By Joel D. Temple, MD

Fetal arrhythmias are estimated to occur in 1-2% of gestations. The majority of these are PVCs and PACs which are generally considered benign. More serious arrhythmias can occur including SVT, atrial flutter, and VT. Management of fetal arrhythmias has been limited by our inability to effectively monitor and diagnose them. The gold standard has been Doppler M mode echocardiography which can demonstrate the timing of atrial and ventricular contractions. Echo, however, does not give information about the electrical activity of the heart and is labor intensive. The fetal ECG can be obtained from the maternal abdomen, but there are significant artifacts in the form of both myopotentials and the maternal ECG. Of particular interest, the maternal ECG (based on voltage potential) does not attenuate and is 10-100 times as strong as the fetal signal. In addition, useful signals are difficult to obtain after 27 weeks, probably due to the insulating properties of the vernix caseosa. Fetal magnetocardiography (fMCG) is a new technique that is particularly useful for evaluating fetal arrhythmias.

As cardiac tissue depolarizes, small currents are generated across the advancing wave front and consequently, an electromagnetic field is generated perpendicular to the current. This field can be detected and is the basis of fMCG. The field generated by the fetal heart is on the order of 0.5-10 pT, or approximately one millionth the strength of the earth’s magnetic field. By comparison,
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the maternal signal is approximately 50 pT. The device used to measure these biomagnetic fields is called a Superconducting Quantum Interference Device or SQUID magnetometer. SQUIDs must be super-cooled and shielded from all electromagnetic interference.

One clear advantage of fMCG is that the signal strength is inversely proportional to the square of the distance from the source. Consequently, if the receiver is placed close to the fetus, the maternal signal will be considerably smaller. The University of Arkansas for Medical Sciences has developed a specialized array called SQUID Array for Reproductive Analysis or SARA. SARA consists of 151 magnetometers arranged to fit the gravid abdomen. The patient leans forward onto the array while seated (Figure 1). There is no trauma to the fetus and minimal discomfort to the mother and extended recording periods are possible.

Background noise is filtered using a first order gradiometer (magnetometer). The maternal signals are identified and averaged using template matching and the maternal signal is attenuated using a technique called orthogonal projection. The result is a signal that is analogous to a surface ECG (Figure 2). If further resolution is needed, signal averaging can be performed.

Fetal magnetocardiography offers some exciting possibilities including the more accurate diagnosis of fetal
Arrhythmias, monitoring for fetal toxicity with drugs such as Flecainide, Sotalol, and Amiodorone leading to safer use of antepartum antiarrhythmics, and prenatal diagnosis of channelopathies such as the Long QT syndrome without the need for amniocentesis.

This technology is currently expensive and cumbersome due to the need for super cooling and electromagnetic shielding. However, work is currently under way towards the development of a “high” temperature SQUID that does not require super cooling.

Fetal magnetocardiography is a safe non-invasive technique allowing monitoring of fetal heart rhythm and providing information and a degree of resolution not previously obtainable (Figure 3). The particular design of SARA allows extended monitoring without apparent harm or discomfort to the mother or fetus. As IMCG becomes more widely available, I believe it will have a significant impact on the way we diagnose and manage fetal arrhythmias.

Editor’s Note: “Fetal Magnetocardiography—An Exciting New Technique for the Diagnosis and Management of Fetal Arrhythmias” by Joel D. Temple, MD was first published in the Pediatric Cardiology Today, a sister publication to Neonatology Today.

Figure 3. (A) FMCG of a twin “A” in atrial flutter with signal averaged ECG. (B) FMCG of twin “B” in sinus. Recordings were obtained simultaneously.

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**Use of Sucrose to Relieve Pain During Eye Exams in Infants**

**Inclusion Criteria**
- **Eligibility:** Ages up to 3 Months, Both Genders
- **Condition:** Apnea of Prematurity; Retinopathy of Prematurity; Pain Control
- **Treatment or Intervention:** Drug- sucrose solution
- **Study Type:** Interventional
- **Location and Contact Information:** Please refer to this study by ClinicalTrials.gov identifier NCT00161694
- **Sponsors and Collaborators:** Weill Medical College of Cornell University

**Exclusion Criteria**
- **Condition:** Any infant who is unable to safely suckle 0.5cc of fluid will be excluded from the study. This includes infants that are being maintained on ventilators and those with serious gastrointestinal complications that may be exacerbated by an oral fluid bolus. Any infant being maintained on narcotics for any reason will not be eligible for the study. All infants with major congenital anomalies will be excluded.

