

neonatal INTENSIVE CARE

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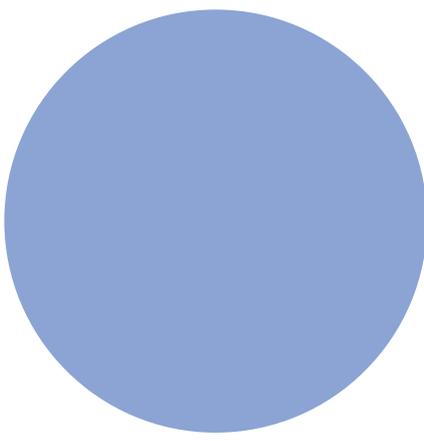
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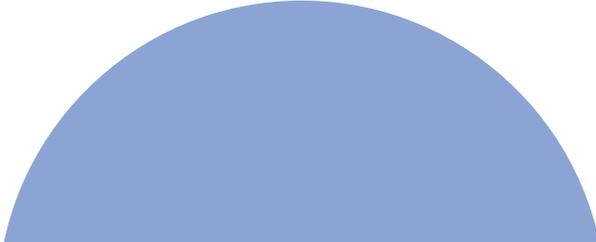
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neonatal INTENSIVE CARE

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May-June 2009

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Editorial

Meconium Stained Amniotic Fluid: Infant Management is Still A Dilemma 40 Years Later

Benamanahalli K. Rajegowda, MD; Muhammad Aslam, MD

The authors are members of Neonatal Intensive Care's Editorial Advisory Board and frequent contributors to the journal.

Meconium is a product of fetal material that is black, tarry, sticky, sterile, and odorless with a varied consistency. Normally no fetus should pass meconium before birth. It is estimated to occur in mature and postmature fetuses with an average incidence of 10-15% of all live births. In a recent report of 2006 vital statistics meconium stained amniotic fluid (MSAF) occurred in 44.8 per 1000 deliveries in the USA. It is thought that any fetal distress can stimulate the gastrointestinal motility with relaxation of the anal sphincter facilitating passage of meconium in utero. It is also believed that the fetus can gasp with the rhythmic movements in utero and can aspirate meconium before the birth. The presence of meconium can significantly increase the risk of acid-base disorders, morbidity and mortality particularly from aspiration into respiratory tract, lung complications, hypoxia, persistent fetal circulation and even death in some unfortunate cases.

Meconium aspiration syndrome (MAS) occurs in about 5-10% of all cases of MSAF. It is very important to prevent the aspiration of meconium in the intrapartum period to avoid complications. Starting in late 1960s, a tremendous progress was made in the management of babies with MSAF in the intrapartum period and immediately after birth to prevent meconium aspiration and its complications. The reduction of MAS in the USA is attributed to several perinatal strategies. These include;

- Maternal-fetal monitoring
- Use of scalp pH for detection of hypoxia
- Use of amnioinfusion in fetal compression syndrome
- Training of maternal-fetal specialists
- Decrease in post-term births (> 41 wks gestational age)
- Training of neonatal-perinatal specialists
- Combined obstetric-pediatric management of MSAF at delivery and soon after birth
- Introduction of routine endotracheal intubation with suction to prevent meconium aspiration
- Routine chest physical therapy, mechanical ventilation, and neonatal care of these patients.

In late 1960s, our early years of experience as a pediatric resident and neonatology fellow, we responded to all MSAF deliveries. We have seen morbid MAS and death of at least 1-2 full term infants per year. In the 1970s, after review and implementation of policy towards MAS, there was a definite improvement in outcome of MAS babies. The important things contributing towards this healthy outcome of MAS were:

- Introduction of guidelines by Gregory et al (J Pediatr, 1974) for the management of infants born with MSAF.
- In 1976, Carson et al (Am J Obstet Gynecol) introduced a combined obstetric-pediatric approach to prevent MAS.
- Our hospital used a modification of these guidelines that only depressed babies with MSAF need to be intubated and suctioned. We implemented this approach at our institution for almost 3 decades. This approach resulted in a decrease in the

Continued on page 36...

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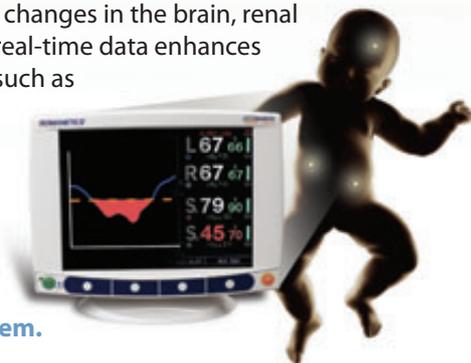


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1. Hoffman GM, et al. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005; pp 12-21. 2. Hoffman GM, et al. Anesthesiology 2005; 103:A1327 3. Dent CL, et al. J Thorac Cardiovasc Surg 2005; 130: 1523-30. 4. Kaufman et al. J Ped Crit Care Med 2008; 9:62-8. 5. Diaz GA, et al. Eur J Paediatr Neurol 2006; 10:19-21 © Somanetics Corporation. Somanetics, INVOS and "Reflecting the color of life" are registered trademarks of Somanetics Corporation. US federal regulations restrict the sale of this device to, or on the order of, licensed medical practitioners.

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STILL THE SAME

The number of stillbirths and deaths shortly after birth remains high, claiming 17 babies every day in the UK, according to a report by the BBC. Every year in the UK nearly 4,000 babies are stillborn and another 2,500 die within four weeks, and this stillbirth rate has not changed for a decade. The Department of Health in England said there had been an increase in midwives and consultant obstetricians, and increased investment in the field, but that many deaths could be avoided by better antenatal care and more funding for research. Part of the problem is a shortage of neonatal nurses, with 1,700 posts needing to be filled and only 14 out of 50 intensive care units in the UK providing minimum standards of one-to-one care for sick and premature babies. Also, moms-to-be are not being made aware of the risks of stillbirth, with 42% of 348 mothers not receiving any information on stillbirth from their midwife, even though many cases occur in low risk pregnancies. A survey of 270 parents whose babies died found that almost half of parents did not feel that everything possible was done to save their baby's life; they felt rushed through their antenatal appointments and not completely confident about the way in which they were cared for in the lead up to their baby's death.

GET OUT OF BED

Infant deaths blamed on accidental strangulation and suffocation in bed have increased sharply in the United States, federal health officials are reporting, reigniting a heated debate over the rising number of parents who sleep with their babies. An analysis of death certificates nationwide found that the rate of fatalities attributed to unintentional suffocation and strangulation in the first year of life quadrupled between 1984 and 2004. In a recent study, the death rate from accidental strangulation and suffocation was 27.3 per 100,000 live births among African Americans, compared with 8.5 among whites, with boys younger than 4 months being the most vulnerable. The study did not examine what is causing the increase, but the trend roughly coincided with a sharp rise in bed-sharing, which has become more popular to help mothers bond and breast-feed. Such deaths can occur when a sleeping parent rolls on top of a baby, a pillow falls on an infant's face, a blanket gets wrapped around the child's neck or when the baby gets wedged between a mattress and a wall. A recent study by Shapiro-Mendoza et al found that the rate of accidental strangulation and suffocation deaths increased from 2.8 to 12.5 per 100,000 live births during with the 20-year study period, increasing the number of deaths from 103 in 1984 to 513 in 2004. Most of the increase occurred after 1996, which is about the same time deaths from SIDS appeared to plateau after falling by about half, the result of a

nationwide campaign to encourage parents to put their babies to sleep on their backs. It also coincided with efforts to investigate sudden infant deaths more thoroughly. The findings provide the first national confirmation for a trend that has been suspected by officials in many cities. The risk is highest among African Americans, the study found. The findings prompted several experts to call for increased efforts to discourage parents from sleeping in the same bed with their babies or in other unsafe places, such as couches, and to educate parents about how they can sleep near their children safely. Proponents of bed-sharing challenged the link between the practice and the increased deaths from accidental strangulation and suffocation. There could be other explanations, they said, and said bed-sharing has many benefits, including helping mothers to breast-feed and form crucial bonds with their children. Others said the key is to teach parents how to sleep safely with their babies. Shapiro-Mendoza and others said the increase in suffocations and strangulations could be due at least in part to a shift in classifying deaths that previously would have been attributed to SIDS. A 2003 national survey found that the percentage of babies sleeping with a parent or other caregiver more than doubled between 1993 and 2000. The practice was especially common among younger and poorer women, those living in the South, African Americans, and Asian Americans. While more-affluent women may bed-share to help bond and breast-feed, poorer women often share a bed for other reasons, for instance, that there's only one bed. Reported by Rob Stein, in the Washington Post.

IT NOW

The New York Times' Steve Lohr recently reported on the inroads electronic record keeping is making in the medical community. According to the article, the government is about to get into electronic technology for health records in a big way. In its economic recovery package, the Obama administration plans to spend \$19 billion to accelerate the use of computerized medical records in doctors' offices. Medical experts agree that electronic patient records, when used wisely, can help curb costs and improve care. According to the Times, such data-processing is already the norm among large medical groups which have invested in IT and say they have benefited from the cost savings. Yet, three-fourths of the nation's doctors practice in small offices, with 10 doctors or fewer, and only about 17% of the nation's physicians are using computerized patient records, according to a government-sponsored survey. How come? Getting up to IT-speed hasn't been reimbursable, for one thing. Now the Obama administration has called for more than \$40,000 spread over a few years for a physician who buys and uses electronic health records and puts them to "meaningful use." Well, there's the rub: the government has yet to define its terms. Consequently, says the Times, "many health experts predict that the meaningful use will be a requirement to collect and report measurements that can be closely correlated with improved health." It is predicted that achieving success in implementation will not be easy. The crucial element, it is said, will be how local organizations help doctors in small offices adopt and use electronic records. The new legislation calls for creation of "regional health IT extension centers." The Primary Care Information Project in New York City is a model. The project began two years ago, with \$27 million in financing. The New York team brought in experts to see how doctors operate, and designed its own software for simple, Web-based electronic health records, but "abandoned that idea once they understood that patient records would have to be tightly linked to billing," per the Times. The staff worked closely with its software

supplier, eClinicalWorks, to tailor the system. The Times says, “They began rolling out the records a little more than a year ago. They are now used by more than 1,000 physicians, mainly in poorer neighborhoods, whose workplaces include two hospital outpatient clinics, 10 community health centers, 150 small group physician practices and one women’s jail, serving a total of one million patients. The rollout is progressing, and the government plan promises to accelerate adoption.” According to a physician who uses the system, “Our experience here is that it’s just hard. It’s not impossible.”

PLAY A PART

As part of its ongoing commitment to promoting open access in the developing world, BioMed Central teamed up with Computer Aid International to support research in Africa. BioMed has chosen to support Kenyatta University in Nairobi to help local scientists conduct vital research directly relevant to local problems in one of the poorest parts of Africa. Many of the university’s academics have been published in open access journals, including those from BioMed Central. In common with most African universities, however, Kenyatta cannot afford new computers, meaning that academics cannot get the access time that they need for researching and preparing papers. BioMed is partnering with Computer Aid International, who provide affordable professionally refurbished PCs to the developing world, to resolve this problem. BioMed Central aims to raise £10,760 in order to provide a container of 225 PCs to the university—enough to give all research departments their own dedicated suite of computers and guarantee that the university’s 720 research staff all get the IT access that they need. You can make a contribution to this project today by visiting the site above. In return for your support BioMed said it would let contributors know how the money is spent and provide updates on the progress of the project.

TWITTER TWINS

Recently, a team of 15 doctors and medical staff separated conjoined twins in six hours in surgery while the main surgeon also posted updates on his hospital blog and took photos. One posting says, “I’m standing here in the operating room looking at the exposed beating heart.” Twittering while you work, while not commonplace, has found some recent adherents in the medical profession. A recent report by CNN said twittering is “getting some buzz, and there’s no question that more doctors—and patients—will be sharing the blow-by-blow of medical procedures on Twitter and Facebook.” For example, CNN reports, a doctor tweeted his own varicose vein removal surgery as it was happening. The doctor said, “I wanted a record for other people who might be interested in the same surgery,” and he also posted photos and video of his surgery. Reported by CNN.

NEW BLUE EYES

The BBC reports that a US clinic is offering parents the chance to select

traits like the eye and hair color of their offspring. The LA Fertility Institutes said it expects a trait-selected baby to be born next year. The clinic also offers sex selection. Fertility experts have said that the service is merely a distraction, and takes the focus off the use of technology to protect against inherited diseases. The technique is preimplantation genetic diagnosis, which involves testing a cell from an embryo before it’s put in the mom’s womb, at which point an embryo is chosen with the desired physical traits, while the others are discarded. One researcher commented, “This is the inevitable slippery slope.” The clinic said it is offering no guarantees about how the actual babies turn out.

2X2

A Michigan woman with two wombs has given birth to twin daughters, one from each uterus. The AP and WLUC-TV reported that the mom’s two healthy babies were delivered seven weeks premature by cesarean section. The 21-year-old Sault Ste Marie woman had uterus didelphys, and doctors said such twin births are rare. The uteri are different sizes, with the larger twin born from the larger uterus. Neonatologists said they had expected the babies to be hospitalized until their lungs stabilized.

JUST SAY YES?

The use of crack cocaine hasn’t led to a generation of damaged babies or kids, according to recent studies. Researchers have been following children who were exposed to cocaine before birth, and their findings suggest that the long-term effects of such exposure on children’s brain development and behavior appear relatively small. Experts now say cocaine’s effects are less severe than those of alcohol and are comparable to those



HEALTH

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of tobacco, two legal substances that are used much more often by pregnant women, despite health warnings. Surveys by HHS in 2006 and 2007 found that 5.2% of pregnant women reported using any illicit drug, compared with 11.6% for alcohol and 16% percent for tobacco. Recent studies have shown that while cocaine slows fetal growth, and exposed infants tend to be born smaller than unexposed ones, with smaller heads, as these children grow, brain and body size catch up. An analysis of a pool of studies of 14 groups of 4,419 cocaine-exposed children ranging in age from 4 to 13 failed to show a statistically significant effect on IQ or language development. In the largest of the studies, IQ scores of exposed children averaged about 4 points lower at age 7 than those of unexposed children. In tests that measure specific brain functions, there is evidence that cocaine-exposed children are more likely than others to have difficulty with tasks that require visual attention and priority setting. Cocaine exposure may also increase the frequency of defiant behavior and poor conduct, but experts say these findings are subtle and hard to generalize, once you add in factors like poor parenting, poverty, and exposure to violence, which can actually cause more problems than coke. Reported by Susan Okie in the New York Times.

SPLIT

A team of Saudi medical experts successfully separated Egyptian twin boys Hassan and Mahmoud recently, the 21st procedure of this type to be performed in the kingdom, the nation's leading surgeon said. The boys were less than a year old. Physicians said separating their urinary system was the major challenge, as well as separating the siblings' local veins and arteries. Reported by CNN.

FORCED LABOR

Mothers in Scotland are being unnecessarily induced into labor, according to a study of 17,000 births by Aberdeen University. Concerns have been raised about pregnant women being induced unnecessarily, after a Scottish audit of 17,000 births. In the UK, the commonest method of induction is the use of a gel containing prostaglandins to bring on contractions and start the labor process. Researchers identified 32% of births in Scotland between 1999 and 2003 were induced, and no clear indication why was available for 28% of the cases. Reported by the BBC.

BOOK REVIEW: ALMOST HOME

Almost Home, by Christine Gleason, MD, tells the stories of preemies in the author's care. Dr Gleason is a leading neonatal pediatric surgeon and Chief of Neonatology and Pediatrics at the University of Washington and Seattle Children's Hospital. Her book offers case studies of more than a dozen preemies and their journey through the NICU, and chronicles her many and varied NICU experiences. Cases cover the lucky to the sublime. Contact Kaplan Publishing or your local bookstore.

SEX AND STEROIDS

The University of California San Francisco recently started a trial to examine the use of steroids to treat congenital adrenal hyperplasia. The severe form of CAH occurs in about one in 15,000 births, and is routinely screened for. About 75% of the severe cases suffer from salt-wasting CAH that can trigger vomiting and dehydration within the first weeks of life. Treatment typically involves taking steroids for life. Girls can suffer an additional complication: external genitalia are virilized, leading to an enlarged clitoris and fused labia that can in varying degrees appear male-like. Many parents choose to have their infant daughters' genitalia surgically reconstructed soon after

birth. Without proper treatment, girls may later develop a deeper-than-normal voice and facial hair and may be infertile. Doctors have used steroids to target CAH in the womb for about two decades, but the treatment is a lot more common today. Although administering steroids to a fetus doesn't prevent the disease, it can avert malformed genitalia in girls. If it's administered when the fetus is only a few weeks old, there's a good chance, if the baby is a boy or an unaffected girl, that the drug won't have to be taken as a lifetime regimen. However, steroids can cause unpleasant side effects in the mom, and is thought to potentially affect the baby's subsequent physical and mental development. Most mothers facing a diagnosis of CAH elect to take the steroid. A recent study backed by the NIH indicates that children exposed to the steroid in the womb don't seem to suffer any effects. The study included 100 subjects, all treated subjects, more than half of whom were treated prenatally. Researchers cautioned that it only treats the birth defect of ambiguous genitalia in girls and not the disease itself. From a report by Gautam Naik, in the Wall Street Journal.

DIDN'T WORK

A treatment thought to improve a preemie's chance of fighting infection due to neutropenia doesn't really do any good, according to a study at Guy's and St Thomas' Hospital. Neonatal specialists have been using the GM-CSF protein for increasing white blood cells and preventing infection, a procedure that has worked in cancer patients and those receiving chemotherapy. But research in 280 babies born at 31 weeks or less found it didn't prevent sepsis. Researchers found no significant difference in deaths from blood sepsis - due to infection in those who had GM-CSF or those who had standard management. White blood cell counts went up, yet this didn't affect survival. Reported by the BBC.

SCREEN TEST

Checking blood oxygen levels increased detection of ductus arteriosus, according to a study at Gothenburg University. Researchers screened all 39,800 babies born in the West Gotaland region of Sweden between July 2004 and March 2007 using pulse oximetry before a physical examination was carried out. Sixty babies were found to have the disorder. A combination of pulse oximetry and physical checks detected 92% of duct-dependent heart disease cases, compared with 72% picked up through physical checks alone. No babies died in West Gotaland from undiagnosed heart disease, while there were five deaths in Swedish regions. The researchers concluded that pulse oximetry was a low risk and low cost strategy.

PLACENTAL EDUCATION

Researchers at the University of California, San Francisco, have discovered the mechanism by which women train their fetuses' budding immune systems: the mother's cells slip across the placenta, enter the fetus's body and teach it to treat these cells as its own. A crucial task of the developing immune system is to learn to distinguish between foreign substances and the self. The system must respond to outside threats but not overreact to harmless stimuli or the body's own tissues. The new findings show how that system is tuned. The researchers worked with lymph nodes and spleens from aborted second-trimester fetuses. They also drew blood from the women who had been carrying these fetuses to test for specific immune responses. The team examined 18 samples of fetal lymph nodes and found evidence of maternal cells in 15 of them. They observed that regulatory T cells were present in large numbers in the fetal lymph nodes and

wondered whether a symmetrical mechanism might be at work in the fetus. The group was able to demonstrate that cells from the mother directly cause fetal tissue to produce more regulatory T cells. These, in turn, help keep the fetal immune system from attacking the mother's cells. Researchers found a specific mechanism for how the mother's cells induce the fetal immune system to be more tolerant. The new finding may also bolster wide-ranging work on autoimmune diseases. By manipulating patients' regulatory T cells, perhaps by modifying the number or activity of these cells, scientists may someday develop new therapies for these diseases. Reported by Amanda Schaffner, in the New York Times.

BACK AND FORTH

A new national report on childbirth suggests that some long-term trends may be reversing themselves. The report, published by the National Center for Health Statistics, found that more babies were born in 2006 than in any year since 1961. After a 14-year period of decline, births among teenagers 15 to 19 rose 3% in 2006 from the year before. The largest increase was in Alaska [there's a joke in here somewhere], where the number of births for this age group rose 19%, but there were significant increases in 25 other states as well. There were 3% more c-section deliveries in 2006, a record high of 31.1% of all births, and the percentage of babies born at low weight rose to 8.3%, the highest in 40 years. Labor was induced in 22.5% of births, a slight increase over 2005 and double the rate of 1990. Over the past several decades, the number of multiple births has increased steadily but has now leveled off for twins at 32.1 per thousand births. The triplet (and higher) rate declined by 5% in 2006 to 1.53 per thousand, a 21% decline since 1998. Reported by the New York Times, © The New York Times.

LIKELY TO DIE

The BBC reported that women in poor nations are 300 times more likely to die in childbirth or from pregnancy complications than those in the developed world, according to a report by Unicef. The lifetime risk in the poorest countries was one in 24, compared with one in 8,000 in richer countries. About 99% of the 500,000 maternal deaths in 2005 occurred outside industrialized nations, more than half of them in Africa, Unicef said. Liberia had the highest rate of neonatal mortality at 66 deaths per 1,000 live births. In Niger, the country with the world's highest maternal mortality, a woman has a one in seven chance of dying, during pregnancy or childbirth. Ireland is the safest place to have a baby; the risk of death is one in 47,600. Unicef also noted that girls who give birth before the age of 15 are five times more likely to die in childbirth than women in their 20s. About four in 10 of all births worldwide are not attended by a doctor or other health professional.

FIRE

Five newborns receiving treatment for a skin ailment at a government hospital in north India died after a fire broke out Saturday, authorities said. The babies were less than 2 weeks old. The cause of the fire was likely an electrical short circuit. The babies were being treated for neonatal jaundice in the phototherapy unit.

EENIE MEENIE...

Kamani Hubbard has six-fully formed and functional fingers and toes on his hands and feet, and San Francisco doctors said they'd never seen a case of polydactyly so remarkable. Some of her family members have six incompletely developed fingers,

but not also the toes. What made the case even more rare is that the extra digits are functional. The delivering pediatrician said, imagine what sort of a pianist a 12-fingered person would be... if nothing else think of their typing skills. The extra digits didn't show up on ultrasound. Reported by KTVU.com.

TOO MANY, EH?

The number of premature deliveries in Canada is rising, with hospitals forced to bear the brunt of the costs, paying nine times more for their care compared to babies that reach full-term, according to the Canadian Institute for Health Information. In 2006-2007, almost 29,000 babies born nationwide were premature, or before 37 weeks gestation, CIHI reported Thursday. This was an increase to 8.1% from 6.6% in the early 1990s, the report said. Caring for preterm babies on average costs a hospital \$9,233 compared with costs of \$1,050 for full-term babies. That amount goes up to \$12,479 when the premature baby is part of a multiple birth such as twins or triplets, CIHI said. Mothers who have diabetes and hypertension were found to be up to six times more likely to have a premature baby than women without these conditions. Mothers aged 35 and older were also more likely to have early deliveries compared with women who give birth between 20 and 34. The statistics also showed that the rate for premature babies born to mothers by Caesarean sections was also higher than by induced or normal vaginal deliveries. Reported by Linda Nguyen, Canwest news service, Vancouver Sun, Ottawa.

HAD ENOUGH

Megan Daum recently wrote in the New York Times that she has "octuplet derangement syndrome," ever since the recent story you've already heard way too much about. Daum noted in her editorial that her "derangement" stemmed from questions about "why so many members of our baby-crazed society insist on glorifying even the most dangerous, irresponsible and (despite a fondness for seeing them as divinely determined) technologically assisted reproductive events." If you've been following the story, by now you know all about: the grandma's denunciation; the mom's plea for fame and money; her doctor's abysmal "success" rate; the death threats against the mom's publicist. When the story broke, the editors of this journal planned a big feature article, but now we're sick of the whole thing, so if you want to read about it, you'll have to google "octuplets."

SPECIAL CARE

Parenting in the Neonatal Intensive Care Unit, by Lisa M. Cleveland, RN, MN, CPNP, IBCLC, appearing in the Nov/Dec issue of Journal of Obstetric, Gynecologic and Neonatal Nursing (JOGNN), published by AWHONN, takes an in-depth look at 60 studies that focus on parents who have infants in the NICU, with the goal of uncovering the specific needs of these parents and what nurses can do to positively support them to establish their role as parents. According to the article, parents with an infant in the NICU have six main needs, including: to receive accurate info, to be able to watch, protect and have contact with their infants, to be perceived positively by the nursery staff, to receive specialized attention (especially dads), and to establish therapeutic relations with the staff. To assist parents with these needs, the article says that nurses can provide support by empowering parents, providing a welcoming environment, and by giving parents a chance to practice parenting skills. NIC will be presenting a more in-depth look at the article in our July/August issue. Contact awhonn.org.

