infections in newborn infants caused by group B streptococci are recorded each year in France; they mainly result from transmission from the mother to the infant. Mortality linked to these infections remains high (50 to 100 deaths each year), and despite antibiotic therapy, 25 to 50% of the infants who survive suffer from neurological after-effects.

The scientists demonstrated that a protein secreted by group B streptococci, called GAPDH, was capable of raising the level of one of the messengers in the immune system, the cytokine IL-10. Such an increase in IL-10 diminishes the immune defenses, so that invasive bacterial infection is facilitated. The researchers also showed that IL-10-deficient mice were much more resistant to infection by group B streptococci. The team concluded that GAPDH could be used to ensure immune protection. The researchers are now working on the development of a vaccination strategy.

HEAD 'EM OFF
Researchers at the University of Virginia Health System have developed a way to monitor babies in neonatal intensive care units and predict sepsis before there is any indication of illness. Results of this research appear in the February issue of the journal Pediatric Research. Researchers were instrumental in developing a novel bedside monitoring system to predict the likelihood that sepsis will occur in a baby in the next 24 hours. The system analyzes heartbeat signals obtained from a standard bedside heart rate monitor and looks for patterns that give an early indication that the baby is getting sick. Characteristics such as decreased variability of the heart rate along with brief episodes of slowing of the heart rate indicate that the infant may be getting an infection. These characteristic patterns can serve as an early warning to the physicians and nurses caring for the infants. After years of testing and clearance from the Food and Drug Administration, academic research hospitals are participating in a multicenter National Institutes of Health-sponsored study to further test if heart rate characteristic monitoring improves outcomes for NICU babies.

The patented monitoring technology was developed by Griffin and Moorman at the University of Virginia Health System. The rights are licensed by the University of Virginia Health System Patent Foundation to Medical Predictive Sciences Corporation in Charlottesville, VA.

HEARTACHE
There is an increased risk of fetal heart problems when mothers carry particular antibodies associated with rheumatic diseases, according to an abstract presented by Yale School of Medicine researchers at the recent Society for Maternal-Fetal Medicine Conference. CHB carries a 20 percent death rate and nearly all survivors require pacemakers. Researchers at Yale’s Department of Obstetrics, Gynecology & Reproductive Sciences helped conduct the PR Interval and Dexamethasone Evaluation (PRIDE) study with a team of other researchers to evaluate an early marker of cardiac injury before there is permanent scarring.

The PRIDE group conducted a longitudinal (observational) study following over 100 women with the anti-Ro and anti-La antibodies to determine if there were early signs of fetal heart problems. They also explored whether early treatment would reverse the problems. The team found that while first-degree fetal heart block may be reversible with the steroid drug dexamethasone, the condition could advance within as little as one week to a third-degree block, which is irreversible even with further intervention.

UP THE DOSAGE
Researchers at the 27th Annual Society for Maternal-Fetal Medicine (SMFM) meeting announced that high-dose progesterone treatment helped at-risk pregnant women avoid premature delivery. In the study, 45 hospitalized women who already had experienced premature labor were randomly divided into a treatment group and an observation group. The 23 members of the treatment group received twice-weekly 341-mg doses of progesterone until week 36. The progesterone injections appeared to prevent continued shortening of the cervix, a factor in premature labor. The study’s purpose was to determine if a higher dose of alpha hydroxy-progesterone caproate (17P), commonly used now to prevent preterm birth among women with that history, can affect cervical changes and thus increase preventive effectiveness in women during their first pregnancy. Findings revealed that 22 percent of the women in the high-dose treatment group had a preterm delivery, compared to 54 percent of those in the observation group. The researchers believe this was the result of reduced cervical shortening and inhibited local inflammation. In an unrelated study, similar 17P treatment reduced the risk of preterm delivery by 85 percent. The study, Alpha Hydroxy-Progesterone Caproate (17P) Treatment Reduces Cervical Shortening Inhibiting Cervical Interleukin-1 Secretion, was the first to address the relationship between progesterone, cervical changes, and preterm deliveries.

BORN TO LOSE
A recent study by Mount Sinai School of Medicine (MSSM) found that children born with low birth weight who suffered child abuse are substantially more likely to develop psychological problems such as depression and social dysfunction in adolescence and adulthood. The study, appearing in The Archives of Pediatric & Adolescent Medicine, was the first to investigate the possible interaction between LBW and later adversity. To examine the possible conjoined effects of LBW and child abuse on adaptation and on the development of
psychiatric and medical problems, researchers looked at data from the John Hopkins Collaborative Perinatal Study, an epidemiologic study that followed random sample of mothers and their children from pregnancy for more than 30 years. They compared outcomes in the transition to adulthood among four groups of children: those with LBW and childhood abuse, those with LBW alone, those with childhood abuse alone and those with neither. The researchers found that participants with both LBW and subsequent child abuse, relative to those with neither risk, were at a substantially elevated risk of psychological problems: a 10-fold for depression; a nearly 9-fold for social dysfunction and an over 4-fold for somatization. However, they were not at an elevated risk for medical problems in adulthood. Those exposed to child abuse were more likely to report delinquency, school suspension, repeating grades during adolescence and impaired well-being in adulthood, regardless of LBW status. For those with LBW alone, the prevalence of those problems was comparable to that of those without either risk factor.

SPRINGTIME ROMANCE
Women who become pregnant in spring are more vulnerable to preterm birth than those who conceive in other seasons, according to researchers at the University of Pittsburgh. Researchers analyzed data from 75,399 deliveries over a 10-year period at the university-affiliated Magee-Womens Hospital of UPMC, grouping each by season of last menstrual period, a date physicians historically have used to estimate conception. Women conceiving in summer had the lowest rate of preterm birth at 8.4 percent, with steadily increased rates for the fall (8.8 percent), winter (9.1 percent) and spring (9.2 percent). Preterm birth also took place less often with conceptions in summer and fall than for those in winter or spring, the researchers noted. In fact, those conceiving in summer or fall had a 25 percent reduction in risk over those who conceived in winter or spring.

EXPLOSIVE RESULTS
A recent Canadian study showed that giving nitroglycerin to women who enter labor early results in significant improvement to their babies’ health. The improvement is most marked in babies who are born very prematurely. The five-year, randomized controlled trial involved 153 women who were recruited at the time they went into preterm labor. The study was organized by the Queen’s Perinatal Research Unit at Kingston General Hospital, with data management by the Ottawa Maternal Neonatal Investigators at the Ottawa Health Research Institute. It revealed that using nitroglycerin patches for pregnant women helps to prolong pregnancy and most importantly improves babies’ outcome, with fewer side effects than experienced through the use of other drugs.

SEXY BABY
Doctors at Newcastle’s Royal Victoria Infirmary used Sildenafil (Viagra) to open up tiny blood vessels in the lungs of an infant weighing 24 ounces whose lung had failed. According to a neonatologist at the hospital where the drug was employed, the problem with preemies is that doctors could blow oxygen into the lungs, but there isn’t enough blood to carry oxygen to the rest of the body. Sildenafil opened the blood vessels so they could capture the oxygen and take it around the body. Reported by the BBC.

THE BREAST OF THEM
 Babies who are breastfed are more likely to move up the social ladder as adults, a study has suggested. A University of Bristol team looked at 1,400 babies born from 1937-1939 and followed their progress for 60 years. Those who were breastfed were 41% more likely to move up in class than those who were bottle-fed.

Experts said the Archives of Disease in Childhood study supported the idea that breastfeeding led to better long-term outcomes for children. The people studied had all originally taken part in the Boyd Orr Study of Diet and Health in Pre-War Britain carried out in 1937-1939. They were followed up until an average age of 73. The study found there was no difference in breastfeeding rates when the researchers looked at household income or social class. Those who had been breastfed had a 58% chance of moving up the social ladder compared to 50% of those who were bottle-fed, a relative difference of 41% when the statistics were adjusted to take into account other factors which might influence the outcome. The longer a child was breastfed, the greater were the chances of upward mobility. In families where one child was breastfed while a sibling was bottle-fed, there was still a difference in their chances of social mobility, with the breastfed child 16% more likely to move up in class. The researchers opined that breastfeeding may affect brain development, or that breastfeeding typically took place in a better environment, or that it indicated better bonding with the mother.

OLDER ISN’T BETTER
Women who have a baby past age 40 are at an increased risk of stillbirth. Researchers at Yale University wanted to see if age alone, rather than a health problem in a previous pregnancy, affected the risk of both stillbirth and the death of a child in the womb for older mothers. They looked at six million babies born to women aged 15 to 44 between 1995 and 1997 and correlated their information with data from the US Centers for Disease Control, which registered the deaths of babies. They calculated that women aged 40 to 44 had three times the risk of stillbirth than women aged 25 to 29. The researchers also found that fetal checks at 38 weeks of pregnancy had the greatest impact on reducing stillbirth rates in older women.

These checks include listening to the baby’s heartbeat and testing the amniotic fluid to pick up any signs of distress. The researchers suggested that 1,700 such checks would be needed to prevent one stillbirth in women aged 35 to 39, compared with just under 500 tests to prevent a baby born to women aged 40 to 44 dying, and concluded that women expecting babies over 40 should be monitored from 38 weeks onwards.

DO NOT DISTURB
Researchers believe that a new noninvasive blood test could be developed to detect genetic abnormalities such as Down’s syndrome in the womb. Current non-invasive tests such as ultrasound are limited, and invasive tests pose a risk to the pregnancy. The new technique works by examining samples of fetal DNA present in the mother’s blood for tiny variations in the sequence of the genetic material. Analyzing fetal DNA from a mother’s blood sample has been possible for some time, but its effectiveness has been limited because only a small amount of the DNA makes its way into the mother’s blood. A team at the company Ravgen, Inc, has been able to maximize the amount of DNA that can be recovered by treating the blood samples with formaldehyde. The researchers took blood samples from 60 pregnant women and searched the genetic material for variations of single nucleotide polymorphisms (SNPs). As each
chromosome has a characteristic pattern of SNPs, the researchers were able to distinguish between DNA from the mother and the fetus. They were also able to determine whether the fetus was carrying extra copies of key chromosomes which cause genetic disease. For example, carrying an extra copy of chromosome 21 causes Down’s syndrome. Of the 60 samples tested, the technique identified the number of chromosomes correctly in 58, including two cases of trisomy 21. The researchers noted that there were still problems to be overcome.

RELAX!
Researchers at Imperial College London found that children whose mothers were stressed out during pregnancy were vulnerable to mental and behavioral problems like ADHD. Stress caused by parental fighting or violence was found to be particularly damaging. Experts blame high levels of the stress hormone cortisol crossing the placenta. The researchers found that high cortisol in the amniotic fluid bathing the baby in the womb tallied with the damage. The babies exposed to the highest levels of cortisol during their development had lower IQs at 18 months. The same infants were also more likely to be anxious and fearful. The work suggested that maternal stress is a true risk factor in its own right, although the researchers acknowledged that genetic factors and home environment after birth would also have an impact on a child’s development.

PRODUCTS

WHAT’S IN A NAME
Tyco Healthcare today announced that Coviden will be its new name once the global healthcare leader separates from parent company Tyco International this spring and becomes an independent, publicly traded company. Tyco Healthcare is a leading global manufacturer and distributor of medical products, with annual sales of nearly $10 billion. Its product portfolio includes disposable medical supplies, monitoring equipment, medical instruments and bulk analgesic pharmaceuticals. The Coviden brand will be the master identifier that unites Tyco Healthcare’s brand names, including Autosuture, Kendall, Mallinckrodt, Nellcor, Puritan Bennett, Syneture, and Valleylab. Its upcoming separation from Tyco International will introduce a new era for the diversified healthcare products organization, which employs more than 43,000 people worldwide. As Coviden, the newly independent company will embark on a distinct new direction that focuses exclusively on healthcare and benefits from increased flexibility to invest in innovation and organic growth. Coviden is an original name, inspired by themes of collaboration and life. It was selected for its global meaning and appeal from among some 6,000 possible names in a rigorous process that began more than nine months ago.

PARTNERSHIP
Draeger Medical, Inc was recently awarded membership into the American Association for Respiratory Care (AARC) Corporate Partner Program. Draeger Medical has earned elite Corporate Partner status because of its exceptional support of AARC and the respiratory care profession. “Without the level of support and commitment exhibited by Corporate Partners such as Draeger Medical, AARC would not be able to advance its mission to promote optimum respiratory care for patients with lung diseases,” said AARC Executive Director Sam Giordano, MBA, RRT, FAARC. As a corporate partner, Draeger Medical provides support to the largest professional association for respiratory therapists and other professionals. Draeger Medical’s support is used to provide much needed educational and research efforts aimed at ensuring that respiratory therapists have the information and tools they need to deliver top quality care to patients with asthma, chronic obstructive pulmonary disease, cystic fibrosis, and other respiratory problems. The Corporate Partner Program is comprised of best-in-class organizations interested in supporting the goals and work of the Association. The program aims to give respiratory care providers information, insights, and innovative approaches to improve performance and advance the health of their patients. Contact draeger.com.

ON ITS WAY
Discover Laboratories, Inc announced that it has received guidance from the FDA in a recent meeting regarding the key remaining steps necessary for potential approval of Surfaxin (lucinactant) for the prevention of RDS in premature infants. The guidance provides the clarity and defined pathway that Discovery believes is necessary to address key remaining issues identified by the FDA Approval Letter, followed by a six-month review cycle by the FDA for potential approval of its New Drug Application for Surfaxin. Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative to animal-derived surfactants. Contact discoverlylabs.com.

ALL IN ONE
Nova Biomedical announced the incorporation of total bilirubin (tBil) to the comprehensive test menu on its Stat Profile Critical Care Xpress (CCX) “All-in-One” Analyzer. Bilirubin is an important indicator of liver function particularly in neonatal applications. With the addition of total bilirubin, the CCX analyzer now offers 20 measured tests, including pH, PCO2, PO2, SO2%, hematocrit and hemoglobin, sodium, potassium, chloride, ionized calcium, ionized magnesium, glucose, BUN, creatinine, lactate, deoxyhemoglobin, oxyhemoglobin, methemoglobin, and carboxyhemoglobin, in a single, compact instrument. While incorporating more on-board tests than any competitive analyzer, the Critical Care Xpress is 20 to 40% smaller and easily transported on its mobile cart. Key CCX features include a color touch screen interface for intuitive, on-screen prompted operation; a single, snap-in reagent pack that eliminates bulky gas tanks, regulators and humidifiers, and the waste containers needed in other analyzer; a fully automated, on-board Auto-Cartridge QC system that eliminates the manual quality control, dramatically reducing labor time and costs; and a unique automated maintenance system that allows the operator to initiate maintenance and then walk away from the analyzer. Contact novabio.com.

STRIP TEASE
The new StatStrip Glucose Monitor from Nova Biomedical has received clearance from the US Food and Drug Administration for use in neonatal testing. While every other glucose monitor may report an error if the hematocrit value is abnormal, StatStrip accurately measures glucose and hematocrit on a single strip, automatically correcting for an abnormal hematocrit value. In addition, its small 1.2 microliter sample volume is attractive for the NICU environment where blood conservation is essential. Introduced in May 2006, StatStrip has rapidly become the gold standard in hospital glucose testing.
GET SMART

Children's Medical Ventures (ChMV), a subsidiary of Respironics, Inc., announced the release of a new patient monitoring system for health care professionals called SmartMonitor 2 Professional Series Light (PS Light). The PS Light is the latest in a series of monitors from ChMV designed to track a patient’s cardiorespiratory activity. SmartMonitor 2 PS Light is specifically intended for hospital use to measure and record a patient’s pulse and respiration, and sounds an alarm if levels fall below defined limits. The “Light” designation refers to the PS Light’s ability to provide high-quality, cost-effective heart and respiration monitoring parameters without integrated pulse oximetry. ChMV currently offers the SmartMonitor 2 PS for healthcare settings requiring patient monitoring with integrated pulse oximetry. SmartMonitor 2 PS Light is cleared for use with infant, pediatric, and adult patients making it ideal for documenting patient response to conscious sedation, post-anesthesia recovery, patient controlled analgesia, and general floor monitoring. The PS Light offers many of the same features found in ChMV's other cardiorespiratory monitors including separate digital readouts for pulse and respiratory rates, device and patient alarms, internal modem, lightweight design and battery backup. SmartMonitor 2 PS Light also incorporates universally recognized symbols that help simplify operation while reducing potential language barriers, utilizes Synergy-E Event Software to review patient event data and is compatible with ChMV’s SmartRecorder. Contact childmed.com or respironics.com.

CASTING A WIDER WEB

Dräger Medical introduces a comprehensive, web-based information management solution that integrates vital OR, PACU and ICU patient information from medical devices and systems across the Acute Point of Care (APOC). Innovian Solution Suite streamlines access to patient information by providing one platform for the critical and perioperative care environments. It strengthens Dräger Medical's suite of information management solutions, which also includes a distributed, client-based anesthesia information management solution for the OR. The new web-based components of the suite include solutions for the perioperative and critical care environments. In the perioperative environment, Dräger Medical’s OR/Anesthesia information management system covers scheduling, pre-op, holding, intra-op and PACU. For critical care there is an ICU documentation system that provides full electronic patient charting, flowsheet, scoring and printed reports. Working together, these solutions continually capture vital patient information from perioperative and critical care medical devices and clinical information systems. That data is integrated into one, easy-to-navigate interface for direct access by clinicians. A more accurate patient record is possible when patient data is automatically placed into the record. With electronic charting clinicians can spend less time writing and have more time for patient care. Dräger Medical's web-based information management solutions support Pick and Go technology. This enables information collected by Infinity monitors during patient transfer to be automatically backfilled into the database. Moreover, because it is built on open standards, it fully supports HL7 interfaces to the hospital information system. Contact draeger.com.

KID STUFF

WeeSpecs Supreme from Children's Medical Ventures combines innovative materials and superior light-blocking features with a line of pediatric frames designed to provide the ultimate in comfort and fit. The exclusive soft touch frame provides support and comfort even for the smallest of faces. The adjustable nose pads ensure a secure fit, and the silicone temples provide flexibility and comfort for even the most active kids. The WeeSpecs Supreme line is available in a variety of vibrant designs, making it the perfect choice for children of all ages. Contact medassets.com for more information.
A low tidal volume strategy for mechanical ventilation has been shown to improve morbidity and mortality in adults with acute respiratory distress syndrome (ARDS) or acute lung injury (ALI). There have been numerous studies supporting this strategy in adults but very few have been done in pediatrics. Does utilizing a low tidal volume strategy work for children? Do protocols in mechanical ventilation for pediatrics work? This newsletter will discuss some of the differences between adults and pediatrics and discuss protocols in children.

Lung development is different in neonates and pediatrics than adults. Lung development starts in utero and “continues to grow and mature over the first 8 years of life.” Due to this difference alone, it would be predictable that ARDS and ALI would affect the neonatal/pediatric lung differently than adults. Newborn infants also have only 1/6th the number of alveoli than adults. Other than physical differences, the causes of ARDS are different in neonatal/pediatric population. I have listed some common causes of ARDS below.

- Neonatal
- Pediatric
- Adults
- Meconium Aspiration
- Acute upper airway obstruction
- Multiple transfusions
- Congenital Diaphragmatic Hernia
- Pneumonia
- Overdose of narcotics
- Prematurity
- Bronchiolitis/Asthma
- Smoke inhalation
- Persistent Pulmonary Hypertension of the Newborn
- Chest trauma
- Near Drown
- Congenital Cyanotic Heart Disease
- Cardiac Arrest
- Sepsis
- Seizures
- Gastrointestinal or hepatic disorder

As we can see, there are some similarities within each group, but there are more differences. Another major difference between adults and children is ventilator length of stay. Pediatrics patients generally have shorter time on the ventilator than adults.

Even with the differences with pediatrics and adults, many pediatric intensivists agree with the opinion of Mehta and Arnold, that “optimal alveolar recruitment with judicious use of positive end-expiratory pressure (PEEP) and low tidal volumes will remain the mainstay for managing respiratory failure in children.”

Ventilator management protocols have been developed for adults are supported by numerous studies. There are far fewer studies in pediatrics. Graham et al discusses the many potential difficulties in creating a protocol for pediatrics from initiation to extubation. One key point made by Graham et al is that “no single ventilator management protocol is applicable to all children who require mechanical ventilation.” They go on to state “the clinician must contemplate the reason why each...
individual patient is intubated... then must consider whether the patient is within the group for which a specific protocol was intended.”

The article also states that most protocols are designed to address a certain phase during the course of illness and we must be aware of the patient's treatment course at all times. The phases of mechanical ventilation as defined by Graham et al are initiation, maintenance, weaning, and discontinuation of mechanical ventilation.

Because mechanical ventilation in neonates and pediatrics are so individualized, closed loop ventilation protocols may benefit this population. Optimal Closed Loop Ventilation systems that adapt to a particular patient's pulmonary mechanics and drive are now available and being employed in several pediatric centers. (vs standard written protocols or knowledge based systems which apply a set of rules to all patients). Closed loop ventilation helps set up a safe "flight plan" in which the clinician can individualize the care for each patient while taking the patient thru all phases of mechanical ventilation. Closed loop ventilation incorporated as part of a multi-disciplinary team approach can result in giving the best possible outcome for our critically ill patients who require mechanical ventilation.