**Location and Contact Information:** UCLA Medical Center, Los Angeles, California, 90095, United States; Recruiting; Samuel Wald, MD, Principal Investigator 310-206-0085; swald@mednet.ucla.edu

**Study chairs or principal investigators:** Samuel Wald, MD, Principal Investigator, UCLA Department of Anesthesiology

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**Study to Test the Pain-Relieving Effect of Laughing Gas in Infants**

**Inclusion Criteria**
- **Eligibility:** Ages 5 Weeks and above; both male and female
- **Condition:** Apnea of Prematurity; Retinopathy of Prematurity; Pain Control
- **Treatment or Intervention:** Drug- nitrous oxide solution
- **Study Type:** Interventional
- **Location and Contact Information:** Please refer to this study by ClinicalTrials.gov identifier NCT00250692

**Exclusion Criteria**
- **Condition:** Any infant who is unable to safely suckle 0.5cc of fluid will be excluded from the study. This includes infants that are being maintained on ventilators and those with serious gastrointestinal complications that may be exacerbated by an oral fluid bolus. Any infant being maintained on narcotics for any reason will not be eligible for the study. All infants with major congenital anomalies will be excluded.

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**Study chairs or principal investigators:** Samuel Wald, MD, Principal Investigator, UCLA Department of Anesthesiology

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**More Information**
- Study ID Numbers: 0412007634
- Last Updated: September 11, 2005
- Record first received: September 8, 2005
- ClinicalTrials.gov Identifier: NCT00161694
- Health Authority: United States: Institutional Review Board
- ClinicalTrials.gov processed this record on 2005-11-16

This study is currently recruiting patients

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**More Information**
- Study ID Numbers: 05-04-029-01
- Last Updated: November 7, 2005
- Record first received: November 7, 2005
- ClinicalTrials.gov Identifier: NCT00250692
- Health Authority: United States: Institutional Review Board
- ClinicalTrials.gov processed this record on 2005-11-16

This study is currently recruiting patients
Study of MEDI-524 (Numax), for the Prophylaxis of Serious Respiratory Syncytial Virus (RSV) Disease in High-Risk Children

More Information
Study ID Numbers: MI-CP110
Last Updated: November 4, 2005
Record first received: August 29, 2005
ClinicalTrials.gov Identifier: NCT00129766
Health Authority: United States: Food and Drug Administration
ClinicalTrials.gov processed this record on 2005-11-16

This study is currently recruiting patients

Purpose: The primary objective of this study is to compare the safety and efficacy of MEDI-524 to palivizumab when administered monthly by intramuscular (IM) injection for the reduction of the incidence of RSV hospitalization among children at high risk for serious RSV disease.

Condition: Respiratory Syncytial Virus Infections

Intervention: Drug: MEDI-524

Phase III

Study Type: Intervventional
Study Design: Prevention, Randomized, Double-Blind, Active Control, Parallel Assignment, Safety/Efficacy Study

Further Study Details: Primary Outcomes: The primary objective of this study is to compare the safety and efficacy of MEDI-524. Secondary Outcomes: To compare the incidence of medically-attended lower respiratory illnesses (LRIs) between treatment groups; To compare the incidence of RSV-specific medically-attended LRI in a subset of patients; To compare the frequency and incidence of medically-attended otitis media (OM) infections between treatment groups; To compare the frequency of prescribed antibiotics for medically-attended LRI and medically-attended OM infections; To describe the trough serum concentrations of MEDI-524; To describe the immunogenicity of MEDI-524

Eligibility: Ages 6 Months - 24 Months, both Genders

Criteria:

Inclusion Criteria:

- 24 months of age or younger at randomization (child must be randomized on or before his/her 24-month birthday) with a diagnosis of chronic lung disease (CLD) of prematurity requiring medical intervention/management (i.e., supplemental oxygen, bronchodilators, or diuretics) within 6 months before randomization—or
- 35 weeks gestational age or less at birth and 6 months of age or younger at randomization (child must be randomized on or before his/her 6-month birthday)

Exclusion Criteria:

- Hospitalization at the time of randomization (unless discharge is anticipated within 10 days)
- Mechanical ventilation or other mechanical support (including continuous positive airways pressure [CPAP])
- Life expectancy < 6 months
- Active RSV infection (a child with signs/symptoms of respiratory infection must have negative RSV testing)
- Known immunodeficiency
- Mother with HIV infection (unless the child has been proven to be not infected)
- Known allergy to Ig products
- Receipt of palivizumab, RSV-IGIV, or other RSV-specific monoclonal antibody, or any other polyclonal antibody (for example, hepatitis B IG, IVIG, VZIG) within 3 months prior to randomization
- Anticipated use of palivizumab or IVIG during the study (blood transfusions permitted)
- Previous receipt of RSV vaccines
- Participation in other investigational drug product studies

Location and Contact Information: This study is recruiting throughout the world

Guisela Torres; 301-398-4222; torresg@medimmune.com

Study chairs or principal investigators: Genevieve Lonsosky, MD, Study Director, MedImmune, Inc.

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The 28th annual Tiny Baby Conference was held this year at Disney World in Orlando, Florida, at the Boardwalk Resort. This meeting, started in 1978 by Drs. Willa Drummond and Gregor Alexander, is one of the longest running meetings of its type in the United States and has been jointly sponsored by The University of Florida and Arnold Palmer Children’s Hospital. This year, however, marks the final edition of the Tiny Baby Conference in its current form. In February 2007, Pediatrix Medical Group will join the meeting sponsors as one of the primary organizers and the conference will morph into the newly titled, “NEO-the Conference for Neonatology,” and be extended by a day. The meeting will be a great focal point for discussion of the major issues in Neonatal-Perinatal Medicine and have a series of world-class speakers for both physicians and nurses. In addition, the great resources of Walt Disney World will be utilized for a series of evening events that promise to provide a great experience for all participants.

At this year’s Tiny Baby, the quality of the meeting once again reached its usual high standards, with a series of interesting and controversial presentations that attempted to address some of the critical issues in newborn care. On the first day of the conference, Joseph Neu, MD, Professor of Pediatrics at the University of Florida, discussed our current understanding of the primary factors involved in neonatal necrotizing enterocolitis (NEC). In a brilliant in-depth review of the topic, Dr. Neu reviewed the variability and complexity of this disease, identifying those factors most likely to result in NEC. Immune factors, inflammatory mediators, the possible role of antireflux therapy, especially H2 blockers, circulatory issues, the possible role of indomethacin, the bacteriology of NEC, as well as numerous other factors, were all carefully evaluated and presented, as well as new avenues of therapy including probiotics. Probiotics refer to non-pathogenic bacteria specifically introduced into the newborn intestine during feeding that may reduce the likelihood of NEC. Following this review, Elizabeth Beierle, MD, Assistant Professor of Surgery from the University of Florida, examined NEC from the surgeon’s perspective, providing a fascinating view of how this entity appears to the surgeon, what factors seem to precipitate NEC, and what surgical interventions are appropriate under a variety of clinical circumstances.

The remainder of the morning then shifted to the neurological assessment and treatment of the NICU patient. Seetha Shankaran, MD, Professor of Pediatrics at Wayne State School of Medicine and Chief of Neonatology at the Children’s Hospital of Michigan, reviewed the pathophysiology of neurological injury in both the term and preterm infant. Dr. Shankaran presented the superb data collected over many years by the NIH Neonatal Network, of which her institution is a member, examining the factors that appear to provoke intracranial hemorrhage (ICH) in the very low birth weight infant, as well as the complications of this event. She also examined the antenatal factors involved...
in this entity, pointing out that our understanding of the etiology of ICH has changed significantly during the past several years, with antepartum factors increasingly being identified as provocative for both ICH and periventricular leukomalacia (PVL) in the neonate. In particular, antepartum infection appears to be a critically important component of the development of ICH and PVL in the premature infant. Dr. Shankaran also examined the role of selective head and body cooling in the treatment of perinatal hypoxic-ischemic injury in the neonate. She cited the exciting work being done in this area and the ongoing studies which will, hopefully, reveal the precise role of this therapy in the armamentarium of the neonatologist.