PRODUCTS

ON THE ALERT

Clinicians now have a helping hand in the early detection of risks during and after surgery on neonatal and infant patients with cerebral and somatic oximetry. Somanetics announced that its OxyAlert NIRsensors, used in conjunction with its INVOS System cerebral and somatic oximeter, enables noninvasive, around-the-clock monitoring, assuring the brain and body are receiving adequate blood oxygenation while undergoing surgery and in recovery. The infant-friendly sensors feature a gentle, medical-grade hydrocolloid adhesive and a flexible sensor pad that conforms to tight curvatures and small areas, like the forehead of neonates. OxyAlert NIRsensors can be placed in up to four site-specific areas of the brain and body to reveal continuous, real-time perfusion data on tissues beneath the sensors. The INVOS System can “speak” for neonates by alerting surgical and care teams in real time when oxygen dips to threatening levels associated with kidney failure, brain damage, shock, neurologic damage, low cardiac output and seizures. When rSO₂ values drop, clinicians can intervene to lessen or prevent potentially life-changing or life ischemic complications. While most traditional vital signs, lab draws and subjective assessments reflect systemic status or may be time-delayed, the clinically-proven INVOS System immediately detects site-specific changes in blood oxygenation in real time. In fact, INVOS System monitoring has been shown to be a better indicator of regional oxygenation issues than systemic vital signs. The INVOS system technology has now been embraced at more than 700 US hospitals, including 80% of those centers performing pediatric cardiac surgeries.

MD WEBSITE

B&B Medical Technologies has launched a new clinician- and product-focused website that gives users every resource needed to access the company’s complete line of specialty airway management products. Designed for functionality and with busy people in mind, the new BandB-Medical.com delivers A World of Products for Better Breathing on the web. Intuitive to navigate and fast to load, the new site includes downloadable training modules and videos, instructions for use, easy-to-customize policies and procedures, catalog sheets, evaluation forms and ordering information. A comprehensive All Products page puts all those resources in a quick, clickable format. B&B Medical Technologies is the leading designer of specialty airway management devices and Heliox nebulizers, providing products that are safe, versatile, cost-effective and convenient.

NANN-e

The National Association of Neonatal Nurses is offering two new digital tools, the NANN eNewsletter and NANN eLearning CNE live webinar and enduring archive. The new NANN e-newsletter will be sent to the association’s 7,400 NANN and NANNP members. NANN emails have the very high open rate of 80%. The e-newsletter is being sent six times this year. NANN is looking for sponsors. Newsletter supporters will receive logo recognition on all e-newsletters, along with a link to the sponsor’s website. NANN is offering CNE through five webinars this year, and also has sponsorship opportunities for these.

MEASURING UP

Siemens Healthcare, siemens.com/healthcare, highlighted its latest ultrasound solutions for obstetrics at the 29th Annual

Meeting of the Society of Maternal-Fetal Medicine in San Diego. The company featured innovative knowledge-based workflow and 4D applications that increase diagnostic confidence and improve clinical workflow. Its syngo AutoOB measurements, available exclusively on Siemens’ premium performance ACUSON S2000 ultrasound system, are an advanced clinical tool that automates routine biometry measurements of the fetus. Up until now, users needed to perform biometry measurements manually, but the syngo AutoOB measurements eliminate this time-consuming manual process by saving up to 75% of the keystrokes in routine fetal measurements. Measurements include the biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), femur length (FL), humerus length (HL), and the crown rump length (CRL). The application also addresses the challenges related to user-dependence and variability, as well as consistency and reproducibility in fetal biometry. In addition, Siemens showcased its Advanced fourSight technology package, which includes Fetal Heart STIC (Spatio-Temporal Image Correlation) imaging on the ACUSON S2000 system. This application captures data over multiple heart cycles to create a 3D fetal heart volume. The Advanced fourSight technology package also features Amnioscopic Rendering, a unique surface rendering tool, which provides photo-realistic images of the fetus.

NOSE NEWS

In its recent newsletter, Vapotherm reports on: Proper Sizing of the Nasal Cannula. The company notes: For safe and effective application of HFT, an open system should be maintained. Appropriate cannula size is selected by the anatomy of the nares. We recommend that fifty percent of the nares should be available for exhalation and maintaining an open system. Vapotherm neonatal cannulas have an inside diameter of less than 2mm. The company refers RTs and neonatologists to the article: Heated Humidified High-Flow Nasal Cannula: Use and a Neonatal Early Extubation Protocol, by Holleman-Duray, D., Kaupie, D., and Weiss, MG. Holleman-Duray describes how the use of High Flow Therapy (HFT; Vapotherm 2000i) supports infants post extubation. The patient data, compared to historical control where CPAP was used prior to their adoption of HFT, resulted in extubation from higher ventilator rates and fewer days on ventilators. This data supports Vapotherm’s proposed mechanisms of action for HFT with respect to CO₂ elimination and improved alveolar oxygen concentrations. In addition, this study showed that incidence of ventilator-associated pneumonia was reduced and infants were discharged with greater weights despite similar lengths of stay and time to full feeds. The decrease in pneumonia is likely associated with reduction in ventilator time, while the greater discharge weights may be indicative of a reduced respiratory work effort (caloric consumption). In other Vapotherm news, Vapotherm wants to know: Is Your Department Using HFT? Vapotherm invites you to share best practices related to High Flow Therapy. Each newsletter highlights one standout hospital, department or clinician on topics including clinical best practices, research or education. Contact Rachael.Osberger@vtherm.com. Also, the company offers new educational opportunities, via CEUs for 2009: The online courses listed here are available free of charge and have been approved by the American Association for Respiratory Care for 1 (CEU) credit hour each. 1) Advances in Respiratory Care: High Flow Therapy Review & Assessment; 2) Neonatal Respiratory Care Curriculum: High Flow Therapy in the NICU; 3) High Flow Therapy: Mechanisms of Action. For more, log in at the Vapotherm Education Center and click on

the Continuing Education Courses for Medical and Allied Health Professionals link.

STICK TO IT

Vermed's Tender Trode Plus line is designed for the unique needs of the neonatal market. Each product is designed with hypoallergenic adhesives for comfort and effectiveness in the NICU. The Extended Wear Neonatal ECG Electrode has a wear time of 6 days. Features include: long term high humidity ECG electrode, its hydrocolloid border provides long-term attachment. It saves nursing time and resources with fewer electrode changes. The hydrogel center provides excellent tracings, it's safe on neonatal skin, designed specifically for the NICU, and has a radiolucent lead. The New Mini Prewired ECG Sensor features: no cumbersome band, micro-size can be used on limbs or on the body, safely secures to limbs without a strap that could reduce circulation. Other products are: adhesive cloth strips for painless removal, pre-cut for convenience. They can be used in place of standard adhesive tape, reduce discomfort and skin irritation, and the new silicone adhesive provides gentle release. The strips are latex-free and hypoallergenic, and the cloth material is comfortable and conforms to difficult body contours. The company's gentle release probe covers offer painless removal, reduce discomfort and irritation on delicate skin. The hydrophobic material will not absorb water. Contact vermed.com.

TESTING...

B&B Medical Technologies' Test Lung-Pediatric offers a solution for performing routine OVP testing and demonstrating operation of mechanical ventilators. With certified resistance and compliance, the 0.5 liter Test Lung-Pediatric is made of Latex-free silicone and space age resins to withstand the rigors of daily hospital and classroom use. The ventilation bag is durable, easily removable and can be cleaned or sterilized as needed. Included with each Test Lung is a Test Lung Connector Kit that adapts to all patient circuits and proximal airway flow sensors. The Connector Kit has three adapters, two with Luer Ports and Caps, allowing practitioners the ability to demonstrate leak performance and patient-trigger function. The Test Lung-Pediatric is compact in design and lightweight. Each 0.5L Test Lung is tested and validated for resistance and compliance in the application range, and has a unique serial number to insure its compliance with specification. It is the ideal tool for teaching and demonstration in addition to performing pediatric ventilator verification testing. A separate kit is available to demonstrate changes in airway resistance. The Precision Resistor Kit is adaptable to both Test Lungs and includes three resistors: Rp5, Rp20 and Rp50. The Precision Resistor Kit is factory calibrated, and can be cleaned and sterilized. Visit bandb-medical.com.

PROBING

Respiratory Technology Corporation, Restech, announced that the Division of Gastroenterology at Seattle Children's Hospital, Seattle, has adopted the Restech Dx-pH Measurement System to detect acid reflux in the airway. The Dx-System provides valuable information about patients' pharyngeal acid exposure and its role in various comorbidities, helping physicians diagnose the cause of each patient's symptoms more accurately, and treat the patient more effectively. At Seattle Children's, the system is being used to evaluate the extra-esophageal manifestations of GERD. The Dx-pH System is said to be noninvasive and well tolerated and enables doctors to more aggressively treat for reflux or to wean off previously started anti-reflux treatments

and search for other causative factors. The miniaturized pH sensor at the tip of the Dx-pH Probe is unique in its ability to measure pH in a non-liquid environment, such as the pharynx. The Probe's miniaturized, patented sensor is housed in the tear-drop shaped tip at the distal end of a thin trans-nasal catheter. An LED blinks during placement, allowing the medical personnel to confirm the proper placement in the oropharynx. The measurements taken by the pH sensor are sent wirelessly to a recording device. Restech also announced that Endo&Lap has become their new distributor in Turkey effective immediately. The recent announcement of the CE Mark approval for the Dx-pH Measurement System has made the system available to physicians throughout Europe. Endo&Lap is a highly respected firm with considerable experience in not only the medical devices industry but also throughout the region. These factors ensure maximum support and expertise to grow sales and enhance customer support in Turkey and other countries that Endo&Lap supplies. Contact restech-corp.com.

Enhancing the Safety of Medical Suction

Patricia Carroll, RN, BC, CEN, RRT, MS

Abstract

Medical suctioning is essential for patient care. However, few clinicians receive training on the principles of physics that govern the safe use of medical suction. While all eight manufacturers of vacuum regulators sold in North America require occlusion of the tube before setting or changing vacuum levels, anecdotal evidence reveals that clinicians are not aware of this requirement or skip this step when pressed for time. This white paper summarizes the physics relating to medical suction, the consequences of damaged mucosa, the risks to patient safety when suction levels are not properly set and regulated, and technology advances that enhance patient safety.

Medical suction is an essential part of clinical practice. Since the 1920s, it has been used to empty the stomach, and in the 1950s, airway suction levels were first regulated for safety. Today, medical suction is used for newly born babies and seniors, and in patients weighing between 500 grams and 500 pounds. Medical suction clears the airway, empties the stomach, decompresses the chest, and keeps the operative field clear. It is essential that clinicians have reliable equipment that is accurate and easy to use.

Why a safety mindset is important

The current focus on patient safety extends to suction procedures and routines. When suction pressures are too high, mucosal damage occurs, both in the airway¹ and in the stomach. If too much negative pressure is applied through a chest tube, lung tissue can be drawn into the eyelets of a thoracic catheter.² Researchers are examining the connection between airway mucosal damage and ventilator-associated pneumonia. In pediatrics, airway suction catheters are inserted to a pre-measured length that avoids letting the suction catheter come in contact with the tracheal mucosa distal to the endotracheal tube.³ Mucosal damage can also be mitigated with appropriate suction techniques, and every effort should be made to reduce this insult to the immune system of patients who are already compromised. Damaged airway mucosa releases nutrients that support bacterial growth,⁴ and *P. aeruginosa* and other organisms are drawn to damaged epithelium.^{5,6} Mucosal damage

in the stomach can result in bleeding and anemia as well as formation of scar tissue.

Physics of suction

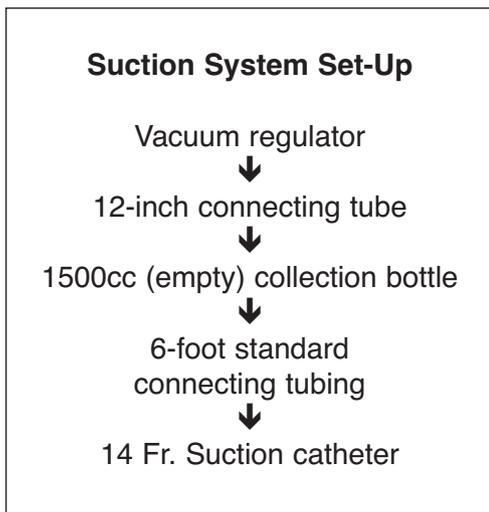
Flow rate is the term used to describe how fast air, fluid, or secretions are removed from the patient. Ideally, clinicians need the best flow rate out of a vacuum system at the lowest negative pressure. Three main factors affect the flow rate of a suction system:

- The amount of negative pressure (vacuum)
- The resistance of the suction system
- The viscosity of the matter being removed

The negative pressure used establishes the pressure gradient that will move air, fluid, or secretions. Materials will move from an area of higher pressure in the patient to an area of lower pressure in the suction apparatus. The resistance of the system is determined primarily by the most narrow part of the system—typically, a tubing connector—but the length of tubing in the system can increase resistance as well. Watery fluid such as blood will move through the suction system much more quickly than thick substances such as sputum. At one time, it was thought that instilling normal saline into an artificial airway would thin secretions, enhancing the flow of secretions out of the airway. However, research shows no thinning occurs and the patients' oxygenation drops with saline installation. Thus, the practice should be abandoned.^{7,8}

Increasing the internal diameter of suction tubing or catheters will increase flow better than increasing the negative pressure or shortening the length of the tube. However, in most clinical applications the size of the patient will be the key factor determining the size of the catheter that can be safely used. Researchers at the Madigan Army Medical Center explored factors affecting evacuation of the oral pharynx for emergency airway management. They tested three substances—90 mL of water, activated charcoal, and Progresso vegetable soup—with the three different suction systems, progressing from a standard 0.25-inch internal diameter to a 0.625-inch internal diameter at its most restrictive point. All systems evacuated water in three seconds. The larger diameter tubing removed the soup 10 seconds faster and the charcoal mixture 40 seconds faster than the traditional systems. The researchers note that this

This article was provided by Ohio Medical.



Box 1. Suction System Set-up.

A nurse passing the bedside of an infant in the ICU saw blood inside the tube used for airway suction. After checking the child's condition, it was evident that bleeding was not expected. Further investigation determined the maximum level of negative pressure set on the wall regulator was -200mmHg; far more than recommended suction levels for infants. The nurse performing the suctioning did not occlude the tubing to set a safe maximum level of negative pressure. *(personal communication to Ohio Medical Corporation)*

Box 2. Case study.

advantage in removing particulate material can speed airway management and reduce the risk or minimize the complications from aspiration.^{9,10,11}

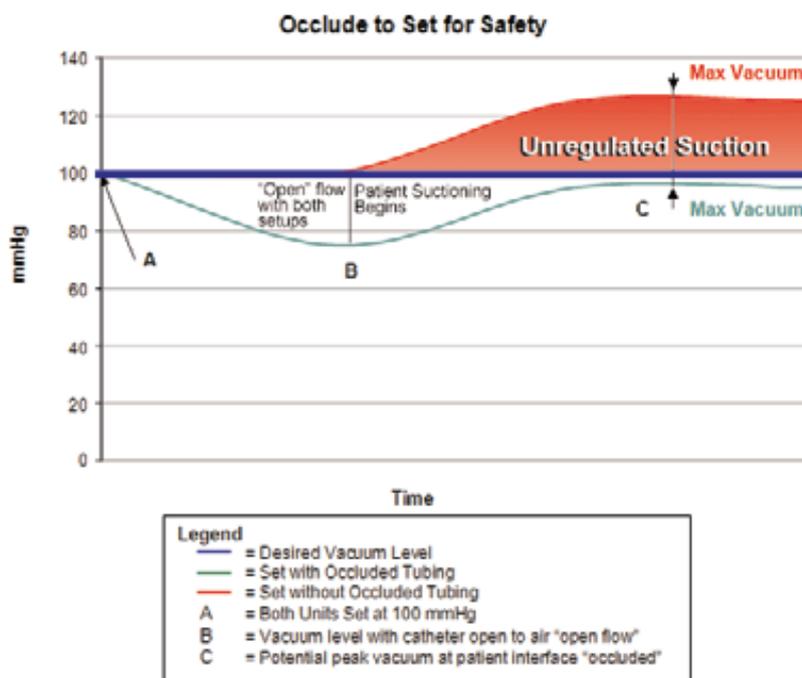
Occlude to set for safety

Vacuum regulators are ever-present in the hospital setting. Clinicians use them daily and may not be as attentive to this equipment with the demands of monitors and devices alarming and competing for the clinician's attention and time. Few clinicians learn the finer points of setting up suction systems. A nursing fundamentals text published in 2007¹² does not specify critical elements except to tell the nurse to follow manufacturers' instructions. The text leaves out the critical, universal "occlude to set" step that is recommended by all eight manufacturers of vacuum regulators used in North America.

While a number of organizations have published guidelines, ultimately the clinicians must determine the maximum allowable level of negative pressure that can be applied to the

patient. This is determined by a number of factors: where the suction pressure is applied (airway, stomach, oral pharynx, pleural space, operative field), the age and size of the patient, the susceptibility for mucosal or other tissue damage, and the risks associated with removing air during the suction procedure.

Once the maximum level has been determined, the vacuum regulator must be adjusted so that the maximum pressure is locked in; that is, the regulator must be set correctly so it will not permit a higher pressure to be transmitted to the patient. With traditional technology, the clinicians must actively occlude the system by either pinching the suction tubing closed, or occluding the nipple adaptor (where the tubing is attached) with the finger. Once the system is occluded, the regulator is set to the maximum desired pressure; then the occlusion is released. If the system is not occluded during set-up, the maximum pressure is then unregulated and can spike to harmful levels (see Figure 1 and Box 2).



Suctioning is a dynamic process. As catheters are used to remove substances from the body, the degree of open flow continually changes based on the fill of the catheter and the viscosity of the substance being removed. Under these dynamic conditions, the regulator continually compensates by adjusting flow rate within the device and the tubing to maintain the desired negative pressure. Periodically, mucus plugs or particulate matter will occlude the patient tube. If the system was not occluded to establish the maximum safe pressure at set-up, pressure will spike to clear the occlusion, and once the occlusion passes, the patient will be subjected to potentially dangerous, unregulated vacuum pressures (see Figure 1).

Figure 1 illustrates results of a bench test of two suction systems. The systems were set-up identically as noted in Box 1. The desired maximum level of suction is 100 mmHg (A). One system was set at 100 mmHg with the system open to flow (red line); the other was set by occluding the system to set 100 mmHg (green line). During open flow, the “occlude to set” system will have a lower pressure than the desired maximum pressure because there are no occlusions in the system (B). Once suctioning begins, a dynamic flow condition occurs with varying levels of obstruction, and pressure rises within both systems. The point of maximum suction is key. In the “occlude to set” system, the pressure never rises above the desired maximum pressure of 100 mmHg. In the other system, pressure in this bench test spiked to 125 mmHg of unregulated suction. Without “occlude to set,” the pressure can rise to 25% higher than the desired maximum level or more, exposing the patient to a safety hazard when regulated suction is needed.

Higher negative pressure is a particular hazard for patients with friable mucosa in the airway or stomach, making it more susceptible to traumatic tears. It is also a hazard for infants who have small lung volumes. When all other variables are stable, a 25% increase in negative pressure will increase the amount of air pulled through the system by 25%. That increase could result in a significant loss of lung volume in intubated neonates and infants.¹³

Breakthrough technologies enhance safety

An ideal patient safety device removes clinician variables as much as possible by providing the added safety passively while the clinician carries out the procedure. Traditionally, the optimal safety of regulated vacuum pressure has depended on the clinicians’ action to occlude the system to set maximum pressure. Now a breakthrough technology from Ohio Medical Corporation in its new Intermittent Suction Unit (ISU), occludes the system automatically when the clinician adjusts the pressure level. This creates a highly effective, passive safety system that removes the clinician variable and protects the patient from unintended, unregulated pressure spikes during suction procedures. The “push to set” innovation assures the clinician that the patient will not be subjected to pressure higher than that set on the regulator.

Another key safety aspect of any vacuum regulator is the ability to quickly adjust to full vacuum mode when emergency strikes and rapid evacuation is essential. An additionally unique concept introduced by Ohio Medical is the dual-spring design of the regulating module contained within the vacuum regulator. This feature provides the clinician with the ability to control vacuum levels more precisely in the clinical range of 0-200 mmHg as well as the ability to achieve full vacuum when

needed with only 2 turns of the knob on the regulator. In other regulators, six or more knob turns are needed to achieve “full vacuum,” and “full vacuum” capability may be limited to the clinical range, not the full system vacuum provided by the Ohio Medical ISU. Since full vacuum is needed in emergency conditions, this enhanced responsiveness saves time when seconds are critical.

While vacuum regulators are often considered basic equipment in the hospital, research and innovation from Ohio Medical Corporation has shown vacuum regulators do have a role in enhancing patient safety in clinical settings. Clinicians should advocate for technology that provides passive safety protection, enhanced control of vacuum pressures, rapid response and ease of use – all of which contribute to a culture of safety around the patient.

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Expressed Breast Milk as “Connection” and its Influence on the Construction of “Motherhood” for Mothers of Preterm Infants: a qualitative study

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Abstract

Background: Breast milk is considered the optimal nutrition for all newborn infants. While there is high initiation of lactation among mothers of preterm infants in Australia, there is a rapid decline of continued lactation. Furthermore, there is an inverse relationship between infant gestation and duration of lactation. To better understand the breastfeeding experience of parents of very low birth weight (VLBW) preterm infants an interpretive phenomenological study was conducted.

Methods: This longitudinal study was conducted using an interpretive phenomenological approach. Data were collected from 17 parents through 45 individual interviews with both mothers and fathers, from birth to 12 months of age. This data was then transcribed verbatim and analysed using thematic analysis.

Results: The analysis identified six primary themes: the intention to breastfeed naturally; breast milk as connection; the maternal role of breast milk producer; breast milk as the object of attention; breastfeeding and parenting the hospitalized baby and the demise of breastfeeding. This paper reports on the theme of “breast milk as connection.”

Providing expressed breast milk offered one way the mothers could be physiologically and emotionally connected to their preterm infant while they were in the constant care of hospital staff. Indeed, breast milk was considered the only way the new mother could connect her body (or part there of) to her preterm baby in hospital. This sense of connection however, comes at a cost. On the one hand, the breast milk offers a feeling of connection to the baby, but, on the other, this connection comes only after disconnection of the mother and baby and—through breast expression—mother and her milk. This ability of breast milk to connect mother and baby makes the expressed breast milk highly valued, and places unexpected pressure on the mother to produce milk as integral to her sense of motherhood.

The author is with Flinders University Rural Clinical School, Flinders University, Adelaide, Australia. Reprinted from BioMed Central, International Breastfeeding Journal, © 2008 Sweet; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License. For references, go to BioMed Central and type in the complete title of the article. The author would like to thank families and colleagues who participated throughout this research.

Conclusion: The findings of this study have implications for healthcare practice. It is evident that the association of breastfeeding success with mothering success only jeopardises some families’ self-esteem and sense of parenting ability. These findings suggest it would be beneficial to find alternate ways to connect preterm infants and their parents in the preterm nursery environment, and find more positive ways to support breastfeeding.

Background

Breastfeeding is widely accepted and advocated as the best source of nutrition for newborn infants. While there is a high initiation rate of lactation among mothers in Australia, it is known that for preterm infants there is a rapid decline during the weeks and months following the birth, at a rate greater than their term infant counterparts. The breastfeeding experiences for these families are inherently different to those of healthy term infants, as the newborn preterm infant is too weak and immature to feed directly from the breast and long-term breast expression becomes necessary.

Preterm birth results in infants requiring long-term hospitalization and family separation. The experience of having a child admitted to a Neonatal Intensive Care Unit undoubtedly creates a stressful situation for the parents. Fenwick conducted a study of parenting in Australian neonatal nurseries and concluded that mothers struggled through intense emotional, cognitive and worry work in an attempt to become “real” mothers to their hospitalized infants. The new mother must commence lactation during this time of intense turmoil. Mother-infant separation has been recognized as a barrier to successful breastfeeding. All breastfeeding mothers have concerns and problems. However, when it involves a preterm infant, the concern in the current literature frequently shifts to the baby. The voices of parents at this time have been neglected in the professional literature. There are many studies on processes to initiate and maintain sufficient lactation following the birth of a preterm baby, but few have specifically studied parents’ issues of breastfeeding preterm infants.

Breastfeeding is the norm in contemporary Australian society. Recent Australian research has demonstrated an association between breastfeeding and maternal identity. Cooke argues that breastfeeding is instinctive—an emotional activity—and is associated with maternal identity and self-esteem. Schmied’s participant women espoused the current socio-political

discourse in favour of breastfeeding at all costs and constructed breastfeeding as something they wanted (and needed) to achieve for their motherhood identity. Indeed much of the research investigating women's perceptions of breastfeeding over the past 20 years has some striking commonalities. It is frequently reported that women demonstrate a strong conviction that breastfeeding is best for babies, while breastfeeding is considered synonymous with being a good mother and a woman's identity or sense of self as a mother. These studies, however, center on mothers of healthy term infants.

Therefore, there is an absence of research investigating the parents' voices and the ways in which they experience breastfeeding for a preterm infant. Furthermore, it is unknown how mothers construct expressing for their hospitalized preterm infants in light of the literature which suggests breastfeeding is synonymous with a mother's sense of motherhood. It is this lack of experiential knowledge in the professional literature that has led to this research study.