SOURCES


SPOTLIGHT ON PHOTOTHERAPY

TAKE A SHOT

Using light instead of a needle, BiliChek from Children's Medical Ventures allows health care professionals to test bilirubin levels regardless of gender, gestational age, or body weight – without needing a blood sample. Only the individual calibration tip touches the baby, so BiliChek greatly reduces the risk of infection or cross contamination. BiliChek is approved for use before, during and post phototherapy making it ideal for the newborn nursery and NICU… Ideal for hospital and home use, the Wallaby 3 Phototherapy System allows a mother to hold and even nurse her baby without interrupting therapy. At 7.2 pounds, the Wallaby 3 is light enough to be easily transported with the baby. There is no infrared or ultraviolet light to harm the baby… The Joey Dosimeter is specifically designed to measure fiber-optic irradiance and validate the performance of the Wallaby 3 Phototherapy System between patients. The sensor head measures 20 square centimeters and performance of the Wallaby 3 Phototherapy System between patients. The sensor head measures 20 square centimeters and can individualize the care for each patient while taking the patient thru all phases of mechanical ventilation. Closed loop ventilation incorporated as part of a multi-disciplinary team approach can result in giving the best possible outcome for our critically ill patients who require mechanical ventilation.

EXECUTIVE PROFILES

INSTRUMENTATION LABORATORY

Ramon E. Benet-Ferran
Ramon E. Benet-Ferran is Vice President, Worldwide Marketing and US Sales and Service, Instrumentation Laboratory.

Who is Instrumentation Labs?

For almost half a century, Instrumentation Laboratory (IL) has set the gold standard in the development, manufacturing, marketing and service of diagnostic instrument for clinical laboratories and point-of-care settings. Singular in our focus, we are the acknowledged world leader in critical care and hemostasis diagnostics. ILs history shines with innovation. In 1959, we were the first to introduce a bloodgas analyzer into routine clinical use; and today, we continue that leadership tradition with the new GEM Premier 4000, the most comprehensive, flexible and user-friendly analyzer on the market. In between is a long history of industry innovation.

Over the years, IL has brought breakthrough clinical functionalities as well as automation, computerization and system integration into the marketplace and continues to pioneer new technologies. In 1967, we introduced CO-Oximetry testing, followed by chemistry and coagulation centrifugal analysis. In 1984, we debuted the first blood gas analyzer with built-in data management and video display. Introducing new levels of efficiency to the market, several years later IL offered a device with disposable cartridge technology. By 2000, IL touched off a revolution in the industry with its standardized critical care testing platform across all hospital locations.

Complementing this innovation has been an ongoing commitment to meeting the full range of needs of our customers and the patients they serve. Our research and development efforts have always been a high priority and driven by the demands of the marketplace to make available the functionality and features our purchasers want and need. Similarly, unwavering dedication to product support and service is an integral part of our corporate philosophy.

How do you provide technical service and support and of what nature?

IL has always been committed to providing a strong group of technical service representatives in the field who are highly skilled and dedicated to supporting our customers. We focus heavily on recruiting professionals with clinical experience so that they know firsthand the needs, goals and workplace of our customers. Our representatives are given extensive product training and are taught to cater to the needs of clients and to provide comprehensive education about the use of IL products. Additionally, we offer onsite product-specific training.

Finally, IL has a highly trained technical support staff accessible on the telephone 24/7 to answer all questions relating to applications, quality control and performance of its equipment. Recently, an independent research group found that IL outranked every other major manufacturer of critical care analyzers in a full range of measures of customer satisfaction. The study of U.S. hospitals at the point-of-care found that IL achieved the highest ratings in overall satisfaction as well as
product satisfaction, ease of use, accuracy, ease of maintenance and much more.

How do you support customer's needs through product development?

At IL, the customer's needs are a major driver, and customer satisfaction is key. Even more important than our support and training is our commitment to addressing the needs of our product purchasers through the design of our products themselves. As part of this philosophy, we are dedicated to offering the most technically advanced, yet user-friendly analyzers on the market.

Our newest technology has been created with several key goals in mind. In addition to cutting-edge, comprehensive clinical functionality, these goals are ease-of-use, reliable operation and results, automated QC procedures, as well as remote connectivity. In some clinical settings, standardization of results in decenteralized testing scenarios also is crucial.

Perhaps the most important of these goals is automated quality control, which we address through our Intelligent Quality Management (iQM) system that brings new efficiency and reliability to the traditional, time-consuming blood gas quality control (QC) process. After all, no one chooses a career in healthcare to spend time with machines. With iQM, IL liberates therapists from traditionally time-consuming tasks. iQM provides a more efficient and accurate alternative to manual QC by automatically and continually checking the IL analyzer to deliver real-time system diagnostics. Time to error detection and correction is just minutes. iQM checks extend beyond analyzer electronics to include sensors and the chemical measurement process, which typically requires manual intervention, even on other advanced analyzers. The process automates all corrective actions, freeing up therapists from labor-intensive manual trouble-shooting, as well as eliminating lengthy equipment training and possible human error that might compromise test results. Also, all regulatory compliance documentation is automated. With this system, routine analyzer maintenance is eliminated through the use of a single cartridge that contains everything needed for whole blood testing. Every three weeks, a new cartridge is simply snapped into place and the analyzer is ready to function. A closed system, the PAK maintains the complete integrity of the testing process throughout the cartridge life. Another benefit of iQM is significant cost-savings realized through elimination of staff time spent with QC, which can amount to 48 hours monthly.

Also key to our product line is leveraging digital technologies to deliver advanced connectivity among our products to maximize efficiency and deliver a higher standard of care. A good example is our GEMweb technology and newest GEMweb Plus system for the GEM Premier 4000 analyzer. This unique suite of information management software enables clinicians, wherever located—across the hallway or the globe—to access and control multiple IL analyzers as if they were in the same room. This means that wherever and whenever needed, therapists and other clinicians can access and track test results, reports and current patient status as well as download and process orders and more. They can manage administrative tasks when convenient by remotely validating samples, accessing compliance documents and troubleshooting testing locations. The most advanced technologies in the world mean nothing if busy clinicians cannot take advantage of them. That's why user-friendly, easily accessible technology is one of our goals. Certainly, our advanced automated iQM and cartridge systems go a long way towards accomplishing that goal. But on a more micro-level, all our technology is designed to facilitate easy learning and operation. For example, our hardware controls are designed with clear, concise, intuitive menus and large touch-screen displays. Software screens are similarly intuitive and designed with an understanding of department workflow. Because critical care and hemostasis technology is our core business, we dedicate our full resources to the product category and make reliability a top priority across our entire product line.

Where do you see the future of your products in relation to end-user requirements?

Again, end-user needs and customer satisfaction drive our product development to a large extent. Our new GEM Premier 4000, ushers critical care analyzer technology into a new era of high performance and ease-of-use and clearly demonstrates our commitment. The GEM Premier 4000 is a state-of-the art device that is the most complete on the market and is extremely sophisticated, yet simple to use. It standardizes, centralizes and controls patient testing throughout the institution—and beyond. A major benefit of the GEM Premier 4000 is the complete integration of CO-Oximetry testing for truly consolidated measurements with the efficiency of a single sample. This, is combined with iQM and GEMweb Plus, adds up to another first in blood-gas monitoring. As technology continues to advance, IL is committed to serving the needs of our customers by staying in the forefront of critical care and hemostasis diagnostics.

BD Medical

Vicki Harder

Vicki Harder is Product Manager/Marketing, BD Medical.

After Sale & Service

Who is responsible within your company, by title or name or job description, for training and education of your staff and your customers?

The sales representatives are responsible for the initial product introduction to the customer. Once the customer converts to our product line, they work with our Internal Clinical Marketing team for actual clinical education of the use of our product with our customers.
INTRODUCTION

Group B streptococcal infection (GBS) is a leading cause of sepsis in neonates with substantial morbidity and mortality. The use of chemoprophylaxis during labor and delivery on all GBS colonized mothers has decreased the incidence of early onset infection by more than 70%. However, bacterial and non-bacterial infections other than GBS may occur. Streptococcus pneumoniae (S pneumoniae) infection is a rare cause of neonatal sepsis reported only as individual cases and institutional reviews with an incidence of 1 to 11% of neonatal sepsis and a mortality of 60% The reviewer only identified 21 cases of invasive S pneumoniae disease in neonates from a total of 4,428 episodes.1 We report an infant with fulminant S pneumoniae sepsis manifested as severe respiratory distress with hypoxia suggestive of PPHN without any premonitory signs and symptoms in the mother.

CASE REPORT

A full term female infant was born precipitously to a 37 years old G13 P11 mother. No documented prenatal care and no maternal labs were available. There was a documented history of cocaine and alcohol abuse in the previous pregnancy. She stated that her membranes ruptured 6-7 hours prior to delivery and a brownish colored fluid (suggestive of meconium) was noted. There was no antenatal and intrapartum fetal monitoring.

At birth, the infant was floppy without respiratory effort and the pediatric team was called to assist. The infant was suctioned with ETT and given IPPV through ETT. APGAR scores were 3, 6 and 7 at one, five and ten minutes respectively. Umbilical arterial pH was not recorded. The infant was stabilized and admitted to NICU.

In the NICU the infant’s birth parameters were weight 3150 grams, head circumference 34 cm, chest circumference 33 cm and length 50 cm. All were appropriate for gestational age of 40 weeks. Vital signs were T 98.8F, HR 105, RR 60 breaths per minute on ventilator, BP 64/33 mm Hg and O2 sat 45% with FiO2 of 100%. Blood glucose was 23 mg/dl. Infant was ventilated with conventional respirator with 100% oxygen, PIP/PEEP 25/5, IMV 65. Umbilical arterial and venous lines were placed. A bolus of D10W was pushed and maintained with 80 ml/kg of D10W with Calcium Gluconate. A chest radiograph showed massive meconium aspiration (Figure 1).

Umbilical arterial blood gas showed pH 7.14, pCO2 74, pO2 25, HCO3 24.9, O2 sat 31% and BE –5.8. Due to continued deterioration in clinical as well as acid-base status of the baby, the ventilator was changed to HFOV with FiO2 100%, rate 10 Hz, MAP 23 and AMP 48. A repeat arterial blood gas revealed pH 7.20, pCO2 74, pO2 24, O2 sat 28, HCO3 31 and BE –2. While stabilizing this infant a CBC and blood culture was obtained and she was started empirically on Ampicillin and Gentamicin. In addition she received a bolus of normal saline and HCO3 and maintained on Dopamine 10 micrograms/kg/min. A cardiology consultation was done and the echocardiogram suggested PPHN (RVH, right to left PFO and pulmonary to aortic shunt at ductal level). The infant was transferred to regional perinatal center at 6 hours of life for possible iNO and ECMO therapy.

Following transfer, the infant was continued on HFOV with 100% oxygen and iNO therapy 20 PPM. Initially the O2 sats were in 60s and slowly trended towards high 80s and 90s. The infant was prepared for ECMO and head ultrasound was done which was normal. Dopamine was weaned off slowly. Respiratory condition improved and HFOV was gradually weaned off to conventional ventilator.

The CBC revealed Leucopenia and Neutropenia (WBC count 2,300 and 10 Polys) and a urine tox screen was positive for cocaine. By 48 hours the initial blood culture obtained at our hospital grew Gram-positive cocci in chains in both bottles, which were later identified as S pneumoniae susceptible to Vancomycin but resistant to Penicillin. The isolate was subsequently identified as serotype 6 by the department of health.
The infant received ID consult and antibiotics were changed to Vancomycin and Cefotaxime to complete 21 days of empiric treatment for meningitis. Due to unstable condition of the baby a lumbar puncture was withheld at that moment. She was started on TPN and transferred back to our hospital with the diagnosis of full term infant with meconium aspiration syndrome, PPHN, S pneumoniae sepsis and cocaine exposure in utero.

A lumbar puncture was done at our hospital when the condition of the infant improved and the spinal fluid was clear and colorless. The cell count was WBC 3/mm³, protein 62mg/dl, Glucose 48mg/dl and culture negative. She had a normal newborn hearing screen and normal eye exam. Neurology consult was done and an MRI was performed with normal results. The infant’s condition improved and she was discharged home and was doing well on a follow up visit.

**DISCUSSION**

Early onset sepsis is defined as occurring within the first seven days of life. It usually manifests as an ascending infection from the maternal genital tract. It can also be the result of an infected placenta. The common microbial pathogens are GBS, Escherichia coli (E coli), and Listeria monocytogenes. Late onset sepsis may occur after seven days of life up to 3 months. It results from nosocomial infections or community acquired sepsis. The most common organisms associated with late-onset neonatal sepsis are Coagulase-negative Staphylococci, Staphylococcus aureus, E coli, Klebsiella, Pseudomonas, Enterobacter, Candida and GBS. S Pneumoniae is an alpha hemolytic Gram-positive diplococcus. It is a normal colonization of the respiratory tract and is present in 50% of the healthy individuals. Neonatal infections with these organisms are unusual ranging from 1-11% but they carry a mortality rate of up to 60%. S Pneumoniae is not part of the normal vaginal flora. In some women it can colonize the vagina and pelvic infection can occur especially in the presence of a predisposing condition (eg use of an intrauterine contraceptive device, recent birth or gynecological surgery). This unusual colonization is possibly explained by contaminated obstetric instruments or by oro-genital sexual practices. An increased number of cases of neonatal sepsis by S Pneumoniae have been reported in recent years but no increase in the relative incidence among neonatal infection has been noted. Changes in sexual practices during pregnancy and improvement in isolation and differentiation techniques of S Pneumoniae from other alpha hemolytic Streptococci could potentially account for the recent increases.

S pneumoniae infection can manifest as early or late onset sepsis. In early onset infection, meningitis is the most predominant and in late onset infection, pneumonia, otitis media, localized infections, DIC, septic arthritis and osteomyelitis are common. Many of the mothers of these infants do have other risk factors like GBS but most of the infants are full term, non-sick looking and screening cultures are not routinely done. Early onset S. pneumoniae neonatal sepsis has a worse prognosis and higher mortality than late onset sepsis. The early onset disease picture is similar to GBS infection but there are only occasional case reports and in the recent reviews only 3 out of 29 infants were early onset disease and the mortality was 14.3%. All deaths were reported within 36 hours of presentation. These deaths were not related to any specific serotype. Invasive S. pneumoniae infection in neonates has also presented with leucopenia and/or neutropenia, but this does not predict poor outcome.

Vaccination of the mothers during pregnancy or the newborns after delivery has been advised by WHO as a strategy to prevent invasive neonatal S Pneumoniae sepsis. There are 2 vaccines available; a 23-valent polysaccharide vaccine and the new protein conjugate vaccine, which is 7-valent. The 23-valent vaccine was safe and immunogenic in pregnant women and transplacental transmission of vaccine-specific antibodies was efficient. Infected serotypes reported include 19, 9, 3, 18, 1, 6, 14, 5 and 12. Serotypes responsible for 26% of invasive S. pneumoniae infections in neonates are 1, 3, 5 and 12 which are not included in the 7-valent vaccine.

The rarity of vaginal colonization by S pneumoniae suggests that this organism carries a higher invasion to colonization ratio than GBS and therefore maternal carriage or neonatal colonization should be more aggressively treated. S pneumoniae should always be considered as a cause of neonatal sepsis. It should be specifically sought in swabs taken from the pregnant mother and newborn, and if isolated, even in the absence of symptoms, antibiotic therapy should be strongly considered for the mother and the baby. In areas where S. pneumoniae resistance is a significant problem serious consideration should be given to adding Vancomycin and/or large dose Cefotaxime.

Mothers of infants affected by early onset pneumococcal sepsis have low pneumococcal antibody levels and run the risk of subsequent babies being similarly affected and therefore vaccination should be considered to prevent recurrence. There is also concern that increasing efforts to prevent GBS neonatal disease may lead to an increase in neonatal sepsis due to resistant organisms like S pneumoniae. Due to the increasing prevalence of penicillin-resistant pneumococci, the relationship between the percentage of mothers colonized with pneumococci and neonatal infections should be determined to develop new prevention and treatment strategies in newborn infants.
Conclusions

S. pneumoniae is not part of normal vaginal flora and thus a rare cause of neonatal sepsis. However, it causes a severe disease in the newborn. Routine screening culture is not suggested but if the infection rate is high in a certain institution there should be a higher index of suspicion. Our case is a full term baby with complicated meconium aspiration and PPHN. Antibiotics were started within 2 hours of life as a part of the management of sepsis work up. If this infant did not have signs and symptoms of meconium aspiration, she could have been transferred to the normal newborn nursery with subsequent delay on management. Rarity of signs and symptoms of sepsis is misleading and a rationale for evaluation and management is to be defined as per institutional policies. After the implementation of routine childhood pneumococcal immunization, the future risk will be less, as most of the population will have antibodies to the organism.

References

Hands-On Approach During Breastfeeding Support in a Neonatal Intensive Care Unit: A Qualitative Study of Swedish Mothers’ Experiences

Lena Weimers, Kristin Svensson, Louise Dumas, Lars Navér, Vivian Wahlberg

Abstract

Background: Assisting mothers to breastfeed is not easy when babies experience difficulties. In a neonatal intensive care unit (NICU), nurses often help mothers by using hands-on-breast without their permission. Little is known about how mothers feel about this unusual body touching. To gain more knowledge from mothers who lived through this experience, this hands-on practice was studied in a NICU in Sweden.

Methods: Between January and June 2001, in-depth interviews were conducted with ten mothers of preterm or sick term infants and all of them experienced the hands-on approach. In this research, Radnitzky’s seven principles of hermeneutic interpretation were applied in order to interpret the meaning of mothers’ responses. This article presents results related to the period of initiation of breastfeeding. This qualitative study was based on a combination of the models of Gustafsson, Orem, and Asrts’ Marte Meo.

Results: Five main themes were identified: insult to integrity, manipulating the baby, understanding and adjustment, breasts as objects, alternatives to this practice. Hands-on help in the breastfeeding situation was experienced as unpleasant and the women experienced their breasts as objectified. The mothers accepted the hands-on help given by nursing staff, even though they considered it unpleasant. Most mothers expressed a need for assistance when starting breastfeeding, but could not suggest any alternative to hands-on help such as demonstrating with an artificial breast and a doll.

Conclusion: The study provides information about how mothers experience unexpected hands-on help with breastfeeding in a NICU, which has not been described previously. Since most mothers in this study regarded this behavior as unpleasant and not helpful mostly because it was unexpected and unexplained, it would be important to either explain beforehand to mothers what type of physical approach could be attempted on their body or better, to avoid this type of approach completely.

Background

Mothers of preterm or sick infants face specific difficulties related to early mother and baby separation in a time of crisis and disillusion; this leads to a lack of appropriate bonding experiences.1,2 The infants being sick or immature, the initiation of breastfeeding often means repeated failures.2 Failures in breastfeeding can lead to anxiety, low self-confidence, and low self-esteem,3,4 and feelings of being a bad mother.5 In these instances, the nursing staff’s knowledge, attitudes and skills have a great impact on the mothers’ self-confidence and ability to initiate breastfeeding.6,7 Self-confidence has been shown as an important predictor for breastfeeding duration.8

Midwives and neonatal nurses who lack knowledge in breastfeeding management experience difficulties in giving timely and adequate information, and in supporting mothers.9 In fact, breastfeeding frequency is increased when nursing staff have theoretical and practical knowledge of good breastfeeding technique.6,10,11 Hedberg-Nyqvist and her colleagues also demonstrated that uniformity of language and approach from nursing staff increase the professional breastfeeding support to mothers.12 Duffy and colleagues have illustrated that professional help with positioning and latching-on to the breast is of importance not only prenatally but also soon after birth, for mothers to understand the “mechanics” of breastfeeding and to readjust immediately incorrect, painful, or ineffective positioning.13 Different approaches have been used to support...
mothers during this learning experience such as verbal or visual
descriptions\textsuperscript{12-14} and demonstrating with an artificial breast and
doll.\textsuperscript{11,13,14,16,17} Our clinical experience also tells us that some
nurses use a hands-on approach on their own body or on the
mother's breast.

Two recent studies in UK and Australia have described negative
effects of hands-on assistance by staff in breastfeeding
situations.\textsuperscript{13,14} They showed that the mothers who were visually
instructed in breastfeeding technique, with an artificial breast
and a doll, experienced fewer breastfeeding problems, were
more likely to breastfeed, and even breastfed longer than those
who were subjects of the hands-on approach. Nothing is known
about how Swedish mothers experience this type of approach.
As Sweden is recognized as a leading breastfeeding culture in a
developed country, it is of interest to know if Swedish mothers
react similarly to this touching of the breast by the staff. It is of
special interest also to study this phenomenon with mothers of
babies with expected breastfeeding problems such as sick or
preterm infants in a NICU.

This article reports on the mothers' experiences with hands-on
support by the nurses when their baby is in a NICU. It originates
from a larger study in which informative and supportive nursing
strategies were examined as potential factors to increase
mothers' self-care capacities.\textsuperscript{18}

In Sweden, most mothers-to-be participate in prenatal education
groups where they normally learn about breastfeeding basics
and day-to-day management. In fact, Swedish prenatal teaching
content respects international recommendations such as those
from the Baby Friendly Hospital Initiative (BFHI).\textsuperscript{19,20} As in
other countries, the quality of information depends on
midwives' attitudes, knowledge, and skills. Living in a country
where the vast majority of women initiate breastfeeding, they
also can benefit from the practical knowledge of mother-to-
mother breastfeeding groups (Ammningshjalpen). Almost all
parents' magazines present a positive view of breastfeeding and
advertisements usually respect the International Code of
Marketing of Breast Milk Substitutes.\textsuperscript{21} Generally speaking,
breastfeeding presents no problem to most Swedish mothers
since they should be knowledgeable about the basics of
breastfeeding from antenatal groups, magazines, and
breastfeeding groups.