The presentations of the first day were completed by Alan Spitzer, MD, Director of Research and Education for Pediatrix Medical Group, who discussed the emerging technique of Cerebral Function Monitoring in the care of the neonatal patient. Dr. Spitzer identified the value of this technique in monitoring normal brain development in the premature infant, as well as the effects of injury, both to the term and pre-term neonate. By following the amplified, integrated EEG recording (aEEG), an improved assessment of the status of brain function can be monitored and a more selective course of therapy can emerge.

The second day of the meeting began with a presentation by Reese Clark, MD, Director of Neonatal Research at Pediatrix Medical Group, on normal blood pressure in neonates. Dr. Clark examined the results of data obtained from the extraordinary Pediatrix Medical Group database, which has information on more than 530,000 neonates. He also demonstrated the effects of pressor medication on the recorded blood pressure in the neonate. This presentation was followed by an outstanding talk by Mark Polak, MD, Associate Professor Pediatrics at West Virginia University, on the role of volume therapy, dopamine, and other pressors in trying to establish an appropriate blood pressure for the neonate. Dr. Polak pointed out that the neonatologist is often overly aggressive in trying to achieve levels of blood pressure and that it is inappropriate to simply chase numbers while ignoring the clinical circumstances and examination of the neonate. He suggested a more moderate approach that appeared to have great merit behind it.

The second day’s sessions were concluded by a series of superlative discussions by Ronald Clyman, MD, Professor of Pediatrics at the University of California at San Francisco, and Carl Bose, Chief of the Division of Neonatal-Perinatal Medicine at the University of North Carolina, that assessed the role of the patent ductus arteriosus (PDA) in neonatal care. Drs. Clyman and Bose examined the PDA from somewhat different perspectives, and came to different conclusions about the urgency of ductal closure in the very premature infant. An excellent question and answer session followed, which revealed the complexity of
The conference was closed by Dr. Robert Christensen, Director of Neonatology Research for Intermountain Health Care and Medical Director of Neonatology at McKay-Dee hospital in Ogden, Utah. Dr. Christensen spoke about the great value of multi-center research programs and presented some of the highly significant work ongoing at Intermountain Health-care in such areas as bilirubin assessment, retinopathy of prematurity, and maternal drug use during gestation. This talk rounded out another outstanding Tiny Baby Meeting, which will become an even more exciting meeting next year as it expands to NEO—the Conference for Neonatology.

Day Three of the Tiny Baby Conference began with discussions of safety and risk management issues in the neonatal intensive care unit (NICU) from Julie Williams, Risk Manager for Women and Newborn Services at Arnold Palmer Hospital for Children and Women, and Robert Ursprung, MD, a neonatologist in the Pediatrix Medical Group practice at Cook Children’s Medical Center in Fort Worth. Dr. Ursprung is also Co-Director of Quality Improvement for Pediatrix Medical Group. Ms. Williams reviewed the potential sources of problems in the NICU and the need for unbiased and blame-free approaches to patient safety issues. Dr. Ursprung reviewed additional sources of error and how systems may fail in the course of neonatal care. Dr. Ursprung presented his work on random audits, an outstanding technique for the identification, review, and prevention of error in the NICU.

These discussions were followed by a return of Dr. Carl Bose, who examined the processes and roles of perinatal inflammation in the etiology of neonatal diseases such as periventricular leukomalacia (PVL), bronchopulmonary dysplasia (BPD), and cerebral palsy. The importance of antenatal inflammation has become increasingly important in the modern era and there are now strong data to implicate inflammation in both preterm delivery, as well as neurological and pulmonary injury in the neonate. Dr. Bose's presentation was further supported by Dr. Alan Spitzer, who addressed the additional issues that appear to provoke neonatal injury beyond perinatal inflammation such as hypo- and hypercarbia.