Phenomenology is a philosophical view of the world in which there is an inseparable connectedness of human beings to the world. Consequently, the world cannot be separated into subject and object; rather, the world can only be described as experienced by human beings. Furthermore, human beings make meaning from lived experiences. It is considering this consciousness, of being in the world that guides phenomenological interpretation, and this study. As van Manen explains: "the world is given to us and actively constitutes by us: reflecting on it phenomenologically, we may be presented with possibilities of individual and collective self-understanding and thoughtful praxis."

The participants in this study anticipated "normal" breastfeeding with expectations of what it ought to be. This study explores the lived reality of breastfeeding for a preterm infant from people living the experience.

Method

This study was conducted to answer the research question: what is the lived experience of parents breastfeeding very low birth weight preterm infants? To enable exploration of the experience from the perspectives of both mothers and fathers, an interpretive phenomenological approach was used. Interpretive phenomenology is a qualitative research approach that systematically investigates people's lives, experiences, understandings and perceptions of what it means to be human. Interpretive phenomenology is a science which is interested in the study of people, of what it is to be human, and offers an advance of our knowledge by increasing our understanding of lived experience. Interpretive phenomenology enables researchers to uncover and interpret the many ways in which people articulate and make sense of their experiences related to health and illness. Thus, phenomenological insight goes beyond merely an adequate technical knowledge—it improves our understanding of the meaning of an experience and is therefore a suitable method for this research question. Phenomenology as a research method is useful to guide pathic understanding of human life, which, in turn, is useful to guide empathetic nursing action. Therefore people's own individual experiences are worthy forms of data to be studied. To conduct phenomenological research is to question the way we experience the world.

Interpretive phenomenology is a philosophical tradition of

reading, reflection and rewriting. It is therefore important to recognize (or remind ourselves) that the goal of interpretive phenomenology is to understand Being. When using interpretive phenomenology, the researcher seeks to give greater access and understanding of the text in its own terms, thereby allowing the reader to notice meanings and qualitative distinctions within the text for themselves as well as from the dialogue provided.

This study was conducted in an Australian metropolitan hospital during 1999 as a supervised doctoral research study. Partial results of this study have been published elsewhere, and this paper presents data not yet published. Ethical approval was gained from both the Hospital and University ethics committees and all local and national research guidelines pertaining to informed consent, participant confidentiality and anonymity were adhered to.

The sample consisted of 10 mothers and 7 fathers who intended their preterm very low birth weight (VLBW) baby to be breastfed. All potential participants were identified from the admissions register in the NICU and parents were approached by the researcher and recruited to the study in the first week after the preterm birth. Parents were excluded from selection if they did not speak English; if their infant had a congenital abnormality likely to affect feeding; or if their infant was considered gravely ill by the attending neonatologist. The researcher had no clinical role in the hospital and therefore was not associated with the care of the mothers or babies.

Data was generated through 45 semi-structured individual interviews. Three interviews were scheduled with each participant; at 2–3 weeks, 8–10 weeks and 12 months post birth. Some parents chose not to complete all three interviews and two families were not contactable for the final interview. These interviews were done in private interview rooms at the hospital, the parents' own home or over the telephone as chosen by the participants. No interview schedule was applied, but rather a spider map of keywords was used to bring up new ideas and areas for further discussion. Participants were encouraged to share their own stories in their own way, proceeding on their own terms while describing aspects important to their own experience. The questions posed during the interviews revolved around the topics of conversation as directed by the participants. To enable spontaneity of discussion, interviews were tape recorded, then transcribed verbatim. Transcripts were analyzed using thematic analysis outlined by Benner which sought to highlight and explore the narrated experiences, perceptions, salient events, discursive patterns and changes over time articulated by the participants. Data analysis and management were supported with the use of N-Vivo, a computer program designed for qualitative data.

Interpretive phenomenology acknowledges that research is necessarily a researcher's interpretation of participants' articulated experiences, and this paper therefore presents the authors interpretation from the data generated from the 17 participants. Qualitative research is context dependent and centred in the time, place and persons from which it has been derived. Furthermore, this study is based upon a group of white, Anglo-Australian heterosexual men and women, and thus interpretations presented cannot be automatically generalized to the broader parent population. However, it is the intent of the author to provide a justified interpretation for the reader, showing similarities and differences evident within the data.

Results

Table 1 outlines the characteristics of the ten participating families. Given that this paper presents the mothers' construction of motherhood, the data from the 10 mothers will predominate.

Following the preterm birth, all of the participant parents displayed overwhelming care and concern for the wellbeing of their baby. Infant survival was of paramount importance and any efforts to breastfeed were overlooked in the early hours and days of the infant's life. The parents were keen to do whatever was in the best interests of their baby. The parents were able to visit their baby but were very limited in the tangible things that they could do for their baby. Once commenced, preterm breastfeeding and provision of milk for their baby was the primary task assigned to mothers at this time. Breast expression gave all of the participant mothers a feeling of contribution. The mothers in this study expressed a level of satisfaction through breastfeeding: of providing something beneficial for their baby that the hospital staff could not provide. Fiona said providing breast milk made her feel like a mother when she felt she had no other mothering role: "I definitely like the idea of her having my milk and it's like I'm giving her something to grow and it's definitely, I like, I do like that idea. That she needs me to grow, it makes me feel, you know, a little bit more like a mother than just, you know, an outsider just looking at her."

For Fiona, her breast milk was something only she could provide that she felt was integral to her baby's need to grow and be healthy. All participants made reference to 'my milk' in a way that highlights its value and places it in high regard. This sense of being the exclusive provider of something her baby required placed a special importance on the mother, her breastfeeding role and particularly on her milk. Fiona did not speak of at-breast feeding being important at this time; it was simply the breast milk that the baby needed and providing this gave her a connection to the baby. Providing breast milk was the only mothering role Fiona felt able to do; otherwise all she would be able to do would be to sit and observe her baby while the hands-on tasks were done by the nurses. The theme of breast milk as connection will be presented through the following sub-themes followed by a discussion and integration with the current literature.

1. Breastfeeding is initially not a priority: For all participant mothers, there was a delay in their initiation of breast expression following birth. No mother expressed her breast milk on the day of the preterm birth. Breast expression was commenced by a few mothers the day after the birth; however, most did not express their breasts regularly until 2–3 days after the preterm birth. Mothers spent most of their time watching their baby and recovering from the birth themselves in those first few days. This delayed initiation of breast expression is incongruous with current research recommendations that suggest the earlier breast expression is commenced the better the lactational outcome. However, in order to understand this experience it is valuable to look at the context and circumstances surrounding the preterm birth and the initiation of expressing, and not just the time that expressing was commenced.

The first few days of life for the baby were significant in affecting the commencement of breast expression. Participants spoke of many factors that negatively affected the initiation of their breast expression. Alison found she spent all of her day by the baby's

bedside and just forgot to express: "My main concern was him, even though they say express or whatever, I was never in my room, I was always downstairs, and all I'm concerned about is him medically, how he is, you know, not my milk supply."

Julie did not express until three days after the birth, and she attributes her delay to express to the ill health of her twin babies. Julie felt that the staff did not encourage early initiation of expressing for her at the time, as her twins were considered critically ill. Once started, expressing her breast milk did give Julie hope that all was going to be all right: "I wasn't bothered the fact that I was starting to do it, I was quite happy to do it, because that sort of gave me hope that they were going to be alright, that mum's milk's going to help them."

Being encouraged to start breast expressing, even days after the delivery, was a welcomed sign of hope for Julie. The sense that her milk would help her babies get better was powerful for Julie and very important for her to provide.

Sharon commenced breast expression a few days after the birth. The reasons for the delay were not clear to Sharon and she would have welcomed the ability to provide breast milk sooner. She spoke of breastfeeding as a way to feel like a mother as opposed to someone who had simply had an operation: "They let me go for the first two [days] ... but I didn't feel as though I'd had a child, because those first two days I used to sit around doing nothing, I had no child in the room with me, so I think it's probably better off in a way for the mothers to start doing it [expressing] the next day. But if I'd gotten on to it [expressing] straightaway it would have made me feel like a mother and not just someone that had an operation in the hospital. I certainly didn't feel like a mother the first two days."

Once expressing was commenced, Sharon found that providing her breast milk was one way she could be mother to her baby while she was in need of intensive care support. Early breast expression would have enabled these mothers to actively mother in the absence of their babies by their sides.

Mothers felt that breastfeeding for a preterm infant was not treated as a priority by many of the hospital staff in the first few days after birth. The midwives on the postnatal ward did not put any pressure on the mothers to express their breast milk. Alison felt that the postnatal midwives forgot about the mothers of preterm infants. She found the midwives on the postnatal ward concentrated on those mothers who had their babies with them, while the midwives in the NICU concentrated on the sick or preterm baby's needs. This lack of recognition as breastfeeding mothers further compounded a sense of isolation. She explains: "Because I didn't have Joel with me, you don't have the nurses and all the people giving you all this information, they're dealing with the breastfeeding issue [s] with the women whose babies are right next to them. Me without having my baby, I didn't have the nurses coming in and having chats to me, they just showed me the machine, what I had to do and that was the end of it. But the whole breastfeeding thing wasn't a priority or a major issue because my baby wasn't with me."

Alison felt that there was no staff member concentrating on the needs of the mothers whose babies were in the nurseries. This sense of isolation was from other mothers who did have their babies, from staff who cared for them, from their own baby and from an active mothering role.

Table 1: Characteristics of participant families

Participant reference	Gender	Number of interviews	Assisted reproduction	Single or multiple birth	Previous children (n)	Distance of usual residence to hospital (kilometres)
1A Sue	Female	3	yes	twins	0	< 10
1B Peter	Male	3	yes	twins	0	< 10
2A Julie	Female	3	no	twins	1	10 – 200
2B Colin	Male	3	no	twins	1	10 – 200
3A Bev	Female	3	yes	twins	0	> 200
3B Brian	Male	3	yes	twins	0	> 200
4A Lisa	Female	3	yes	single	0	< 10
4B Paul	Male	3	yes	single	0	< 10
5A Chris	Female	3	no	single	1	Interstate
5B John	Male	3	no	single	1	Interstate
6A Sharon	Female	1	no	single	3	10 – 200
7A Alison	Female	3	yes	single	0	> 200
7B Dennis	Male	3	yes	single	one	> 200
8A Fiona	Female	2	no	single	nil	10 – 200
9A Helen	Female	3	no	twins	three	10 – 200
9B Wayne	Male	2	no	twins	three	10 – 200
10A Nicole	Female	1	no	single	nil	< 10

The production of breast milk is commenced for nurturing a live newborn. To commence breast expression for a sick or preterm infant is assuming the infant's survival. The low importance placed on early breast expression by staff could be related to the potential demise of the sick infant; the absence of the baby with the mother in the postnatal ward; or possibly to the lack of need for breast milk to feed the baby with in those early days. Whatever the reason, the lack of encouragement from some of the hospital staff sent a powerful message to these new parents—that the baby's immediate needs were the focus of attention and that breast milk was not valued at this time.

By the end of the first week after birth, mothers were being encouraged to express their breast milk. Helen spoke of this 'step' of the preterm breastfeeding experience: "I know why they do it, because they want you to focus on that more, because that's the next step, the milk supply. Like you've got over the section, and now I have to really focus in on the milk."

Helen believed that her traumatic birth and her infants' first critical few days of life were the factors that affected the commencement of her lactation. Helen suggested that once she had coped with these early crises the expressing was introduced by the staff as the next important task.

2. Being a "good" parent: Throughout the entire preterm birth experience there was a sense of all participant parents being committed to their newborn baby just as any new parent is to their newborn infant. The baby's needs were always the first priority for these families and, given the prematurity of the baby, putting the baby first was seen as even more important. Parents were prepared to do what ever the hospital staff suggested as potentially beneficial for the preterm newborn. With the newborn infant in hospital, parents constantly strove to achieve the ideal of the good parent. Breastfeeding, being the feeding of choice for these parents and the hospital staff alike, was seen as something done by a good parent.

Parents continually spoke of breastfeeding as being best for their baby, of offering great benefits to their preterm infant. The 'best for baby' focus was present throughout the entire breastfeeding experience from intention to cessation. Because of the strong focus on the baby, the ways in which parents spoke of the

reasons or benefits for their breastfeeding were limited. Julie said: "So everything you're doing is for your girls, I think. And I suppose you do it for yourself too. But I personally don't benefit anything from it, if you can understand that. I don't see it for my benefit at all, it's for my girls' benefit."

By demonstrating only child-focused benefits Julie denied her own agency. This practice of only presenting child-focused discussions and decision-making was common among participants as one way to demonstrate being a good parent—a good parent always puts the child first. To make a decision against what is best for the baby would be extremely difficult and with breast milk the known best milk for her babies, any such decision would be against the notion of being a good parent.

All parents spoke of breastfeeding being synonymous with good parenting. This finding is also present in the works of, for example, MacLean, Maushart, Schmied and Fenwick. This is not surprising given that the dominant discourses on infant feeding insist that "breast is best" for the infant's physical and emotional wellbeing. Furthermore, "good mothers" are expected to place their infant's needs above their own and deal cheerfully and patiently with the loss of sleep and time for oneself and other privations that caring for a baby entails. The participants spoke of being willing and able to do whatever this preterm breastfeeding required in order to perform as a good parent.

3. Breastfeeding as a marker of "good" motherhood: While participants could see that they had to express in order to establish and maintain lactation, and to provide milk to their preterm baby who was too weak initially to feed at the breast, they also felt it had a morality for them. Many of the participants spoke of breastfeeding as an integral part of being a mother; it was a mother's job—an inherited role of having a baby. Julie expressed a strong belief that breastfeeding was a mother's job: "Because you're the only one that can do it, no one else can do it for you. Um, I don't know, it might be just a mother thing, I mean you hear these women that just don't even bother trying because, you know, I can't stand that. I suppose it's a natural thing, that's what we've got boobs for, isn't it?"

Julie felt an obligation to breastfeed because it is a job of motherhood; physically and morally it was her gendered role.

Bev felt that breastfeeding was integral to motherhood and something she just had to do as a mother: "Like I said, I'd feel terrible, I'd feel guilty if they were on formula and I knew that I could... if you tried a little bit more, or whatever, to keep it going, because I really want to keep them on breast milk if I can."

For Bev, good mothers breastfed, and she felt a moral imperative to work hard at her lactation for her twins. Succumbing to formula was interpreted by Bev as failing at this one aspect of motherhood. In order to be a good mother there was no alternative for her other than to persevere with breastfeeding, despite the difficulties involved following the preterm birth. She could not stand back and watch the hospital staff care for her babies if she were not doing what she could to help the babies also, which included breastfeeding.

Breastfeeding was seen by the participants as something a mother needed to do for her baby. It was seen as something done by a good mother and therefore was viewed as a marker of good motherhood. This evaluation of goodness of motherhood gave the women a sense of moral imperativeness to succeed at their breastfeeding despite the difficulties that arose. In the context of the hospitalised preterm infant, breast milk expression was their only tangible mothering role; thus they experienced significant pressure to succeed at this one role that they could perform. These mothers felt that their status as the mother and as a good mother was related to their ability to provide sufficient milk.

Sue was successful in providing sufficient milk but feels that if she had not been able to then she certainly would have felt guilty and inadequate: "I probably would have felt quite disappointed if I wasn't able to do it and maybe I would have felt as though I was letting them down a bit or maybe I was inadequate."

Mothers who were unable to meet their infants' needs found this a negative impact on their performance. Chris expressed her disappointment when her breast milk volumes did not meet the demand: "Yeah, inadequate. Like you weren't doing what you were supposed to be doing, or getting, that you were a bit of a failure."

Chris struggled to keep up her milk supply throughout the baby's hospital stay, and her sense of inadequacy never went away. Alison also had trouble supplying sufficient milk for her baby. Alison spoke of breastfeeding as being her role and responsibility, and spoke of feelings of guilt regarding her inadequate milk volume: "It is my responsibility, because I want the best for him. And my milk is the best for him, there's no two ways about that, and like I said ... I think every time I have little milk I feel guilty."

Some mothers saw breastfeeding duration as another marker of good motherhood. Julie was concerned that after having decided to breastfeed, changing her mind and giving up would be inferred as failure or as not being a good mother to her babies: "I think I made the decision in the beginning that that's what I wanted to do so I think I felt that I have to stick to it."

Julie constantly compared herself with other mothers and felt she could prove herself as being a good mother, 'a better mum', by lasting longer at breastfeeding than other mothers did. Throughout her preterm breastfeeding experience, Julie was motivated by competing with other mothers. When asked why she persisted so long she replied: "[to be] a better mum than

anybody else. Certainly not a bad mum. I tried and I did what I could."

Julie's determination to continue and persevere with the expressing in order to increase the duration of lactation and at-breast feeding was important to her own sense of self as a mother. Her determination to continue breastfeeding was her marker of success as a good mother.

Fiona, on the other hand, by the time of her second interview, felt that she had expressed and breastfed for a sufficient duration to not be deemed a bad mother. At this stage, Fiona had been expressing for over eight weeks and was nearing the time of her baby's discharge home: "It's comforting to know that if I did give up now people wouldn't kind of go 'sigh' oh, you know, that's disgraceful, it's your child, you should try harder. I know that I have that support that people would understand, but at the same time it was good to just try a little bit harder."

At this stage of her breastfeeding experience Fiona was confident that her family and friends would support her decision to stop if she chose to. She felt she had passed the moral breastfeeding marker for duration, even though she had not yet achieved her goal of exclusive at-breast feeding.

Most of the women in this study continued to express their breast milk even though they had variable, and in most cases insufficient, milk volumes for the infants' daily needs. The routine of breast expression, and the strain this placed on daily life, was largely overlooked by these mothers because of the importance they placed on succeeding at this chosen part of care for their infant and for their own sense of achievement of motherhood. Breastfeeding was a highly valued undertaking in the preterm environment. It was important to these families that they were seen as persisting with their breastfeeding, at all costs. Sharon was the only mother who ceased her breast expressing efforts a few weeks after birth, and she did so after being unable to establish sufficient lactation to meet her baby's needs. She felt satisfaction for having given breastfeeding a try and did not express feelings of moral failure as a mother. Sharon perceived her attempts to establish lactation were sufficient to be considered a good mother; she had undertaken the moral imperative to breastfeed albeit for a short duration.

By believing that good mothers breastfeed their babies naturally and breast expressing was not the same as at-breast feeding, the women felt that some at-breast feeding was necessary to be a good mother. These mothers of preterm infants had significant innate pressure to succeed at expressing to enable them to do at-breast feeding. If they failed at expressing and never got to at-breast feed then, in their view, they never really got to breastfeed properly—they just provided breast milk. It is the at-breast feeds that are seen as important for the mother to achieve fully this aspect of her maternal role, as without these she has missed out on the essence of the breastfeeding experience she so desired.

4. "So much is taken out of your hands": All of the women in the study made some reference to the importance of "my milk" to their motherhood, particularly in context of the preterm birth. The mothers felt that providing breast milk was the most active and valuable contribution they could make. Julie spoke of the importance of her milk: "I think you get that feeling that you're doing something for your babies, even though they're not with you. You just think milk is for babies and this is my milk and this

is what you're contributing to your babies." Similarly, Fiona said: "there's a certain satisfaction in giving your child your milk."

This suggests that providing their own breast milk is one way that these mothers of preterm infants feel connected to their hospitalized infant. Lisa explained: "With a preterm baby, there's so little you can do for them, so much is taken out of your hands and [expressing breast milk is still something I know that I'm doing for her and I guess a lot of the time when I'm expressing at home I'm thinking about her."

For Lisa, there was so little mothering she felt able to do, as all the usual child care roles were performed by the hospital staff. Providing her breast milk was one mothering role she felt able to do and one that encouraged and enabled her to think about her baby. Even though she was separated from her milk and her baby, the breast milk acted as a form of physical and emotional connection for Lisa to her infant.

All of the mothers spoke positively of their breastfeeding role and the contributive value it offered them. Breast expressing for Sue was her major mothering task in those early weeks of her baby's life: "It's the only thing you can actually do for them because they are prem, apart from going and sitting and touching them and changing their nappy occasionally and having them out for a hold. There's not really much you can do to care for them. But at least if you are expressing your breast milk, it is something that you know you feel you're contributing to their well being."

Nicole also spoke of the closeness she felt by providing her expressed breast milk for her baby: "I feel closer to him that he's having some of my milk, I'm giving him something to help him grow."

Despite her desire to breastfeed, Fiona expressed the importance of the object breast milk for her daughter. This came at a time when her baby was too immature to breastfeed, and when the reality of at-breast feeding seemed unattainable, but the production of milk was real: "I've even considered maybe if she doesn't ever [at-breast feed], if we don't ever get it, if she just doesn't suckle, maybe I will just keep on expressing for months, and just bottle feed her, so she's still taking my milk."

Lisa had similar thoughts about the need for the object milk as opposed to at-breast feeds: "I will be really disappointed if I get to the stage of breastfeeding her and I can't, or she won't take it. But at least I'll know that all this time she's had my milk anyway."

The disconnection of the milk from the mother became overwhelming in the experience of these women, even to the point that both women doubted ever achieving the 'real breastfeeding' that they desired. It is evident from these participants that there remained a connection of the baby receiving 'my milk', but, at the same time, it highlights the value of the object milk as being the important aspect of the preterm breastfeeding experience. Further discussion of the objectification of breast milk has been presented previously.

Providing breast milk for your child is an exclusive act of motherhood regardless of the infant's gestation. Expressing and providing breast milk was one way the participant mothers believed they were able to connect to their premature baby, despite their physical separation. Breastfeeding was one way

these women were able to take part as a mother in the hospital nursery environment while most of their babies' needs were being attended to by the midwifery, nursing and medical staff. While expressed breast milk offered a form of connection and closeness for the participants to their newborn premature infant, it also became a burden. Women received emotional satisfaction from providing breast milk for their infants and expressed great pleasure in being able to perform this motherhood role; however, it was evident that these women felt much moral obligation to persist with their breast expression. The mothers believed that not to achieve the desired breastfeeding, to have insufficient breast milk, or to give up would be a failure of their motherhood.

5. "You have to do it"—Expressing is not a choice: In order for a mother to breastfeed a preterm infant weeks after birth, she must initiate and maintain her lactation. The only way of doing this is to wet nurse another baby, or to express milk regularly from the breasts. Wet nursing is not socially acceptable in mainstream contemporary Australian society and is not usually performed. Therefore, in our society, there is no option—expressing must be done. Expressing becomes a necessity for the mother who plans to breastfeed her preterm infant.

It was not by choice that participants were expressing, but rather a necessity by the choice of wanting to breastfeed. Expressing is the necessary precursor to the desired breastfeeding in their present situation. Helen spoke of the preterm breastfeeding experience as having two distinct parts. She says: "It's like in two parts. There's the expressing part and now there's [at-breast feeding], which is the normal part. [The] really nasty bit is the expressing all the time. It's horrible. You're going to have to do it, but it's really hard."

Helen referred to the milk production role as nasty and horrible, but she was quick to downplay her feelings by suggesting it is alright and even good to be doing it. By doing this she is reinforcing the good mother discourse. For Helen the task of expressing is not enjoyable and indeed creates a burden for these women, but the benefits are good; there are constant conflicting tensions. The tasks of breast expression create a burden for these women. For Helen, it is her continued lactation and ability to now at-breast feed that has made the milk producer role sustainable. The breast expression was horrible, nasty and good depending on which way it was considered; as everyday reality, as a role of motherhood or from altruism.

Breast expression is not unique to the preterm situation. For families with a term birth who choose to breastfeed, the infant will be feeding at the breast from birth and no expressing is usually necessary. However, families with an infant born at term may choose to express their breast milk if mother and child are to be separated for a period of time, such as for a social outing or if the mother goes back to work. In these circumstances, expressing is not a long-term necessity, but it is a choice to manage a short-term situation in addition to the usual established at-breast feeding. Expressing for a preterm infant is different to expressing for a term infant. With preterm birth, expressing is a necessity to establish and maintain breast milk supply, often for long periods of time, prior to the baby being discharged from hospital.

Julie found there was no choice of who does what with breastfeeding; if you want your babies to get breast milk then only the mother can do it; it was her gendered role: "Well, of

course you keep going. You do it because you feel you have to do it. That's where I suppose you feel a bit selfish, because you're feeling you have to do it, because your husband can't do it."

The dependence on the woman as sole provider of milk was evident in the father's narratives. The fathers showed an understanding of the role their wives/partners were required to undertake with regard to the expressing; however, some spoke of their regret at not being able to help or take over. Indeed, Peter thought breastfeeding was physically the mother's job, and therefore it was only she who suffered emotionally if it were not successful. He said: "It's only the mother that can do it, so it's only the mother that actually gets that feeling of incompleteness."

Despite the active role in assisting in breast-expressing tasks that some families participated in, such as milk transportation and pump setting up and cleaning, ultimately breastfeeding the preterm infant was a component of motherhood.

Discussion

This paper has explored the breastfeeding experiences of parents of VLBW preterm infants. It has identified the connection between breastfeeding in this context and the mothers' sense of self and the maternal identity this gave them. The participant parents interpreted the importance of their lactation not only for the baby but also to their sense of motherhood. The meaning they ascribed to breastfeeding was far broader than simply that of infant nutrition. Benner and Wrubel explain that: "In the phenomenological view the person is seen as attuned to and concerned with a world of significance." Breastfeeding was of great significance and meaning to the participant parents. It became the most important way mothers could actively participate in the care of their preterm child. In the NICU environment, supplying breast milk became a salient way in which to be a "good parent." Although with this connection came contradictions and ambiguities.