Mothers of sick babies or preterm infants are the exception.
Very often, either they did not participate in breastfeeding
classes since they gave birth too early, or what they learned
doesn't apply to their particular situation, their babies
presenting complications with the initiation of breastfeeding.
Infants in a NICU also often have been fed in many different
ways before the actual initiation of breastfeeding, such as tube,
cup, or bottle feeding. We know that breastfeeding frequency is
enhanced when the baby first sucks from the breast rather than
from a bottle.\textsuperscript{22} We also recognize the importance of skin-to-skin
contact for both mother and baby for the initiation of
breastfeeding,\textsuperscript{23-26} and especially when the infant is
premature.\textsuperscript{1,27,28} All these have to be taken into consideration
when sick or premature babies are to initiate breastfeeding.
Their mothers need not only good explanations and adequate
guidance, but also specialized support to help them with
breastfeeding.\textsuperscript{29,30} This professional service should also be in line
with the same BFHI recommendations pertaining to mothers'
teaching, but obviously need to be adapted to the condition and
maturity of the infant. Weimers and Nystrom have produced an
adapted guide for the Ten Steps to Successful Breastfeeding in
the NICU.\textsuperscript{31} Other studies have demonstrated that breastfeeding
rates can be increased when applying the Baby Friendly
Initiative program in the NICU.\textsuperscript{32-34}

The importance of maternal confidence and knowledge in the
success of breastfeeding is well recognized.\textsuperscript{15,16,18} What is not so
well understood is how this self-confidence can be enhanced or
hindered during the first breastfeeding experiences. We believe
that some approaches, such as hands-on support by the nurse,
could be negative to the development of a mother's self

![Figure 1. A teaching situation: Nurse giving hands-on help.](image1)

![Figure 2. A teaching situation: Nurse with doll and artificial breast and
mother with baby.](image2)
Table 1: Semi-structured interview guide

1. Can you tell me about your breastfeeding experiences in NICU during the first days after birth? Tell me about your experience of the support you received from the nurses during your initial breastfeeding situations?

2. Did the assistance, the information, and the support you received in NICU, influence your attitude towards breastfeeding? Did it influence your breastfeeding experience for you and your baby? Do you think it matters how nurses help you and your baby in a breastfeeding situation?

3. Did you receive hands-on assistance from the nurses in NICU when you were attempting to breastfeed? If yes, how did the baby react? How did you feel about this at that time? At this moment thinking back, have your feelings altered towards hands-on assistance?

4. Did you experience that you needed hands-on assistance from the nurse in breastfeeding situations? Would an artificial breast and a doll have been an alternative when guiding you instead of the hands-on approach?

5. Can you describe what an ideal teaching or support breastfeeding situation would be like for you in NICU? What would be important for you? What should the nurses take into consideration when guiding you?

As supplementary addition to each question 1–5: Can you describe in more words what you mean? Do you have any comments, questions about the subjects we have just discussed? Have I understood you correctly?

confidence when initiating breastfeeding, and especially in the NICU where this could be particularly difficult if the baby is either sick or premature.

"Hands-on breast" assistance by the nurse is even more common when sick and preterm babies initiate breastfeeding; unexpectedly, that is, without asking permission of the mother, nurses grasp the mother's breast with their own hands to place it into the infant's mouth, and they also help the mother with manually milking the breast for milk expression. In this study, hands-on help is what is meant when nursing staff unexpectedly and actively touch the mother's breast and/or the baby's head, neck, or back with their hands to get the baby to the breast or when the nurse touches the breast during manual milking of the breast (See Figure 1). As explained by Ingram and colleagues from the United Kingdom\textsuperscript{13} and Fletcher and Harris from Australia,\textsuperscript{14} we believe that a mother would benefit more from a "hands-off" approach to reinforce her self-confidence since she would learn to put the baby to the breast herself rather than having the infant latched-on for her. However, this is only presumed to be similar for Swedish mothers since no study is reported on this subject. One of the objectives of this study was to reveal Swedish mothers' experiences of hands-on nursing approach to support breastfeeding initiation in a NICU.

Methods
Research question
How do mothers experience support by nursing staff in breastfeeding situations while their baby is in the NICU? This was the general question underlying this qualitative study. We report here only the sub-question pertaining to the hands-on approach: How do mothers experience hands-on support by nursing staff in breastfeeding situations while their baby is in a NICU?

Sample
Between January and June 2001 two independent nurses from the NICU at the selected hospital alternately informed potential mothers about the study. To be included in the study, mothers had to understand Swedish but not necessarily be of Swedish origin, to have given birth to either a premature infant or a sick baby requiring hospitalization in the NICU, and to be breastfeeding. Also, according to the inclusion criteria, 50% of the babies should be full term sick infants and 50% premature, in order to represent the two main patient categories in the NICU. There was no preset number of mothers; the researchers included any interested mother until saturation of data was reached.

Procedure
The mothers were recruited in a NICU at a university hospital in Stockholm, Sweden. This NICU consists of four rooms accommodating a total of twenty babies, two isolation rooms where parents can stay, and two rooms exclusively for parents. As for background data per representativeness of the sample, during 2001, 564 newborns had been admitted to this unit, 50% were premature babies. The staff consists of nurses, pediatric nurses, and nurse-midwives who have responsibility for these babies and their parents, including professional assistance with breastfeeding. Pediatricians and one nutritionist are also important professionals in the team to assist with nutrition aspects.

Qualitative in-depth interviews were used to elicit mothers’ experiences with breastfeeding support. The interviews were conducted after discharge of the baby, either at home or elsewhere, as per the mother's choice. The interviews were conducted by the researcher according to a predetermined semi-structured guide (see Table 1); they were audio-recorded and field notes were documented. All information was confidentially handled as per the rules of the Karolinska Institutet Research Ethics Committee which approved this study (Dnr 460/00). Each interview lasted between 30 and 90 minutes and all were performed within a six month period. An interview outline was used, based on the chosen theoretical frameworks which guided this study, but this was only a guideline since we were interested in the inductive method of describing mothers’ experiences and not their answers to specific closed questions.
Table 2: Description of the sample of “mother-child dyads”

<table>
<thead>
<tr>
<th>Age of mother</th>
<th>Previous children</th>
<th>Preterm infants</th>
<th>Twins</th>
<th>Full term infants</th>
<th>NICU Stay</th>
<th>Hands-on help</th>
<th>Age of infants at interview</th>
<th>Breastfeeding at interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 y.o.</td>
<td>No</td>
<td>X</td>
<td></td>
<td>2 weeks</td>
<td>Yes</td>
<td>2 1/2 month</td>
<td>Exclusive breastfeeding</td>
<td></td>
</tr>
<tr>
<td>29 y.o.</td>
<td>No</td>
<td>X</td>
<td></td>
<td>2 days</td>
<td>Yes</td>
<td>2 month</td>
<td>Exclusive breastfeeding</td>
<td></td>
</tr>
<tr>
<td>32 y.o.</td>
<td>Yes</td>
<td>X</td>
<td>X</td>
<td>1 month</td>
<td>Yes</td>
<td>3 month</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>35 y.o.</td>
<td>Yes</td>
<td>X</td>
<td>X</td>
<td>2 weeks</td>
<td>Yes</td>
<td>2 1/2 month</td>
<td>Partial breastfeeding</td>
<td></td>
</tr>
<tr>
<td>29 y.o.</td>
<td>No</td>
<td>X</td>
<td>X</td>
<td>1 month</td>
<td>Yes</td>
<td>2 1/2 month</td>
<td>Partial breastfeeding</td>
<td></td>
</tr>
<tr>
<td>35 y.o.</td>
<td>Yes</td>
<td>X</td>
<td>X</td>
<td>2 month</td>
<td>Yes</td>
<td>4 month</td>
<td>Partial breastfeeding</td>
<td></td>
</tr>
<tr>
<td>31 y.o.</td>
<td>No</td>
<td>X</td>
<td>X</td>
<td>4 month</td>
<td>Yes</td>
<td>4 1/2 month</td>
<td>Partial breastfeeding</td>
<td></td>
</tr>
<tr>
<td>32 y.o.</td>
<td>Yes</td>
<td>X</td>
<td></td>
<td>1 1/2 month</td>
<td>Yes</td>
<td>4 month</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>29 y.o.</td>
<td>No</td>
<td>X</td>
<td></td>
<td>2 weeks</td>
<td>Yes</td>
<td>3 month</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Note: Sick full term infants who are admitted to the NICU usually suffer from hypoglycemia, infection or are under observation after a complicated birth.

Theoretical framework

The study was based on three intermeshed theories: Gustafsson’s SAUK model,35,36 Orem’s self-care theory,47,48 and Aarts’ Marte Meo pedagogical approach.39 In the breastfeeding support interventions, these three theories complement each other.

Gustafsson describes the interrelations which should take place between a professional and a client, influencing self-knowledge and self-esteem of both parents and staff. This “confirming care” is of importance especially when we are vulnerable, so here it is particularly relevant for parents who are very emotional with their premature or sick newborn. The abbreviation (SAUC) for this model stands for Sympathy-expressing, Acceptance-establishing, Understanding, Competence-manifesting.35

Very much linked to the Gustafsson’s model is the self-care model from Orem.37 In her description of the nurse’s role, Orem insists on actions empowering parents who act as self-care agents for their dependent newborn. Nurses can help parents understand the baby’s experiences, so they can gradually learn how to take responsibility for this new baby, with actions to encourage their self-knowledge and their self-confidence as new parents.

In supporting positive actions from the parents, nurses can reinforce their self-confidence in caring for this fragile baby; this is the basis of the Aarts’ pedagogical model. In fact, according to Aarts, the Marte-Meo method should be used as a code of conduct with the parents.39 For her, the very first step consists of increasing parents’ knowledge so to help them feel competent and essential to their baby’s health from this very moment.

Data analysis

Interviews were transcribed from their audio-recorded form onto paper using Word software. Then, Radnitzky’s principles for hermeneutic interpretation were used to analyze those qualitative data.40 For this type of analysis, the person analyzing the data should have knowledge about the subject being analyzed and make sure she is open to neutrality of the data as well as to interpretation involving constant renewal and creativity. The interpretation is considered complete only when the text is well integrated and does not contain any logical contradictions. This model extends understanding from what is called a hermeneutic circle or coil. The interviews are carefully analyzed to identify significant clusters of information, sequences of meaning under the form of themes and sub-themes. Theme interpretations are given to these clusters of information and then tested against the text as a whole or against other texts. The text should be understandable from its own context, not needing any additions from other sources or contexts. Mothers should be included into the study until saturation of data is reached, i.e. until there is repetition of what has already been revealed by the mothers in the study.

In this present research on the experiences of mothers with support given by the NICU staff during breastfeeding situations with their premature or sick baby, fifty initial themes were identified, later on reduced to ten main themes after discussions with experts and close comparison of data from the interviews. This article only focuses on one of these main themes: the hands-on approach of the staff in supporting mothers to breastfeed. From the analysis of data and following lengthy discussions with experts, this main theme was revealed from the interviews into five sub-themes: Insult to integrity, Manipulating the baby, Understanding and adjustment, Breasts as objects, Alternatives to hands-on support.

Credibility of the findings

Lincoln and Guba refer to credibility as the confidence one can have in the neutrality and conformity of the results to the message of the informants.41 Tobin and Begley insist on the importance of establishing credibility and confirmability.42 So, in order to avoid biases during the analysis, an expert researcher has listened to tapes, read a transcription of the interviews, and compared them; the reviewer agreed that the written texts corresponded to the recorded interviews. Afterwards, initial identification of themes and sub-themes was done by the principal investigator. Two other researchers agreed on the results of the analysis of a random selection of 50% of the written interviews. Quotes from the mothers themselves are presented as examples of the results and they serve to illustrate the discussion.

Results

Sixteen mothers were informed about the study and twelve agreed to participate. The four mothers who refused to participate did not give reasons for their refusal. Twelve mothers answered all questions from the semi-structured questionnaire, including two mothers who did not experience the hands-on approach. We did not wait for the 50% of mothers from each category as intended since we had already reached saturation of data with 12 mothers. This article deals only with
the ten mothers who have experienced hands-on approach. Eight of the ten mothers were of Swedish origin and two were of other ethnic background. The mothers were aged 26 to 35 years; five were multiparas and five primiparas. Seven mothers had given birth to premature newborns including three mothers who had twins. Three mothers of sick term infants were also recruited in order to have representation of infants from each category of babies in the NICU. The mother-child pairs are briefly described in Table 2. At the time of the interviews, eight mothers were breastfeeding, three of them exclusively. Two were not breastfeeding.

Results have been subdivided into sub-themes: Insult to integrity, Manipulating the baby, Understanding and adjustment, Breasts as objects, Alternative to hands-on approach.

Insult to integrity
Mothers felt they needed support and assistance when starting to breastfeed their premature or sick newborn, especially on how to hold the baby and to offer the breast so the baby could latch-on as easily as possible. Eight out of ten mothers described how annoyed they felt when nurses gave hands-on help without information in advance: "To be honest, she went straightforward and took my breast, and pushed it into the baby’s mouth. You are nice and do not say anything even though you are boiling from anger when she does that. She does not ask and I do not want her help. You say perhaps mildly that it is okay, I could do this by myself."

These mothers said they experienced the hands-on assistance as slightly brutal, unpleasant, and that it violated their integrity. Two mothers explained that older nurses, with much clinical experience, often helped using the hands-on approach. Mothers said it mattered more to them if they trusted the person who was helping.

“She tried to open the mouth… it was okay that some did this but it was difficult for me when I did not know the staff well. I think they should have asked. They pushed the head until, from my point of view, it was almost suffocated… it did not help at all.”

Two mothers did not regard the hands-on help as unpleasant. They considered it valuable and thought it was easier to know how to do it if you had seen someone else doing it: “I think it was quite good to get some help. Perhaps it would have been nice if we had talked about it before.”

Four mothers reported the importance of how nurses supported them but how they sometimes felt that their intimate territory was not respected: “It was as if she (the nurse) went over a line. She sat too near to me and disturbed me when I practiced (breastfeeding). She stood too long and inspected in some way.”

Mothers gave suggestions on how to improve breastfeeding support. All of them said it was important that the staff asked before they gave the hands-on help: “It might have been better if they had spent more time and had sat down. He (the baby) could have the opportunity to find the breast by himself and I could have seen how he works, if he needed help and in what way, instead of pushing him there at once.”

Manipulating the baby
Mothers who had received hands-on help spoke about when their babies were learning to suck. One experience that seems to have been negative to eight mothers was when the nurse squeezed the breast into the baby’s mouth. The mothers reported this as a strange feeling, and they did not want it to be repeated: “The first times… I wondered what they were doing. They just pushed the breast into (the baby’s) mouth. It surprised me that they did this at all… It was mostly in the beginning it was slightly unpleasant… It was a strange feeling.”

Three mothers reported that the nurse pushed one of the child’s arms behind the back while they were breastfeeding. The mothers did not understand the reason for this, as they thought the baby liked to have the arm at the breast while sucking. Seven mothers also felt exposed when other persons and staff were around while the nurse was touching them with her hands on their breast: “You are so exposed in some way. I thought this was bothersome… I thought it felt too private when people were around, other mothers and fathers, and they pulled and pushed the breasts any way.”

Understanding and adjustment
Eight mothers said they felt shy from the start, when expected to breastfeed in the nursery in front of parents and nursing staff. They described how they got used to this after a while. In the NICU, mothers were breastfeeding in a room shared by five babies and their parents as well as the nursing staff. Mothers report that they understand nurses doing this hands-on in front of everyone since they were used to it and they felt it was normal: “It might be their way of doing it, to get you going with the breastfeeding… but I do not like it. It might be difficult to do it in another way. I do not think it is funny when someone is pulling at your breast, but you have to accept the situation.”

Most of the women said they did not understand why the physical help was given. They really wondered about its purpose. They stressed that as time went by, they grew dependent on staff for assistance in breastfeeding, and sometimes wondered how they would manage when the staff would be no longer available.

The two mothers who did not dislike the hands-on approach explained this type of help suited them but they could understand that other mothers would not appreciate it: “I do not care if someone touches me. If I think of other mothers I met there, who were not so self-confident, they might have thought it more pleasant to look first and then try.”

Breasts as objects
Five women felt that their breasts did not belong to them, that they were not parts of their body, more like inanimate objects. Two mothers even reported that they developed a new relationship with their breasts when they started to breastfeed. When the nursing staff touched the breasts, two mothers felt that their breasts were transformed into objects rather than a part of themselves: “My breasts were changed… They felt more as objects. It was somewhat unpleasant but it felt strange to touch them by yourself afterwards… I have still not recovered the feeling that everything is normal.”

Alternatives to hands-on support
All mothers expressed a need for assistance when starting breastfeeding, but were not positive about the use of hands-on approach. The mothers did not recognize that alternatives to hands-on help in the breastfeeding situation existed: “It was

neonatal INTENSIVE CARE Vol. 20 No. 2 • March-April 2007
good that they showed it but the situation is not so funny because you are so exposed, but I do not think there is any alternative.”

After the mothers shared their spontaneous thoughts about the hands-on approach with the researcher, they were asked if they could suggest some alternatives. All the mothers described how they would have preferred the breastfeeding guidance given to them, for example, that nurses sit down besides them and spend more time sharing information and practical advice. The mothers were then questioned about the use of a doll and an artificial breast in order to demonstrate positioning and latching-on (Figure 2). No mother had even considered this alternative. Nine of them were positive about this visual alternative. Two mothers explained that this could also be a way of confirming that they had understood correctly: “I have never thought about it. It might be an alternative, and perhaps already from the start.”

After sharing their thoughts with the investigator, several mothers realized they perhaps would have needed a different type of support from nurses: “I now realize that it was not exactly the type of help I needed.”

The original research report illustrates more examples of each category.18

**Discussion**

According to Orem, the aim of nursing care with persons capable to act on their own care or that of their dependents, is to inform the persons, and to support them in their self-care capacities.37,38 According to this, mothers should get individualized and respectful support to learn how to take care of their babies in NICU. In this study, most mothers described how they received care they did not understand, through professional behaviors they did not like, and that made them upset. According to Gustafsson, healthcare workers intend to perform good care but do not necessarily behave in such a way that achieves this.36 In fact, some behaviors described by the mothers in this study appeared unacceptable to them. However, nurses were not questioned as to their behaviors and the meaning they give to them; this could be an interesting exploratory study to do. We already know that the environment in a NICU may not be optimal for nurses with all the premature or sick babies, and anxious parents. Nurses need to be knowledgeable in specialized and more medical types of neonatal care, but also in normal newborn care such as breastfeeding. However, babies in the NICU rarely behave like term healthy newborns when it comes to breastfeeding. So nurses have to be more knowledgeable but also more patient, with the babies and with the parents. Gustafsson36 and Orem37,38 argue that the nurse’s role involves being sensitive to the parents’ anxiety and need of support, that the nurse needs to help parents understand the difficulties their baby is experiencing and the different ways they could use to compensate or adjust to them. Aarts39 would encourage nurses to teach parents in a very personalized manner so they can realize that there are many pathways to successful breastfeeding and that they will gradually find them with their baby and feel more and more competent about it. In this study, most mothers felt that the permitting dialogue was missing, that they had not been informed about the hands-on approach so they could agree to it.

**Insult to integrity**

The mothers reported about their experience from hands-on assistance in the breastfeeding situation, describing it as unpleasant, shocking, irritating, and disrespectful. We have not found any other study that reports mothers' experience with the hands-on approach or which has evaluated the mothers’ feelings in that situation. Most were concerned with breastfeeding outcomes and not mothers’ feelings. One of our basic questions remains unanswered: Is it possible that mothers’ feelings in this type of situation explain the shorter period of breastfeeding when the staff use hands-on? We believe this practice is intrusive and disempowering for mothers, and that it could hinder their self-confidence to breastfeed, as Ingram and colleagues point out in the background of their article.11

Orem suggests different care systems, one of which is the support and information system for persons capable to care for themselves and their dependents.37,38 To enhance the mother’s self-confidence, this type of care system is warranted. Nurses may spontaneously choose Orem’s first system: the “doing it for the person who can’t do it,” by lack of time, as support and information are expected to take a long time. However, they have to realize that the hands-on approach may be quicker to perform, but may hinder the mother's confidence in her capacities in the long run. In fact, if more time was spent on support and information in the first place, mothers would feel respected and guided into becoming more competent to care for their special baby; they could quickly become more knowledgeable and more autonomous. In this study, it was the opposite for eight mothers out of ten; they felt their integrity was not respected by the hands-on approach which had not been explained before being performed.

**Understanding and adjustment**

The eight mothers who reported that they did not agree with this spontaneous hands-on approach showed understanding and acceptance of the nurses’ actions. This understanding could be explained by the mothers’ dependence on nursing staff for this very special care their baby needed in the NICU, but it could also be explained by their wish for the best care possible for their fragile baby. According to Stern,2 in showing acceptance, mothers may try to protect this new life and in doing so, choose to trust the nurses’ competence.

The mothers also reported that the hands-on assistance was often performed without information or teaching beforehand on how to help baby adequately to the breast, and even without previous attempts from their part to have the infant attached to the breast. They accepted the hands-on assistance as they did not know any alternative to this practice to help them with the new breastfeeding situation. The mothers in this study stressed that they needed the nurses’ support and because of this, they chose not to say they did not appreciate the hands-on approach. They felt dependent so they adjusted to the nurses’ behaviors. Armgaard argues that by giving freedom to act, you participate in the exercise of power.43 By not saying anything about what they disliked, the mothers did not have the opportunity to be involved in the decisions concerning their body and their wishes for positive experience in breastfeeding their fragile infant. We don’t know of any study which reported similar feelings and experiences of mothers.

**Breasts as objects**

Women and society in general, have given different meanings to
breasts, and to breast touching by other people. Breasts are associated with the passage from girlhood to adulthood, sexual pleasure, and eroticism. But breasts also are inevitably linked to breastfeeding. Modern women often express feelings about their breasts,14 how they seem: too large, too small or not “good enough,” and how feminine or not feminine they feel when looking at them. From all times, breasts have been linked to both good and evil, leading to this ambivalent view of breasts as per their maternal and their sexual aspects.14 Breasts having different meanings for different women, more attention needs to be paid to professional behavior when teaching breastfeeding and especially latching-on to the breast.