The conference was closed by Dr. Robert Christensen, Director of Neonatology Research for Intermountain Health Care and Medical Director of Neonatology at McKay-Dee hospital in Ogden, Utah. Dr. Christensen spoke about the great value of multi-center research programs and presented some of the highly significant work ongoing at Intermountain Health-care in such areas as bilirubin assessment, retinopathy of prematurity, and maternal drug use during gestation. This talk rounded out another outstanding Tiny Baby Meeting, which will become an even more exciting meeting next year as it expands to NEO—the Conference for Neonatology.

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Newborns are Unable to Mount an Effective Immune Response to Most Vaccines

Newswise — Newborn babies have immature immune systems, making them highly vulnerable to severe infections and unable to mount an effective immune response to most vaccines, thereby frustrating efforts to protect them. Researchers at Children’s Hospital Boston now believe they have found a way to enhance the immune system at birth and boost newborns’ vaccine responses.

In a study published in the April 25, 2006 online edition of the Journal Blood, Ofer Levy, MD, PhD and colleagues in Children’s Division of Infectious Diseases show that the newborn immune system functions differently than that of adults, but that one portion of the immune response is fully functional and can be harnessed to boost immunity in these tiny infants, possibly making infections like respiratory syncytial virus, pneumococcus, pertussis, HIV and rotavirus much less of a threat.

For about a decade it’s been known that the first line of defense against infection is a group of receptors known as Toll-like receptors (TLRs) on the surface of certain white blood cells. Functioning like an early radar system, TLRs detect the presence of invading bacteria and viruses and trigger production of “danger signals” — proteins known as cytokines that trigger other immune cells to mount a defense against the infection. People have 10 different kinds of TLRs, and Levy’s team decided to examine how well they function in newborns by studying white blood cells from their cord blood.

“We found that when most Toll-like receptors are stimulated, newborns’ immune responses are very impaired,” Levy says. “But there was one important exception.”

Levy’s team, including Harvard graduate Eugenie Suter and senior author Michael Wessels, MD, showed that one TLR, known as TLR8, triggered a robust immune response in a group of white blood cells (called antigen-presenting cells) that is crucial for vaccine responses. When TLR8 was stimulated by various agents that mimic viral antigens, the cells produced normal, adult levels of two key cytokines — TNF-alpha and IL-12 — and another immune-system stimulant, CD40.

“These findings suggest that agents that stimulate TLR8 could be used to enhance immune responses in newborns, perhaps as adjuvants given along with vaccines,” Levy says. “We plan to test this approach in animals, and eventually in human babies.”

Levy notes that the ability to vaccinate newborns — rather than wait until they reach 2 months of age — would provide important global health benefits. “Birth is a point of contact with healthcare systems,” he says. “Families may not see a health care provider after that. From a global health perspective, if you can give a vaccine at birth, a much higher percentage of the population can be covered.”

Conceivably, TLR8 stimulators could also be given alone in special circumstances — to help a baby fight off an infection in progress, or as a preventive measure in the event of a disease outbreak or bioterrorist threat, Levy adds.

Levy’s team is uncovering other differences between the newborn and adult immune systems that could lead to additional targets for drugs or vaccines. A related paper, to be published soon in the journal Pediatric Research, finds that when newborns’ TLRs are stimulated during the first week of life, their white cells’ production of the cytokine IL-6, which inhibits parts of the immune response, is greater than that in adults.

A third study, to be published in the Journal of Immunology, finds that newborns’ cord blood also has high levels of adenosine, providing an explanation for newborns’ altered immune response: adenosine alters the physiology of white cells to suppress production of TNF-alpha (but not of IL-6) when TLRs are stimulated. When Levy’s team used antagonists to inhibit adenosine’s activity, newborns’ white blood cells produced normal, adult levels of TNF-alpha in response to bacterial and viral triggers. “In the future, we could try to block adenosine in newborn animals to see if this helps protect against infection,” Levy says.