The participants demonstrated a strong relationship between providing expressed breast milk and which provided them with a sense of connectedness, despite the physical separation. Providing milk gave the participant mothers an important role in the care of their preterm infant. Providing expressed breast milk gave them agency as the mother. The mothers craved for an active parenting role, and this new role of breastfeeding mother was undertaken in a very positive and determined way. In the early days and weeks, mothers spoke of their breastfeeding as the only thing they could do for their baby. There is conflict in their conversations because they wanted to be closer to their baby and have a more participatory role, but were unable to do this at the time. Breastfeeding offered them a way in which to feel connected to their babies and feel a sense of satisfaction in assisting their babies' wellness; of giving "my milk," while at the same time feeling the sadness of being separated. Providing expressed breast milk was filling a void in their maternal experience, albeit in only a small way. Similarly, Golembeski found that, for her cohort of 20 American mothers of high-risk infants, they "had pride because this was milk that only they could provide." Moreover, one mother said that bringing the milk to the hospital was "so exciting and it made me feel like a real mother." While there were only a few examples in Golembeski's study, it is evident that the findings of this present study are similar to those of other groups of study participants.

It is evident that the participant mothers were embroiled in a mass of conflicting ideas and notions. Expressing was viewed as a necessary step to achieve at-breast feeding although most women viewed it with conflicting emotions. They wanted to breastfeed so therefore they had to express their breasts; but expressing was not their choice. Furthermore, they wanted a participatory role in the child's care but could only provide breast milk; they were providing for their baby but not actually feeding them; someone else was administering their breast milk to their babies. The breast milk offered a means of connection to the baby, but only after disconnection of the mother and baby and the mother and her milk. They desired physical closeness and something special from their breastfeeding experience, but they were only able to have technical provision with mechanical equipment. They aspired to a shared parenting discourse, but expressing breast milk was only a mother's job. In addition, the outcome of her lactation rested solely with her. With so much conflict and tension surrounding their breastfeeding experiences, it is possible to see how it influenced both positively and negatively, their construction of motherhood.

For this group of Australian parents, the notions of good motherhood and breastfeeding were synonymous. Although their breastfeeding was not a priority in the early days after birth, once the infant survived the first days of life breastfeeding was commenced. A delay in breastfeeding initiation for mothers of preterm infants has been documented before; however, ascertaining qualitative reasons for this have been overlooked as evidence. This study found the onset of breastfeeding became significant for the participant mothers, as this gave them a symbol of mothering and assisted in the establishment of their new identity. The commencement of breastfeeding gave them hope that their baby would survive and eventually go home with them.

Many studies have explored the ways in which "good mothers" and "good fathers" have been defined—for example, by parents themselves, by experts and in texts on parenting, and such notions have changed little over the past 30 years. Authors such as Chodorow and Oakley first questioned the way motherhood was defined by society. Since then, others have contributed to the debates about parenting and the social and cultural imperatives of good parenting. These works show that a good mother is thought to be one who, for example, is self-sacrificial; always places the infant's needs above her own; is always present for the child; and displays unconditional love and care for the child while remaining calm, patient and in control of her own emotions. Therefore, the notions of good motherhood are drawn from a child-centred discourse and have a strong emphasis on the importance of child welfare.

Marshall undertook an analysis of childcare and parenting manuals available to prospective and new parents. The various accounts of motherhood in this literature construct motherhood as a wholly positive experience. Marshall coined the phrase the Ultimate Fulfillment account to describe the way these manuals direct women to expect motherhood to be satisfying and important: something special that is essentially a creative and positive experience. Marshall goes on to explain that "the Ultimate Fulfillment account constructs the experiences of the 'natural' mother unproblematically, in essentially positive terms," and, furthermore, "shrouds any negative or ambivalent feelings a women may experience by characterising them as unnatural." The mothers in this present study worked hard to

portray a positive tone in their experiences amid much conflict and tension. Undoubtedly, they had a positive expectation of at-breast feeding. It is evident that breastfeeding the preterm infant left them desituated from people, places, meanings, experiences and expectations—all involving new and unanticipated connotations, concerns and practices. To be desituated, is to have taken-for-granted aspects of life disrupted, and the new experience to be foreign. These mothers worked hard to justify themselves as ‘good mothers’, ascribing to the ultimate fulfilment account, down playing negative and ambivalent feelings.

Hays also found that such manuals consider mothers to be primarily responsible for raising children, a notion supported by Lupton and Nippert-Eng. Both mothers and fathers in this study have shown that they too believed that at least with regard to breastfeeding the newborn the mother is solely responsible. Hays argues that the contemporary cultural model of socially appropriate mothering takes the form of an ideology of “intensive mothering” and that in this gendered model, mothers are expected to expend a tremendous amount of time, energy and money raising their children. Such images of motherhood and parenting are socially constructed and ever powerful.

Lupton and Fenwick, while discussing the perspectives of ‘good motherhood’ in the literature, recognise that such constructions of motherhood are based on mothers of healthy and well infants and that few sociologists have turned their attention to women whose infants are hospitalised immediately after birth. Little discussion in the literature exists of how the notion of ‘good’ motherhood is assimilated into the practices of women whose experiences do not fit the normal schema of new motherhood, such as with preterm birth. Some researchers have begun to investigate and document such experiences.

Susan Johnson, an Australian novelist and newspaper editor, suggests breast milk is deeply symbolic and “to some women, at least, it represents nothing less than the whole of one’s ability to mother.” Recent research has shown that a vast majority of Australian women equate breastfeeding directly with the notion of being a good mother and, in so doing, will maintain a strong commitment to breastfeeding despite enormous difficulties. Breastfeeding is something women in those studies wanted to achieve. Furthermore, “in the early months of first-time motherhood, breastfeeding was also a focal point of both intense satisfaction and intense distress.” Lupton and Fenwick, while studying mothers of preterm infants, found that mothers placed more emphasis on breastfeeding as a component of good mothering than did nurses. They suggest this was primarily due to mothers seeing breastfeeding as a uniquely maternal practice, an act of love and nurture and one that was uniquely theirs that could not be overtaken by the nurses or anyone else. All participants in this present study maintained a strong commitment to the breast is best rhetoric and directly equated their ability and persistence to provide expressed breast milk with their sense of self as being a good mother. Their breastfeeding was considered an essential practice of good mothering given the preterm birth and the baby’s “need” for breast milk. Breastfeeding was portrayed as crucial to their maternal identity, as, in this environment, they were very limited in ways to perform their motherhood role.

Limitations of this study: As with all research, there are limitations with this work. This study was conducted on a relatively small sample group of 17 parents; 10 mothers and

7 fathers. This study was conducted with Australian middle-class Caucasian families who chose to breastfeed their preterm infants. However, the clinical management of preterm infants and the care provided to breastfeeding mothers of preterm infants is not the same in all institutions and therefore the parental experience of breastfeeding preterm infants will not necessarily be the same. As human beings we all have different views, opinions, history, expectations and experiences, and no two will be exactly the same. However, commonalities do exist in similar, or like groups experiencing similar human experiences such as breastfeeding preterm infants. Consequently, the thoughts, feelings and practices described throughout this study will not be generalisable to all parents of preterm infant populations, but it is hoped that the commonalities and highlighted differences with the provided interpretation have revealed meanings of the human experience.

Conclusion

The findings of this study have implications for all who care for parents of preterm infants as well as breastfeeding advocates. The results presented here, extend the body of work that has identified the powerful discourses that currently position breastfeeding as crucial to the construction of motherhood. The participant mothers highlighted the positive aspects of their breastfeeding as it allowed them to connect to their absent babies and to perform as mothers when all other mothering tasks were taken out of their hands. This ability to provide breast milk made them feel valuable and unique—being the only person able to provide this milk. Therefore providing breast milk was very important for their sense of motherhood. Despite the sense of connection afforded, the period of breast milk provision was also experienced by these mothers as disempowering, disconnected and negative. It is evident that the association of breastfeeding success with mothering success only jeopardises some families’ self-esteem and sense of parenting ability. In Australia, the promotional messages about breastfeeding being best have been very successful in improving breastfeeding rates. However, Australian parents also associate breastfeeding with good parenthood and crucial to the mothering role. This view places undue stress and anxiety on all women and even more so on women whose experiences do not meet the norm, such as parents of preterm infants. These findings suggest it would be beneficial to find complementary ways to connect preterm infants and their parents in the preterm nursery environment, and find more realistic and sustainable ways to promote and support breastfeeding. As a health professional, I recognize this poses new challenges of how we might promote and protect breastfeeding for preterm infants while simultaneously giving families a realistic picture of the difficulties and potential outcomes of breastfeeding.

Ventilating Infants in Critical Care Air Transports

Over the past two years, more than 40 critically ill infants have received intensive care quality ventilation in air transports within Sweden and destinations in northern Europe. These transport opportunities have evolved from a close collaboration between the Swedish Air Ambulance company (Svensk Flygambulans AB) and the Astrid Lindgren Children's Hospital at the internationally renowned Karolinska Hospital in Stockholm, as well as new technological solutions that provide support to ventilated infants in fixed wing aircraft.

Critical Care News met with team members of this collaborative effort from both groups; representatives from PETS (Pediatric Emergency Transport Service) at Astrid Lindgren Children's Hospital, as well as representatives from Swedish Air Ambulance, to hear about how this collaborative effort and transport solutions developed within the group. The Pediatric Emergency Transport Service (PETS) at Astrid Lindgren Children's Hospital and the Swedish Air Ambulance company each have a longstanding tradition of transporting critical care and emergency patients.

The PETS service—with origins in the early 90's

The Astrid Lindgren Children's Hospital within Karolinska Hospital in Stockholm has a long and well-established tradition of transporting children, primarily newborn infants, originating from a decision to centralize cardiac surgery in Sweden to the university hospitals in Lund and Gothenburg in the 1990's. Dr Tova Hannegård Hamrin, anesthesiologist at Karolinska's Astrid Lindgren Children's Hospital, outlines the development process after that point: "We came to believe that there were many critically ill children in general ICUs in hospitals around Sweden, who would perhaps get better care in a dedicated pediatric intensive care unit. That is how the idea for PETS was born, and it started as a project in 2005. We have observed that more and more hospitals have contacted us to transport and treat more and more children." Dr Hamrin has been involved in the PETS program from the very beginning, and is currently responsible for PETS operations, which is a part of the Department of Pediatric Anesthesia and Intensive Care group at Astrid Lindgren Children's Hospital. "Last year we had 27 PETS transports in total, from January to April this year we are already up to 18 PETS transports, an increasing tendency. I think this increase is due to familiarity and confidence, once a hospital has heard about the program and sent one of their children to us and seen that it works, they want to use us again. PETS are not only air transports, but also land based ambulance and helicopter

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intensive care transports as well. Whatever the transport means, the program can be considered as a mobile ICU for infant and pediatric patients."

The PETS program has twelve physicians as well as twelve nurses, in order to provide staffing around the clock. Dr Hamrin explains: "In the very beginning, staffing was on voluntary basis among our colleagues. A patient transport request came to the doctor on call at the PICU, who then contacted us by mobile text messages that were sent to all of us, and those who had the opportunity to accompany the patient transport could respond. From the beginning of this year, we have chosen to have one physician on rotation for transports for one week at a time. We are also working on a proposal for a rotational schedule among our pediatric intensive care nurses and pediatric anesthesia nurses. It is extremely important that our PETS staff have a good knowledge of how we care for our patients, and that they have worked at least two years at our unit in the hospital."

Swedish Air Ambulance—over 30 years of operations

The Swedish Air Ambulance company started its operations in 1976 with the very first air ambulance in Sweden, and has continually developed ever since. Last year over 1,100 patients in different categories were transported, in a fleet of three Beechcraft 200 aircraft based in Sweden. Managing Director Åsa Englund states, "We fly primarily in Sweden and northern Europe on flights between 2-3 hours. After that, refueling is usually necessary, but is also dependent upon the load that the aircraft is carrying. Each flight has a captain, co-pilot, and aircraft nurse. We have a high requirement for our nurses, who must have flight medical training, emergency training, and maintain clinical competence in order to provide patient care, in case there are situations where no PETS team members are present. Over 90% of the transports are planned, and 10% are acute, according to Åsa Englund, and the company transports in any situation around the clock.

Registered Flight Nurse Carina Ramstedt explains: "It could be a patient that has to be transferred to a specialty center for transplantation, or a patient returning home after specialized care. Sometimes we get patients that have become ill during a business trip or vacation trip. We can provide flight support like an ambulance, ICU or sometimes the patients are capable of sitting upright. We also act as an extended arm. We had a number of patients that arrived in Sweden after the tsunami 2004, who were transported back to their home hospitals."

Collaboration leads to new infant transport solutions

Karolinska Hospital and Swedish Air Ambulance have collaborated with patient transports for many years, in many different patient categories. The PETS group has used different



Infant patient in aircraft, ready for air transport from Sweden to northern Europe, with BabyPod and SERVO-i transport solutions.

transport solutions for infants, with different experiences and drawbacks. Dr Hamrin explains about some of the limitations they have encountered and the discovery of the infant pod solution: “When you transport with an incubator, the infant is the component that weighs the least. Transport incubators are large and cumbersome, and not easy to work with. One of our colleagues heard about the infant pod solution in Great Britain, where it has been in use for some time. We purchased one infant pod (BabyPod manufactured by Advanced Healthcare Technology Ltd, UK) and started to use it for transports of our infants with congenital heart disease, and it worked very smoothly. In about the same time frame, the SERVO-i ventilator became available for air transports. The transport incubators today have a rather basic ventilator solution that does not provide high quality ventilation treatment. “The Swedish Air Ambulance became very interested in the infant pod solution that the PETS group had discovered, since it is a much simpler solution to travel with when a transport incubator is not really needed. Dr Hamrin states that the only time when a transport incubator may be needed is when the infant cannot maintain body warmth, which generally is only a problem with premature babies, in her opinion.

Annika Schön, anesthesiology nurse in the PETS group, describes the infant pod solution: “The infant pod is lightweight as it is composed of styrofoam, and has a five point strap system



Demonstration of the BabyPod mounting on the transport stretcher with SERVO-i ventilator anchored in place.



Swedish Air Ambulance acting Managing Director Åsa Englund has been employed at the company since 2001, and has been actively involved in the technological developments.

crossing over the child as a harness to keep the infant in place on the mattress. The mattress is a vacuum type, which can be adjusted if the child needs further support within the pod. The pod is affixed to the stretcher at the hospital, and the concept works as one unit from the hospital to the aircraft, during flight and upon arrival at the receiving hospital.”

Intensive care ventilation in-flight

The pod solution became very popular for transporting infants, but ventilation was an issue that still needed to be addressed. Swedish Air Ambulance Flight Nurse Carina Ramstedt describes some of the practical problems of the past: “For infants, the greatest concern has always been the risk of extubation when entering or leaving the aircraft. We always worry about tubes or cords fastening somewhere, or movements that might disturb the patient and the equipment, such as one of the staff stumbling, etc.”

For the PETS team, the quality of ventilation treatment for infants has been a primary concern. Dr Hamrin explains: “When PETS began, more than 70% of our transported patients were referred because of respiratory insufficiency. In transporting these infants with sick lungs, it can affect the level of treatment quality to transport without a high quality ventilator. We were purchasing the SERVO-i in the hospital to replace our old SERVO 300 fleet in the PICU, and as the SERVO-i can be adapted for transports and was approved for flight, the idea was born to transport with a ventilator that provided ICU-quality ventilation, and to use it on the infant during the entire course of therapy, including bedside. This helps us maintain the same ventilator quality without interruption.

“The Swedish Air Ambulance company was attentive to us when we discussed the fact that the old model of baby transport ventilator was not sufficient for these infants with sick lungs. In the process we took a SERVO-i ventilator and received flight approval for it, and they followed the same process. They also heard about the transport cage to attach and stabilize the SERVO-i to the stretcher, and informed us, as they have always been very attentive to our requirements in regard to ventilation quality during the transport process. The collaboration continues to develop.”

The Swedish Air Ambulance company initiated a process to be able to use the SERVO-i ventilator in flight. Åsa Englund clarifies: “We developed the solution to anchor the ventilator and cage to the stretcher on a bottom plate, which is stable from all directions. After that we conducted a series of tests to evaluate



Carina Ramstedt is Flight Nurse at Swedish Air Ambulance.

stability, electrical disturbance on other instrumentation, and tests to establish that the ventilator was not affected by changes in cabin air pressure or vibrations, and tests of the connecting cables as well.” The Swedish Air Ambulance company appreciated the concern about the quality of ventilation in flight. Åsa Englund points out: “It is important that transport of these small ICU infant patients should just be considered as a continuation of the treatment and care they have received at bedside. They are treated in the pediatric ICU, and during the air transport process the treatment should continue smoothly at the same level as at bedside, the only difference is that we are moving the patient from Point A to Point B.”

Single unit concept—infant pod and SERVO-i mounted to the same stretcher

After the different stages of the process, with the discovery of the infant pod solution by the PETS team, and the flight validation of the SERVO-i and transport cage solution by Swedish Air Ambulance, the one unit concept was first utilized during an infant transport flight from Sweden to Dublin, Ireland. Carina Ramstedt recalls the first experience: “The opportunity of mounting the ventilator on the same stretcher where the child is positioned in the pod makes the solution a single unit, which provided a new sense of security. In the past, it has always been a concern with separate lifts of the ventilator and the child, with concern for the tube and risk of extubation. The single unit concept of infant pod and SERVO-i worked very well, and made our work easier.”

Annika Schön who has flown for many years with PETS at Karolinska Hospital in cooperation with Swedish Air Ambulance, agrees that the current single unit solution that so many have contributed to, with the infant pod and SERVO-i ventilator both fixed on the same stretcher has made the process much easier. “Since the children we treat have respiratory problems, we do not like the traditional infant incubator-based transport ventilators. These old traditional infant transport ventilators have a lower level of clinical performance, and sometimes we had to increase sedation for the patient in order to ventilate them on the older transport ventilators. Since we have SERVO-i in the PICU, it delivers ventilation with the clinical performance that is required by these infants with respiratory problems, at bedside in the PICU as well as in the air during transport. This is the most optimal situation for the patient if they receive their treatment on the same ventilator at bedside in the ICU prior to transport, in flight during transport and at bedside at the PICU at the receiving hospital. This also means that treatment parameters,



The ventilator is securely mounted to the stretcher by means of a special transport cage, which maintains stability throughout the flight.

such as settings and sedation levels, can remain the same. For us staff members, it is also optimal from the perspective that we are working with the same equipment in flight that we know and use at bedside in the unit.”

She has also noted increasing trends in acceptance and utilization of the solution: “From November 2006 up to and including the year 2007, we had 27 air transports with the single unit infant pod/SERVO-i ventilator solution. Interestingly, so far [in 2008] in the first four months from January to May first, we have already had 18 transports. There is a growing tendency to request and utilize this solution. I think perhaps it is due to the fact that hospitals throughout the country are becoming familiar with this possibility, contacts have been established and they see that the transport solution has worked well. I think that we have passed an initial level of knowledge and acceptance, and the requests for infant transports with this solution will continue to grow.”

Bedside quality ventilation therapy—wherever the infant may be

Dr Hamrin also addressed the benefits of using the same ventilator in the ICU and in the air. “We have many SERVO-i ventilators that are approved for flight, so it is a benefit if the child can continue ventilation on the same ventilator upon arrival without having to switch ventilators. It is what is best for the infant, and reinforces our ambition to provide the same level of quality in ventilation therapy in the air as well as bedside in the PICU.” The infants that are critically ill are most often on Pressure Control ventilation, according to Dr Hamrin. “We can change setting parameters during transport, just like we might do bedside in the PICU. We do not usually require muscle relaxants for the infants during transport. Sedation may be used during



Swedish Air Ambulance Beechcraft 200 aircraft.



The single unit concept, with ventilator and infant pod attached to the same stretcher, has increased ease-of-use and minimized risks, according to staff members.

transport, since the child may be critically ill prior to transport and is sedated at the hospital of origin. We try to use the same trigger settings in transport that have been used at bedside. We try to stabilize before leaving the hospital of origin and want to be satisfied with all treatment parameters, prior to transport, so that the trip goes as smoothly as possible.”

The infant clinical situation and need for transport can vary, depending upon each individual patient scenario. Annika Schön of the PETS staff has seen different situations throughout the years. “Usually we receive a request for consultancy from another hospital in Sweden, where they might have a case that has a difficult clinical situation, most frequently a child with respiratory insufficiency that is difficult to manage, and they ask for advice. In these situations, we may offer to take this child, with a difficult respiratory insufficiency, to be transported to our center for treatment. Other diagnoses may include sepsis, meningitis, lung disease or perhaps an infant with cardiac difficulties. All of these infants are in need of qualified ventilatory treatment. We also have cases of children receiving Extra Corporeal Membrane Oxygenation or ECMO, which need to be transported, or returned to their home hospital post ECMO treatment. Many of the children with cardiac difficulties have been born with abnormalities and are in need of heart surgery in



Tova Hannegård Hamrin, MD, is Director Pediatric Anesthesia at Astrid Lindgren Children’s Hospital, and has been responsible for the PETS program since 2005.



Annika Schön, RN, has been part of the PETS group at Astrid Lindgren Children’s Hospital from the very beginning.

specialist hospitals in another part of the country. We should also mention here that the infant pod has also been used for children up to 6-8 kilos.”

Carina Ramstedt of Swedish Air Ambulance concurs. “We fly everything between short 30 minute jumps to up to 3 hours, with infant transports. Our most frequent route is Stockholm—Malmö, 1 hour and 15 minutes for infants needing heart surgery at Lund University Hospital. But flight length depends upon the destination; to Ireland or other parts of northern Europe it may be 2.5 to 3 hours, and to different regions of Sweden it might be 1-2 hours. Among the longer range flights, we have been to Paris, France where there is a radiologist who is a specialist on birth deformities in infants. When we fly to Dublin, Ireland or to Germany it may be in connection with ECMO cases. Usually these infants are transported post ECMO treatment, and in some cases we have accompanied children to Germany for treatment when the ECMO facility in Sweden has had no available capacity.”

The infant transport process—meticulous planning and mobilization

Staff members from PETS and Swedish Air Ambulance are required to follow detailed routines and checklists at each institution, prior to transport. The PETS team members take about one hour to mobilize, from the point of contacting medical staff at home, who initiate the preparation process on the way to the hospital, depending upon the patient situation. According to Dr Hamrin, the same routines and checklists are followed, whether the patient transport is land based, helicopter or fixed wing aircraft. “We have different partners for each alternative, and we always choose the appropriate transport alternative depending upon the patient situation. We receive a call from a referring hospital, often from an intensive care physician, and we find out as much as we can about the clinical situation; which medications the child has received, type of ventilation therapy, drains and which infusion pumps are being used. This gives us a picture of the situation in regard to what we need to bring with us for this particular patient.

“We have a transport inventory where we keep our equipment, and where we have packed and sealed transport bags for different patient age groups; newborn infants, small children

and teenagers who are almost fully grown. If the child is receiving a certain type of medication that we normally do not keep in inventory, we make sure that we have it with us. We keep a standard assortment of materials in the bags, which are always filled and on standby, but there can be special needs to customize in special situations. We test all equipment before we leave, see that the batteries are charged for the monitors and infusion pumps, and anything that runs on electrical current. We also double-check if we need oxygen or NO with us.

“These preparations are mainly logistical, but critical for us to ensure that everything works as smoothly as possible when we receive the child. It is an advantage that we have a relatively small size working group, and once you have done a certain number of transports, the logistics become routine fairly quickly. When we return to our hospital, we complete the patient records and equipment log sheets, and see to it that the equipment is in good working condition for the next transport, we refill the bags and inventory to replace anything that has been used. The bags are then sealed so the next staff members on the next transport can feel confident that everything is in order.”

Routines and checklists are also carefully followed by the Swedish Air Ambulance group, according to Åsa Englund: “The care team is a combination of PETS staff members and the aircraft staff, or 3 persons in total. One aircraft nurse, who is an anesthesia nurse responsible for the cabin and the equipment and safety within the aircraft, and one PETS nurse, who can be a pediatric anesthesia nurse or a pediatric intensive care nurse, and one pediatric anesthesiologist from PETS accompanies the patient. Usually there is no room in the aircraft for family members, who have to make the trip on a commercial flight. Each transport situation is unique and requires careful preparation, in terms of the flight and the patient. We follow thorough and detailed checklists.”

Prepared for any eventuality

In attending to infant care in flight, the noisy environment can often be a challenge in a fixed wing aircraft and especially on helicopter flights, according to Annika Schön. “It can be problematic to hear equipment alarms during flight, which means that it is especially important that the user interface has a good and clear visual display.”

As an anesthesiologist, Dr Hamrin addresses additional challenges in treating ventilated infants in transport. She says that the worst case scenario would be an accidental extubation and losing the airway, requiring re-intubation. “Fortunately this has never happened to us. Another negative case scenario would be cases with diaphragmatic herniation with high airway pressures, where there is a risk of pneumothorax, but fortunately that has never happened to us either. However, we do plan and prepare to be able to handle any type of situation.” The new technology and solutions have also contributed to minimizing these risks.