Breast touching by other people is also very much a social act, generally accepted between intimate partners. The body itself, and not only breasts, is known to have its own territory (near zone) which cannot be crossed without permission, against often only intimate partners. According to Norberg and colleagues, if this is not respected, the person will feel invaded and often react strongly or escape inside her body so not to be concerned about what happens on the body surface.15

In this study, the hands-on assistance contributed to the mothers having an altered opinion of their own breasts. Mothers reported that their breasts became objects, handled by strangers in order to get baby to latch-on. They also felt their body territory was invaded but could not react too much to it since breasts now had become utilitarian in order to feed their newborn.

Alternatives to hands-on support
All mothers expressed a need for assistance when starting breastfeeding, but could not suggest any alternative other than verbal explanations and more time devoted to be present near the mother. Maybe the fact that they understood and adjusted to this approach explains that they did not look for other ways to deal with this teaching situation. When presented with the possibility of doing this type of teaching with a doll and a breast made of fabric, nine mothers agreed they would have preferred this method but had not thought about it. There are different ways to communicate, educate and inform mothers how they could support the babies to latch-on without the staff using hands-on. For example, nurses could use verbal information, videos about latch, group teaching, and so on.10 The use of a doll and an artificial breast is easily acceptable within the framework used for this study. In fact, this method connects to Orem's information and support system since the purpose is to create a milieu that, through education, stimulates Orem’s information and support system since the purpose is to create a milieu that, through education, stimulates confidence and autonomy, and professional approaches to attain the mother's own capacities and self-confidence. More research is needed pertaining to approaches for supporting and teaching parents in breastfeeding situations with fragile infants in NICU.

This study also emphasizes the importance of basing nursing research on nursing theoretical frameworks in order to guide reflection and action. It has contributed to increased knowledge in three nursing theories, Gustafsson’s, Orem’s, and Aart’s, and about interrelations between those three theories. We have shown that they complete each other in explaining the capacities of the person, the nurse’s role in supporting mothers’ confidence and autonomy, and professional approaches to attain this goal. More research needs to be done in this area.

References
11 Duffy EP, Percival P, Hershaw E: Positive effects of an


14 Fletcher D, Harris H: The implementation of the HOT program at the Royal Women’s Hospital. Breastfeed Rev 2000, 8:19-23.


Provision of Taped Conversations With Neonatologists to Mothers of Babies in Intensive Care: Randomized Controlled Trial

Tieh Hee Hai Guan Koh, Phyllis N Butow, Michael Coory, Donna Budge, Li-An Collie, John Whitehall, Martin H Tattersall

Abstract

Objective: To determine whether providing mothers of babies in neonatal intensive care units with audiotapes of their conversations with a neonatologist improves recall of information and psychological wellbeing.

Design: Randomized, single blinded trial.

Setting: Neonatal intensive care unit, North Queensland, Australia.

Participants: 200 mothers of babies in a neonatal intensive care unit.

Interventions: Mothers given (n=102) or not given (n=98) audiotapes of their conversations with a neonatologist.

Main outcome measures: Recall of information, attitudes to and use of the tape, satisfaction with conversations, postnatal depression, anxiety, general health, and stress about parenting, at 10 days and four and 12 months.

Results: 91% (n = 93) of mothers in the tape group listened to the tape (once by day 10, twice by four months, and three times by 12 months, range 1-10). At 10 days and four months, mothers in the tape group recalled significantly more information about diagnosis, treatment, and outcome than mothers in the control group. At four months mothers in the tape group were 75% more likely to recall all of the information about treatment than mothers in the control group (59% vs. 34%; risk ratio 1.75, 95% confidence interval 1.27 to 2.4). Six mothers, all in the control group, could not recall their conversations. No statistically significant differences were found between the groups in satisfaction with conversations (10 days), postnatal depression and anxiety scores (10 days, four and 12 months), and stress about parenting (12 months).

Conclusion: Providing the mothers of babies in neonatal intensive care units with audiotapes of conversations with a neonatologist enhanced their recall of information (up to four months). The taped conversations did not affect the mothers’ wellbeing or satisfaction with the neonatologist.

Introduction

The parents of babies in neonatal intensive care units often do not recall information. Effective communication between doctors and parents underpins family centered care and is a key recommendation of the Bristol inquiry. Several studies have found that giving adults with cancer an audiotape of their initial conversations with oncologists improved their psychological distress, anxiety, satisfaction with conversations, and recall of information whereas other authors found no benefits. No reports exist on the effect of providing the mothers of babies in neonatal intensive care units with an audiotape of their conversations with the neonatologist. We carried out a randomized single blind trial to compare the effects of providing or not providing mothers of babies in neonatal intensive care units with an audiotape of their conversations with the neonatologist. We hypothesized that giving the mothers the tape would improve their recall of information and reduce psychological morbidity.

Methods

The neonatal intensive care unit at the Townsville Hospital, the regional neonatal unit for North Queensland, has three full time neonatologists and comprises 10 intensive care cots and 20 step-down cots. The unit looks after 150 ventilated babies a year. Mothers were eligible for the study if their babies were admitted to the unit, they understood English or had an interpreter; and they consented to be recruited. We excluded mothers receiving psychiatric care or those whose baby needed to be transferred interstate during the first week of life.
The study was a randomized controlled trial of audiotape provision, with the neonatologist and neonatal team blinded to the participant’s allocation. Before the first conversation the mothers completed a questionnaire eliciting personal details, anxiety scores, and preferences for information and involvement in decision making. The researcher then contacted a clinical trials centre randomization service and the mother was allocated to receive or not to receive a copy of the taped conversations with a neonatologist. The randomization schedule was generated using a computerized sequence with variable blocks. After randomization the initial conversation and subsequent conversations of significance (as identified by the neonatologist—for example, babies with pneumothorax, patent ductus arteriosus needing treatment, necrotizing enterocolitis, fits, cerebral injuries) were taped using a portable cassette recorder (PMD101; Marantz) and a copy retained for transcription and analysis. The mothers in the experimental arm received a tape of each of the conversations and a portable tape recorder (TCM-353; Sony).

Ten days and four months after the initial conversation the researcher carried out a structured interview with the mothers to document their recall of the diagnosis, tests, treatment, and outcome of their babies as conveyed by the neonatologist. Mothers also completed a questionnaire to ascertain views of the taping, use of the tapes, anxiety state, general health, depression, marital satisfaction, social support, and satisfaction with conversations held with the neonatologist.

At 12 months’ follow-up mothers were sent the same questionnaire by post, with a stamped addressed envelope for return of the completed questionnaire. Non-respondents were telephoned a maximum of twice and contacted once by post.

Outcome measures
Recall of information was assessed by face to face or telephone interview. The interview opened with a broad question inviting mothers to report what the neonatologist had told them and their understanding of what that meant. If the answers were incomplete then five prompts followed on diagnosis, tests, treatment, and prognosis; responses were recorded on an interview form. Transcripts of each taped conversation were coded by a neonatologist (THHGK) to itemize the information in each category. The number of facts recalled by the mothers was expressed as a percentage of the total facts presented. 

We used the Spielberger state anxiety inventory to measure anxiety. Postnatal depression was measured with the 10 item Edinburgh postnatal depression scale, which assesses the intensity of depressive mood during the past seven days, with a cut-off score of 12. General psychological morbidity was assessed using the general health questionnaire-12 (0 scores for non-cases, 1 or greater for cases).

The parental stress index, a self-report inventory with 101 items, measures the stress associated with a child’s characteristics and with the parenting role. We summed the scores for each child and parent domain, with the total score being the sum of the two domains. We used a 25 item five point Likert scale adapted

Table 1 Baseline characteristics of mothers with babies admitted to a neonatal intensive care unit provided with or without an audiotape of their conversations with a neonatologist. Values are numbers (percentages) of mothers unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Tape group (n=102)</th>
<th>Control group (n=98)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age (years)</td>
<td>28.1 (5.3)</td>
<td>27.2 (5.8)</td>
<td>P=0.27, K=1.1</td>
</tr>
<tr>
<td>Ethnicity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>86 (84)</td>
<td>81 (83)</td>
<td></td>
</tr>
<tr>
<td>Aboriginal and Torres Straits Islanders</td>
<td>14 (14)</td>
<td>14 (14)</td>
<td>P=0.87, χ²=0.27</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (2)</td>
<td>3 (3)</td>
<td></td>
</tr>
<tr>
<td>Marital status:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partner</td>
<td>92 (90)</td>
<td>86 (88)</td>
<td>P=0.58, χ²=0.3</td>
</tr>
<tr>
<td>Single</td>
<td>10 (10)</td>
<td>12 (12)</td>
<td></td>
</tr>
<tr>
<td>Education:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>School certificate*</td>
<td>21 (22)</td>
<td>32 (38)</td>
<td>P=0.03, χ²=6.9</td>
</tr>
<tr>
<td>Higher school certificate†</td>
<td>41 (43)</td>
<td>23 (27)</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>33 (35)</td>
<td>30 (35)</td>
<td></td>
</tr>
<tr>
<td>Parity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>38 (38)</td>
<td>45 (46)</td>
<td>P=0.29, χ²=2.4</td>
</tr>
<tr>
<td>2-4</td>
<td>57 (56)</td>
<td>44 (45)</td>
<td></td>
</tr>
<tr>
<td>≥5</td>
<td>6 (6)</td>
<td>8 (8)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)state anxiety total score</td>
<td>51.7 (15.1)</td>
<td>51.3 (12.4)</td>
<td>P=0.81</td>
</tr>
<tr>
<td>Gravida:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>29 (29)</td>
<td>34 (35)</td>
<td>P=0.45, χ²=1.6</td>
</tr>
<tr>
<td>2-4</td>
<td>58 (57)</td>
<td>47 (49)</td>
<td></td>
</tr>
<tr>
<td>≥5</td>
<td>14 (14)</td>
<td>16 (17)</td>
<td></td>
</tr>
<tr>
<td>Previous preterm deliveries:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>90 (88)</td>
<td>75 (78)</td>
<td>P=0.06, χ²=3.6</td>
</tr>
<tr>
<td>Yes</td>
<td>12 (12)</td>
<td>21 (22)</td>
<td></td>
</tr>
<tr>
<td>In vitro fertilisation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>100 (98)</td>
<td>95 (97)</td>
<td>P=0.62, χ²=0.24</td>
</tr>
<tr>
<td>Yes</td>
<td>2 (2)</td>
<td>3 (3)</td>
<td></td>
</tr>
<tr>
<td>Caesarean section:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>40 (39)</td>
<td>46 (47)</td>
<td>P=0.46, χ²=1.5</td>
</tr>
<tr>
<td>Elective</td>
<td>21 (21)</td>
<td>15 (15)</td>
<td></td>
</tr>
<tr>
<td>Emergency</td>
<td>41 (40)</td>
<td>37 (38)</td>
<td></td>
</tr>
</tbody>
</table>

*School years 7-10.
†School years 11 and 12.
Table 2 Baseline characteristics of babies admitted to a neonatal intensive care unit. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Tape group (n=102)</th>
<th>Control group (n=98)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>58 (57)</td>
<td>55 (56)</td>
<td>P=0.17, $\chi^2=1.89$</td>
</tr>
<tr>
<td>Female</td>
<td>44 (43)</td>
<td>33 (34)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) gestational age (weeks)</td>
<td>32.6 (0.48)</td>
<td>33.6 (0.51)</td>
<td>$P=1.5$</td>
</tr>
<tr>
<td>Mean (SD) birth weight (g)</td>
<td>2114 (1122)</td>
<td>2210 (1122)</td>
<td>$P=0.6$</td>
</tr>
<tr>
<td>Plurality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton</td>
<td>90 (88)</td>
<td>92 (94)</td>
<td></td>
</tr>
<tr>
<td>Twin</td>
<td>10 (10)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>Triplets</td>
<td>1 (1)</td>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td>Clinical risk index for babies score:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>79 (78)</td>
<td>70 (71)</td>
<td>P=0.33, $\chi^2=2.22$</td>
</tr>
<tr>
<td>6-10</td>
<td>19 (19)</td>
<td>26 (27)</td>
<td></td>
</tr>
<tr>
<td>&gt;10</td>
<td>4 (4)</td>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td>Hyaline membrane disease:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>10 (10)</td>
<td>15 (15)</td>
<td>P=0.17, $\chi^2=3.5$</td>
</tr>
<tr>
<td>Mild</td>
<td>20 (20)</td>
<td>11 (11)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>72 (71)</td>
<td>72 (74)</td>
<td></td>
</tr>
<tr>
<td>Sepsis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>75 (74)</td>
<td>66 (67)</td>
<td>P=0.34, $\chi^2=0.9$</td>
</tr>
<tr>
<td>Yes</td>
<td>27 (27)</td>
<td>32 (33)</td>
<td></td>
</tr>
<tr>
<td>No of days on ventilator:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td>25 (25)</td>
<td>28 (29)</td>
<td>P=0.33, $\chi^2=3.4$</td>
</tr>
<tr>
<td>2-3</td>
<td>37 (36)</td>
<td>24 (25)</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>19 (18)</td>
<td>19 (19)</td>
<td></td>
</tr>
<tr>
<td>&gt;6</td>
<td>22 (22)</td>
<td>27 (28)</td>
<td></td>
</tr>
<tr>
<td>No of days to reach full feeds:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-3</td>
<td>25 (25)</td>
<td>23 (24)</td>
<td>P=0.50, $\chi^2=2.3$</td>
</tr>
<tr>
<td>4-7</td>
<td>30 (29)</td>
<td>32 (33)</td>
<td></td>
</tr>
<tr>
<td>8-11</td>
<td>20 (20)</td>
<td>12 (12)</td>
<td></td>
</tr>
<tr>
<td>&gt;12</td>
<td>27 (27)</td>
<td>31 (32)</td>
<td></td>
</tr>
<tr>
<td>Intraventricular haemorrhage:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>93 (91.2)</td>
<td>91 (92.9)</td>
<td>P=0.91, $\chi^2=19$</td>
</tr>
<tr>
<td>Grade I or II</td>
<td>4 (4)</td>
<td>3 (3)</td>
<td></td>
</tr>
<tr>
<td>Grade III or IV</td>
<td>5 (5)</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>83 (81)</td>
<td>80 (82)</td>
<td>P=0.88, $\chi^2=0.25$</td>
</tr>
<tr>
<td>Simple</td>
<td>9 (9)</td>
<td>10 (10)</td>
<td></td>
</tr>
<tr>
<td>Complex</td>
<td>10 (10)</td>
<td>8 (8)</td>
<td></td>
</tr>
<tr>
<td>Outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Died</td>
<td>14 (14)</td>
<td>9 (9)</td>
<td>P=0.56, $\chi^2=0.03$</td>
</tr>
<tr>
<td>Alive, uncertain prognosis</td>
<td>9 (9)</td>
<td>8 (8)</td>
<td></td>
</tr>
<tr>
<td>Alive, good prognosis</td>
<td>79 (78)</td>
<td>80 (82)</td>
<td></td>
</tr>
<tr>
<td>Length of stay (days) in neonatal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>intensive care unit:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-9</td>
<td>21 (21)</td>
<td>21 (21)</td>
<td>$P=0.91, \chi^2=1.56$</td>
</tr>
<tr>
<td>10-19</td>
<td>22 (22)</td>
<td>25 (26)</td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>17 (17)</td>
<td>11 (11)</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>14 (14)</td>
<td>14 (14)</td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>9 (9)</td>
<td>10 (10)</td>
<td></td>
</tr>
<tr>
<td>≥50</td>
<td>19 (19)</td>
<td>17 (17)</td>
<td></td>
</tr>
<tr>
<td>Apgar score at 5 minutes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-3</td>
<td>3 (3)</td>
<td>6 (6)</td>
<td>P=0.55, $\chi^2=1.2$</td>
</tr>
<tr>
<td>4-7</td>
<td>30 (29)</td>
<td>27 (28)</td>
<td></td>
</tr>
<tr>
<td>8-10</td>
<td>68 (68)</td>
<td>65 (66)</td>
<td></td>
</tr>
</tbody>
</table>

from scales of proved sensitivity to tape provision to measure satisfaction with the conversation.\textsuperscript{17}

Satisfaction with the tape was measured using a scale based on usefulness of tapes to patients with cancer.\textsuperscript{18} We elicited information and preferences for involvement using a scale assessing the type and amount of information required and the level of involvement in decision making.\textsuperscript{19} Satisfaction with an

Table 3 Mothers having 100% recall about diagnosis, tests, treatment, and outcome of their babies in a neonatal intensive care unit, according to group. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Tape group (n=102)</th>
<th>Control group (n=98)</th>
<th>Relative risk* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>73 (72)</td>
<td>52 (53)</td>
<td>1.35 (1.08 to 1.69)</td>
<td>0.007</td>
</tr>
<tr>
<td>Tests</td>
<td>43 (42)</td>
<td>39 (40)</td>
<td>1.06 (0.83 to 1.34)</td>
<td>0.734</td>
</tr>
<tr>
<td>Treatment</td>
<td>64 (63)</td>
<td>47 (48)</td>
<td>1.83 (1.04 to 3.21)</td>
<td>0.035</td>
</tr>
<tr>
<td>Outcome</td>
<td>84 (82)</td>
<td>65 (66)</td>
<td>1.24 (1.05 to 1.47)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Table 4 Postnatal depression and psychological morbidity at follow-up in mothers of babies in a neonatal intensive care unit, according to group. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Measure</th>
<th>Tape group (n=102)</th>
<th>Control group (n=98)</th>
<th>Relative risk* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edinburgh postnatal depression score (&gt;12)*</td>
<td>48 (47)</td>
<td>40 (41)</td>
<td>1.15 (0.84 to 1.58)</td>
<td>0.37</td>
</tr>
<tr>
<td>4 months</td>
<td>13 (13)</td>
<td>18 (18)</td>
<td>0.9 (0.46 to 1.76)</td>
<td>0.75</td>
</tr>
<tr>
<td>12 months</td>
<td>12 (12)</td>
<td>10 (10)</td>
<td>1.15 (0.52 to 2.5)</td>
<td>0.72</td>
</tr>
<tr>
<td>General health questionnaire score (&gt;11)*</td>
<td>66 (65)</td>
<td>65 (66)</td>
<td>0.99 (0.8 to 1.2)</td>
<td>0.92</td>
</tr>
<tr>
<td>4 months</td>
<td>41 (40)</td>
<td>35 (36)</td>
<td>1.13 (0.8 to 1.6)</td>
<td>0.51</td>
</tr>
<tr>
<td>12 months</td>
<td>23 (23)</td>
<td>23 (24)</td>
<td>0.96 (0.6 to 1.6)</td>
<td>0.88</td>
</tr>
</tbody>
</table>

*Mothers with score \(>12\) most likely to have a depressive illness and should be further assessed. 10 score for non-cases, 1 or greater for cases of greater distress.