Levy believes the differences his team has uncovered in newborns’ immune response patterns may serve an evolutionary purpose. Nature may suppress babies’ production of inflammatory cytokines like TNF-alpha and IL-12 before birth because they can trigger preterm labor, while increasing production of adenosine and IL-6, which may have a protective effect on the pregnancy.

The current study was funded by the National Institutes of Health and the Patterson Trust. For more information visit: www.childrenshospital.org.

Pediatric End-of-Life Care Lacking—Parents Recommend Six Areas of Importance

It’s a scenario that most people can’t even bring themselves to think about: the death of a child.

That may explain, in part, why pediatric end-of-life care hasn’t received much attention, and why palliative care for children isn’t widely available.

But a new study in the March issue of Pediatrics brings the issue to the forefront by reporting what parents who have lost their children said was needed most during the dying process.

“We can’t always prevent someone from dying, but we can create a better situation,” said Dr. Linda Siegel, a pediatric critical care and palliative care expert at Kravis Children’s Hospital at Mount Sinai Medical Center, in New York City. For
example, she said, a child can die with monitors screeching and a code team present, shocking their heart, trying to revive them, or a child can die with a parent holding them, the room lights low and soft music playing in the background.

"Health-care providers need to be aware of the impact they have on the family at the end of life. Those memories, they carry with them for the rest of their lives," she said.

Dr. David Steinhorn, medical director of palliative care at Children's Memorial Hospital in Chicago, echoed Siegel's sentiments, "This is such an important area. You only have one chance to do end-of-life care right. We can't make it 100% pain-free or free of pain and anxiety, but we can minimize those aspects," he said.

The Boston researchers sent questionnaires to the families of 96 children who had died in one of three Boston-area hospitals. Fifty-six parents returned the questionnaires.

Of those who responded, 64% were mothers, 75% were married, and 91% were white. The average age was 42. Half of the respondents were Catholic, 34% were Protestant, 5% were Jewish, 2% were Muslim and 9% identified no religious affiliation.

Parents identified six areas of critical importance that could improve pediatric end-of-life care:

1. Honest and complete information. Families wanted health-care providers to be forthcoming with information and not try to withhold information to protect them.

2. Ready access to staff. In a rushed hospital setting, it's easy for a parent to miss the doctor on rounds. Parents suggested setting up a regular time for bedside consultations.

3. Communication and care coordination. Often, an ill child will have many different specialists caring for him or her. Some parents found talking to so many doctors confusing, particularly if doctors expressed differing opinions.

4. Emotional expression and support by staff. Parents wanted to know that staff members cared and were "real people."

5. Preservation of the integrity of the parent-child relationship. Parents wanted health-care providers to acknowledge their vital role in their child's life. They wanted to be respected and included in the decision-making process.

6. Faith. Faith was a double-edged sword for this group of parents. Some found comfort in their faith and sought counsel from religious personnel. Others felt betrayed by their beliefs at this difficult time.

Parents felt it was important for doctors to give them the big picture and to be honest with them about their child's situation, no matter how grim the prognosis. "What we cannot handle is not knowing what is going on," wrote one parent.

But it isn't always easy for doctors to deliver a poor prognosis, admitted Dr. Eugene Perlov, a physician with the hospice division of the Visiting Nurse Service of New York.

"[Health-care providers] have a hard time talking about bad news. We're so invested in good outcomes, which is natural because our mission is to heal," he said.

And, that's exactly where palliative care can come in, said Steinhorn.

"Palliative care brings in a whole set of additional support when no more curative measures are available," he said, though he added that pediatric palliative care isn't available at most hospitals, even children's hospitals, yet.

Both Steinhorn and Perlov pointed out another important obstacle to increasing the availability of palliative care -- it's currently hard to get insurance reimbursement for such care.

Siegel said palliative care can be helpful from the time of diagnosis through to the end of the child's life, however, "We need to support parents emotionally. We need to help them maintain hope, but prepare them for what's going to happen," she said, adding that there can be reluctance to calling on palliative care specialists. "It's so unnatural for children to die before their parents, it's hard for everyone to shift to palliative care."
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