Intensive care transport trends in the future

Representatives from both groups shared the opinion that the trend for air transports of ventilated patients will continue to grow in the future. In regard to the infant transport solution, Annika Schön feels that there is still potential for further development of the concept. “The next step is perhaps a bit larger stretcher for larger children, where the ventilator can also be mounted to serve as a one unit concept. And developments

for weight reduction will continue to be important—weight is always a factor for consideration in air transports.”

Åsa Englund expressed that the limitations of current land based ambulance models will continue to be a factor for increases in air transports. “I believe that the number of transports will steadily increase, even in the adult patient category. In terms of adults, there is a problem today that conventional ambulances are limited and cannot transport intensive care patients, and there are very few mobile ICU ambulances that are equipped and tested.”

Dr Hamrin cited the needs of continuing development and the increasing focus on centralization and quality care in transport as important issues for the future. “There is a need for continued development. Weight and space are always important issues in transport situations and will continue to be so. Alarms can be difficult to hear in the air, especially in helicopters. This means that we continuously need to keep our eyes on the user interface screen, and to be able to see the screen values and alarms clearly.

“There is an increasing tendency to centralize specialized treatments at certain centers, which means an increase in the need for patient transports. There is a movement to more and more quality care during the transport. I think that if you are going to transport intensive care patients, by whatever means, the goal must be to provide the same level of intensive care treatment, and not to accept a lesser level of care during the transport, after receiving the patient. That simply is indefensible.”

Biography

Tova Hannegård Hamrin received her medical degree at Karolinska Institute, Stockholm, Sweden in 1990. Her internship and residency in Anaesthesiology and Intensive Care took place at Sundsvall Hospital, Sweden 1990-1994. She was certified as a specialist of Anesthesia and Intensive Care by the Swedish National Board in 1998 and worked as a specialist at Stockholm South Hospital, Sweden from 1994-2001. Dr Hamrin was Specialist in Paediatric Anaesthesiology and Intensive Care from 2000 to 2007 at Astrid Lindgren Children’s Hospital, Karolinska University Hospital, Stockholm, Sweden. She currently holds the position of Director, Paediatric Anaesthesia at Astrid Lindgren Children’s Hospital and has been responsible for the PETS (Paediatric Emergency Transport Service) program from 2005 to the present time.

Annika Schön obtained her initial nursing degree in 1986, and worked initially in the adult intensive care unit of St. Göran’s Hospital in Stockholm. She received her nursing degree in anaesthesiology at the Karolinska Institute University Hospital in 1990-1991, where she also worked within the central anesthesia clinic, as well as within intensive care in the ambulance service at that institution. Annika Schön has held positions within pediatric intensive care at St Göran’s Hospital since 1995 and at the Astrid Lindgren Children’s Hospital in 1998, where she has been part of the PETS (Paediatric Emergency Transport Service) group from the start. Annika Schön is also currently working to achieve her PhD degree at the Institute for Women’s and Children’s Health at the Karolinska Institute. Åsa Englund received her initial nursing degree in 1987, and her nursing degree in anaesthesiology in 1993. She was employed as an emergency room nurse at the Halmstad Community Hospital in 1988 and as an anesthesia nurse at the Varberg Community Hospital in 1993. During the years of 1999-2000, Åsa Englund

was employed as registered nurse on an international cruise ship, with nursing responsibility for guests as well as for fellow staff members from over 50 countries. Åsa Englund started working at SOS Flygambulans (currently named Svensk Flygambulans—Swedish Air Ambulance) in 2001 as head nurse with responsibility for 15 nursing staff members. She became Operations Manager for the company in 2006, in charge of over 30 staff members and responsible for the medical department, marketing and property and operations. Åsa Englund became acting Managing Director of Swedish Air Ambulance in 2007. In this capacity she is currently responsible for corporate accounting, PR, marketing and chief of staff, and is a member of the management group as well as the board of directors.

Editorial...continued from page 6

incidence of intubation in the delivery room with a resultant reduction in cases of severe MAS requiring neonatal intensive care admissions, mechanical ventilation, morbidity from cardio-respiratory problems and death. All cases of severe MAS were reviewed and possible etiologies included aspiration in utero or failure of additional combined obstetric-pediatric management.

At present, in our institution, neonatal response team (neonatology attending, pediatric resident and neonatal nurse) attends almost all MSAF irrespective of the maternal-fetal condition. We strictly follow Carson's et al approach instructing all obstetricians to suction the baby's mouth with bulb or DeLee suction followed by nasopharynx as soon as the baby's head is delivered at the perineum. This is an important step, does not hurt the baby and removes any material in the mouth before the infant takes deep inspiratory breaths and inhales it. When the baby's complete body is delivered we request the obstetrician to hold the baby in left hand in prone position with the head turned to the side and to repeat the suction of the oropharynx using the bulb suction. After this, the baby can be handed over to a neonatal response team for assessment of the clinical condition of the baby. There are two approaches used based on the infant's clinical condition:

1. If the infant is active, vigorous, with HR > 100 bpm, continuous respirations, crying with good color, tone and reflexes, i.e., Apgar score > 7, we only suction the oropharynx with bulb and then we dry and stimulate the infant and observe.
2. If the infant is inactive with HR < 100 bpm, irregular respirations, poor color, tone and reflexes (Apgar score < 4-5) we do not stimulate the infant nor dry him/her, we perform a direct laryngoscopic visualization of the oropharynx for any secretions or meconium and staining of the vocal cords. If no meconium or vocal cord staining is seen we give PPV either via bag and mask or intubate if no response. If meconium is seen in the oropharynx or oozing from the trachea, we intubate the baby and suction the baby using a meconium aspirator and give PPV through endotracheal tube.

The combined obstetric-pediatric approach was questioned by Vain et al in (Lancet, 2004) in addition to reports of Falciglia et al (Obstet Gynecol, 1988 and Am J Obstet Gynecol, 1992) stating that there is no benefit in oropharyngeal suctioning by the obstetricians during delivery of MSAF. Based on the evidence provided by the studies of Vain and Falciglia et al, there are no clear benefits of obstetric suction, but the issue of MSAF is still very debatable. We agree with intubation and suction only for

She also retains overall responsibility as Ambulance Chief for the flight planning center and medical departments. Carina Ramstedt obtained her initial nursing degree in 1973 and her nursing degree in anesthesiology at Uppsala University Hospital in 1976. From 1976 to 1986, Carina Ramstedt was employed as a nurse at the Pediatric Intensive Care Unit of Queen Silvia's Children's Hospital in Göteborg. She has also worked as an ambulance nurse as well as nursing positions within coronary care and neurosurgical departments. Carina Ramstedt was also employed by the Swedish Defence Department as a field nurse with assignments in Lebanon in 1990 and in Bosnia- Herzegovina in 2000. She is currently employed as Flight Nurse at Swedish Air Ambulance, where she has been working since 2001.

depressed babies with MSAF in addition to combined obstetric-pediatric management. From our experience:

1. There is no need to routinely intubate and suction all MSAF infants to prevent MAS.
2. Selective approach with intubation and suction may be useful in depressed babies when there is meconium and secretions oozing from the trachea or vocal cords are stained.
3. Regardless of the timing of meconium aspiration, in utero or during birth or immediately after birth, simple atraumatic suctioning using bulb by an obstetrician after delivery of the head and body is the single most important procedure to prevent major aspiration even when the infant is vigorous at birth.

In our experience of 30 years the combined obstetric-pediatric approach has prevented not only MAS but also resulted in a reduction in morbidity and mortality with improved outcome of MSAF infants. However, based on the evidence-based medicine review of the few public reports, ACOG and AAP have recommended that the routine obstetrician's suction of the oropharynx is not beneficial. This recommendation is reflected in the most recent edition of the neonatal resuscitation textbook by AAP.

But given the beneficial effects seen in during our careers, we recommend that the simple procedure of oropharyngeal suction by the obstetricians should continue in all MSAF babies. We are happy to state that we have never had severe cases of MAS leading to complications like persistent fetal circulation, pulmonary hypertension and requiring vigorous ventilator support, treatment with iNO and ECMO. In fact, we have not seen any mortality in full term infants with MAS. These beneficial outcomes guide us to keep our old tradition in place of newer recommendations of evidence-based medicine as long as it does not cause injury to the infant and continues to prevent complications in MSAF infants.

SIDS And Safe Sleep

Laszlo Sandor

New practices and products can ameliorate the danger of SIDS. Neonatal Intensive Care looks at how a comprehensive program for NICU nurses and parents at St Joseph's Hospital Health Center in Syracuse, NY, has influenced care strategies through direct applications of procedures that promote safe-sleep compliance.

Background

Many recommendations have been promulgated for safe-sleep procedures in the NICU. According to the journal, *Advances in Neonatal Care*, "Clear policies regarding infant sleep practices must be written and enforced. Parent education needs to be an integral part of the policy. Role modeling sleep practices in the hospital and instructions regarding safe bedding materials must also be included."

The American Academy of Pediatrics, under the aegis of its Back to Sleep campaign, has published specific guidelines for SIDS prevention that include: the providing of a firm sleep surface; no soft objects or loose bedding in the sleeping area; no smoking; no bed-sharing; a regulated temperature for the infant, and supine positioning. The latter recommendation has provided the greater challenge toward implementation in the NICU, where nurses are often faced with a dilemma, in that clinical strategies have often been thought to necessitate the prone positioning of infants. It's difficult to get healthcare practitioners to change longstanding procedures; also, until recently, there has been no rigorous attempt to promulgate the benefits of switching infants to the supine position in the NICU. However, the AAP's recommendations, reinforced by clinical evidence, are finding their place in this critical care environment.

Beyond the hospital environment, NICU nurses have also had little guidance about what to tell anxious parents when they are taking their tiny infants home. A recent study revealed that only half of the surveyed nurses provided sleep-positioning instructions for parents, and that the AAP's recommendations weren't being consistently promulgated.

St Joseph's Hospital Center in Syracuse, NY, recently put into practice a program aimed at both SIDS strategies in the NICU and an educational component for when infants are discharged.

Education Is Key

St Joseph's developed an education module that includes

Laszlo Sandor is a contributing editor to *Neonatal Intensive Care*. HALO SleepSack and HALO SleepSack Swaddle are registered trademarks of Halo Innovations, Inc. Editorial material for this article was provided by the company.



The HALO SleepSack.

an online SIDS teaching tool, updates on sleep positioning, instructions for discharge education, SIDS education as a regular component of new nurse training, and the use of products that enhance safe SIDS procedures, including the use of a "sleep sack" and "crib card."

The hour-long computerized educational component of St Joseph's nurse training program is designed to provide a set of empirical standards for use by NICU nurses, and is consistent with the aforementioned AAP guidelines. While the computerized training schema, which is undergoing NNP review and approval, is still in the process of fine-tuning, it is envisioned that the process will provide a valuable teaching tool.

Aspects of the program include a SIDS "Crib Card" for post-NICU caregivers to review while their infant is still in the unit. The card, which is to be placed in the crib or incubator, promulgates supine positioning, and incorporates all of the AAP's recommendations for safe sleep [see sidebar].

Supine Sleep in the NICU

Initially, the supine-positioning of infants in the NICU met with some resistance. The *Journal of Neonatal and Perinatal Nursing* has noted that during prone sleep, "an infant is at risk for rebreathing oxygen-poor air trapped in an air pocket created by soft bedding. Prone sleep is deeper and more prolonged than supine sleep. Without an underlying disorder, the challenged infant would arouse and react to environmental conditions and restore homeostasis. In association with an underlying disorder, the additional compromises to arousal may not be overcome."

Stepping Up

The Five Steps to Home

1. No loose bedding, pads, stuffed toys in the crib. (Infants in the NICU or hospital are supinely positioned a week before discharge.)
2. Don't overheat the room, and don't bundle the baby while it's sleeping. The ideal room temperature is between 65 and 71 degrees. Don't cover the baby's head. Don't sleep with your baby in the same bed.
3. Watch the baby! Babies can play on their bellies so long as they're observed.
4. Tell nannies and grannies: this baby sleeps on its back, only.
5. Put out that cigarette. No smoking in the home.

It was also noted that this issue has been studied. There has been a welcome rise in the use of a supine sleep position for infants. "There is no evidence of an increased risk of death from aspiration."

According to a survey about infant sleep positioning in *Advances in Neonatal Care*, up until recently, "supine position was identified as the best sleep position for preterm infants in [only] 5.1% of respondents. Among the 95% of respondents choosing a non-supine sleep position, neonatal nurses identified the best sleep position as prone." Contrary to common perception, the study pointed out, "Although reflux and cardiorespiratory events are common in preterm infants, there is little evidence to suggest that they are causally related." Another concern was the possibility of plagiocephaly without stenosis. Despite anecdotal evidence, it has been noted that without a population-based study of its incidence, it remains unclear if and by what degree plagiocephaly without stenosis is occurring. In any event, the sections on Plastic Surgery and Neurological Surgery of the American Academy of Pediatrics Committee on Practice and Ambulatory Medicine continue to support the benefits of supine sleep.

As a result of careful study, and after giving due consideration to the special needs of tiny babies in the NICU, St John's NICU and hospital policy has been brought up to date and now eliminates prone or side-positioning of healthy infants, and also requires stabilized NICU infants to be supinely positioned. The policy also encodes and enforces the use of "sleep sacks" to maintain normal infant body temperature. In addition, NICU nurses were instructed to discuss discharge procedures with parents, and to document discharge instructions to parents or other post-hospital caregivers.

Warming Trend

In addition to enforcing the supine positioning of infants, a major component of St Joseph's program to promote safe sleep is making sure that infants don't become overheated. To this end, the hospital currently uses the HALO SleepSack wearable blanket. SleepSack wearable blankets are designed to keep the baby at the proper temperature, and are also designed so they can't cover the infant's head. Initially, St Joseph's used a locally-manufactured "sleep sack." Some nurses were resistant to use of the "sleep sack," believing the infants weren't warm enough, and that the use of a sack would cause a return to the incubator.

However, St Joseph's decided that the sack was in fact the best option, and initiated a study using the HALO SleepSack Swaddle (Halo Innovations, Inc, MN; halosleep.com). The Swaddle by Halo is an all-around covering that provides extra warmth, and the use of this product has improved nurse compliance. St Joseph's now also uses the HALO SleepSack wearable blanket for all infants when they're transferred to an open crib.

The SleepSack's design also encourages proper sleep positioning. In a recent study, 74% of parents using the SleepSack at home placed the infant in a supine position because the zipper was located on the front. In addition, the design kept infants from turning over, scrunching under the blanket, and overheating. By 2006, St Joseph's reported that all the infants in the NICU were sleeping supine and in a SleepSack or SleepSack Swaddle. By the following year, 70% of infants were lying supine in both cribs and incubators. Some of the infants had an increased oxygen demand, but oxygen administration was proportionately increased.

Sharing Beds

St Joseph's also instituted the AAP's recommendations on bed sharing. Infants rooming with their mothers in the maternal-child unit of the hospital were provided with their own bassinet, and twins were also kept in separate beds. Nurses observed mothers and babies and offered instructions on safe-sleep procedures. Mothers who were tired and falling asleep with their infants were told to put the baby in the crib or call hospital staff to do so. Mothers were told about the dangers of falling asleep in the same bed with their babies. It was hoped that the in-hospital instruction and example would encourage mothers not to bed-share once they took their infants home.

In addition, St Joseph's also bought HALO SleepSack Swaddles for term infants and incorporated their use into the daily sleep-care of the infants.

Summary

The safe-sleep model based on the AAP's Back to Sleep campaign offers a practical approach to implementation of the AAP's SIDS-reducing recommendations. St Joseph's education campaign, with its computerized teaching component, begins at the nursing level, and mandates and codifies safe sleep principles. The basics of SIDS-preventive safe sleep procedures are, concurrently, an integral part of St. Joseph's discharge procedures. While it has been recognized that ingrained nursing practices relating to sleep positioning would be a challenge to implement, St. Joseph's sought to offer a comprehensive program that has made this possibility into a reality.

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Transposition of the Great Arteries

Paula Martins, Eduardo Castela

Abstract

Transposition of the great arteries (TGA), also referred to as complete transposition, is a congenital cardiac malformation characterized by atrioventricular concordance and ventriculoarterial (VA) discordance. The incidence is estimated at 1 in 3,500–5,000 live births, with a male-to-female ratio 1.5 to 3.2:1. In 50% of cases, the VA discordance is an isolated finding. In 10% of cases, TGA is associated with noncardiac malformations. The association with other cardiac malformations such as ventricular septal defect (VSD) and left ventricular outflow tract obstruction is frequent and dictates timing and clinical presentation, which consists of cyanosis with or without congestive heart failure. The onset and severity depend on anatomical and functional variants that influence the degree of mixing between the two circulations. If no obstructive lesions are present and there is a large VSD, cyanosis may go undetected and only be perceived during episodes of crying or agitation. In these cases, signs of congestive heart failure prevail. The exact aetiology remains unknown. Some associated risk factors (gestational diabetes mellitus, maternal exposure to rodenticides and herbicides, maternal use of antiepileptic drugs) have been postulated. Mutations in growth differentiation factor-1 gene, the thyroid hormone receptor-associated protein-2 gene and the gene encoding the cryptic protein have been shown implicated in discordant VA connections, but they explain only a small minority of TGA cases.

The diagnosis is confirmed by echocardiography, which also provides the morphological details required for future surgical management. Prenatal diagnosis by foetal echocardiography is possible and desirable, as it may improve the early neonatal management and reduce morbidity and mortality. Differential diagnosis includes other causes of central neonatal cyanosis.

The authors are with the Serviço de Cardiologia Pediátrica, Hospital Pediátrico de Coimbra, Coimbra, Portugal. Reprinted from *BioMed Central, Orphanet Journal of Rare Diseases*, © 2008 Martins and Castela; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution. The authors would like to thank Prof R. Anderson for his tutorship and continuous support, Drs Graça Sousa and António Pires for their guidance, Gemma Price for kindly supplying the schematic drawings used in the manuscript and Cambridge University Press for permitting their reproduction.

Palliative treatment with prostaglandin E1 and balloon atrial septostomy are usually required soon after birth. Surgical correction is performed at a later stage. Usually, the Jatene arterial switch operation is the procedure of choice. Whenever this operation is not feasible, adequate alternative surgical approach should be implemented. With the advent of newer and improved surgical techniques and post operative intensive care, the long-term survival is approximately 90% at 15 years of age. However, the exercise performance, cognitive function and quality of life may be impaired.

The transposition of the great arteries was first described by Mathew Baillie in 1797, in the second edition of the book “The Morbid Anatomy of Some of the Most Important Parts of the Human Body.” However, the term “transposition” was only applied in 1814, by Farre, meaning that aorta and pulmonary trunk were placed (positio) across (trans) the ventricular septum. In fact, this congenital cardiac malformation is characterized by atrioventricular concordance and ventriculoarterial discordance. In other words, the morphological right atrium is connected to the morphological right ventricle which gives rise entirely to or most of the aorta; the morphological left atrium is connected to the morphological left ventricle from where the pulmonary trunk emerges.¹

The term congenitally corrected transposition of the great arteries describes a different entity that conjugates atrioventricular and ventriculoarterial discordance.² In the old nomenclature, completed transposition was used to describe either congenitally corrected or uncorrected transposition. In both situations, the great arteries were completely or predominantly misplaced across the ventricular septum. The designation “incomplete transposition” was reserved to other types of malpositions of the great arteries, such as double outlet right and left ventricle. At present, the term complete transposition is usually used to describe only the physiologically uncorrected transposition.

The prefixes a-, d- and l- transposition describe the spatial relationship between the aorta and the pulmonary trunk, and should not be used to define this anomaly.³ In d-transposition, the aortic valve lies to the right of the pulmonary valve. This is the most frequent arterial arrangement present in the hearts with

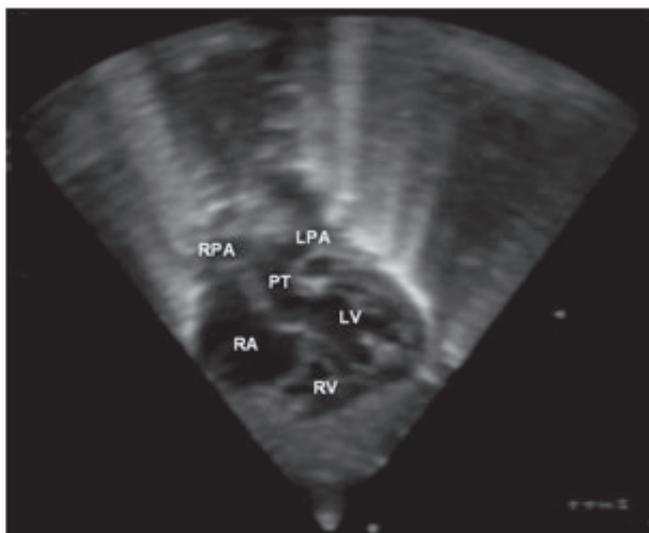


Figure 1. This subcostal view shows the left ventricle originating a vessel that bifurcates, which is thus identified as the pulmonary artery.

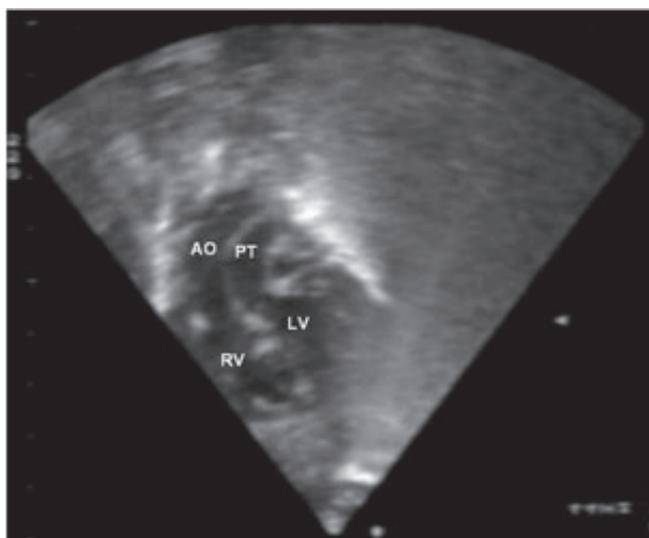


Figure 2. Subcostal view showing discordant ventriculoarterial connections together with the presence of parallel, rather than crossing, great arteries arising from the ventricles.

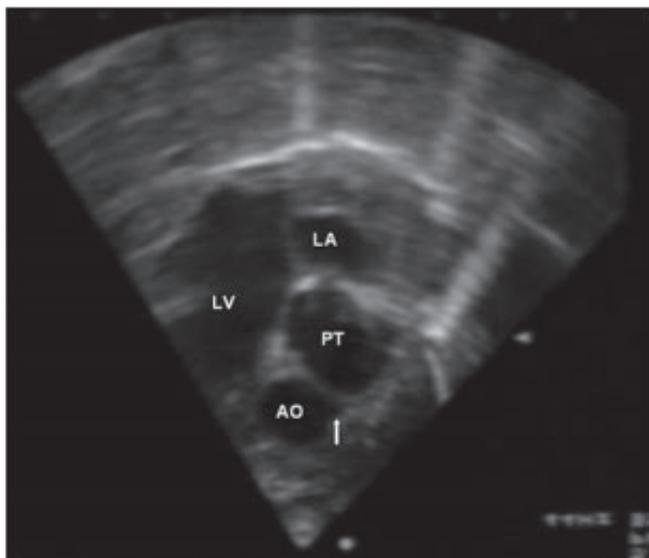


Figure 3. Short axis view showing the aorta giving rise to the coronary arteries (arrow) in an anterior position and to the right. The pulmonary trunk is placed in a central position.

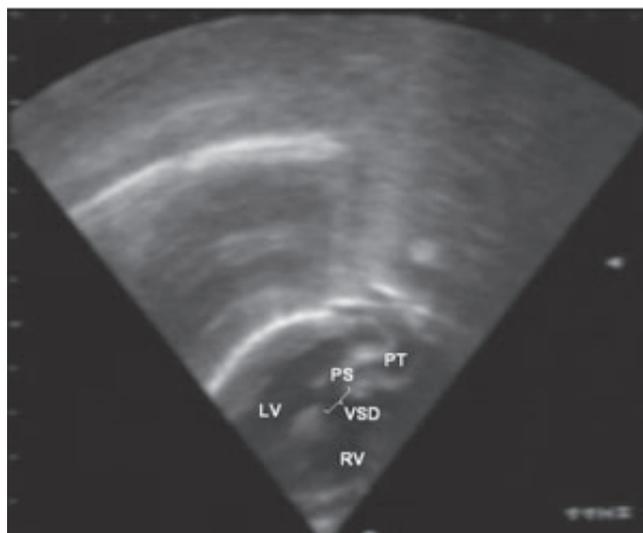


Figure 4. Echocardiography of a complex transposition with a ventricular septal defect and pulmonary stenosis.

concordant atrioventricular and discordant ventriculoarterial connections. However, other possibilities of arterial distribution exist in this setting, thus the two concepts are not synonyms.⁴ In congenitally corrected hearts, the aorta usually lies on the left (l-transposition), but then again this is not an absolute finding. The a-transposition refers to the anterior position of the aortic valve in relation to the pulmonary trunk.