Table 5 Psychometric outcomes, satisfaction with conversation, and parenting stress index

<table>
<thead>
<tr>
<th>Measure</th>
<th>Tape group (n=102)</th>
<th>Control group (n=98)</th>
<th>Adjusted difference in means (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>State anxiety inventory score*</td>
<td>2.03 (-1.42 to 5.48)</td>
<td>0.25 (-2.84 to 5.05)</td>
<td>0.58</td>
<td></td>
</tr>
<tr>
<td>4 months</td>
<td>2.04 (-0.96 to 4.96)</td>
<td>0.167 (-0.39 to 6.27)</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>0.42 (-2.2 to 3.05)</td>
<td>0.75 (-4.36 to 3.94)</td>
<td>0.92</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with conversation†</td>
<td>0.11 (-4.04 to 4.05)</td>
<td>0.99 (0.58 to 4.00)</td>
<td>0.738</td>
<td></td>
</tr>
<tr>
<td>Parental stress index‡</td>
<td>0.03 (0.02 to 1.77)</td>
<td>0.62 (0.28 to 1.39)</td>
<td>0.079</td>
<td></td>
</tr>
<tr>
<td>Parental domain</td>
<td>0.43 (0.12 to 1.62)</td>
<td>0.230 (0.50 to 1.88)</td>
<td>0.778</td>
<td></td>
</tr>
</tbody>
</table>

*Higher scores denote greater anxiety.  
†Five point Likert scale; higher scores denote higher satisfaction.  
‡Higher scores denote higher stress.

intimate relationship was measured using the relational interaction satisfaction scale.\textsuperscript{20} For social support we used the six item Sarason social support questionnaire to assess the size of the support network (availability score) and satisfaction with support (satisfaction score).\textsuperscript{21}

The clinical risk index for babies is a scoring system predicting mortality in hospital among high risk babies in neonatal care.
Table 6 Mothers with 100% recall of diagnosis, tests, treatment, and outcome of their babies in a neonatal intensive care unit, at 10 days and 4 months follow-up, according to babies’ prognosis. Values are numbers (percentages) unless stated otherwise.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Tape group</th>
<th>Control group</th>
<th>Relative risk (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babies with a good outcome (tape group n=79; control group n=81)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 days:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>59 (75)</td>
<td>41 (51)</td>
<td>1.47 (1.15 to 1.89)</td>
<td>0.002</td>
</tr>
<tr>
<td>Tests</td>
<td>32 (41)</td>
<td>33 (41)</td>
<td>0.99 (0.58 to 1.26)</td>
<td>0.82</td>
</tr>
<tr>
<td>Treatment</td>
<td>52 (66)</td>
<td>39 (48)</td>
<td>1.37 (1.04 to 1.8)</td>
<td>0.024</td>
</tr>
<tr>
<td>Outcome</td>
<td>68 (86)</td>
<td>57 (70)</td>
<td>1.22 (1.04 to 1.46)</td>
<td>0.016</td>
</tr>
<tr>
<td>4 months:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>52 (66)</td>
<td>42 (52)</td>
<td>1.27 (0.98 to 1.65)</td>
<td>0.07</td>
</tr>
<tr>
<td>Tests</td>
<td>36 (46)</td>
<td>31 (38)</td>
<td>1.19 (0.82 to 1.7)</td>
<td>0.35</td>
</tr>
<tr>
<td>Treatment</td>
<td>48 (61)</td>
<td>30 (37)</td>
<td>1.16 (1.17 to 2.3)</td>
<td>0.003</td>
</tr>
<tr>
<td>Outcome</td>
<td>67 (85)</td>
<td>57 (70)</td>
<td>1.20 (1.02 to 1.43)</td>
<td>0.029</td>
</tr>
<tr>
<td>Babies with a poor outcome (tape group n=23; control group n=17)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 days:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>14 (61)</td>
<td>11 (65)</td>
<td>0.94 (0.58 to 1.52)</td>
<td>0.804</td>
</tr>
<tr>
<td>Tests</td>
<td>11 (48)</td>
<td>6 (35)</td>
<td>1.53 (0.63 to 2.9)</td>
<td>0.43</td>
</tr>
<tr>
<td>Treatment</td>
<td>12 (52)</td>
<td>8 (47)</td>
<td>1.11 (0.58 to 2.09)</td>
<td>0.75</td>
</tr>
<tr>
<td>Outcome</td>
<td>16 (70)</td>
<td>8 (48)</td>
<td>1.48 (0.83 to 2.6)</td>
<td>0.15</td>
</tr>
<tr>
<td>4 months:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>13 (57)</td>
<td>7 (41)</td>
<td>1.37 (0.70 to 2.69)</td>
<td>0.34</td>
</tr>
<tr>
<td>Tests</td>
<td>9 (39)</td>
<td>4 (24)</td>
<td>1.66 (0.61 to 4.5)</td>
<td>0.30</td>
</tr>
<tr>
<td>Treatment</td>
<td>12 (52)</td>
<td>3 (18)</td>
<td>2.96 (0.88 to 8.87)</td>
<td>0.026</td>
</tr>
<tr>
<td>Outcome</td>
<td>8 (35)</td>
<td>4 (24)</td>
<td>2.8 (1.12 to 6.87)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Table 7 Psychological wellbeing and stress about parenting of mothers with babies in a neonatal intensive care unit with a poor outcome. Values are percentages (numbers) of mothers unless stated otherwise.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Tape group</th>
<th>Control group</th>
<th>Relative risk (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edinburgh postnatal depression score &gt;12‡:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 days</td>
<td>60 (12/20)</td>
<td>36 (5/14)</td>
<td>1.68 (0.76 to 3.7)</td>
<td>0.16</td>
</tr>
<tr>
<td>4 months</td>
<td>33 (6/18)</td>
<td>20 (2/12)</td>
<td>0.64 (0.29 to 1.45)</td>
<td>0.31</td>
</tr>
<tr>
<td>12 months</td>
<td>19 (3/16)</td>
<td>27 (3/11)</td>
<td>0.69 (0.17 to 2.8)</td>
<td>0.60</td>
</tr>
<tr>
<td>General health questionnaire score &gt;11:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 days</td>
<td>79 (15/19)</td>
<td>71 (10/14)</td>
<td>1.1 (0.73 to 1.7)</td>
<td>0.62</td>
</tr>
<tr>
<td>4 months</td>
<td>56 (10/18)</td>
<td>50 (6/12)</td>
<td>1.1 (0.55 to 2.2)</td>
<td>0.76</td>
</tr>
<tr>
<td>12 months</td>
<td>40 (8/15)</td>
<td>50 (6/12)</td>
<td>0.8 (0.35 to 1.9)</td>
<td>0.60</td>
</tr>
<tr>
<td>Parenting stress index score &gt;85%*:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child domain</td>
<td>40 (2/5)</td>
<td>25 (2/6)</td>
<td>1.6 (0.32 to 8.0)</td>
<td>0.57</td>
</tr>
<tr>
<td>Parents domain</td>
<td>67 (10/15)</td>
<td>90 (9/10)</td>
<td>0.74 (0.49 to 1.1)</td>
<td>0.18</td>
</tr>
</tbody>
</table>

*Mothers with score >12 most likely to have a depressive illness and should be further assessed.
‡Score for non-cases, 1 or greater for cases of greater distress.
§Score greater than 85% indicating greater stress.

For dichotomous variables we set missing values to the mean of the other group.

We used linear and logistic multiple regression to analyse the effects of tape provision on mother’s psychological outcomes, controlling for imbalances in baseline characteristics between the two groups. We prespecified subgroup analyses according to whether the babies had good or bad prognoses.

For recall of information (dichotomized as 100% recall or less than 100% recall) we calculated that a sample size of 100 mothers in each randomized group would be sufficient to detect differences as small as 20% between the groups at a 0.05 level of significance with 80% power. This calculation assumed that the percentage of mothers in the control group with 100% recall was 50%. We used 50% because there were no published studies to guide us, and 50% gave the largest sample size for a given absolute difference. A sample size of 100 in each group was also sufficient to detect mean differences of 0.3 of a standard deviation on the psychological adjustment and parent satisfaction measures, with a power of 80%.

**Results**

Between July 1999 and December 2001, 288 mothers of babies admitted to the neonatal intensive care unit of Townsville Hospital, North Queensland, were eligible for the study. Thirty-two mothers were not approached. Two hundred of the remaining 256 mothers (78%) agreed to participate. Overall 102 mothers were randomized to receive audiotapes of their conversations with a neonatologist and 98 mothers were randomized to no tape (figure).

No important differences were found between those mothers who refused to participate and those who accepted on variables for both the mothers and their babies except that for mothers who refused more were of Aboriginal descent (43% v. 13%), parity was higher (3 v. 2), fewer babies were born in the Townsville Hospital (29% v. 65%), and the babies had fewer congenital abnormalities (7% v. 15%).

Baseline characteristics of the mothers and babies were similar in both groups except that mothers randomized to receive the tape were more likely to have had less education than those in the control group (tables 1 and 2). Measures of mothers’ baseline preferences for information and role in decision making, anxiety, and social support showed no significant differences between the groups. The modal number of conversations taped was one per mother (range 1-11), and no significant differences were found between the groups.

Participation rates at follow up at 10 days and four and 12 months were up to 95%, 89% and 84%.

**Statistical analysis**

We determined the study protocol a priori and collected and analyzed the data on an intention to treat basis using SPSS version 10.0.5 for Windows (1999). Analyses were two tailed, controlling for imbalances in baseline characteristics between the two groups. We documented severity of illness at birth and common neonatal complications.
Mothers’ impressions of having conversations taped, and use of tapes
Most (84-98%) of the mothers in both groups responded that having their conversations with the neonatologist taped did not annoy or embarrass them or cause them to be anxious. Most (71-92%) of the mothers given the tapes stated that the taped conversations helped their understanding, reminded them of what had been said, and helped their family to understand and recall information.

After one week 86 of the 95 (91%) mothers who responded had listened to the tape. Eighty of 84 (95%) mothers at four months and 76 of 79 (96%) at 12 months had listened to the tape at any time since randomization. Mothers listened to the tape a modal of once by 10 days, twice by four months, and three times by 12 months (range 1-10 for each assessment time). Partners listened to the tape in 49% (n = 44) of instances, grandparents in 7%, relatives or friends in 1% and a mix of partner, grandparents, and relatives in 14%. By 12 months 7% of the tapes were not listened to by anyone else.

Recall of information and psychological morbidity
At 10 days and four months mothers in the tape group had significantly greater recall of information on the diagnosis or outcome of the baby and on tests or treatment, respectively (table 3). The difference between the two groups remained significant in multivariate analysis. Six mothers, all in the control group, could not recall any information. With and without adjustment for baseline differences, no differences were found between the two groups in the incidence of postnatal depression, anxiety scores, general psychological wellbeing, parenting stress, and satisfaction with conversation (tables 4 and 5).

Impact of babies’ outcome
For babies with a good outcome significantly more mothers in the tape group compared with the control group had 100% recall of information at 10 days of their babies’ treatment or outcome and at four months of their babies’ diagnosis, treatment, or outcome (table 6). For babies with a poor outcome no differences were found between the groups in recall of information at 10 days whereas at four months significantly more mothers in the tape group had 100% recall of information of their babies’ treatment (table 6). No differences were found between the two groups in psychological wellbeing and parenting stress of mothers for babies with a poor outcome (table 7). Mothers of babies with a poor outcome in the tape group were, however, significantly more satisfied with the conversation (table 8).

Discussion
Providing the mothers of babies in a neonatal intensive care unit with an audiotape of their conversations with a neonatologist improved their recall of information at 10 days and at four months. The tapes did not influence parental wellbeing or stress about parenting. The mothers of babies with a poor outcome who received the tape were significantly more satisfied with the conversation.

Effective communication underpins family centered care in neonatal intensive care units. Interventions to improve mothers’ understanding need to be cheap and simple and provide an opportunity for review of information.

Two observational studies in neonatology reported the feasibility of taping conversations with parents and most of the neonatologists were happy for their conversations to be recorded. The mothers in our study attended a regional neonatal intensive care unit, were prospectively recruited, and were followed up to one year. The cohort included a racially and socioeconomically diverse sample of mothers whose babies had a wide spectrum of clinical conditions. The two groups had similar baseline characteristics. The incidence of postnatal depression at the three follow-up periods (10 days and four and 12 months) was similar to that reported among mothers with babies in neonatal intensive care units in another study, suggesting that our cohort is representative of such mothers.

Most of the mothers in both groups were positive about having their conversations with the neonatologist taped. Overall, 96% of mothers listened to the tapes and found them helpful in recalling information. The tapes improved recall of information up to four months. That six of the mothers in the control group could not recall their conversations with the neonatologist has important medical implications, especially when obtaining consent for treatment or participation in trials.

The mothers of babies with poor outcomes did not seem to be helped by the tapes at 10 days’ follow-up; at four months, however, these mothers recalled significantly more information on the treatment and outcome of their babies compared with the control group. This may have been due to the mothers being in shock about their babies’ condition at 10 days; the tapes allowed them to listen at home when they had had time to adjust to their situation. Mothers of babies with a poor outcome were significantly more satisfied with the conversation than mothers in the control group. The results need to be interpreted with caution, however, as the number of mothers with babies given a poor outcome was small.

No significant difference was found between the groups for postnatal depression, anxiety, psychological wellbeing, or parenting stress scores at 10 days and four and 12 months. Thus the benefits to recall do not seem to be associated with negative psychological effects.

The limitations of our study include a higher refusal rate for non-white mothers. No significant differences were, however, found between the groups in the proportion of mothers who were non-white. The trial involved three neonatologists so the results may be different with other neonatologists.

Assuming that mothers are well enough to discuss their situation, successful taping depends on three things: a good quality tape recorder, a quiet room in which to hold conversations between the mother and key health professionals; and use of updated, concise, and clear language, avoiding terms such as “certain” or “100% confident.” The doctor should make a copy of the tape for storage.

Suggestions for future research
Taping medical conversations has immense potential for research, education, and audit in neonatology (for example, discussing specific conditions such as extreme prematurity, Down’s syndrome, antenatal counseling, postmortem results, seeking consent). Neonatologists need to follow oncologists and

neonatal INTENSIVE CARE Vol. 20 No. 2 • March-April 2007
develop guidelines for the use of audiotaping. Future studies could focus on the fathers of babies, on the interaction between doctors and parents, and on whether doctors in neonatal intensive care units could benefit from listening to tapes of their conversations and receiving feedback on their communication skills.

**Conclusion**

It is practical to tape conversations between the mothers of babies in neonatal intensive care units and neonatologists. In our study the tapes were listened to both by the mothers and by family members. At 10 days' and four months' follow-up the tapes improved the mothers' recall of information provided by the neonatologist and did not influence their wellbeing or stress about parenting. The mothers of babies with poor outcome who received the tapes were significantly more satisfied with the conversation than similar mothers in the control group.

**References**

2. Kmietowicz Z. Premature baby was not put on ventilator. BMJ 1996;313:963.
Home Delivery And Newborn Care Practices Among Urban Women In Western Nepal

Chandrashekhar T. Sreeramareddy, Hari S. Joshi, Binu V. Sreekumaran, Sabitri Giri and Neena Chuni

Abstract
Background: About 98% of newborn deaths occur in developing countries, where most newborn deaths occur at home. In Nepal, approximately 90% of deliveries take place at home. Information about reasons for delivering at home and newborn care practices in urban areas of Nepal is lacking and such information will be useful for policy makers.

Methods: A cross-sectional survey was carried out in the immunization clinics of Pokhara city, western Nepal during January and February, 2006. Two trained health workers administered a semi-structured questionnaire to the mothers who had delivered at home.

Results: A total of 240 mothers were interviewed. Planned home deliveries were 140 (58.3%) and 100 (41.7%) were unplanned. Only 6.2% of deliveries had a skilled birth attendant present and 38 (15.8%) mothers gave birth alone. Only 46 (16.2%) women had used a clean home delivery kit and only 92 (38.3%) birth attendants had washed their hands. The umbilical cord was cut after expulsion of placenta in 154 (64.2%) deliveries and cord was cut using a new/boiled blade in 217 (90.4%) deliveries. Mustard oil was applied to the umbilical cord in 53 (22.1%) deliveries. Birth place was heated throughout the delivery in 88 (64.2%) deliveries. Only 100 (45.8%) newborns were wrapped within 10 minutes and 233 (97.1%) were wrapped within 30 minutes. Majority (93.8%) of the newborns were given a bath soon after birth. Mustard oil massage of the newborns was a common practice (144, 60%). Sixteen (10.8%) mothers did not feed colostrums to their babies. Prelacteal feeds were given to 37 (15.2%) newborns. Initiation rates of breast-feeding were given to 57.9% within one hour and 85.4% within 24 hours. Main reasons cited for delivering at home were preference (25.7%), ease and convenience (21.4%) for planned deliveries while precipitate labor (51%), lack of transportation (18%) and lack of escort during labor (11%) were cited for the unplanned ones.

Conclusion: High-risk home delivery and newborn care practices are common in urban population also. In-depth qualitative studies are needed to explore the reasons for delivering at home. Community-based interventions are required to improve the number of families engaging a skilled attendant and hygiene during delivery. The high-risk traditional newborn care practices like delayed wrapping, bathing, mustard oil massage, prelacteal feeding and discarding colostrums need to be addressed by culturally acceptable community-based health education programs.

Authors Sreeramareddy, Joshi and Sreekumaran are with the Department of Community Medicine, Manipal College of Medical Sciences; Giri is with the Department of Pediatrics, Manipal Teaching Hospital, Manipal College of Medical Sciences, and Chuni is with the Department of Obstetrics and Gynecology, Manipal Teaching Hospital Manipal College of Medical Sciences, Pokhara, Nepal. The authors are grateful to Dr. P Ravi Shankar for proof reading the earlier drafts of the manuscript. The authors are also thankful to the staff of UNICEF and Pokhara Municipal Corporation for their cooperation during the study. The authors also thank all the mothers who participated in the study. This article is reprinted from BioMed Central, © 2006 Sreeramareddy et al; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License.
relatively easy access to institutional maternity services in urban areas. Previous studies about home deliveries in urban and periurban areas of Kathmandu have reported poor maternal education, multiparity and low socioeconomic status as the predictors of home deliveries. A study carried out in Kathmandu reported cost and convenience as the reasons for delivering at home.

The World Health Organisation's (WHO) guidelines for essential newborn care include the following: hygiene during delivery, keeping the newborn warm, early initiation of breast-feeding, exclusive breast-feeding, care of the eyes, care during illness, immunization and care of low birth-weight newborns. Therefore it is necessary for the mother and her family to understand these aspects of childbirth and newborn care and be prepared to react to the potential danger signs. A study from rural areas of Makawanpur district, Nepal reported that a very large proportion (>90%) of deliveries took place at home. The study also reported that only six percent of home deliveries were attended by skilled government health workers and newborn care practices were unhygienic and high-risk. Such high-risk practices have also been reported from the remote Jumla district, Nepal. Newborn care practices may change over time and may be different in urban areas. A study from low socioeconomic settlements of Karachi, Pakistan has reported that traditional newborn care practices were high-risk and emphasized the need for community-based interventions to promote proper newborn care practices in urban areas.

Implementation of an effective program for promotion of childbirth and newborn care practices requires understanding of the community and household traditional newborn care practices. Such information will enable the development of programs to promote culturally sensitive and acceptable change in practices. Information about the reasons for delivering at home is also necessary for healthcare planners to design appropriate maternity services. Information about reasons for delivering at home, home delivery and newborn care practices in urban areas of Nepal is lacking. Therefore, we undertook this study in an urban population of western Nepal with the following objectives:

1) to describe the home delivery and newborn care practices and
2) to assess the reasons for delivering at home.

**Methods**

**Study setting**

Nepal has a population of about 23 million people, 80% of whom live in rural areas. With an estimated per capita income of $289 per year, Nepal is a poor developing country in south Asia. Life expectancy at birth has increased, but at 60 years it is still lower than neighboring south Asian countries. Infant mortality rate is amongst the highest in the region. Due to high maternal mortality rate, life expectancy for women is lower than that for men. Gender disparities are also common in terms of literacy. Only 26% of Nepal's women are literate compared to 62% of men. Curative preventive health care are organized primarily by the Ministry of Health through hospitals located at central regional and district levels, and primary health centres, health posts and sub-health posts located at the community level. Private hospitals and clinics exist mostly in urban areas. Missionary and not-for-profit hospitals also operate in a few areas. Nepal spends about five percent of its gross domestic product on health of which only one quarter comes from the public sector and the remainder is paid for by the individual households.

Kaski is one of the 14 districts in the western development region of Nepal. The district has a land area of 2017 square kilometers and a population of 380,527. Kaski district has 43 village development committees and Pokhara sub-metropolitan city whose population is 156,312. Pokhara sub-metropolitan city is administratively divided into 18 municipal wards. In each of these wards immunization clinics are conducted once a month in the child health centers. The child health centers are managed by the Urban Basic Services of Pokhara Municipal Corporation, United Nations Children's Fund (UNICEF) and
Manipal College of Medical Sciences (MCOMS) each providing manpower, vaccines, medicines and technical input respectively. Since primary immunization in Nepal is completed at one year of age, the majority of the children attending these clinics were infants. A few children who missed measles vaccine between nine and 12 months are older than a year when they attend the immunization clinic.

Study design and participants
The institutional ethics committee of MCOMS approved this study. A cross-sectional study was carried out in the immunization clinics of Pokhara city. We included the mothers of all the infants who were brought for immunization during the months of January and February, 2006. The framework used for the design and presentation for our study was based on a similar study carried out earlier in a rural area of Nepal. A semi-structured questionnaire was developed for the purpose of this study and was pre-tested among 25 mothers during the month of January, 2006. After pre-testing, the questionnaire was modified according to local traditions and cultural sensitivity. The questionnaire sought information about sociodemographic characteristics of the family, planned or unplanned home delivery, reasons for delivering at home, the details of events that took place at delivery and after birth till initiation of breast-feeding. The details included attendance at delivery, cleanliness and hygiene practices during delivery, thermal control and infant feeding. The information about the reasons for delivering at home was sought by both open and closed-ended questions. Those women who reported that they had decided to deliver in a hospital but could not reach the hospital after the onset of labor pains due to various reasons were categorized as unplanned home deliveries. Those women who reported that they had decided to deliver at home were categorized as planned home deliveries.

Two health workers were trained to administer the questionnaire during a one-day training conducted by the investigators at MCOMS. The health workers were stationed at the registration counter and enquired from the mothers about place of delivery. The mothers of the infants who reported that they delivered at home were invited to participate. Verbal consent was sought and the respondents were assured that the interviewers were not a part of the health service team and services would not be denied if they declined to participate in

<table>
<thead>
<tr>
<th>Table 2: Cleanliness and hygiene practices during delivery</th>
<th>Number of births (N = 240)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instrument used for cutting umbilical cord</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New or boiled blade</td>
<td>217</td>
<td>90.4</td>
</tr>
<tr>
<td>Sickle</td>
<td>7</td>
<td>2.9</td>
</tr>
<tr>
<td>Household knife</td>
<td>6</td>
<td>2.7</td>
</tr>
<tr>
<td>Old unboiled blade</td>
<td>4</td>
<td>1.7</td>
</tr>
<tr>
<td>Unknown</td>
<td>6</td>
<td>2.5</td>
</tr>
<tr>
<td><strong>Dressing applied to umbilical stump</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nothing</td>
<td>163</td>
<td>67.9</td>
</tr>
<tr>
<td>Oil</td>
<td>47</td>
<td>19.6</td>
</tr>
<tr>
<td>Oil and turmeric</td>
<td>5</td>
<td>2.1</td>
</tr>
<tr>
<td>Antiseptic</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Unknown</td>
<td>23</td>
<td>9.6</td>
</tr>
<tr>
<td><strong>Cloth used for wrapping the baby</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Old washed cloth</td>
<td>177</td>
<td>73.8</td>
</tr>
<tr>
<td>Old unwashed cloth</td>
<td>37</td>
<td>15.4</td>
</tr>
<tr>
<td>New unwashed cloth</td>
<td>16</td>
<td>6.7</td>
</tr>
<tr>
<td>New washed cloth</td>
<td>8</td>
<td>3.3</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
<td>0.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3: Practices related to maintenance of the warm chain for the newborn</th>
<th>Number of births (N = 240)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heating of the birth place</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>103</td>
<td>42.9</td>
</tr>
<tr>
<td>Before birth</td>
<td>26</td>
<td>10.8</td>
</tr>
<tr>
<td>After birth</td>
<td>23</td>
<td>9.6</td>
</tr>
<tr>
<td>Throughout birth</td>
<td>88</td>
<td>36.7</td>
</tr>
<tr>
<td><strong>Time to wrapping the baby</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 5 minutes</td>
<td>33</td>
<td>13.8</td>
</tr>
<tr>
<td>≤ 10 minutes</td>
<td>100</td>
<td>45.8</td>
</tr>
<tr>
<td>≤ 20 minutes</td>
<td>205</td>
<td>85.4</td>
</tr>
<tr>
<td>≤ 30 minutes</td>
<td>233</td>
<td>97.1</td>
</tr>
<tr>
<td>≤ 60 minutes</td>
<td>240</td>
<td>100</td>
</tr>
<tr>
<td><strong>Time to bathing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 5 minutes</td>
<td>35</td>
<td>15.5</td>
</tr>
<tr>
<td>≤ 10 minutes</td>
<td>113</td>
<td>50.2</td>
</tr>
<tr>
<td>≤ 20 minutes</td>
<td>200</td>
<td>88.9</td>
</tr>
<tr>
<td>≤ 30 minutes</td>
<td>216</td>
<td>96.0</td>
</tr>
<tr>
<td>&gt; 60 minutes</td>
<td>225</td>
<td>100</td>
</tr>
</tbody>
</table>
After obtaining verbal consent, the health worker carried out the interview and recorded the necessary information on a semi-structured questionnaire. All the interviews were supervised by the chief investigator and a staff nurse who trained the interviewers. The data were coded and analyzed using the SPSS package (Statistical Package for Social Sciences). Frequencies and percentages of different variables were calculated. Chi square test was used to test if the observed differences between planned and unplanned deliveries were statistically significant. A p value of 0.05 was considered significant.