These different classifications and nomenclatures have led in some cases to the inadequate or imprecise use of certain terms. To avoid ambiguity, it is important to use a description based on segmental analysis, and therefore, in our opinion, transposition of the great arteries should be defined as concordant atrioventricular and discordant ventriculoarterial connections.

Epidemiology: The hearts with atrioventricular concordance and ventriculoarterial discordance represent 5–7% of all congenital heart diseases,⁵ corresponding to an incidence of 20 to 30 per 100 000 live births. There is a male predominance with a male/female sex ratio that varies, in the literature, from 1.5:1 to 3.2:1.⁶⁻⁸ In 10% of the cases, this cardiac lesion is associated with other noncardiac malformations.⁹

Pathology: In the hearts with transposition of the great arteries, atriums and ventricles retain their typical configuration, and conduction tissue assumes a similar distribution. A right-sided subaortic infundibulum usually separates the tricuspid from the aortic valve, and fibrous continuity is present between the mitral and the pulmonary valve. Coronary arteries' anatomy may assume diverse patterns of epicardial distribution, but they invariably originate in the aortic sinuses facing the pulmonary trunk. This fact is constant and independent of the two great vessels' spatial relation. In 50% of the cases, the ventriculoarterial discordance is an isolated finding. This condition is designated as simple transposition. By contrast, complex transposition includes all the cases with coexisting malformations, such as ventricular septal defects, left ventricular outflow tract obstruction, aortic arch anomalies, and anomalous venous systemic return. Ventricular septal defects are particularly common, and their location and size are variable. They may be associated with a certain degree of malalignment between the outlet and trabecular septum. If an anterior and rightward deviation of the outlet septum is present, concomitant

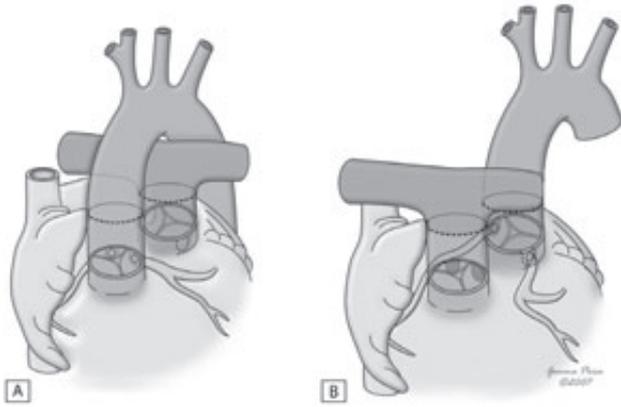


Figure 5. The figure illustrates the arterial switch procedure. It shows the connection of the proximal great arteries to the distal end of the other great artery, as well as the transfer of coronary arteries to the new aorta.

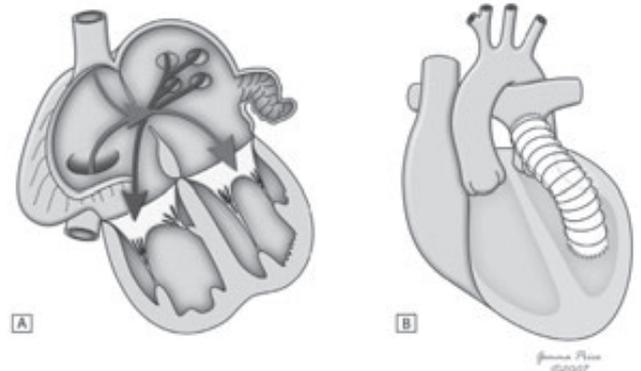


Figure 7. This figure shows the common principle subjacent to intra-atrial switch. Figure 7A shows in diagrammatic fashion, the redirection of pulmonary and systemic venous flows at atrial level. An external conduit (B) is placed to overcome the obstruction within the left ventricular outflow tract.

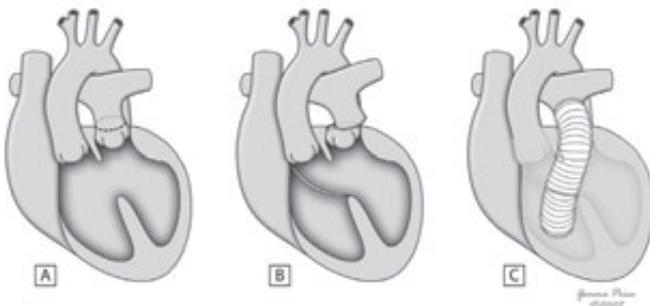


Figure 8. The figure shows the main steps of Rastelli procedure in the setting of a deviated outlet septum (A). A patch is placed to create an interventricular tunnel (B), and an extracardiac conduit is placed between the right ventricle and the pulmonary arteries (C).

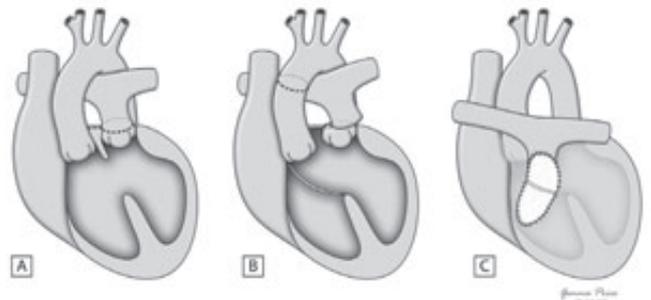


Figure 9. This figure shows the innovations of the REV procedure relative to the Rastelli procedure, with resection of the muscular outlet septum (B) and use of Lecompte manoeuvre (C) which avoids the use of an extracardiac conduit.

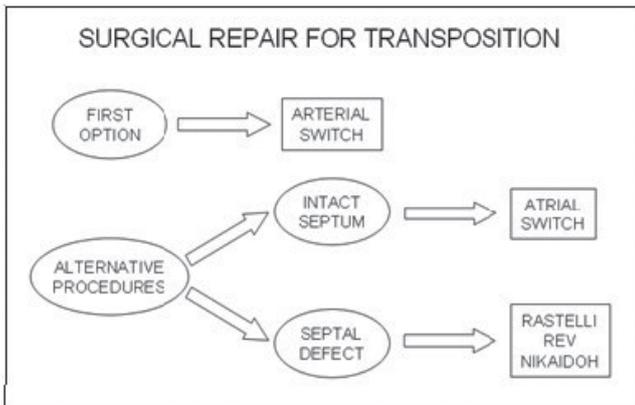


Figure 6. Surgical procedures used in the correction of the transposition of the great arteries.

pulmonary overriding and subaortic stenosis can be expected. In these cases, hypoplasia, coarctation, or even interruption of the aortic arch may be encountered. On the other hand, if the outlet septum is deviated posteriorly and leftwards, it may lead to subpulmonary stenosis.¹

In fact, left ventricular outflow tract obstruction is present in one-eighth to one-third of cases, being far more common in the presence of a ventricular septal defect than when the ventricular

septum is intact. This impediment to the flow of blood can be caused by a wide spectrum of lesions, either at valvar or subvalvar level, and deviation of the muscular outlet septum is but one of them. Bulging of the septum, a fibrous shelf or fibromuscular tunnel, tissue tags, and anomalous attachment of the atrioventricular valvar tension apparatus can also be substrates for stenosis.¹⁰

A careful assessment of all these morphological variants is of the uttermost significance, particularly for surgical planning and in foreseeing eventual complications.

Pathophysiology: In the hearts with concordant atrioventricular and discordant ventriculoarterial connections, the systemic and pulmonary circulations run in parallel, rather than in series. As such oxygenated blood flows through a closed circuit that involves the lungs and the left cardiac chambers. On the other hand, systemic blood flow is supplied by another closed circuit that begins and ends in the right cardiac chambers. In this setting, survival is only possible, if there is adequate mixing between the two circulations, be it between the septums or through the arterial duct.¹¹

Clinical manifestations: The parallel circulation just described results in a significant hypoxemic status that is observed clinically by central cyanosis. The bluish discoloration of the skin and mucous membranes is therefore the basic pattern of

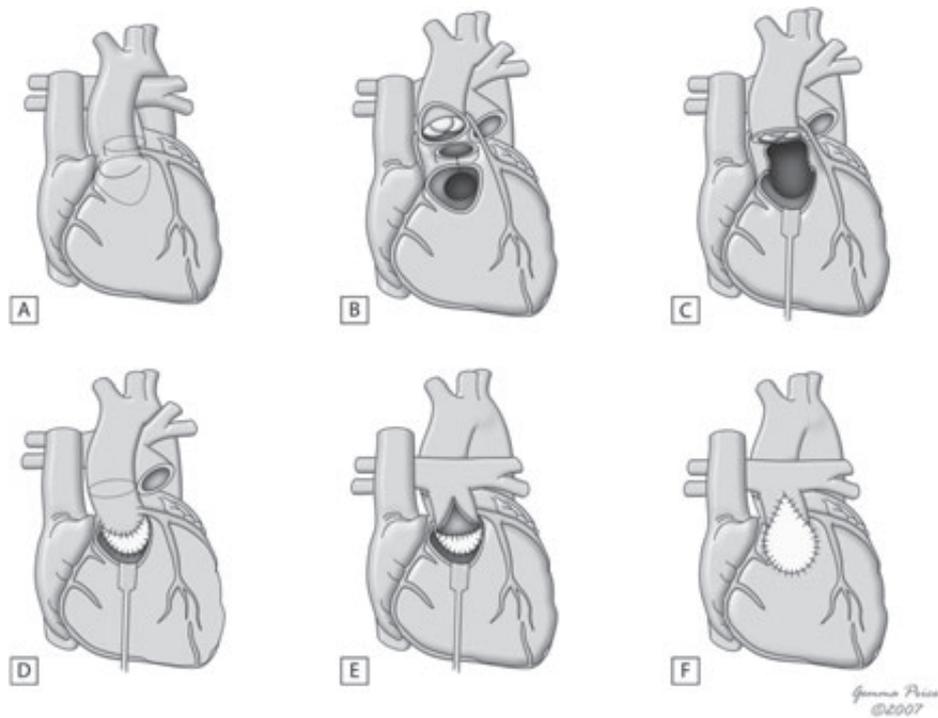


Figure 10. The figure shows the major issues of Nikaidoh's procedure. Figure 10A shows the areas for harvesting the aortic root and transection of the pulmonary trunk. In 10B, the aorta and pulmonary trunk have already been disconnected from their previous insertion, and the line of division of the outlet septum is shown. Figures 10C and 10D show aortic translocation and reconstruction of the left outflow tract, with a pericardial patch used to close the ventricular septal defect. In 10E and 10F, the pulmonary trunk is sutured to the right ventricular outflow tract, and the reconstruction is completed with a pericardial patch.

clinical presentation in transposition. Its onset and severity depend on anatomical and functional variants that influence the degree of mixing between the two circulations.

Limited intercirculatory mixing, usually present if the ventricular septum is intact or the atrial septal defect is restrictive, is related to progressive and profound central cyanosis evident within the first hours of life. Likewise, associated left ventricular outflow tract obstruction or pulmonary obstructive disease can reduce the blood flow to the pulmonary vascular bed, and thus contributing to a marked cyanotic state. However, if no obstructive lesions are present, and there is a large ventricular septal defect that allows for satisfactory mixing between the two circulations, cyanosis may go undetected and only be perceived during episodes of crying or agitation. In these cases, signs of congestive heart failure prevail due to excessive ventricular workload. Tachypnoea, tachycardia, diaphoresis, poor weight gain, a gallop rhythm, and eventually hepatomegaly can be then detected later on during infancy. Heart murmurs associated with left outflow tract obstruction, persistent arterial duct or due to a septal defect may be heard, but they are not a constant finding.

Etiology: The exact etiology of this disease is still unknown. However, some associated risk factors, namely gestational diabetes mellitus,^{12,13} maternal exposure to rodenticides and herbicides,¹⁴ and maternal use of antiepileptic drugs¹⁵ have been postulated. Significant advances in the understanding of the underlying genetic mechanisms have been achieved over the last decade. Several mutations have been implicated as the cause of discordant ventriculoarterial connections. The genes involved so far are the growth differentiation factor-1 gene,¹⁶ the thyroid hormone receptor-associated protein-2 gene,¹⁷ and the gene

encoding the cryptic protein.¹⁸ They are localised in different chromosomes and their mutations only explain a small minority of the clinical cases.

Diagnostic methods: Diagnosis involves careful history taking and physical examination of the patient under good light condition. When these and the hyperoxia test are suggestive of a cyanotic congenital heart condition, further investigations are required. A chest X-ray and an electrocardiogram may be helpful at this stage, but their respective findings are not specific. In transposition, a narrowed superior mediastinum gives to the cardiac silhouette a characteristic egg-shaped appearance on chest radiography. Cardiomegaly with increased pulmonary vascular markings may be found if a ventricular septal defect is present. The main electrocardiographic features are a rightward deviation of the QRS complex axis associated with right ventricular hypertrophy; biventricular hypertrophy is evident in conditions that lead to a left ventricular overload.

The definitive diagnosis relies however on echocardiography. This imaging modality provides accurate morphological and functional assessment of the heart, being able to show the specific features of the transposition of the great arteries. In the four-chamber view, one assesses atrioventricular concordance, but the ventriculoarterial discordance is better observed using other incidences. In the five-chamber, parasternal long-axis or even subcostal view, the vessel arising from the morphologically left ventricle has a posterior course and bifurcates immediately, being identified as the pulmonary trunk. The morphologically right ventricle is related to a vessel that gives out the coronary, head and neck arteries, thus the aorta. The proximal portions of the two arteries run parallel to each other, rather than in the

usual cross pattern, giving it a typical and easily recognisable appearance in the parasternal long-axis and subcostal views. In the short-axis view, the pulmonary trunk is usually in a central position, with the aorta being placed anteriorly and to the right.

The evaluation of the coronary artery pattern^{19,20} and exclusion of other malformations are two important aspects that need to be addressed prior to surgery. Furthermore, the Doppler study also provides functional information and complements the data provided by the two-dimensional echo. Flow through the arterial duct and septal defects are visualised, being an indicator of the adequacy of mixing between the systemic and pulmonary circulations. Moreover, it is possible to measure gradients through obstructive lesions and to assess the function of the atrioventricular and semilunar valves.

As echocardiography in experienced hands is a reliable diagnostic tool providing high sensitivity and specificity, the need for catheterisation is limited to cases that require clarification of certain anatomic and haemodynamic aspects not clearly identified by echocardiography.²¹⁻²⁴ Likewise, CT or MR imaging can also offer additional details of some associated lesions.

Prenatal diagnosis by fetal echocardiography is possible and desirable, as it may improve early neonatal management, thus reducing related morbidity and mortality.^{25,26} This method has proven to be very accurate, not only in the diagnosis of the disease and associated malformations, but also in planning the most appropriate surgical approach.²⁷

Differential diagnosis: Differential diagnosis should include other causes of central neonatal cyanosis. In this clinical setting, the hyperoxia test provides a simple means of assessing preductal PaO₂ response to 100% inspired oxygen, aiding in the differentiation between cyanosis caused by cardiac disease from that caused by neurological or pulmonary disorders.

In the neonates with parallel circulation, on a 100% inspired oxygen, a blood sample collected from the right radial artery will typically show a PaO₂ less than 50 mmHg. In this case, further exams should be carried out in order to confirm the diagnosis.

Management

Palliative treatment: The initial aim in the management of the affected newborns is to assure acceptable intercirculatory mixing. The presence of an atrial or a ventricular septal defect that provides satisfactory mixing, permits corrective surgery at a later stage without the prior need for palliative procedures. Nevertheless, this is not the most common situation, and usually a first stage treatment is required.

Intravenous prostaglandin E1 infusion is used to maintain arterial duct patency leading to an increment in pulmonary blood flow, which increases pulmonary venous return and left atrial pressure, thus promoting left to right flow at atrial level.²⁸ Early and late side effects may be observed, namely apnoeas, bradycardia, systemic hypotension, fluid-electrolyte disturbances, fever and cutaneous flushing. Long-term use is associated with cortical hyperostosis, an effect that does not seem to be dose-related. Monitoring in an intensive care unit is therefore advised.²⁹

Although intercirculatory mixing improves, prostaglandin action is frequently modest and insufficient to assure a satisfactory

oxygenation of the systemic blood, either in simple or complex transposition. Balloon atrial septostomy, also known as the Rashkind procedure, assumes therefore an important role in the pre-operative management of these babies. This technique involves the placing of a balloon-tipped catheter in the left atrium, via the oval foramen. The balloon is then inflated and pulled back into the right atrium, tearing the atrial septum. In some centres, this procedure is echocardiographically guided providing reliable visual guidance without exposure to ionising radiation. Thus, the risk of complications is minimised and the final diameter of the interatrial orifice can be accessed.³⁰ The result is considered successful when an atrial septal defect with at least 5 mm in diameter, an increased flapping motion of the inferior rim of the atrial septum is observed and there is an increase in the oxygen saturation.³¹

Balloon septostomy is an effective and safe procedure for creating long lasting adequate interatrial communications.³² It has largely replaced other more aggressive interventions such as blade atrial septostomy and surgical atrial septectomy. At the present, their use is limited to specific situations, mainly related to the rigidity of the interatrial septum. Balloon dilatation may also be required, especially in older patients in whom good palliation was not achieved by usual septostomy.

In addition to these measures, medical support is usually necessary to optimize the clinical condition. Mechanical ventilation and oxygen may be needed in the unstable newborn with severe hypoxemia. Nevertheless, it should be emphasized that these measures are not universally beneficial to these patients. For example, oxygen therapy may promote ductal closure, compromising intercirculatory mixing. Furthermore, aggressive ventilator settings (Positive Inspiratory Pressure and Positive End Expiratory Pressure) leading to excessive alveolar distension should be avoided so that intercirculatory shunts are not disturbed.

The correction of metabolic acidosis with bicarbonate is important, as it may compromise myocardial function and in case of cardiac failure, inotropic agents or diuretics may be necessary.

Corrective treatment

The arterial switch operation is the procedure of choice used to achieve complete physiological and anatomical repair. Its supremacy has been corroborated by long-term results that show preservation of good left ventricular function, sinus rhythm and a low mortality with a survival rate of 88% at both 10 and 15 years. The rare post operative complications are mainly related to prolonged peri-operative ischemia times, aortic regurgitation and coronary artery obstruction, which may result in myocardial ischemia or even infarction. A low reoperation rate has also been reported, pulmonary stenosis at the site of reconstruction being the most common cause.³³

In this surgery, the aorta and pulmonary trunks are sectioned and their distal extremities are transposed and anastomosed; coronary arteries are then translocated to the neo-aorta (Fig. 5). The correction should be ideally performed in the first month of life. Several factors may however interfere with this timing, namely missed diagnosis and preoperative complications, such as multiorgan failure, renal failure, active infection, severe acidosis or subarachnoidian hemorrhage, that postpone the procedure until the clinical condition is more stable. On the

Table 1: Different types of corrective surgeries and respective early mortality, late survival, complications and probability of reoperation

Type of surgery	Era	Early mortality	Late survival	Major complications and incidence	Reoperations
<i>First choice</i>					
• Arterial switch [33,47]	1975	3.8%	88% (10 and 15 yrs)	Pulmonary stenosis (3.9%) Aortic regurgitation (3.8%) Coronary lesions (2%)	4.5–18%
<i>Alternative procedures</i>					
• Simple TGA					
- Atrial switch [41,42]	1960s	16.5%	77.7% (10 yrs) 67.2% (30 yrs)	Arrythmia (47.6 – 64.3%) Tricuspid regurgitation (34.9%) Systemic ventricular dysfunction (11.5–14.6%) Baffle related problems (5.6%)	5.1%
• TGA with VSD ± LVOTO					
- Rastelli [48]	1969	7%	80% (10 yrs) 52% (20 yrs)	RVOTO (64%) Arrythmias (24%) LVOTO (16%)	44%
- REV [43]	1982	12.5%	84% (5 yrs)	RVOTO (19%)	10%
- Nikaidoh [49]	1984	5%	95%	RVOTO (26%)	47%

other hand, if palliative measures have had poor results or resulted in untoward complications, an emergency arterial switch maybe needed sooner.

In the specific context of transposition with intact septum, the newborn should be operated preferably within the first two weeks of life. This would ensure that left ventricle has not suffered significant involution, and its contractility is still able to support the systemic circulation. In older neonates and young infants, the left ventricle may need to be retrained, before the arterial switch is attempted, by pulmonary artery banding, with or without an associated Blalock-Taussig shunt. This intermediate step should establish a left/right ventricular pressure ratio between 0.6/0.75 without compromising the required pulmonary blood flow.³⁴ This pressure ratio is a known inducer of left ventricle remodelling. The exact indications for the two-stage arterial switch are still controversial, and, besides patient age, other factors should be considered, such as left ventricular wall thickness, left ventricular volume and corresponding estimated mass, left ventricular pressure and the degree of interventricular septum bounding.³⁴⁻³⁶ According to existing evidence, a short time interval between the two operations,³⁷ usually one week, is sufficient. Nevertheless, the decision to proceed to the arterial switch is based on the evolution of the echocardiographic parameters concerning both left ventricle structure and haemodynamic performance. The results reported appear to be very encouraging, showing a survival rate and freedom of reoperation at five years of 90% and 97%, respectively.³⁸

In complex transposition, the arterial switch procedure should be tailored towards the individual morphological aspects and complementary interventions may be necessary to repair concomitant malformations. In fact, an associated atrial defect, or more commonly the septostomy defect, can usually be closed by direct suture. Closure of the ventricular septal defect may require the use of a patch to close the communication or, if very small, may just be left open. An obstruction within the aortic arch is best repaired concomitantly, if necessary using a pulmonary homograft to enlarge the aorta.³⁹ Some lesions causing left outflow tract obstruction may be effectively resected, re-establishing an adequate patency. Complex coronary patterns may require individualized techniques for

coronary transfer, adapted to the ostial anatomy and coronary course.

Two morphologic features may preclude however the use of this operation: an outflow tract obstruction lesion that can not be satisfactory relieved by resection and certain coronary artery patterns that may pose difficulties during coronary transfer.

Whenever the arterial switch is not feasible, alternative approaches are required – Fig. 6.¹⁰ A repair at atrial level, either by a Mustard or a Senning procedure, is particularly suitable for hearts with an intact ventricular septum. The systemic venous return is redirected at atrial level to the left ventricle. Likewise, pulmonary venous blood is diverted to the right ventricle. When there is an obstruction at the left ventricular outflow tract, an extracardiac conduit is placed between the left ventricle and the pulmonary trunk- Fig. 7.⁴⁰ The main complications of these techniques are sinus node dysfunction, obstruction to either pulmonary or systemic venous return, supraventricular tachyarrhythmias, residual interatrial shunt, right ventricular dysfunction and pulmonary vascular obstructive disease. These factors are associated with a less satisfactory survival rate of 77.7% and 67.2% at 10 and 30 years respectively, with an early mortality accounting for 16%.⁴¹ Particularly adverse outcomes are present in patients with an advanced New York Heart Association functional class or with arrhythmias.⁴²

In the presence of a ventricular septal defect, the most used options are the REV procedure or its modification and the Rastelli operation. In both, an intraventricular tunnel passing through the septal defect is created to connect the left ventricle to the aorta. In the Rastelli procedure, an extracardiac conduit is placed connecting the right ventricle to the pulmonary artery (Fig. 8). However, in the REV technique, this is accomplished through the LeCompte maneuver, which brings the pulmonary trunk forward, allowing its direct implantation in the right ventricle (Fig. 9). Apart from avoiding the use of an extracardiac conduit, the REV procedure has a further advantage in which it involves the resection of the muscular outlet septum, providing better alignment between the aorta and the left ventricle. As expected, late results in terms of reoperation are significantly different in the two procedures. In fact, Rastelli operation was associated with a greater risk of reintervention due to left

ventricular outflow tract obstruction, and extracardiac conduit problems such as obstruction, requiring eventual replacement. However, similar early and late mortalities were reported.^{43,44}

The Nikaidoh's procedure is also an option in the setting of discordant ventriculoarterial connections, ventricular septal defect and left outflow tract obstruction, especially if inadequate anatomy for a REV or Rastelli is present.⁴⁵ The repair is achieved by removing the aortic root with its coronaries attached, and translocating them to the prior pulmonary position. The obstruction in the left ventricular outflow tract is relieved through outlet septum bisection and resection of the pulmonary valve. Both ventricular outflow tracts are then reconstructed, using patches either to close the ventricular septal defect or to adapt pulmonary trunk to the right infundibular area (Fig. 10). The major handicaps of this approach are its technical difficulty, as well as a relatively high rate of reoperation due to right ventricular outflow tract obstruction and pulmonary insufficiency; moreover, unusual coronary patterns may also represent an additional problem. Despite all these disadvantages, a recent study comparing REV, Rastelli and Nikaidoh's performances has highlighted the superiority of Nikaidoh's approach in obtaining a better physiologic cardiac hemodynamics⁴⁶ (Table 1).⁴⁷⁻⁴⁹ Further studies are however necessary to perfectly establish the role of this surgical approach in transposition correction.

Prognosis

Until mid twentieth century, the treatment of transposition was restricted to few palliative measures and the natural history of the disease with its poor prognosis was an undeniable reality. By that time, the average life expectancy for a newborn with transposition was 0.65 years and the mortality rate at one year was 89.3%.⁵⁰ With the advent of newer and improved surgical techniques as well as post operative intensive care, the scenario has completely changed, and very encouraging long-term survival rates almost achieving 90% at 15 years of age have been reported. The potentialities of the current corrective surgery modalities are also underlined by a low 10-year re-intervention rate (6%) and a corresponding event-free survival of 88%.⁵¹ Nevertheless, recent studies have pointed out to a reduced exercise performance, a compromise in cognitive functioning, and an unfavorable health-related quality of life.^{51,52} Further improvements are therefore necessary and they may be achieved in the future by reinforcing prenatal diagnosis and by establishing strategies to minimise surgical complications.

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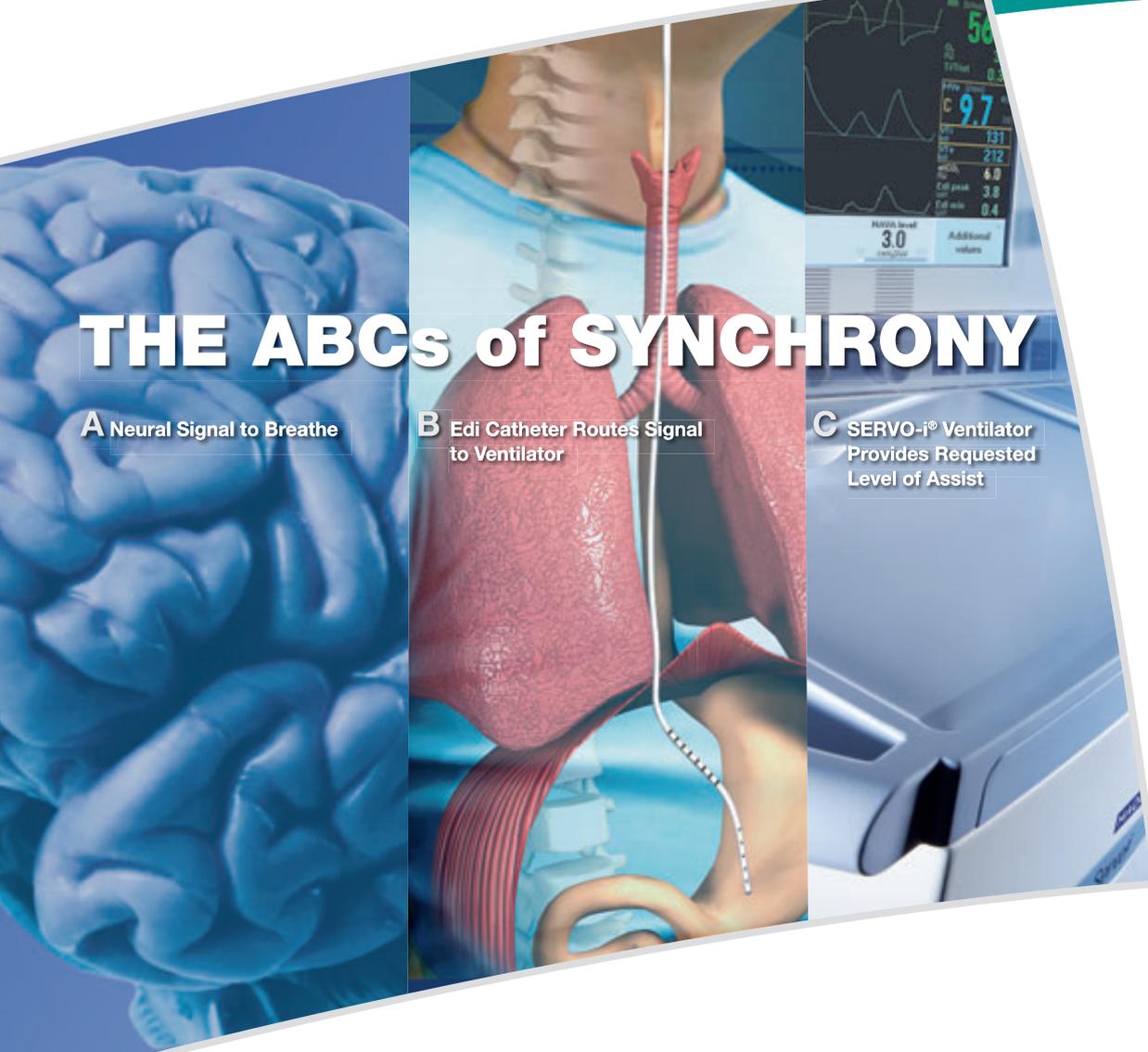
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Evidence-Based Ethics – What It Should Be and What It Shouldn't

Daniel Stretch

Abstract

Background: The concept of evidence-based medicine has strongly influenced the appraisal and application of empirical information in health care decision-making. One principal characteristic of this concept is the distinction between “evidence” in the sense of high-quality empirical information on the one hand and rather low-quality empirical information on the other hand. In the last 5 to 10 years an increasing number of articles published in international journals have made use of the term “evidence-based ethics,” making a systematic analysis and explication of the term and its applicability in ethics important.

Discussion: In this article four descriptive and two normative characteristics of the general concept “evidence-based” are presented and explained systematically. These characteristics are to then serve as a framework for assessing the methodological and practical challenges of evidence-based ethics as a developing methodology. The superiority of evidence in contrast to other empirical information has several normative implications such as the legitimization of decisions in medicine and ethics. This implicit normativity poses ethical concerns if there is no formal consent on which sort of empirical information deserves the label “evidence” and which does not. In empirical ethics, which relies primarily on interview research and other methods from the social sciences, we still lack gold standards for assessing the quality of study designs and appraising their findings.

Conclusion: The use of the term “evidence-based ethics” should be discouraged, unless there is enough consensus on how to differentiate between high- and low-quality information produced by empirical ethics. In the meantime, whenever empirical information plays a role, the process of ethical decision-making should make use of systematic reviews of empirical studies that involve a critical appraisal and comparative discussion of data.

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Background

The concept of evidence-based ethics, modeled after the concept of evidence-based medicine, has increasingly found application in international journals in the past decade, ranging from a relatively uncritical use of the term to attempts at its explication to variously justified repudiations of the term. However, so far this discussion has been lacking a thorough explication of the term “evidence-based” (EB) and the concept behind it. EB means more than one might suspect from a translation one meets with frequently, roughly speaking: “based on the latest and best available empirical information.” For example, we see a relatively trivial definition of evidence-based ethics along these lines in Pascal Borry et al: “Ethical decision making must necessarily be based on the use of the latest and best available medical research findings.” Alongside this relatively unspecific explication of the concept of EB, the discussion so far also lacks an analysis of the practical problems that threaten to arise on any non-trivial determination of what evidence-based ethics might mean.

The concept of EB was first used in 1992 in the context of clinical medicine. In the following years the term was increasingly extended to other areas far removed from the medical clinic. The most frequently cited characterization of evidence-based medicine (EBM) comes to us from David Sackett and was published in 1996 in the British Medical Journal (BMJ) under the title “Evidence-based medicine. What it is and what it isn't.” However, the article failed to do justice to the various normative dimensions inherent in the EB concept, and as of today these have hardly been explicitly discussed and analyzed in any conceptual work on EBM. This implicit normativity holds not just for medicine (EBM) but equally for all those areas of study that have already been enriched by the EB concept or might be in the future. With the arrival of the EB concept in medical ethics or bioethics at the very latest our specialized discussion should explicitly identify these normative aspects and subject them to critical analysis. To guarantee the responsible employment of a reasonable and non-trivial reading of the concept, the following will expand on Sackett's descriptive characterization of EBM (“what it is and what it isn't”) and discuss what an evidence-based ethics “should and shouldn't be.” In contrast to the non-trivial interpretation that follows, a trivial reading would be a definition of evidence-based ethics that

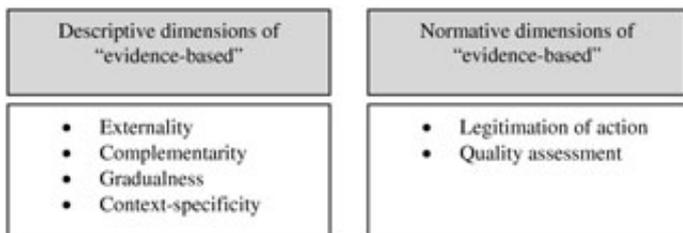


Figure 1. Descriptive and normative dimensions of the concept "evidence-based".

amounts to simply taking empirical information into account in ethical decision-making without specifying this any further.

To provide a more accurate picture of the challenges and peculiarities of evidence-based ethics, this article is divided into three sections. The first is a systematic presentation of central descriptive and normative dimensions inherent in a non-trivial reading of the EB concept. The second section will then discuss the ethical problem areas associated with these normative dimensions using examples from EBM. In a final step these practical problems will be mapped onto the particularities of applied ethics (such as the concept of evidence in interview or other socio-empirical research) in order to clarify the challenges and limits of evidence-based ethics.

The critical analysis of the particularities of evidence-based ethics is important to ward off the potential misuse of the EB concept in medical ethics in a timely manner. But beyond this the results of this analysis are also significant for two further debates within modern bioethics. On the one hand, the results help to clarify more precisely how ethics conceives itself in its relation to empirical data per se. And on the other hand, they will shed light on the relevance of ethical and methodological problems in assessing the quality of empirical ethics research in practice.

Discussion

In Sackett's definition, EBM is described in a more general version as follows: "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the medical care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research."

In the context of evidence-based ethics it is not the specification of EB for medicine that interests us so much but the characterization of what evidence or EB means in general. Textbooks and other writings on EBM provide us with further specifications of the content and the scope of the EB concept. The following derives several characteristic descriptive dimensions of the concept from these specifications, and supplements them with the normative dimensions not explicitly discussed by Sackett and other authors (see figure 1).

Externality: In medicine and medical ethics we encounter empirical information in various forms, such as quantitative and qualitative indications of the benefit and harm of medical measures, reports of the number of organ donations, or on the level of satisfaction with clinical ethics consultation. This empirical information can be divided into the information that one has garnered in the course of one's life and professional experience (thus internally) and information that others have garnered (externally) in studies. As emphasized in the quotation

from Sackett, the concept of evidence in EB stands for externally generated empirical information.

Complementarity: External evidence alone cannot influence any decisions – it always exists in a complementary relation to context-specific framing conditions, ethical principles and other decision-theoretical elements. Furthermore, typically various pieces of empirical information play a role in decisions. In the medical context, besides the internal and external information on the benefit of a measure, the individual or group-specific preferences of the patients in particular should also be taken into consideration. Complementary elements in ethical decisions also include context-sensitive ethical principles or norms.

Gradualness and context-specificity: On a reasonable, non-trivial reading evidence (which is external) cannot be simply equated with empirical information per se. Not all available empirical information on a certain question counts directly as evidence according to the EB concept. Empirical information has to hold up under critical appraisal, a sort of qualifying exam, in order to be accepted into the higher class of evidence. Sackett writes: "Because the randomized trial, and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the 'gold standard' for judging whether a treatment does more good than harm. [...] And if no randomized trial has been carried out for our patient's predicament, we must follow the trail to the next best external evidence and work from there."

According to this conception of EB only the available information that is sufficiently reliable (as determined by context) and demonstrates internal and external validity can be called evidence. This point is of central importance – in principle each question prompts a new decision about which information is to be considered evidence. The reliability determines how exactly a study measures a certain characteristic. There are various measures for quantifying the reliability of a test that cannot be individually discussed here. The criterion of validity is divided into internal and external validity. Internal validity pertains to the credibility of the results within the study. In view of the diverse possible sources of systematic bias and the influence of chance, the EB concept demands that we only consider the results of those studies that reduce the risk of systematic bias and the influence of chance as much as possible. The external validity, on the other hand, describes the validity of the results outside the population considered by the study. Thus external validity is often used as a synonym for generalizability.

Hence there is a gradual relationship between empirical information per se and the empirical information that the EB concept considers evidence. In the field of medicine, for example, this often leads to a situation where, despite the availability of results from studies on the benefit of a certain medical procedure, its efficacy or effectiveness is not considered evidence-based, since the quality of the studies (their internal validity) or the generalizability of their results (external validity) have not been judged satisfactory. Here we have to keep in mind that medical and statistical experts often arrive at different answers to the central question: is the effectiveness of this specific medical intervention evidence-based or not? Examples of this include the controversy surrounding the early detection of breast cancer with mammography screening or medication for the treatment of Alzheimer's disease (cholinesterase inhibitors). How to best approach this situation of a dispute among experts

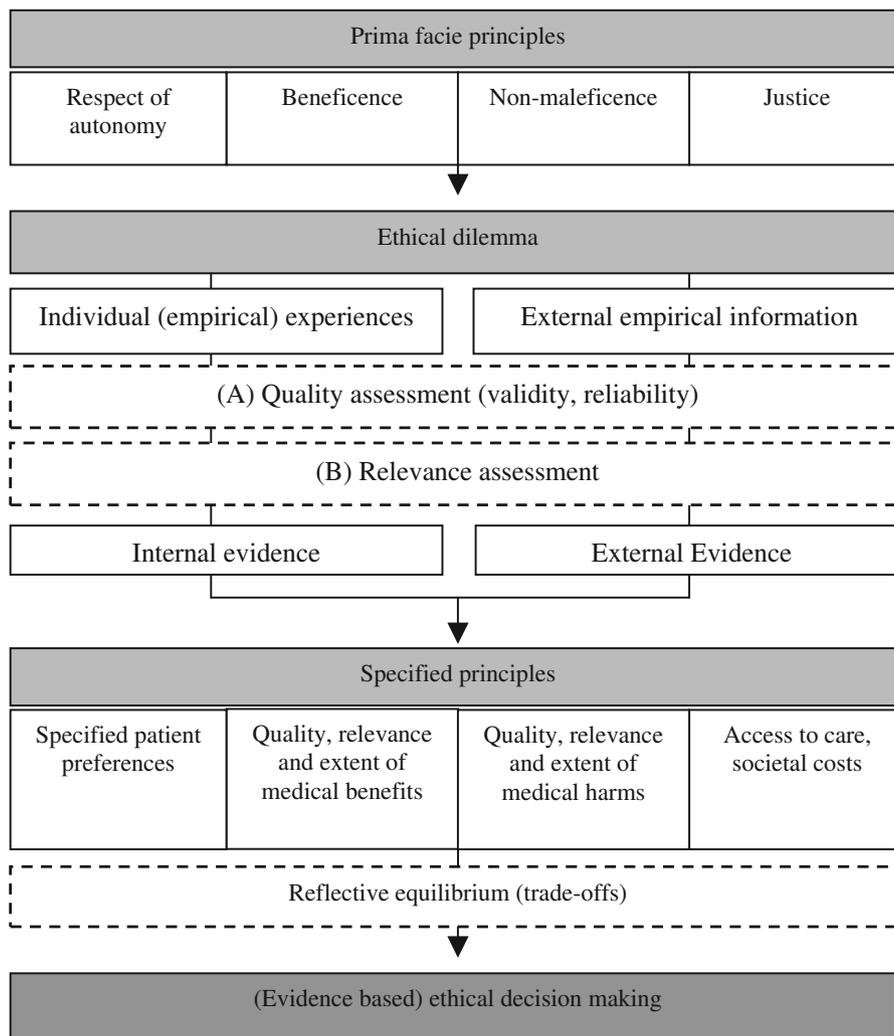


Figure 2. The process of decision-making in an evidence-based ethics.

is at present an unresolved problem in EBM and medical ethics that has generated astonishingly little discussion.

Normative dimensions of “evidence-based”: Legitimation of action: The EB concept includes the normative dimension of the legitimation of action. Whenever empirical information plays a role in decision-making (be it medical, ethical, or health policy decisions), according to the EB concept the information should be given preference that fits or best fits the criteria of evidence (see above). Empirical information that reaches the highest EB status should be trusted more in action-oriented decisions than empirical information that does not satisfy the criteria of evidence. The legitimation of action that this involves does not arise on its own, nor are we dealing with a naturalistic fallacy. Rather the typical case is that previous specification of principles and other deliberative processes determined what empirical information is needed to arrive at a rational decision through ethical principles. Thus in medical and ethical decision-making, for example, the benefit of a medical procedure plays a central role. Very often it is not clear whether a procedure produces significant and clinically relevant benefits, despite the availability of studies. However, should it be determined at a later time with newer and better studies that the benefit of the procedure is evidence-based, this will count strongly in favor of legitimating the use of the procedure as well as its funding by health insurance. This situation would only present us with a

naturalistic fallacy if the significance of medical benefit for the decision-making process were not determined in advance and thus was already posited as a normative judgment.

Quality assessment: The decision as to what should be considered evidence is based on the quality of the underlying studies, ie their reliability and validity. Only the empirical information supported by a context-sensitive study of appropriate quality is to be considered evidence. But who can or should decide, using which criteria, whether the quality standards have been met or not? In actual medical practice and in empirical ethics we will have to continually lower the bar, since the perfect study without any susceptibility for systematic bias does not exist. This holds for experimental studies that generate the greater share of evidence in medicine and even more for qualitative studies and survey research that, according to the overview taken by Borry et al, represent the most common form of empirical research in ethics. In many cases a high internal validity and a high external validity are mutually exclusive. So where should the optimal quality of study be pegged at? How far can the optimal quality be removed from the maximum? These decisions in assessing the quality of empirical information and their underlying studies imply various value judgments concerning the relevance of outcome parameters to the patient, the weighing of costs and benefits, the tolerance of uncertainty due to suboptimal study quality, and

others. With regard to the tolerance of uncertainty, for instance, we must acknowledge that every choice in this regard requires balancing the uncertainty of being wrong in our inferences about study quality with the probability of missing important information from studies of suboptimal quality. The answer to how much uncertainty in study quality we are willing to accept ought to be dependent on the context (eg, severity of disease, existence of alternatives) and on the preferences and values of the particular stakeholder population to which the empirical information will be applied. Because there is no one size fits all approach for determining how much uncertainty should be tolerated in designing clinical studies or survey research, it becomes important for users of empirical data to be given more information about the investigators tolerance of uncertainty and their rationale for their choices in a given circumstance. A more thorough analysis of these various value judgments is beyond the scope of this paper.

Evidence and consensus: In the following the descriptive and normative dimensions of the EB concept will serve as a framework for a critical analysis of the associated challenges in general and for an evidence-based ethics in particular. It is important to keep in mind that the basic idea underlying the EB concept deserves our strong endorsement from an ethical perspective. When empirical information plays a role in decision-making, it should be weighted differently depending on its quality. However, from an ethical perspective the application of the EB concept becomes problematic when it is used uncritically or misused in order to legitimate actions. When a group of experts determines that the benefit of a certain medical procedure is evidence-based, this has a strong legitimating effect on certain actions at present. Doctors could come into conflict with their liability in civil law if they do not take evidence-based action, and insurance companies find it much harder to justify themselves if they wish to not fund evidence-based procedures. Yet before we can determine which empirical information deserves the “evidence-based” seal of quality, we first need context-specific standards for the optimal or at least sufficient internal and external validity. The search for consensus on such standards runs into significant problems in the case of internal validity, and the question of external validity only exacerbates them. Within EBM, for example, it is a matter of contentious debate whether the demands for internal validity are met by the use of a certain experimental study design (randomized controlled trials) or whether further aspects have to be considered (eg the dropout rate of the study participants). With the qualitative and quantitative empirical studies in medical ethics we can expect analogous controversies concerning the optimal methods of sampling, the evaluation of survey questions or the best ways to carry out interviews and analyze and interpret the results.

Depending on how strict we make the criteria for the needed empirical information to count as evidence-based, we will come to different conclusions about the underlying question (In EBM the question at issue is generally the quantitative and qualitative extent of benefit and harm from certain medical interventions. In empirical ethics (mostly interview research) the question is to determine majority views or to analyze opinions and attitudes). The selection and concretization of these criteria always involves normative judgments (see above). This would not in itself be so problematic, were it not for the fact that in practice we see various decision-makers frequently working with different criteria of assessment – hence the need to make

these normative judgments transparent. If they are not made sufficiently transparent, as we unfortunately see most of the time in practice, there is an ethically problematic latitude in the EB concept that allows for manipulation, namely: the exploitation of the EB concept for the dimension of legitimation of action even though there is no sufficient consensus regarding the relevant normative values posited in the quality assessment dimension. In other words: decisions can then be legitimated under the “evidence-based” seal of approval even though there is no consensus concerning what should count as evidence and what not in the particular context. Of course, this also works the other way round: The EB concept can also be exploited to argue against certain actions, e.g. the clinical use or coverage of medical interventions.

These considerations should have made it clear that the often criticized dimension of legitimation of action is not, in itself, the real ethical problem with the EB concept. Quite the contrary, it represents the reasonable and yet crucial ethical demand that medical and ethical decisions should be based on reliable and valid information, not on whatever information might have been gathered together arbitrarily or that might otherwise be susceptible to bias. Rather, for EBM and evidence-based ethics the particular ethical and methodological challenges are to analyze the normative judgments for distinguishing evidence from empirical information per se and account for them in practice with sufficient transparency. Before we can critically analyze this normativity implicit in the dimension of quality assessment of empirical information we need to have sufficient transparency about these value judgments in the first place.

What an evidence-based ethics should be: In order to analyze the particularities of an evidence-based ethics, the following will begin by outlining a conception of the relation between normative and empirically descriptive statements. The relation between norms and facts has become an occasion of controversial debate in the past years, with the notable key terms including the “empirical turn in bioethics” and the “social science critique of bioethics.” In a nutshell, as it relates to applied ethics, we could paraphrase Kant: thoughts (ethical principles, norms) without content (empirical information, evidence) are empty, intuitions (empirical information, evidence) without concepts (ethical principles, norms) are blind. Thus normative and empirical statements should not be seen as competing for justificatory authority in ethical decisions, and hence there is not necessarily any danger of running into the naturalistic fallacy. Rather, we should see the relation between norms and facts in the decision-making process as complementary. Each is necessary but not by itself sufficient for decision-making in applied ethics. The role of both ethical principles and empirical information is shown schematically in figure 2.

The classical principles of medical ethics need to be given more specific content in actual cases – the principles of beneficence and non-harm, for example, only take on real concrete form once the dimensions of benefit and harm have a clear and specific content. To assess the justness of an action we need empirical data on distribution or on the possibilities of access to the health care system. Patient autonomy in turn is tied to the availability of patient preferences (individual or group-specific), which also have to be ascertained empirically.

Besides this interactional scheme, the figure also shows the characteristic normative dimensions of an evidence-

based ethics. In the processes of quality assessment (A) and relevance assessment (B) typically there is some available external empirical information that does not reach the status of evidence. We could picture these processes as a sieve that sorts out some empirical information and leaves behind only external evidence. Only after a sufficiently critical assessment of the internal and external validity of the available empirical information are we justified in speaking of external evidence as the foundation for the specification of ethical principles. In principle we could conceive a similar process for one's own (empirical) experiences. In an ethical dilemma one could classify one's previous experiences as potentially distorted (quality assessment) or as not relevant for the case at hand (relevance assessment). Those experiences considered adequate and relevant could be termed internal evidence, in analogy to external evidence. However, since this assessment process cannot be examined intersubjectively and remains of necessity purely subjective, this internal evidence cannot be counted as evidence in the sense of evidence-based ethics (see the dimension of externality).

According to the interactional scheme in figure 2, a reflective and/or deliberative element has to precede the decision at the end in evidence-based ethics as well. The weighing of specified principles against each other is basically no different from what coherence theories of ethics call reflective equilibrium. In reflective equilibrium the ethical and conceptual aspects have to be weighed against each other together with empirical information. This reflective equilibrium is susceptible to bias when methodologically bad and hence false or potentially misleading empirical information is taken into consideration. An evidence-based ethics only makes use of the best empirical information available in the case at hand in reflective equilibrium and sets (context-specific) minimal standards for the quality of empirical information that deserves the label of external evidence.

The limits of an evidence-based ethics in practice: Having presented a rational and non-trivial reading of evidence-based ethics as a theoretical conception, this paper is now particularly concerned to identify the limits of evidence-based ethics in practice and the risks that go along with it. Whether the idealized conception of an evidence-based ethics presented in the previous section can be realized in the conditions of actual practice depends on several factors.

Before we can speak of evidence-based ethical decisions in practice, we have to demonstrate the extent to which we can assume a consensus on the specific use of the concept of evidence. To avoid misuse of the dimension of action legitimation or at least constrain it within certain limits we need a transparent justification for the use of the EB concept. This justification is not found in the articles cited at the beginning of this paper that use the concept of evidence-based ethics.