### Results

Out of the 1320 infants who were brought to the immunization clinics during the study period, 246 (18.6%) were born at home. Six infants were brought by a family member other than the mother or a relative. The information provided by these respondents was not reliable. Hence they were excluded from the analyses. One hundred and forty (58.3%) of these 240 home deliveries were planned whereas 100 (41.7%) were unplanned.

#### Sociodemographic profile of the respondents

The median age of the infants was four months (interquartile range, 4 months). One hundred and twenty two (50.8%) infants were males and 118 (49.2%) were females. The median age of the mothers was 24 years (interquartile range, 7 years). The majority of the mothers were Hindus (196, 81.7%) followed by Buddhists (33, 13.8%). Ninety three (38.8%) respondents were illiterate and only 53 mothers (13.7%) had education of high school and above. The mean monthly family income was 6360 Nepalese rupees (Approximately 90 USD).

#### Antenatal care and past obstetric performance of the respondents

Out of the 240 mothers interviewed, 73 (30.4%) had not gone for any antenatal visit and only 25 (10.4%) mothers had at least four antenatal visits as recommended by the National Safe Motherhood Program of Nepal. The majority of women received antenatal care from the publicly funded Western Regional Hospital, Pokhara. Seventy (29.2%) mothers did not receive tetanus toxoid vaccine during their previous pregnancy and 86 (35.8%) received two doses of tetanus toxoid as recommended by the National Safe Motherhood Program. Of the 173 multiparous women, 148 (85.5%) had delivered at home at least once before. Only 55 mothers (24.6%) had at least one institutional delivery in the past. Seven mothers reported of having a still birth (2.9%), 16 a neonatal death (6.7%) and four a post-neonatal death (1.7%) after their previous home deliveries.

#### Birth place and attendance at delivery

The majority (92.5%) of the deliveries took place either in a separate room or inside the house and the remaining 18 deliveries (7.5%) took place outside the house, either in the backyard or other places. One hundred and twenty eight (53.3%) deliveries were attended by neighbors, 51 (21.3%) were attended by family members and 38 women (15.8%) gave birth alone. Only 15 (6.3%) deliveries were attended by skilled personnel ie auxiliary nurse midwife or health assistant and 13 (5.4%) delivers were attended by traditional birth attendants (Table 1).

#### Cleanliness and hygiene practices during delivery

Ninety two mothers (38.3%) recalled that the birth attendant’s had washed their hands and 116 (48.3%) recalled that they did not do so. Thirty two mothers (13.3%) could not remember at all. Clean home delivery kits (CHDK) are currently manufactured and distributed in Nepal. Each kit contains a plastic sheet, a clean razor blade, a surface for cutting cord, soap, and a cord tie. Forty six (19.2%) mothers responded that CHDK was used and 168 (70%) had not used one during their last delivery. The umbilical cord was cut after the expulsion of placenta in 154 (64.2%) deliveries. The umbilical cord was cut with a new or boiled blade in 217 (90.4%) deliveries and in 17 (7.1%) deliveries a sickle/household knife or an old unboiled blade was used. The stump of umbilical cord was left undressed in 177 (73.8%) deliveries. In all the instances mustard oil was used. Applications like turmeric and antiseptics were also reported by the mothers. The newborn was often wrapped in an old washed cloth (177, 73.8%) (Table 2).

### Table 4: Type and timing of first feed

<table>
<thead>
<tr>
<th>Newborn’s first feed</th>
<th>Number of newborns (N = 240)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast milk/Colostrum</td>
<td>190</td>
<td>79.2</td>
</tr>
<tr>
<td>Ghee or Oil</td>
<td>19</td>
<td>7.9</td>
</tr>
<tr>
<td>Breast milk from other woman</td>
<td>13</td>
<td>5.4</td>
</tr>
<tr>
<td>Honey</td>
<td>5</td>
<td>2.1</td>
</tr>
<tr>
<td>Cow’s or buffalo’s milk</td>
<td>4</td>
<td>1.7</td>
</tr>
<tr>
<td>Glucose water</td>
<td>4</td>
<td>1.7</td>
</tr>
<tr>
<td>Plain water</td>
<td>3</td>
<td>1.3</td>
</tr>
<tr>
<td>Formula feed</td>
<td>2</td>
<td>0.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time to breast-feed</th>
<th>Number of newborns (N = 240)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediately after birth</td>
<td>3</td>
<td>1.3</td>
</tr>
<tr>
<td>≤ 15 minutes</td>
<td>29</td>
<td>12.1</td>
</tr>
<tr>
<td>≤ 30 minutes</td>
<td>67</td>
<td>27.9</td>
</tr>
<tr>
<td>≤ 60 minutes</td>
<td>139</td>
<td>57.9</td>
</tr>
<tr>
<td>≤ 24 hours</td>
<td>205</td>
<td>85.4</td>
</tr>
<tr>
<td>≤ 48 hours</td>
<td>230</td>
<td>95.8</td>
</tr>
<tr>
<td>&gt; 48 hours</td>
<td>240</td>
<td>100</td>
</tr>
</tbody>
</table>
Table 5: Reasons for choice of planned and unplanned home deliveries

<table>
<thead>
<tr>
<th>Reason given</th>
<th>Planned</th>
<th>Unplanned</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preference for home delivery</td>
<td>36</td>
<td>-</td>
<td>36 (15)</td>
</tr>
<tr>
<td>Home delivery is easy and convenient</td>
<td>30</td>
<td>-</td>
<td>30 (12.5)</td>
</tr>
<tr>
<td>All my previous deliveries were at home</td>
<td>25</td>
<td>-</td>
<td>25 (10.4)</td>
</tr>
<tr>
<td>Hospital is too far</td>
<td>12</td>
<td>4</td>
<td>16 (6.7)</td>
</tr>
<tr>
<td>Worries about cost in the hospital</td>
<td>10</td>
<td>8</td>
<td>18 (7.5)</td>
</tr>
<tr>
<td>Financial problems at home</td>
<td>7</td>
<td>2</td>
<td>9 (3.7)</td>
</tr>
<tr>
<td>Family members prefer home delivery</td>
<td>5</td>
<td>1</td>
<td>6 (2.5)</td>
</tr>
<tr>
<td>Fear of hospital</td>
<td>6</td>
<td>-</td>
<td>6 (2.5)</td>
</tr>
<tr>
<td>Health worker lives close to house</td>
<td>3</td>
<td>-</td>
<td>3 (1.2)</td>
</tr>
<tr>
<td>Precipitate labor*</td>
<td>-</td>
<td>51</td>
<td>51 (21.3)</td>
</tr>
<tr>
<td>Lack of transport during labor</td>
<td>-</td>
<td>18</td>
<td>18 (7.5)</td>
</tr>
<tr>
<td>Lack of escort during labor</td>
<td>-</td>
<td>11</td>
<td>11 (4.6)</td>
</tr>
<tr>
<td>Onset of labor before the expected date</td>
<td>-</td>
<td>4</td>
<td>4 (1.7)</td>
</tr>
<tr>
<td>Other reasons</td>
<td>6</td>
<td>1</td>
<td>7 (2.9)</td>
</tr>
<tr>
<td>Total</td>
<td>140</td>
<td>100</td>
<td>240</td>
</tr>
</tbody>
</table>

Figures in parentheses indicate percentage
* Precipitate labor: Labor that results in rapid expulsion of fetus

Maintenance of warm chain for the newborn

Since more than 90% of the deliveries took place in a room or inside the house, information about heating of the birthplace was also asked. In 137 (57.1%) deliveries the birth place was heated. In 88 out of these 137 (64.2%) deliveries birth place was heated throughout the delivery and in 23 (16.8%) instances it was heated after delivery. The heating of birth place was statistically significant between planned and unplanned home deliveries. The time taken to wrap the baby was usually prolonged. Only 100 (45.8%) newborns were wrapped within ten minutes and 233 (97.1%) newborns were wrapped within 30 minutes after birth. By one hour all the newborns were wrapped. Two hundred and twenty five (93.7%) out of 240 newborns were bathed after birth. Almost all of these newborns were bathed within six hours after birth. Nearly half of them were bathed within ten minutes, 88.9% within half an hour and 96% within one hour (Table 3). The application/massage of the newborn with oil was a common practice and 144 (60%) newborns received an oil massage any time after birth. Almost all of these newborns received mustard oil massage.

Newborn feeding

All the newborns were breast-fed. Clarified butter (ghee), oil, honey, sugar or animal milk was sometimes given to the newborns (37/240, 15.4%) before the initiation of breast-feeding. Ghee or oil was given to 19 (7.9%) newborns. Overall, 203 mothers (84.6%) had given colostrum or breast milk to their babies as the first feed. Thirteen mothers (5.4%) had given breast milk from other lactating mothers when there was a delay in initiation of breast-feeding. Twenty six out of 240 (10.8%) mothers had discarded colostrum before initiating breastfeeding. The rates of initiation of breastfeeding were 57.9% within one hour and 85.4% within 24 hours (Table 4).

Discussion

The present study highlights that home deliveries are not only common in rural areas but also in urban areas where maternity services are relatively easily accessible. An earlier study from rural Nepal reported that 93% of the deliveries took place at home.7 The proportion of home deliveries in the present study is similar to that reported from earlier studies in Kathmandu and its surrounding areas. These studies reported that the proportion of home deliveries increased, the farther one gets from urban areas.5,7

Interestingly, some findings of the present study are similar to the previous study from rural Nepal.8 It was surprising that skilled attendance of government health workers or traditional birth attendants, use of CHDK and hygiene practices during delivery was low in urban areas as well. Practices like heating the birth place, applying mustard oil to the stump of the umbilical cord, and bathing the baby soon after birth were common in urban areas. Early initiation of breast-feeding, use of prelacteal feeds and breast-feeding from another woman are also common practices prevalent in urban areas.

Attendance during delivery

Most deliveries took place either in a separate room or some place inside the house which is similar to the report from an earlier study.3 An earlier study has highlighted that cattle-shed deliveries were contributing to higher rates of infant mortality in the remote rural areas of Nepal.8 Such practices were not reported in our study. Studies from rural areas have underscored the role of mother-in-law assistance during the delivery and care of newborn.9,10 But in our study, mother-in-law was present during delivery in only a small proportion (5%) of home deliveries. More than half of the deliveries were attended by neighbors. Such a difference may be due to demographic structure of the urban population in which many families may
Hygiene and thermal control

A study from India has reported that infection accounts for up to 40% of neonatal deaths. Therefore, the WHO emphasizes five cleans during the delivery. The ‘five cleans’ are: a clean place, a clean surface; clean hands; clean cord and dressing; and a clean tie. In our study only one-third of the attendants had washed their hands before delivery which is less than previous reports from rural areas. CHDK was used only in 19% of the deliveries which is higher than earlier reports. A qualitative study from rural areas of Nepal reported that despite perceived usefulness and awareness, the use of CHDK was low, and the common reasons cited for their non-use were lack of awareness about the kit or difficulty in procuring a kit locally. The study also reported that CHDK had a limited influence on general hygiene practices. In our study, despite the low usage of CHDK, new/boiled razor blade was used to cut the cord in a majority (90.4%) of deliveries. This practice is encouraging as compared to practice in rural areas where sickle or wooden knife was used in nearly one-third of deliveries and old/unboiled blade in 23%. This practice was complemented by leaving umbilical stump undressed which is similar to the practice in rural areas. The practice of applying unsterile substances like oil or ghee is a more important risk factor than the means of cutting the cord as reported in earlier studies. The common substances applied to the cord were mustard, oil, turmeric and disinfectants. This practice was similar to the reports from earlier studies from rural Nepal and urban settlements of Karachi, Pakistan.

The WHO has focused on thermal control of newborns in the essential newborn care. Previous studies from Nepal, India and Bangladesh have reported on health beliefs about pregnancy and childbirth. The common view is that pregnancy is a ‘hot’ state and postpartum is a ‘cold’ one. Neonatal hypothermia in Nepal has been described earlier. In our study, we found that in 46% of the instances birth place was heated during or throughout the delivery. This proportion is less than that observed in a rural study. The practice of waiting for the placenta to deliver before cutting the umbilical cord was observed in 64% of the deliveries, a rate similar to that reported in a qualitative study. This practice delays immediate wrapping of the baby. This further compounded by bathing the baby soon after birth which seems to be a universal practice. In our study, 90% of the newborns were given a bath within one hour after delivery. Similar practices have been reported earlier.

Application/massage of mustard oil to the newborn is a well established practice in Nepal. In our study, 60% of the newborns received a mustard oil massage soon after birth as in an urban population of Pakistan. Recently there have been increasing concerns about this traditional practice of massage with mustard oil as it is thought to predispose the newborn to the risk of hypothermia. Earlier studies have raised concerns about the traditional practices of applying mustard oil to the umbilical cord stump and mustard oil massage after delivery.

Infant feeding

In our study the only traditional newborn care practice which seems to be healthy and encouraging is breastfeeding. As reported in the earlier studies, rates of initiation and exclusive breastfeeding are high. However, practices like prelacteal feeding and discarding colostrum which still persist in urban areas are a cause of concern. Qualitative studies suggest that the traditional practice is to give a taste of non-breast milk food and usually only once. In our study, 15% of the newborns received a prelacteal feed which is similar to that reported previously. In our study, only ten percent of the mothers discarded colostrum which was in contrast to 40% in rural areas. Use of formula feeds was minimal and feeding with bottle and nipple almost non-existent in Nepal. A recent qualitative study from rural Nepal reported that grandmothers held colostrum in high regard, did not use prelacteal feeds and also supported early initiation of breastfeeding. These findings have positive implications on child nutrition.

Reasons for delivering at home

Studies carried out in Kathmandu and its surrounding areas have reported socioeconomic status and multiparity as strong predictors of the place of delivery. In our study the reasons for planned home deliveries were related to ‘preference’ for home delivery and perception of home deliveries as easy and convenient and experience of previous home deliveries. For unplanned home deliveries the reasons cited were precipitate labor and lack of transport and lack of escort during labor. Similar findings were reported from an earlier study in Kathmandu. In urban areas there is a mix of traditional families and recent economic immigrant families. In rural areas women have a strong cultural preference for home deliveries because institutional deliveries are inaccessible. This could be the reason for women indicating “preference” as the reason for delivering at home. The decision making process in the family about the place of delivery is also an important aspect about the reasons for home deliveries. We could not explore the details of this aspect in our study. Therefore we are planning to undertake an in-depth qualitative study to explore the reasons for delivering at home.

The findings of our study suggest that easy access to maternity services may not be enough to ensure the use of such services. Lack of utilization may be influenced by income, education, and cultural beliefs. In Pokhara, institutional delivery facilities are available at the Western Regional Hospital, Manipal Teaching Hospital of MCOMS and a few private hospitals. Since the services at all these facilities have to be paid for, financial constraints may be the main reason for not using these facilities. A large section of this urban population may be recent economic migrants and nuclear families. Earlier studies have confirmed the extremely low presence of skilled government health staff or traditional birth attendants during delivery in rural areas of Nepal. Maternal and child health workers who are identified as key birth attendants by the policy makers were not present at delivery in our study either. This study highlights that skilled attendance at home deliveries is very low in urban areas also. Previous studies found that about 15% of mothers had delivered alone at home. This may emphasise the low status of women in the society and the gender inequities in health. For many of these urban families pregnancy and the process of childbirth may not be a concern or priority. It takes huge efforts to change this tradition of home deliveries and lack of skilled attendance during delivery in home setting. There is an ongoing debate about reinforcing home-based birthing strategies with skilled attendants in developing countries. A study from India has reported that infection accounts for up to 40% of neonatal deaths. Therefore, the WHO emphasizes five cleans during the delivery. The ‘five cleans’ are: a clean place, a clean surface; clean hands; clean cord and dressing; and a clean tie. In our study only one-third of the attendants had washed their hands before delivery which is less than previous reports from rural areas. CHDK was used only in 19% of the deliveries which is higher than earlier reports. A qualitative study from rural areas of Nepal reported that despite perceived usefulness and awareness, the use of CHDK was low, and the common reasons cited for their non-use were lack of awareness about the kit or difficulty in procuring a kit locally. The study also reported that CHDK had a limited influence on general hygiene practices. In our study, despite the low usage of CHDK, new/boiled razor blade was used to cut the cord in a majority (90.4%) of deliveries. This practice is encouraging as compared to practice in rural areas where sickle or wooden knife was used in nearly one-third of deliveries and old/unboiled blade in 23%. This practice was complemented by leaving umbilical stump undressed which is similar to the practice in rural areas. The practice of applying unsterile substances like oil or ghee is a more important risk factor than the means of cutting the cord as reported in earlier studies. The common substances applied to the cord were mustard, oil, turmeric and disinfectants. This practice was similar to the reports from earlier studies from rural Nepal and urban settlements of Karachi, Pakistan.

The WHO has focused on thermal control of newborns in the essential newborn care. Previous studies from Nepal, India and Bangladesh have reported on health beliefs about pregnancy and childbirth. The common view is that pregnancy is a ‘hot’ state and postpartum is a ‘cold’ one. Neonatal hypothermia in Nepal has been described earlier. In our study, we found that in 46% of the instances birth place was heated during or throughout the delivery. This proportion is less than that observed in a rural study. The practice of waiting for the placenta to deliver before cutting the umbilical cord was observed in 64% of the deliveries, a rate similar to that reported in a qualitative study. This practice delays immediate wrapping of the baby. This further compounded by bathing the baby soon after birth which seems to be a universal practice. In our study, 90% of the newborns were given a bath within one hour after delivery. Similar practices have been reported earlier.

Application/massage of mustard oil to the newborn is a well established practice in Nepal. In our study, 60% of the newborns received a mustard oil massage soon after birth as in an urban population of Pakistan. Recently there have been increasing concerns about this traditional practice of massage with mustard oil as it is thought to predispose the newborn to the risk of hypothermia. Earlier studies have raised concerns about the traditional practices of applying mustard oil to the umbilical cord stump and mustard oil massage after delivery.

Infant feeding

In our study the only traditional newborn care practice which seems to be healthy and encouraging is breastfeeding. As reported in the earlier studies, rates of initiation and exclusive breastfeeding are high. However, practices like prelacteal feeding and discarding colostrum which still persist in urban areas are a cause of concern. Qualitative studies suggest that the traditional practice is to give a taste of non-breast milk food and usually only once. In our study, 15% of the newborns received a prelacteal feed which is similar to that reported previously. In our study, only ten percent of the mothers discarded colostrum which was in contrast to 40% in rural areas. Use of formula feeds was minimal and feeding with bottle and nipple almost non-existent in Nepal. A recent qualitative study from rural Nepal reported that grandmothers held colostrum in high regard, did not use prelacteal feeds and also supported early initiation of breastfeeding. These findings have positive implications on child nutrition.

Reasons for delivering at home

Studies carried out in Kathmandu and its surrounding areas have reported socioeconomic status and multiparity as strong predictors of the place of delivery. In our study the reasons for planned home deliveries were related to ‘preference’ for home delivery and perception of home deliveries as easy and convenient and experience of previous home deliveries. For unplanned home deliveries the reasons cited were precipitate labor and lack of transport and lack of escort during labor. Similar findings were reported from an earlier study in Kathmandu. In urban areas there is a mix of traditional families and recent economic immigrant families. In rural areas women have a strong cultural preference for home deliveries because institutional deliveries are inaccessible. This could be the reason for women indicating “preference” as the reason for delivering at home. The decision making process in the family about the place of delivery is also an important aspect about the reasons for home deliveries. We could not explore the details of this aspect in our study. Therefore we are planning to undertake an in-depth qualitative study to explore the reasons for delivering at home.

The findings of our study suggest that easy access to maternity services may not be enough to ensure the use of such services. Lack of utilization may be influenced by income, education, and cultural beliefs. In Pokhara, institutional delivery facilities are available at the Western Regional Hospital, Manipal Teaching Hospital of MCOMS and a few private hospitals. Since the services at all these facilities have to be paid for, financial constraints may be the main reason for not using these facilities. A large section of this urban population may be recent
economic migrants from rural areas. This may be the reason for urban-rural similarities observed in home delivery and newborn care practices in our study.