Another practical problem facing us is how to provide the EB concept with specific content depending on the methods used in studies. For example, the results of psychometric studies to determine the decision-making competence of patients with dementia could be relevant to research ethics. In the ethical discussion of advance health care directives, in turn, the results of quantitative and/or qualitative interview studies to determine patient preferences can be relevant. Various studies are available for both of these problem areas that can be expected to vary

greatly in their validity and reliability. Which of these studies should be considered evidence according to the assessment steps (A) and (B) in figure 2? We need objective criteria or adequate procedures for reaching consensus in order to justify why certain ethically relevant empirical information does or does not deserve the status of evidence. Of course this condition can only be realized if objective criteria are available to distinguish evidence from other ethically relevant empirical information. Here we still find great obstacles in practice, which again can be characterized by comparison to the practice of EBM. As already discussed, there is a contentious discussion within EBM as well concerning what one "may" or "should" with justification call "evidence-based." We can distinguish between two different problematic situations in EBM practice. Firstly, it is often a matter of contention whether certain medical decisions or recommendations are at all evidence-based or not, where some people consider the criteria for EBM to be satisfied and others not. An example is the discussion of the medical benefit of Alzheimer's treatments. Several studies taking a general view of the situation conclude that their benefit is evidence-based, while others point to methodological flaws in the studies and take a very critical stance towards the use of the EB concept in this context. A second example can be found in the discussion of the benefit of mammography screening for early detection of breast cancer. Again several studies speak in favor of an evidential basis of its benefit while others come to the opposite conclusion and argue that to the contrary, the preponderance of harm over benefit is evidence-based. The normative judgments mentioned above that go into the assessment of the quality of studies play a decisive role in these differences. This presents modern medicine as well as applied ethics with a practical problem of ethics and decision theory.

What problems does all this imply for an evidence-based ethics? As long as the relevant evidence of evidence-based ethics relates to the beneficial and harmful results of medical interventions, we can assume similar problems to those described in medicine. However, a more in-depth look at the practice of evidence-based ethics will have to consider the fact that most studies grouped under the heading "empirical ethics" use non-experimental methods taken from the social sciences. Quantitative and qualitative interview and questionnaire studies are conducted quite frequently in the course of projects on applied ethics. These research methods can generate valuable empirical information for ethics. The goal of such investigations could be to determine patient preferences, the values of certain stakeholders in the field of health care, or attitudes and experiences with certain informed-consent procedures. Here as well studies can demonstrate better or worse methodological quality (internal validity, reliability) and can be more or less generalizable (external validity). Yet the discussion of when we are justified in calling the results of these types of studies evidence is still in its very beginning stages. The assessment of the internal and external validity of qualitative interview research in particular is the subject of much controversy. This discussion also gives rise to the question of whether validity and reliability criteria as they have traditionally been used can even be applied to these types of studies. But for quantitative research that uses questionnaires we also still lack a generally accepted gold standard of quality assessment.

These problems do not speak against carrying out these sorts of studies or using the results in making ethical decisions.
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Setting Priorities in Global Child Health Research Investments: Assessment of Principles and Practice

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This article reviews theoretical and practical approaches to priority setting in global child health research investments. It also provides an overview of previous attempts to develop appropriate tools and methodologies to define priorities in health research investments. A brief review of the most important theoretical concepts that should govern priority setting processes is undertaken, showing how different perspectives, such as medical, economical, legal, ethical, social, political, rational, philosophical, stakeholder driven, and others will necessarily conflict each other in determining priorities. We specially address present research agenda in global child health today and how it relates to United Nation's (UN) Millennium Development Goal 4, which is to reduce child mortality by two-thirds between 1990 and 2015. The outcomes of these former approaches are evaluated and their benefits and shortcomings presented. The case for a new methodology for setting priorities in health research investments is presented, as proposed by Child Health and Nutrition Research Initiative, and a need for its implementation in global child health is outlined. A transdisciplinary approach is needed to address all the

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perspectives from which investments into health research can be seen as priorities. This prioritization requires a process that is transparent, systematic, and that would take into account many perspectives and build on advantages of previous approaches.

Among the many challenges in global child health today, the main is that 10.6 million children younger than 5 years still die each year. In The World Health Report in 2002, the World Health Organization (WHO) identified the leading health risks in developing countries as underweight, unsafe sex, unsafe water, sanitation and hygiene, iron deficiency, and indoor smoke from solid fuels. Each of those risks heavily affects children in a more or less direct way. However, many health interventions that could reduce this burden are available. Globally, the coverage for most of those interventions is below 50%, and the children who do not receive them are usually also the poorest and those exposed to multiple risk factors listed above.

At a turn of the Millennium, United Nations defined its 8 priorities for further development—"Millennium Development Goals." One of these goals is to reduce child mortality by two-thirds between 1990 and 2015. Achieving this goal required a reliable assessment of the main causes of child deaths. In 2001, the WHO established the external Child Health Epidemiology Reference Group (CHERG) to develop estimates of the proportion of deaths attributable to each of the main causes in children under 5 years of age. This was needed as a starting point in further planning and setting priorities, because previous estimates varied widely with certain organizations or research groups overemphasizing the importance of some diseases. After reviewing all the available information, CHERG estimated that, over the period 2000-2003, six causes accounted for 73% of deaths in children younger than 5 years: pneumonia (19%), diarrhea (18%), malaria (8%), neonatal pneumonia or sepsis (10%), preterm delivery (10%), and asphyxia at birth (8%). Undernutrition, as a major risk factor in children, was estimated to represent the underlying cause of 53% of all child deaths globally.

Jones et al estimated that, if the existing interventions for which there is sufficient or limited evidence of the effect, and which are feasible for delivery at high coverage in low-income settings, were made available universally, a disproportionately high figure of 63% of child deaths would be prevented each year. Subsequently, Bryce et al demonstrated that there were no financial obstacles to fund such an effort given the amount of funding available, but there is lack of knowledge on how to do

it. Strategies are needed to reach the poor and deprived children and to sustain their coverage, and they need to be developed through further research.

Although the interventions and the financial resources needed to achieve Millennium Development Goal 4 seem available, more than half of the period (1990-2015) set by the UN has passed and mortality of children globally has not decreased enough. It is becoming apparent that the achievement of this goal may soon be out of reach. Why is this the case? One of the answers may lie in current practices in which funding priorities are being set in global child health research. Pneumonia and diarrhea, as an example, are jointly responsible for nearly 40% of all child deaths globally, which is about the same as the number of deaths from smoking, double the number of deaths from HIV/AIDS, and is 25 times the number of deaths from war globally. Interventions (antibiotics and oral rehydration therapy) have been developed and have been shown to be highly cost-effective in preventing deaths from both diseases in the mid 1980s, but this appears to be where research interest ended.

There is considerably less interest in research on how to implement these interventions in the context of health services in countries with limited resources. Implementation research is not ranked highly by the scientific community or by most funding agencies. As it is rarely considered a research priority, research on new interventions far exceeds that on delivery. A vaccine against measles has been available for decades and it is highly cost-effective and deliverable, but even in this case only about 50% of world's children have been vaccinated.

Research funding for global child health currently favors opening new frontiers with their attractive promises over realizing the full public health impact of the interventions which led from past advances in knowledge. Even if work on new research avenues proves successful, the beneficiaries are only those who can afford the results of the research success. This further increases already unacceptable levels of inequity. The methodology for setting investment priorities is needed which could carefully balance between long-term investments and supporting research on better use of the existing knowledge.

Current areas of progress in health research can be classified into four large (and to some extent overlapping) categories from the perspective of their potential to reduce persisting mortality and morbidity burden. Assessment of existing and averted disease burden can be achieved through epidemiological research. Further reduction of disease burden can then be achieved through health policy and systems research, research to improve existing interventions, and research for development of new health interventions. The key challenge in setting investment priorities for health research is to find the right balance of investments into those 4 different "instruments" of health research. The aim should be to achieve maximum gains in disease burden reduction with improved health information, efficiency of health systems, and deliverability of available interventions, while still supporting long-term strategic investments into new interventions with large potential to remove the existing disease burden.

History: The Commission on Health Research for Development, started in 1990, is usually referred to as the first truly significant international initiative aimed toward systematic approach to setting priorities in global health research. It reviewed global

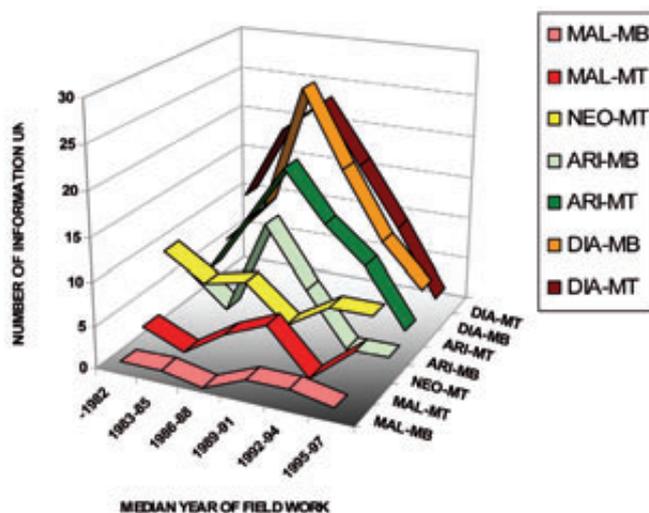


Figure 1. Number of papers with policy-relevant information on epidemiology of specific childhood illnesses in developing countries identified by Child Health Epidemiology Reference Group shows depleting interest in diseases that continue to kill most children. MAL – malaria; NEO – neonatal causes; ARI – acute respiratory infections; DIA – diarrhea; MB – morbidity; MT – mortality (7).

health needs and priorities for health research and identified great inequity in the allocation of research funds globally—the “10/90” gap, where less than 10% of global health research funds is devoted to 90% of the world's health problems. This led to subsequent promotion of the concept of Essential National Health Research (ENHR), in which countries take responsibilities to delineate a research agenda by themselves.

The second major initiative in similar direction came from the World Health Organization (WHO), when the Ad Hoc Committee on Health Research Relating to Future Intervention Options (AHC) was formed in 1994. The Committee's mandate was to address: 1) priorities for health research and development, 2) prospects for funding, and 3) institutional changes that might enhance the output of ongoing research and development investments at the time. In 1996, Ad Hoc Committee pretime. In 1996, Ad Hoc Committee presented a report “Investing in Health Research and Development,” that recommended policies for investments into research and development of particular relevance to poor nations. Ad Hoc Committee is also credited with conceptual framework showing the relationship between different “instruments” of health research and their potential to reduce different components of disease burden, as presented in the previous section.

In 1998, the Global Forum for Health Research (GFHR) began its operations with the main focus on helping to correct this “10/90” gap. It had been holding annual conferences at which ideas and strategies for correcting the “10/90” gap” were exchanged. Working as a consultant for Global Forum for Health Research, Hyder wrote a report on priority investments in research and development (“best buys”) identified by Ad Hoc Committee. Through structured interviews and comprehensive review of the literature, and a number of other methods that took into account issues such as dynamic nature of “best buys,” time factor, baseline status, and research intensity, 17 research and development priorities were identified and classified as either “Strategic research,” “Package development and evaluation,” and “New tool or intervention development.”

In October 2000, an International conference on health research

and development was held in Bangkok, Thailand. The conference was chaired by an international organizing committee formed by the representatives of the WHO, The World Bank, Global Forum for Health Research, and the Council on Health Research and Development. COHRED reviewed experiences and lessons from developing countries. The issues addressed were systematically categorized into the processes and methods for priority setting, assessing the results of Essential National Health Research strategy, defining who sets priorities and how to get participants involved, the potential functions, roles, and responsibilities of various stakeholders, information and criteria for setting priorities, strategies for implementation, and indicators for evaluation.

The next major global initiative emerged at the World Economic Forum, held in Davos, Switzerland, in January 2003. Bill and Melinda Gates Foundation (BMGF) announced the release of \$200 million to support the initiative of “The Grand Challenges” in global health research. This was based on a model formulated by the mathematician David Hilbert, who defined ultimate problems in mathematics and prizes were then offered to anyone who would succeed in solving them. This initiative resulted in more focused research by scientists in mathematics and resulted in major progress in the field at the time.

The identification of “Grand Challenges” was achieved with financial support from BMGF and the National Institutes of Health. It gathered a scientific board of 20 scientists and public health experts from 13 countries (including some developing countries), while the scientific community supplied ideas for challenges. “Grand Challenge” was described as “...a call for a specific scientific or technological innovation that would remove a critical barrier to solving an important health problem in the developing world with a high likelihood of global impact and feasibility.” More than 1000 submissions were received from scientists and institutions in 75 countries, and scientific board reached the decision on declaring 14 submissions as “Grand Challenges.” Grants of up to a total of \$20 million were then made available by Bill and Melinda Gates Foundation to remove these major obstacles to progress against diseases that disproportionately affect the developing world. All of the identified “Grand Challenges” fell into 7 broad categories, as follows: “Improving childhood vaccines,” “Creating new vaccines,” “Controlling insects that transmit agents of disease,” “Improving nutrition to promote health,” “Improving drug treatment of infectious diseases,” “Curing latent and chronic infections,” and “Measuring disease and health status accurately and economically in poor countries.” The “17 Best Buys” and the “14 Grand Challenges” addressed very similar problems and some of them entirely overlapped. The key difference was that the “17 Best Buys” were generally very specific technologies or interventions already under a certain degree of development and targeted at specific diseases, while the “Grand Challenges” were more broadly and generally defined and could impact several diseases and conditions.

To improve the process in which the respected scientists discuss and decide on funding priorities based on their own views and knowledge, Global Forum for Health Research developed a useful tool, the “Combined Approach Matrix” (CAM). The tool has proven to be highly useful for systematic classification, organization, and presentation of the large body of information that is needed at different stages of priority setting process, so that the decisions made by the members of

decision-making committees could be based on all relevant and available information, rather than their own personal knowledge and judgment. CAM incorporates “economic” dimension of priority setting process along one axis, and “institutional” dimension along the other, thus covering the information on the determinants of health at the population level. Components of “economic dimension” are “disease burden,” its “determinants,” “present level of knowledge,” “cost and effectiveness,” and “resource flows.” Components of “institutional dimension” are “the individual, household and community,” “health ministry and other health institutions,” “sectors other than health,” and “macro-economic policies.” CAM can be applied at the level of disease, risk factor, group or condition, and also at local, national, or international level.

2007—Research challenges to improve maternal and child survival

Over the past several years, The Lancet journal bravely engaged into advocacy of international health issues through publication of several series of papers focusing on main priority areas in international health. Recently, The Lancet expanded this effort through conducting a Delphi process similar to the one that had led to the “Grand Challenges” among a wide range of academics and professionals who had experience in developing countries. The coordinators of the process ranked by their perceived importance a limited number of very general and broad research themes in child health, maternal health, health systems, and community development.

All the initiatives from the past aiming to set priorities in health research investments resulted in apparent benefits and successes. The benefits were that discussions over these issues were taking place and highlighted many important factors relevant to setting health research priorities. The successes were that a more specific research focus was agreed, which then attracted attention of many researchers groups. The investments began to follow the specified goals. Such situation was more favorable than having no priorities, when each research group followed its own path.

However, the past approaches were also not free from certain shortcomings. Identified interventions and research questions that were outlined as the priorities were not compiled in a truly systematic way, using scientifically convincing conceptual framework and objective and repeatable methods, but rather through consensus reached by panels of experts. This often made it difficult to present the identified priorities to wider audiences as legitimate and fair, as the decisions could be seen as driven by research interest bias of individual experts.

Also, the claim of “best buys” was not supported by scientific and repeatable arguments. The “best buys” were not consistent or informative with respect to their potential for targeted disease burden reduction. The category of “package development” represented a mix of health policy and systems research options and options to improve the existing interventions. Similarly, some items among the “best buys” listed as “new tools or interventions” were clearly research options addressing the improvement of efficacy, affordability, deliverability, or sustainability of existing interventions. More fundamentally, the claim that the proposed items are indeed “best buys” was not convincingly demonstrated in a scientifically based, repeatable manner.

The decision-making process leading to the concept of “Grand

Challenges,” although better designed, informed, explained, and documented, had a somewhat biased focus from the start. The whole process was designed so that it largely promoted very difficult upstream technology developments. Among the “challenges,” there is hardly any that addressed the improvement of efficacy, effectiveness, deliverability, affordability, and sustainability of the existing interventions, so that these important instruments of health research were nearly ignored. This is particularly unfortunate, because one of motivations behind the “Grand Challenges” initiative was to promote equity. Equity, however, is best promoted through delivery of the already existing and effective interventions to all children.

One of the conclusions of the recent Lancet’s Child Survival series was a concern that global child health is perhaps losing its focus. Amid the large number of new interventions advertised and validated, levels of attention and effort directed at new, complex, and expensive interventions seem to be receiving higher profile and funding priority than the efforts to save millions of children by applying insecticide-treated materials, oral rehydration therapy, or promoting breastfeeding, all at a tiny fraction of costs of the former. Combined Approach Matrix was launched, aiming to ensure that decision-makers are better informed about these facts and realities when making their decisions. However, the CAM also has its shortcomings. Although it is an extremely helpful tool for gathering and organizing information needed for priority setting process, it does not in itself represent an algorithm for making the decisions on the priorities by ranking or separating the competing investment options. Therefore, in the absence of reliable information, which is usually very scarce for developing countries, most of the decisions will still be based on discussions and agreements within the panels of experts. The recent effort by The Lancet made a step further in specifying broad research avenues that should be considered priorities, but did very little to point to more specific research programs or research questions which should be initiated or addressed urgently.

Need for systematic methodology for priority setting in global child health research investments

Today, investments into health research on new interventions far exceed those on delivery in spite of the evidence that emphasizes large potential contribution of the latter to mortality burden reduction. The dominant model of research priority setting is driven by criteria such as interests of different advocacy groups, media exposure, interests of donors, individual biases of the members of policy-making panels, attractiveness of research results, novelty of proposed research and potential for publication in high-impact journals. We are concerned that continuing application of these criteria in decisions over investments into health research is resulting in gross under-achievement of potential disease burden reduction and is actually generating further health inequity. Even when new research avenues succeed in the development of new interventions, the initial beneficiaries usually are those who can afford the results. More complete coverage of the population in need often lags decades behind.

The current model of research priority setting is a closed circle set to increasingly favor basic research and generate ever-increasing inequity. A major underlying problem is lack of clear criteria and principles that would guide health research investments based on a vision of what the endpoints of such investments should be. If we can agree that the ultimate

endpoint of any health research should be reduction of disease burden and improvement of health, then some of the criteria needed for prioritization of investments should include: 1) usefulness of the proposed research in terms of its potential to lead to development of new or improved health interventions, 2) true effectiveness of those interventions, 3) their deliverability, affordability, and sustainability in the context of interest, and 4) their maximum potential to reduce persisting disease burden in an equitable way.

In addition, there is growing need to make decisions on research priorities not only globally, but also at lower levels—regional, national, and local community levels, and at single health facilities. Because of this, a methodology proposed to assist in health research priority setting should ideally have a form of an algorithm, that would be able to rank the priorities in very specific research programs or questions in a given setting (global, regional, national, and local) and for a given disease, risk factor, or a set of diseases and risk factors. Such methodology should also be simple enough for application, so that it could gain popularity among the users. It should provide simple, intuitive, and easily understandable answers, so that they could be presented to policy-makers from different regions of the world and be understood in the similar way. The methodology should be able to incorporate the available information relevant to priority setting (such as that compiled by Combined Approach Matrix).

The future application of this new methodology in the area of child health would greatly benefit from a particularly favorable knowledge base, represented in recently defined global burden of disease and death in children based on collective review of over 17,000 sources and references published over the past two decades, that was performed by WHO Child Health Epidemiology Reference Group (CHERG). It would also have a solid base for comparatively evaluating the competing interventions, through the recently completed “Disease Control Priorities Project II.”

Designing a new methodology respecting the principles of fair and legitimate priority setting

There are several fundamental principles that need to be respected in order to develop, promote, and implement priority setting methodology that would have a chance to become widely accepted and used. To begin with, Daniels and Sabin defined two main principles that must underlie any process of setting priorities—legitimacy and fairness. Legitimacy can only be insured by involving a large and diverse range of stakeholders from different regions and with different backgrounds into development of such methodology.

Respecting the principle of fairness is an equally difficult, but in many ways even more complex problem. There are different perspectives from which prioritizing between two or more competing options for health research investments can be made (eg, medical, economical, legal, ethical, social, political, rational, philosophical, stakeholder driven, and others). Even if each process from each single perspective was driven through “perfect” decisions, the outcomes will necessarily conflict each other. Therefore, developing methods for setting priorities fairly will be a highly complex and multidimensional process that will require wide agreement of numerous experts from different disciplines working collaboratively to produce such methods.

A standard multidisciplinary approach, where researchers work in parallel from their respective disciplinary bases to address

a common problem (as has been usually done in the past), would not have a capacity to address this particular problem. A transdisciplinary approach, where researchers of different backgrounds work jointly, using shared conceptual frameworks to draw together disciplinary specific knowledge and address common problems, will be significantly more likely to meet the target. Encouraging steps in providing theoretical guidelines for achieving success in transdisciplinary priority setting were made by Gibson et al, who managed to merge ethics principles on how priority-setting should be made, with empirical observations on how priority setting is made in absence of any guidelines (“The diamond model”) into a single model. Their further collaboration with leading representatives of economy-based model of priority setting (“Program budgeting and marginal analysis”) resulted in the development of a joint model that incorporates principles and knowledge from all three disciplines—theory of ethics, theory of economy, and qualitative assessment of how model-free priority setting is made in practice—into a satisfactory general model. The task for Child Health and Nutrition Research Initiative (CHNRI) experts will be to collaborate with those experts and continue to expand their work by incorporating the principles from medical dimension (eg, public health reasoning), social dimension (eg, concern about equity), and public opinion dimension (eg, respecting stakeholders’ views) into an even more general transdisciplinary framework that could be useful

in setting health research priorities at all levels. It would also remain open to emerging ideas, such as recently presented decision theory and “value of information” concept.

Conclusion

The dominant model of priority setting in health research investments today continues to result in gross under-achievement of potential disease burden reduction among world’s children and is actually generating further health inequity. There is growing need for a sound and informed process to make decisions on health research priorities, both globally and at lower levels—regional, national, and local community levels, and at single health facilities. A methodology in a form of algorithm that would enable this and that would be simple and practical enough to gain wider acceptance is much needed. In the series of papers that will follow this assessment of the past approaches, Child Health and Nutrition Research Initiative will propose a methodology for prioritization in global and national child health and nutrition research that attempts to satisfy most of those requirements. The proposed methodology will not seek to replace the existing methodologies, but will attempt to build upon their experiences, supplement them with input of knowledge and concepts from new and different perspectives, and seek to bring them all together and enhance transdisciplinary approach.

Evidence...continued from page 53

They do, however, clearly point to the practical problems that arise in using the concept of evidence-based ethics. Without the appropriate tools to distinguish better and worse empirical studies, the EB concept cannot find any application in ethics.

Conclusion

A rational, non-trivial reading of the EB concept has to be distinguished from empirical information per se. Because of its normative dimension of action legitimation, we need a transparent and rational justification of the context-specific use of the EB concept in medicine as well as in ethics. This is to be ensured through an explicit discussion within each field as to the validity and relevance of the empirical information to be considered evidence.

The relation between norms and facts was described as complementary in applied ethics. Empirical information per se is necessary to give concrete and context-specific reality to ethical principles. Yet neither empirical information nor ethical principles are sufficient for an ethical decision-making process in the context of medical ethics. The necessary interdependence of norms and facts is not sufficient to fully characterize the concept of evidence-based ethics. A rational, non-trivial reading of evidence-based ethics is characterized by a well-justified, context-specific differentiation between empirical information per se and the more qualitatively valuable evidence that has greater weight in the legitimation of action.

Yet so long as no criteria or standards with sufficient general acceptance are available to justify a transparent characterization of empirical information as evidence, we should refrain from using the EB concept in the context of applied ethics. An unexamined use of the EB concept in applied ethics without context-specific justification should be seen very critically due to its legitimating effect on actions. Hence collaborative, interdisciplinary work is needed, for example between

professional societies in medical ethics and the social sciences, to work out agreed-upon criteria and standards. These standards for quality assessment in empirical ethics could then be used to assess research proposals or manuscripts submitted to journals. They could also be helpful in critically interpreting the results of studies in empirical ethics.

Until these quality assessment measures can be found for empirical ethics, it is likewise problematic to speak of “empirically supported ethical decisions” if there is no differentiation between various levels of quality of empirical information and hence no transparent discussion of the internal and external quality of the empirical information. A middle course between the evidence-based ethics that is not currently possible and a merely superficial treatment of empirical information is an ethics that calls for the critical appraisal of empirical information in the context of totality of data. Here, in a first step, systematic reviews aim to identify all studies that focused on research questions relevant for a certain ethical dilemma. In a second step the review need to critically appraise, compare and discuss the empirical findings. The critical appraisal includes the following three aspects: (i) the validity of the data, (ii) the transferability of the data to the context under discussion and (iii) the relevance of the results for the decisions or recommendations at issue. In the discussion one has to interpret and qualitatively compare findings of different studies that investigated similar research questions.

A critical appraisal of empirical ethics can only be implemented in practice if the question of what comprises better or worse empirical information in ethics can be intersubjectively discussed and negotiated. This article has presented various difficulties that require further pragmatic discussion for their solution. Furthering this process of clarification, which has been neglected so far, is at least as important as the current intensive discussion about the relation between ethics and empirical information.

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