In our study, 70% of the home deliveries were unplanned. These women would have sought institutional delivery if an ambulance service or local facility for delivery was made available. In this respect it may be worth investing in satellite maternity services run by midwives. Mothers might prefer to utilize such local and user-friendly services rather than a tertiary care hospital. Also the mothers need to have information about how to access a trained traditional birth attendant or a midwife during the delivery.

The National Safe Motherhood Program of Nepal emphasizes the provision of round-the-clock emergency obstetric services including transport and financial assistance. The program has recently implemented the scheme of financial incentives for the mothers who chose institutional delivery. In our study, one-third of the mothers had not gone for antenatal checkups and only a third of them received two doses of tetanus toxoid during their previous pregnancy. There may be many cultural constraints for use of maternity services e.g. decision of the husband or mother-in-law which often over-rides that of the mother. The reasons for low uptake of maternity services in the urban population may be due to socioeconomic and cultural factors. Therefore interventions should address not only the medical problems but also need to deal with wider social problems. Interventions should also focus to improve the status of women in society including increasing female literacy and empowerment to tackle the maternal health problems.

A recent qualitative study carried out in Kathmandu reported that attitudes of pregnant women, husbands and service providers were favorable towards encouraging greater male involvement in maternal health services. Further studies are needed about quality of the available maternity services and cultural beliefs about pregnancy and childbirth.

The present study may have both selection and information bias. Since our survey was carried out in immunization clinics, selection bias cannot be ruled out. We might have missed to interview those mothers who delivered at home and did not attend immunization clinics. However, the sample of mothers interviewed may be representative of the urban population since those mothers who delivered at home and did not attend the immunization clinics. The high infant mortality rate in study area means that ten percent of the children who were born at home may have not reached their first birthday. Therefore, ten percent of the mothers did not attend the immunization clinics. We included only those deliveries that took place within one year in order to avoid recall bias over a longer period of time. However, we cannot rule out some amount of recall and reporting bias. Hence the interpretation and generalisability of our findings may be limited.

In our study, all the women who had delivered at home agreed to participate in the study. The interviewers identified themselves as independent researchers rather than as a part of the health service team present in the immunization clinics. The respondents were assured of providing health services regardless of their decision to participate in the interview and verbal consent was sought. All the women agreed to participate in the study after receiving such an assurance. The possibility that the women considered interviewers as a part of the health service team cannot be ruled out. The mean monthly family income of the respondents was approximately US$90. But the annual per capita income of Nepal is US$289. The reported monthly family income of this urban population is higher than the national average. The families in this urban population may be more affluent than an average Nepali family since Nepal is an agrarian economy. In Nepal, the majority of the population is mainly dependent on subsistence farming with seasonal migration to India or other countries.

Despite the above-mentioned limitations, our study has obtained important information about home delivery and newborn care practices and reasons for delivering at home. This information has many policy implications about the ongoing safe motherhood and child survival programmes in Nepal. There needs to be more focus on the skilled attendance and hygiene during delivery and the use of CHDK in the urban population also. Some high-risk newborn care practices like delayed wrapping, immediate bathing, mustard oil massage, applying mustard oil to the cord; prelacteal feeding and discardingcolostrum need more attention. This information will assist in planning public health interventions to change the behaviour. Expanding skilled attendance during delivery is an important issue since these urban women prefer home deliveries and home deliveries are perceived as easy and convenient.

Conclusion

There is a need for community-based interventions to improve the uptake of publicly-funded maternity services. Health promotion interventions are required to improve the number of families engaging a skilled attendant and hygiene during delivery. High-risk traditional newborn care practices need to be addressed by culturally acceptable community-based health education programs to improve newborn care practices.

References

10. Thapa N, Chongsuvivatwong V, Geater AF, Ulstein M: High-risk childbirth practices in remote Nepal and their


30 Goodburn E, Rukhsana G, Chowdhury M: Beliefs and practices regarding delivery and postpartum maternal and morbidity in rural Bangladesh. Stud Fam Plann 1995, 26:22-
Abstract
The pathogenetic mechanisms leading to the development of congenital heart disease and congenital intracranial arteriovenous malformation are still unclear. We report on a monochorionic twin pregnancy with twin-to-twin transfusion syndrome (TTTS), in which vein of Galen malformation (VGM) was diagnosed in the donor twin and transposition of the great arteries (TGA) in the recipient twin. The development of TTTS, VGM, and TGA in a single monochorionic pregnancy could be pure coincidence, but there might also be a causative link. We discuss the possible contribution of genetic factors, fetal flow fluctuations, vascular endothelial growth factors, and the process of twinning itself to the development of these congenital anomalies.

Introduction
Vein of Galen malformation (VGM) is a rare congenital intracranial vascular malformation that often leads to intractable high output cardiac failure in the newborn. VGM affects approximately 1 per 25,000 births. Transposition of the great arteries (TGA) is a congenital heart defect in which both the aorta and pulmonary trunk are connected to the wrong ventricle, resulting in separated systemic and pulmonary circulation. TGA accounts for 5% to 7% of all congenital heart defects, affecting 1 per 3000 live births. Twin-to-twin transfusion syndrome (TTTS) complicates about 15% of monochorionic pregnancies and results from unbalanced blood flow between the donor and recipient twin via placental vascular anastomoses.

We report a case of a monochorionic twin pregnancy complicated by these three disorders: TTTS, VGM in the donor twin, and TGA in the recipient twin. The odds of these 3 rare congenital anomalies occurring together are extremely low. We therefore hypothesize on a possible association between the three disorders.

Case report
A 32-year-old primigravida was pregnant with monochorionic diamniotic twins. A first trimester ultrasound scan at the referring center showed increased nuchal translucency of twin A, and amniocentesis was performed. Fetal karyotyping revealed a 46,XY karyotype. The mother was referred to our center at 18 weeks of gestation because of intrauterine growth restriction and decreased amniotic fluid of twin B. Ultrasound examination revealed an oligo/polyhydramnios sequence (deepest vertical pockets of twins A and B were 8.5 and 2.0 cm, respectively). The bladder of twin A and twin B was enlarged and collapsed, respectively. Doppler studies of twin A were within normal ranges whereas Doppler studies of twin B showed absent end-diastolic flow in the umbilical artery. Twin-to-twin transfusion syndrome Quintero stage III was diagnosed. Twin B, the donor, was small-for-gestational age (below the 5th percentile for estimated fetal weight) and had no fetal abnormalities. Biometry of twin A, the recipient, was appropriate for gestational age (20th percentile for estimated fetal weight) and had no fetal abnormalities. Biometry of twin A, the recipient, was appropriate for gestational age (20th percentile for estimated fetal weight).

Echocardiography of twin A showed a ventricular septal defect, double outlet right ventricle with myocardial hypertrophy, and a small pulmonary artery. After counseling of the parents, umbilical cord coagulation of twin A and amniodrainage were performed. From then on, twin B was monitored sonographically biweekly. Amniotic fluid and bladder filling normalized, fetal weight increased but remained below the 5th percentile, and nondeteriorating signs of brain sparing were detected (absent end-diastolic flow in the umbilical artery with increased end-diastolic flow in the middle cerebral artery). The donor twin was born at 30 weeks of gestation by cesarean section because of late decelerations on the cardiotocography after spontaneous rupture of membranes. Birth weight was 800 g (below the 3rd percentile for birth weight) and head circumference was 26 cm (3rd percentile for head circumference). Apgar scores were 9 and 9 at 5 and 10 minutes,
respectively. The infant developed respiratory distress syndrome and required mechanical ventilation and a single dose of surfactant. A routine cerebral ultrasound scan on day 1 showed a large cystic lesion posterior to the third ventricle with a pulsatile flow suspect for VGM. Cerebral magnetic resonance imaging and magnetic resonance angiography were consistent with VGM. There were no signs of hydrocephalus or coexisting cerebral damage. During the first week, the infant developed progressive respiratory failure. Echocardiography showed signs of high output cardiac failure without evidence of structural cardiac anomalies. Endovascular treatment with embolization of the VGM was not possible due to the small size of the infant. Despite maximal medical treatment with high-frequency ventilation, diuretics, and inotropic support, his pulmonary and cardiac conditions worsened and he died 49 days after birth. The parents did not give permission for autopsy.

Autopsy on the recipient twin (weight, 93 g) showed a macerated fetus. The congenital heart disease was classified as TGA with a large ventricular septal defect and overriding pulmonary orifice. There were no additional visceral anomalies. Brain autopsy was not performed.

On macroscopic examination, the placenta was composed of a single placental mass (17 x 13 x 3cm; total weight, 183 g). The insertion of the umbilical cord of the donor twin was velamentous, whereas the insertion of the recipient twin's umbilical cord was marginal. The placental part of the recipient twin was macerated. A large superficial velamentous anastomosis was detected between both cords. This was identified as an arterioarterial anastomosis. Whether other placental vascular anastomoses were present could not be determined because of extensive maceration of the placental part of the recipient twin.

Discussion

This is the first report of a case of monochorionic twins with TTTS, VGM, and TGA. The pathogenesis of each individual disorder is poorly understood. Vein of Galen malformation is an embryonic aneurysmatic vascular dilatation arising from direct arteriovenous communications between the arterial network and the median prosencephalic vein. The insult causing the development of VGM occurs between the 6th and 11th weeks of embryonic development. Although this developmental theory is generally accepted, it is unclear which factors play a role in the pathogenesis of VGM. Retrograde transmission of increased venous pressure due to venous obstruction is indicated as a possible cause of VGM development.

Transposition of the great arteries represents a septation defect of the common outflow tract of the heart. The insult causing the development of TGA occurs around the 5th week of embryonic development. The etiology of TGA remains largely unknown. Both genetic factors and environmental factors have been linked to the pathogenesis of TGA.

Twin-to-twin transfusion syndrome results from an unbalanced blood flow through placental vascular anastomoses. Blood is pumped through arteriovenous connections from the donor twin to the recipient twin, resulting in hypovolemia, oliguria, and oligohydramnios in the donor and hypervolemia, polyuria, and polyhydramnios in the recipient. Other pathophysiologic mechanisms may also be important in the development of TTTS. Activation of the renin-angiotensin-aldosterone system and other hormones such as fetal atrial natriuretic peptide, brain natriuretic peptide, endothelin-1, and insulin-like growth factor II may contribute to the development of TTTS. Twin-to-twin transfusion syndrome usually occurs during the second trimester of pregnancy but has occurred even at 10 weeks of gestation. Because the odds of these 3 rare congenital anomalies occurring together in a single monochorionic twin pregnancy are extremely low, we searched for possible pathogenetic links that may have led to the combination of these 3 disorders.

First, the overall incidence of congenital malformations in monozygotic twins is 2 to 3 times higher than in singletons, which may have contributed to the occurrence of the congenital abnormalities in this case. The exact mechanism for the increased rate of congenital malformations in monozygotic twins remains unknown. The twinning process itself with postzygotic unequal division of the inner cell mass and disturbance of laterality may contribute to the development of congenital abnormalities. Disturbances of laterality can have a major influence on the embryogenesis of the heart and the development of congenital heart defects in twins.

Second, fetal blood flow fluctuations may result in a defect in embryogenesis. Increased resistance to venous outflow at an early embryonic stage has been associated with the development of VGM, and fetal flow fluctuations in early cardiogenesis may lead to congenital heart defects. Hemodynamic disturbances are known to occur in TTTS due to placental vascular connections and may have affected cerebral and cardiac blood flow, inducing the development of VGM and TGA. However, TGA has not previously been reported in TTTS, and only 1 case of VGM has been described in monochorionic twins, without TTTS. Most congenital heart disorders in TTTS are due to increased volume load, resulting in ventricular hypertrophy, tricuspid regurgitation, and right ventricular outflow tract obstruction.

Third, genetic factors are increasingly linked to multiple disorders. Congenital heart defects have a multifactorial etiology in which several genetic loci interact together with or without environmental factors. However, TGA is rarely associated with genetic syndromes. Some gene mutations have been described, but their low frequency cannot explain the high incidence of this disorder. Furthermore, there is a low risk of recurrence among relatives of affected patients. To date, VGM has not been associated with a genetic syndrome and familial recurrence has never been reported. A genetic explanation for the combination of both disorders in 1 pregnancy therefore seems less likely.

Last, because both TGA and VGM are vascular disorders and develop in the same embryonic period, we speculate whether growth factors such as vascular endothelial growth factor (VEGF) may play a role in their pathogenesis. The influence of VEGF on endocardial cushion formation and its potential effect on heart septation has been documented, and VEGF may be involved in the development of intracranial arteriovenous malformations. However, an association between VEGF and the development of VGM has not been reported previously.

In conclusion, the association of VGM, TGA, and TTTS in a pair of monochorionic twins is either a very rare coincidence or due to a common pathogenetic mechanism. Hemodynamic and/or
endothelial factors may play an important role in the pathogenesis of the triad of TTTS, TGA, and VGM.

References
Abstract
With increasing advances in the field of perinatal medicine and new breakthroughs in technology, the perinatal mortality has shown a steady decline worldwide. This has given rise to a new dimension, that of developmentally oriented care of these sick neonates while they are still in intensive care. NIDCAP & developmentally supportive care is aimed at decreasing the stress levels in these babies by individualized care which also involves the family. Growth and development has been shown to get enhanced by this approach. There are only a few well designed studies on this issue of extreme importance. This article presents a brief review of current literature as well as outlines relevant policies followed in the author’s unit.

The Neonatal Intensive Care Unit (NICU) environment is dominated by life support systems of ever increasing complexity and in the midst of such technology, developmental assessment and care of the critically ill newborn is often relegated to being a follow-up issue. Though advances in neonatology have led to increased survival of very premature babies, pulmonary morbidity and neurodevelopmental outcome remain two major issues of concern. In the not so distant past, newborns were considered to be unaware of their environment and unable to participate in meaningful interaction. But now we do know that they respond to touch, can differentiate between and show preference for certain stimuli, and they are capable of protecting themselves from the environment (e.g. by moving away from painful stimuli). In recent years, the advent of Neonatal Individualized Developmental Care and Assessment Program (NIDCAP) has led to a greater emphasis on developmental care for high-risk infants and their families to enhance neuro-developmental outcomes.

Developmental care is an approach that uses a range of medical and nursing interventions that aim to decrease the stress of preterm infants in NICU. This article reflects current thought on this topic along with a brief description of relevant policies followed in the unit.

Developmentally Supportive Care
The concept of Developmentally Supportive Care underlines an approach that focuses on minimizing noxious stimuli while individualizing infant care and stimulation based on observable physiologic responses and behavioral cues. A hierarchical framework for understanding premature infant behavior has been proposed by Al et al in their Synactive theory which forms the basis of developmentally supportive care.

In practical terms, a well regulated infant generally maintains stable temperature, color, heart rate, respirations and saturations, and demonstrates good muscle tone, maintains tucked flexion at rest and during handling, and has smooth well modulated movements. He often establishes and maintains clearly defined sleep and awake states, moving smoothly between states, without much energy expenditure. On the other hand, a less well-organized ill term or preterm infant may have unstable cardiac functioning, changes in rate and character of breathing with desaturations and changes in skin color. Tremors, startling, gagging, hiccoughs and spitting up are other responses. Motor responses may take the form of flaccidity of extremities and trunk, finger splays (opening hands and spreading fingers), facial grimacing and frowning and protective measures such as hand on face, arm extensions as if to signal, stop. Growth and development may be enhanced by consistently providing infants and their families with family-centered, developmentally supportive care.

Development of human neonatal brain may be negatively influenced by conventional noxious NICU environments and practices. Experiences of pain during neonatal period have been linked with long lasting accentuated pain responses, altered neuronal circuits, learning deficits, and behavioral changes in rodents. Chronic suppression of REM sleep results in behavioral changes in the adult and reduced cerebral cortical size. It has been suggested that the infant’s sensory experience in NICU
environment, including exposure to bright lights, high sound levels, and frequent noxious interventions, may exert deleterious effects on the immature brain and alter its subsequent development. Als et al. in a study aimed at testing the neurodevelopmental effectiveness of NIDCAP on VLBW infants. In a meta-analysis, Jacobs and collaborators reduced duration of oxygen requirement of 41 days (95% CI 16.8 to 65.3). A Cochrane review also reported a relative risk for the NIDCAP infants of moderate-severe pulmonary radiographic findings of 0.34 (95% CI 0.15 to 0.81). In addition, a mean difference in the mental developmental index at 9-12 months of age of + 16.6 (95% CI 9.3 to 23.8) was described. A Cochrane meta-analysis including 20 studies, states positive impact on tube to bottle transition, behavior (improvement in sleep states, decreased stress behavior during gavage feeding), and length of hospital stay by using non-nutritive sucking.

Neonatal Individualized Developmental Care and Assessment Program (NIDCAP)

So far, there have been three randomized controlled trials (RCT) on the effect of full implementation of NIDCAP on VLBW infants. In a meta-analysis, Jacobs and collaborators report separately on these trials and show a mean difference in length of ventilation of 27.7 days (95% CI 7.5 to 43.9) and reduced duration of oxygen requirement of 41 days (95% CI 16.8 to 65.3). A Cochrane review also reported a relative risk for the NIDCAP infants of moderate-severe pulmonary radiographic findings of 0.34 (95% CI 0.15 to 0.81). In addition, a mean difference in the mental developmental index at 9-12 months of age of + 16.6 (95% CI 9.3 to 23.8) was described. A Cochrane meta-analysis including 20 studies, states positive impact on tube to bottle transition, behavior (improvement in sleep states, decreased stress behavior during gavage feeding), and length of hospital stay by using non-nutritive sucking.

Neonatal Individualized Developmental Care and Assessment Program (NIDCAP)

So far, there have been three randomized controlled trials (RCT) on the effect of full implementation of NIDCAP on VLBW infants. In a meta-analysis, Jacobs and collaborators report separately on these trials and show a mean difference in length of ventilation of 27.7 days (95% CI 7.5 to 43.9) and reduced duration of oxygen requirement of 41 days (95% CI 16.8 to 65.3). A Cochrane review also reported a relative risk for the NIDCAP infants of moderate-severe pulmonary radiographic findings of 0.34 (95% CI 0.15 to 0.81). In addition, a mean difference in the mental developmental index at 9-12 months of age of + 16.6 (95% CI 9.3 to 23.8) was described. A Cochrane meta-analysis including 20 studies, states positive impact on tube to bottle transition, behavior (improvement in sleep states, decreased stress behavior during gavage feeding), and length of hospital stay by using non-nutritive sucking.

Neonatal Individualized Developmental Care and Assessment Program (NIDCAP)

Encouraging parental participation: It is the endeavor of the whole medical and nursing team to demystify and demedicalize the NICU environment for families. Parents are taught appropriate touch to “tune in” with the baby and to provide or assist with infant’s care. Family needs are considered when planning care and feed times. This advocates an individualized approach to family centered care with emphasis on promoting infant organization and enhancing optimal neuro-developmental outcomes. The goal is to support the family by helping them to develop such care skills and techniques, thus including the family as a part of the healthcare team. In order to promote family centered, developmentally supportive care, the health care team must recognize that the entire family experiences a crisis when their infant requires intensive medical care. They might feel a loss of control, grief regarding the loss of the perfect and healthy baby, uncertainty about the outcome, dealing with unfamiliar procedures and people; adjusting to their infant’s altered appearance and not knowing what to do, how to act, or where to turn to for information and advice. The author’s unit follows strategies to develop collaborative relationships and these include encouraging parental suggestions for, and participation in, planning and implementing care strategies for the infant, promoting and practicing open, honest communication among all members of the health care team and parents and sharing information in a timely and supportive manner. It’s important to foster a non-judgmental atmosphere in which parents can openly express feelings and concerns. Altering the NICU environment is a component of NIDCAP.

The preterm infant’s brain is extremely sensitive and has limited ability to buffer the vast amount of input. This input can be in the form of noise, bright lights, handling and positioning. The US Committee to Establish Recommended Standards for Newborn ICU Design in its Fifth Consensus Conference has laid down guidelines for light and sound in NICU.

Noise

In utero, infants are exposed to sound of 40-60 dB, yet the NICU environ typically provides sound at 70-80 dB. An IV pump alarm can record 60-78 dB, tapping fingers at incubator: 70-95 dB, bubbling water in ventilator/hood tubing: 62-87 dB, closing a solid plastic porthole: 80-111 dB and pulse oximeter alarm: 86 dB. These can lead to startles, apneas, bradycardias, color changes, desaturations, and alterations in blood pressure and cerebral blood flow, which may lead to IVH. It’s important to promptly attend to, rather anticipate, monitor alarms, open and close incubator doors gently, and to use blanket coverings over incubator to decrease noise level. We provide soft music as auditory stimulus when appropriate, monitoring the infants response. Teaching rounds should be conducted in an unobtrusive manner. All these interventions are followed at the hospital’s neonatal unit. A novel suggestion would be tape recordings of parents’ voices which may be tolerated by the tiniest infant and may enhance parent-infant bonding.

Light

One of the most important stimuli is light, and bright light may come from phototherapy, procedure spot lights, etc. It has been suggested over-stimulation may interfere with the development of the central visual system. The infants’ overall socialization skills may also be affected. Bright lights increase the incidence of squinting and “shutting out” behaviors, whereas when exposed to reduced levels of lighting, infants seem more interested in and capable of engaging. Policy at our unit includes dim lights, maintaining a safe level of accurate clinical observation as well as modifying lighting to simulate day-night patterns. Individualized bedside lighting is used and incubators are covered with blankets. Adequate eye protection is provided while receiving phototherapy or during procedures like IV cannulation. There should also be a two hour period in the afternoon, the quiet time, in which all non-urgent procedures be suspended, and babies given an opportunity for an afternoon nap.

Tactile stimuli

The unborn infant lives in a warm, fluid-filled environment, gently rocked by constant oscillations of amniotic fluid. Caregiving at NICU can be intrusive and stress producing. It may also contribute to aversive behavior and they may associate all touch with pain, responding by squirming, crying, and recoiling arms and legs. Handling the infant gently, avoiding sudden changes in posture will help promote their tactile and vestibular development. Talking to them prior to touching and repositioning them is also helpful. We consistently provide comfort measures with traumatic and painful procedures. Assisting the infant in achieving a calm and regulated state before beginning an intervention may improve tolerance and help him recover more easily. Blanket rolls are provided to define boundaries. It is important to coordinate blood sampling, X-rays and multi-disciplinary activities, and allow adequate rest-periods or quiet times.

Nursing staff at our unit observe the following policy while doing cares on babies. Interruption is avoided in an infant who
has achieved deep sleep. If the intervention can be briefly postponed, we wait until the infant transitions to light sleep or drowsiness before beginning cares. Infant’s arousal to more awake state is facilitated by speaking softly while gently touching his head or back. Infant’s readiness and availability for interactions is assessed and lighting and noise is reduced. They stay at bedside for several minutes after completing care to ensure that the infant has returned to drowsy or light sleep states. If necessary, containment is provided by placing a hand on the infant’s back and speaking softly until he has successfully returned to sleep. A multidisciplinary team participates in discharge planning, which includes medical and nursing staff, social worker, health visitor, community nurse, dietician, development and supportive nurse along with parents.

**Strategies in the developing world**

Many aspects of developmentally humanized supportive care are already in place and have been pioneered in developing countries. Exceptional amongst them is kangaroo care. Offering parents the opportunity to hold their infant kangaroo style, is an important part of tactile care. Kangaroo holding may help facilitate the family’s psychological healing, enhance parent-infant bonding, and improve lactation. Cochrane’s review of studies on kangaroo care, most of which have been done in developing countries, have recorded improved growth. Parental involvement can be much increased and improved. Allowing parents into the NICU, rather than a door-step update will go a long way in relieving anxiety. Talking to babies, reducing noise and light levels, and administering a small amount of sucrose or breast milk prior to sampling are features that can easily be adapted. Clinical Nurse Educators can play a big role in shaping the future direction of nursing care. The practices mentioned here can serve as guidance but each unit has to adapt keeping in mind respective cultural and traditional issues.

In conclusion, developmentally supportive care is individualized rather than protocol driven. What works for one infant may or may not work for another. In addition, what works for an infant today may or may not work for the same infant tomorrow.

Therefore, ongoing assessment and evaluation of the infant’s behavioral cues are needed to plan appropriate care giving strategies. Although the theoretical framework underlying developmental care interventions is supported by research, the trials have been relatively few and with a small number of infants.

**References**

Background
A clinical trial is a research study in which human volunteers are treated and observed to answer a particular biomedical question. Clinical trials are one of the most valuable sources of evidence to determine which therapies are safe and effective. However, instances of selective reporting of results to benefit proprietary interests rather than public health have recently come to light. For example, in 2004, GlaxoSmithKline settled a US$2.5 million lawsuit for suppressing trial results showing that its antidepressant paroxetine (Paxil) increased suicidal ideation in children. More recently, Merck and Pfizer have been criticized for witholding results showing increased risk of heart disease from COX-2 drugs such as rofecoxib (Vioxx), which was withdrawn from the market because of these risks.

A complete public register of trials and the subsequent release of all results are crucially important to prevent drug and device makers from skewing the public record on the effectiveness of therapies. However, even when local laws require that trials be registered, compliance has been incomplete. In the United States, the Food and Drug Administration Modernization Act requires that all trials on life-threatening diseases be registered into ClinicalTrials.gov (a register maintained by the National Institutes of Health), yet only 48% of industry-sponsored trials were registered during the initial period of the law’s implementation. Moreover, trials are sometimes registered with uninformative data (eg, not giving the name of the tested drug), thus subverting the central purpose of registration, which is to increase transparency.

In reaction to this general state of affairs, an influential group of medical journal editors recently declared that they will publish only previously registered trials. In addition, legislation is being introduced in many jurisdictions to impose broader mandates on trial registration and reporting (eg, Fair Access to Clinical Trials Act in the US Congress). The World Health Organization (WHO), recognizing the highly international nature of modern clinical trial conduct, is establishing policies and standards for trial registration and reporting worldwide. A global commitment is, thus, emerging to ensure that key information about all clinical trials are registered, and that each trial’s results are fully reported.

At a time when over 20,000 new trials are initiated worldwide each year, and with over 294,000 trials already indexed in PubMed, careful thought should be given to how computers could be used to manage the deluge of information. The current consensus is to attempt to code some of the registration data fields (eg, condition, interventions, and outcomes) using a standard medical vocabulary (e.g., International Classification of Diseases and SNOMED), and to report trial results in English in at least a PDF version of the International Conference on Harmonisation E3 guidelines (http://www.ich.org/). However, computers cannot read or understand prose very well at all. For example, the sentence “mean creatinine was 1.9 (95% confidence interval, 1.2–2.6) in the intervention group and 2.4 (95% confidence interval, 1.9–2.9) in the comparison group” is not directly usable by search engines, statistical programs, or decision support systems. The prose reporting of trial information could be powerfully augmented by a computable repository of trial information—a global trial bank. Unlike prose, computable information is structured and coded for computation and allows the use of advanced information technologies for knowledge management. With billions of dollars spent annually on drugs and other health interventions, the world cannot afford to keep knowledge from clinical trials only in prose.

The Global Trial Bank Project
Global Trial Bank (GTB) is a nonprofit organization formed under the auspices of the American Medical Informatics Association, Bethesda, MD. Reprinted from PLoS Med 2(11): e365. 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. Copyright: © 2005 Sim and Detmer.
Association (http://www.amia.org), a professional scientific association. GTB’s goal is to speed the dissemination, understanding, synthesis, and translation of clinical trials to improve human health. To reach this goal, GTB seeks to make available open-access and computable peer-reviewed results from all clinical trials conducted worldwide, regardless of whether the results are favorable or not, to provide an unbiased knowledge base for improving human health. Through the GTB Web site (http://www.globaltrialbank.org), clinicians and patients will be able to accurately retrieve relevant trial results, and scientists will be able to analyze data across trials to compare and contrast trials and to generate new findings and insights. The key features of GTB are as follows.

**Sufficient detail for science**

GTB will collect necessary protocol and results information in sufficient detail to allow the scientific community to assess a study’s scientific strengths and weaknesses, and to properly interpret the findings. This includes information on study design (e.g., allocation concealment), study execution (e.g., withdrawal rates and compliance), and study results (e.g., subgroup results and adverse events). The data collected will be compatible with the WHO Registration Data Set as well as the CONSORT statement on trial reporting (http://www.consort-statement.org/).

**Computable information**

GTB will collect the following information in structured, coded form: eligibility criteria, interventions, outcomes, and summary results for outcomes at all predefined time points for all intervention and comparison groups and predefined subgroups. GTB will then be able to support queries such as “retrieve all trials on women over age 60 with heart disease in which a beta-blocker was studied, and that report heart attack rates at three and five years for which at least 80% of the participants were followed up.” Such detailed queries and analyses will enable much more powerful computer-assisted interpretation, application, and data mining of clinical trial information than is possible today.

To further support clinical trial knowledge management, GTB will provide standards-compliant interfaces for information and decision support systems to directly access the GTB database over the Internet. This will allow third parties to provide
customized solutions without having to manually transcribe data from text articles to another computer.

**Integrated peer review**

We anticipate that protocol information will be either downloaded directly from a trial register if not registered directly with GTB or entered by the trialist. Protocol information will not be peer reviewed. It is critical, however, that trial results be peer reviewed. Results will come from three sources: (1) results reported in peer-reviewed mainline journals, (2) results reported in non-peer-reviewed publications or Web sites (e.g., pharmaceutical company sites), and (3) results reported directly to GTB.

Results not directly reported to GTB will be captured semiautomatically with some input by GTB staff and/or the trialist. GTB will link to peer-reviewed publications and will not perform further peer review on these trials. There is a precedence, called “trial bank publishing,” for publishing trial results as both prose journal articles and trial bank entries. It is a model akin to the publication of genomic information in both GenBank and traditional scientific journals.

Trial results that have not been previously peer reviewed will be submitted to PLoS Clinical Trials (http://www.plosclinicaltrials.org), a new PLoS journal, for peer review. PLoS Clinical Trials anticipates accepting all trials that meet a set of minimum requirements regardless of outcome or “clinical interest” to maximize the number of trials that are reported to the public. PLoS will also provide annotated commentaries on accepted studies and a discussion forum for open postpublication peer review of all GTB entries of completed trials.

**Challenges**

GTB reflects a new approach to publishing clinical research: publishing in both prose and computable form, as well as publishing all results, not just “clinically important” ones. As such, GTB faces undeniable challenges. The work of data entry must be reasonable. The coding of data fields in a controlled medical vocabulary (e.g., SNOMED) must be relatively easy and reproducible. The publishing model should result in overall strengthening of the quality and usefulness of clinical trial publishing. And finally, the operation must be open access yet financially self-sustaining. Intermediate solutions to these challenges are available and will provide opportunities for continuing improvement.

**Conclusions**

The reporting of clinical trial results as both prose and computable data is arguably a natural progression in the development of electronic publishing. Coupled with emerging international policies on clinical trial registration, GTB offers the most advanced computable repository of trial protocol and results information to promote biomedical discovery as well as transparency and accountability in clinical trial research. With its additional features of being nonprofit, open access, and peer reviewed, we anticipate that GTB will become a major global resource for knowledge management in biomedicine.

GTB builds upon the National Institutes of Health–funded research of the Trial Bank Project (http://rctbank.ucsf.edu/) and PLoS’s vision of a new, more inclusive approach to make peer-reviewed clinical trial results available to the public. GTB has formed an international advisory board and received a seed grant, and is actively forming additional partnerships and seeking foundation funds for start-up.
Where There Is No Internet: Delivering Health Information via the Blue Trunk Libraries

Pascal Mouhouelo, Auguste Okessi, Marie-Paule Kabore

The Technology Gap

“Information access,” argued Packenham-Walsh and colleagues in the BMJ, “is the sine qua non of the professional development of all health workers—the most vital asset of any healthcare system.” And the development of the Internet has brought hope that access to health information might one day become universal. Access to online databases gives users the opportunity to retrieve a wealth of relevant and up-to-date information. Every day, health-related books, research, and other articles are retrieved from the Internet, which has led to a worldwide information revolution (see appendix).

However, the World Health Organization (WHO) is very much aware that there are many areas in the world where access to the Internet is not yet a reality. In developing countries, a large proportion of the population, including health professionals, has no or only poor access to the Internet. Even printed materials, such as up-to-date books, current periodicals, and newspapers, are scarce. In this situation, professionals are obliged to rely on the knowledge acquired during their original training to care for patients, to prevent disease, and to promote health.

In many regions, the health district centers are staffed by nurses, midwives, and community health workers who, having finished their basic studies, receive little in the way of continuing education, as libraries rarely exist at the district level or in regional hospitals. The distribution of CD-ROMs to developing countries is an important initiative, which has proven to be a valuable source of health information. For example, the health-related CD-ROMs from TALC (Teaching-aids At Low Cost, http://www.talcuk.org) and those distributed by the WHO and the joint United Nations Programme for HIV/AIDS (UNAIDS) are much appreciated by their users. The CD-ROM is an important tool for information delivery in Africa because it does not take up a lot of space and shipping it is inexpensive.

Unfortunately, there are still many areas in the developing world that have neither computers nor a reliable electricity supply. Thus, in spite of the rapid development of information and communications technologies, the gap between “the haves and have-nots” continues to blight isolated areas (those outside a capital city). In those areas, the appropriate solution to information access is still printed material. In response to this need for printed health information, WHO librarians created the Blue Trunk Library (BTL) project.

What is the Blue Trunk Library?
The idea of creating the BTL collection stemmed from the conclusions of a joint survey conducted by the ministry of health and the WHO country office in Guinea to define the continuing education needs for health workers based in the health districts. The survey found that these workers needed to broaden their skills. Therefore, the WHO library was asked to compile a collection of appropriate books to suit the different education needs of health district workers at various professional levels. The WHO library in Geneva started the BTL project in 1998. Guinea was the first country to benefit from this prototype, which was then extended to other African countries before being taken up in developing countries in other parts of the world. There are English and French versions of the BTL.

The BTL is “a ready-to-use documentation module” of about 150 WHO and non-WHO books and manuals fitted into a blue metal trunk. The materials are arranged and filed in such a way that users can easily identify the ones that they need. Fourteen topics have been chosen using a basic classification code, e.g., General Medicine and Nursing (100), Community Health (110), and these codes are written on each filing box.

The content is selected by the WHO press unit and the WHO library in collaboration with a group of WHO health professionals. The BTLS composition varies according to the books available in each language. For example, Médecine Tropicale by Marc Gentilini is selected for the French version of the BTL, while the Oxford Handbook of Tropical Medicine is selected for the English version. Books dealing with specific...
diseases are removed or replaced according to the needs of the specific geographical area that is receiving the BTL.

Each BTL costs US$2,000, which includes training users but not the cost of shipping (it costs about US$717 to send a BTL to Lusaka, Zambia, and about US$620 to Yaoundé, Cameroon). The BTL project is funded by international and bilateral donors such as the United Nations Children’s Fund (UNICEF), the United Nations Development Programme (UNDP), the WHO, the German Council for Sustainable Development (GTZ), the United States Agency for International Development (USAID); Belgian, Italian, French, German, and Irish embassies; and nongovernmental organizations such as Save the Children, Merlin, and Entre-Aide. These donors and NGOs have funded BTLs in countries where they have development projects. Funders purchase a BTL directly from the BTL management team in Geneva (bluetrunk@who.int).

In countries where at least 20 BTLs have been acquired, the ministry of health appoints a national coordinator, and assistants are selected from the health districts to attend a training session in the use of the BTL. The BTL project supports this training, which is facilitated by WHO librarians and national health librarians.

The African Experience

Health districts in the anglophone and francophone countries of Africa have been the major beneficiaries of the BTL. Training sessions have been organized in 14 countries, including Burundi, Guinea, Ethiopia, Republic of Congo, Mauritania, and Mali. Commitment to this project is shared both by donors (funding a BTL addresses the information needs of isolated rural Africa) and by the community health workers (who are given an opportunity to broaden their skills).

To date, the sub-Saharan countries have acquired about 850 BTLs out of the total of 1,488 distributed worldwide. The ambitious objective is to provide each health district with one BTL, but these districts are not the only health-related structures in need. For example, the WHO Regional Office library has received requests from nursing schools and NGOs in Zimbabwe, Burundi, Sierra Leone, and the Republic of Congo.

One of the problems the project is facing is how best to reach African lusophone countries. While it is reasonably easy to identify suitable materials in English and French, this is not the case for Portuguese learning materials. We tried to translate some of the BTL contents into Portuguese, but with little success because of the large number of books that needed to be translated. Collaboration with institutions in Brazil that generate health materials themselves is likely to be a more fruitful strategy. Portuguese-speaking countries should not be left out and should have their own BTL. The WHO publishes a large volume of health materials in Spanish, and so a Spanish version of the BTL may also be developed. Another long-term strategic plan is to update the content of BTL.

The Impact of the Library

While there has not yet been a formal evaluation of the impact of the BTL, BTL training sessions have provided an opportunity for WHO facilitators to determine how appropriate and relevant the project is in different countries. In their written and oral reports, health workers who received training have said that the BTL has helped them to improve the quality of health care in remote areas. For example, they have said that the library helped them in making decisions such as diagnosing and managing diseases.

Marie Khemesse Ngom, at Senegal’s Ministry of Health, commented: “Many reasons explain why the Blue Trunk Library is very much used. The users refresh their knowledge after their initial skills acquired in schools. They use this collection in order to read new techniques, standards, and practices in health and medicine. In Kédougou, the Blue Trunk Library manager said that since this collection has been installed in their health district, every year many health workers are passing their professional exams in hygiene and public health. In Nioro, the health district doctor thanks the Blue Trunk Library because he has specialized in Public Health.”

The BTL is distributed along with a variety of tools—such as questionnaires for users, managers, and national coordinators—that WHO librarians or information officers use to collect comments and give feedback to the WHO regional offices and to the headquarters in Geneva.

In some countries, national health promotion teams are using the BTL materials for community health education by creating posters and simple brochures in local languages based on the English or French manuals in the library. The WHO Eastern Mediterranean Region (EMRO), which has its headquarters in Cairo, Egypt, and which has already purchased about 250 BTLs, receives the contents of the BTL from the WHO headquarters and “manufactures a wooden Blue Trunk Library equipped with four wheels.” It also adds Arabic materials published in the EMRO Region to the original collection. Two other WHO regional offices—in Southeast Asia and the Western Pacific—have purchased BTLs, and we hope to extend the project to the Caribbean and Latin America.

References

Drowning or Thirsting: The Extremes of Availability of Medical Information

Medical researchers in the developed world increasingly feel overwhelmed by the mass of published information, both on paper and on the Web. MEDLINE/ PubMed, the National Library of Medicine’s electronic database, gives an idea of the scale of the problem: it contains references to more than 16 million articles in some 4,800 biomedical journals. Even this volume is dwarfed by the unindexed, “gray,” literature lurking in the world’s digital databases.

Navigating this sea of information is not straightforward, even for experienced researchers or clinicians. At least MEDLINE provides some sort of mark of respectability, and most professionals feel comfortable using information from this source. One obstacle they face is that only a small proportion of indexed papers are freely available as full text either from PubMedCentral or from a journal’s own website. But those able to pay, or with access to a well-resourced library, can eventually get access to pretty much any information they want, and have some idea of its reliability. For these medical researchers and clinicians, the crucial questions then become “how appropriate is this paper for me, and how does it sit in the context of other research?”

The challenge for biomedical publishing, at least in the developed world, is now less how to produce and distribute a vast amount of literature and more how to navigate it. Just as sophisticated computer algorithms are required to derive knowledge from genomes, they are also needed to extract information from the ever-growing bibliome. New search and aggregation engines are continuously under development, which mine and analyze the published literature in increasingly subtle and systematic ways. These tools are crucially reliant on the free availability of papers, not just abstracts but also the whole text and the data behind it.

Given the information overload of the developed world, it’s easy to forget that not everyone has the same problem. In many areas of Africa, medical libraries contain virtually no information whatsoever, so while the rest of the world craves more sophistication in their searching and analyses of the literature, medical workers there lack even the most basic medical information, either on paper or electronically.

The article here by Pascal Mouhouelo and colleagues describes a low-tech initiative to address this lack of information: the evocatively named Blue Trunk library. This library contains within it carefully selected books covering topics from “care of the critically ill patient in the tropics and subtropics” to “young people and substance abuse.” This project is nothing short of a lifesaving initiative—a trickle of information to an information-parched part of the world; the contrast with the information overload of the developed world is yet again a shaming example of global disparities. So ironically, while the developed world increasingly turns away from paper, it remains an information lifeline for Africa. But interestingly, electronic devices may eventually provide innovative solutions to bridge this information gap. Already, mobile phones are more reliable than landlines in much of the less-developed world, and as companies scramble to develop cheap handheld devices for use in the most inaccessible places, new technology may leapfrog the developed world’s computers to allow direct access to medical literature. Equality of information may then be a reality, an essential prerequisite to health equality.

Copyright © 2006 The PLoS Medicine Editors. This is an open-access article distributed under the terms of the Creative Commons Attribution License.

Appendix

The Online Health Information Revolution

- The WHO has created its own online bibliographical database, WHOLIS, at http://www.who.int/library/database/index.en.shtml. Other organizations that generate specialized knowledge have launched similar databases.
- The WHO Regional Office for Africa has created AFROLIB, an online library database at http://afrolib.afro.who.int.
- The WHO also leads HINARI, the Health InterNetwork Access to Research Initiative, at http://www.who.int/hinari/en, a program that provides nonprofit institutions in some developing countries with free or very low cost online access to the major journals in biomedical and related social sciences.
- The Global Information Full Text (GIFT) initiative has also been launched for all the WHO offices (it is only accessible to WHO staff). This initiative is a global site license for online access to a targeted selection of the major international databases and full-text journals in the scientific, health, and biomedical fields.
- An increasing number of medical and scientific journals—including those published by Biomed Central (http://www.biomedcentral.com) and PLoS (http://www.plos.org)—are adopting an open-access publishing model, in which articles are freely available and readers are licensed to download, distribute, and translate all works.
Isn’t it strange how a peculiar number such as 20.9 can make us stop for a moment? And for what? Is it the Olympic record for the 200 meter dash, or the square root of 438? Or maybe it has no meaning at all and you just wasted the last 20.9 seconds of your life?

The reality is 20.9 is the heartbeat and focus of our company. It is the reason we put so much time and effort into researching and developing our products. It is also a measurement of our precision and quality.

So what’s in it for me, you ask?

Well, you have two choices:

One, you can ignore everything you just read and wish that you had just skipped past this page in the first place. Or, you could be one of the lucky 209 people to visit:

www.whatis209.com

enter promo code: NI0207
Is Time Running Out?

24 hour monitoring.

Reliable in up to 100% relative humidity.

Colorimetric breath indicators for visualization of exhaled CO₂ for verification of proper intubation.

24 hours/100%

StatCO₂® End Tidal CO₂ Detectors

a higher standard in end tidal CO₂ detection.

Patent US 6,502,573 B1
other patents pending

Be sure to visit us at Booths 556, 558 and 560 at the American Association of Respiratory Care Meeting, Las Vegas Convention Center, Las Vegas, Nevada, December 11 - December 14, 2006.
Create a more nurturing environment and increase efficiency. Dräger Medical’s CareArea™ Solutions for Perinatal Care integrate leading-edge medical systems and services to help you evolutionize the acute point of care.

To see the many ways our ongoing integration can impact your business of care, contact Dräger Medical today.