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Summer 2007

Mannequins Teach Art of Neonatal Care

It is hard to achieve competence at tasks where other people's lives are in your hands, especially when the most critical events are uncommon. Airline pilots prepare for this dilemma with simulators that mimic every part of the cockpit environment and help them deal with perilous real-time situations. At the Komansky Center for Children's Health/Weill Cornell Medical Center, pediatricians and obstetricians have begun to use their own simulators: highly sophisticated remote-controlled mannequins that look and feel like babies and can be programmed to display realistic signs of cardiorespiratory arrest, respiratory distress, arrhythmia, and even cyanosis.

"We are a beta site for a neonatal simulated mannequin," explained Jeffrey M. Perlman, MD, Chief of the Division of Newborn Medicine. "It gives you a heart rate. You can hear breath sounds. The baby turns blue. You can put in lines or a breathing tube. You can control with a computer where you want the heart rate to be. The breath sounds can disappear in 1 or both lungs. The delivery team can attach the baby to monitors and see and hear that the heart rate is low. Depending on the response, you can allow the heart rate to either increase or decrease and correspondingly allow the baby's condition to improve or deteriorate."

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High-Density EEG May Yield Insights Into Development of Premature Brain

The majority of extremely premature, very-low-birth-weight infants initially survive with the intervention of neonatal intensive care, and most then appear normal upon discharge home. However, some of them later exhibit unexplained intellectual, behavioral, and movement problems, prompting the question of whether and how aspects of their care and treatment in the neonatal intensive care unit affected their development. Researchers at Morgan Stanley Children's Hospital of NewYork-Presbyterian are using a new device with a large array of sensors to measure brain waves through the scalp of these infants, with the aim of shedding light on why they develop the way they do.

High-density EEG can create sensitive spatial maps of brain function.

"The brain has been called a forgotten organ," said Philip Grieve, PhD. "In the nursery, it's the thing we are trying to keep healthy and protect, but you are always deducing how the brain is func-

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Webcasts:

Bubble CPAP

(originally aired November 2006):
Visit: childrensnyp.org/cpap

Pediatric Capsule Endoscopy

(originally aired May 2007):
Visit http://www.or-live.com/nyp/1771/
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Controlled Head-Cooling Device Effective for Perinatal Asphyxia

In December 2006, the FDA gave its final approval to the Cool-Cap, a device that reduces the body temperature of newborn infants by circulating cold water over the head. Controlled hypothermia has been shown to provide modest improvements in the outcome of babies with perinatal asphyxia, an uncommon condition resulting from oxygen deprivation and often leading to severe neurologic and developmental impairment.

"Up until now, the only thing we could do in terms of treating these babies was supportive," said Richard Polin, MD, Director of the Division of Neonatology at the Morgan Stanley Children's Hospital of NewYork-Presbyterian and Professor of Pediatrics at Columbia University College of Physicians and Surgeons. "If they needed ventilation, we provided ventilation; if blood pressure was dropping, we provided medications or fluids to affect blood pressure. If we look at all the major studies that have used hypothermia in infants with asphyxia, cooling has had only a modest benefit in reducing neurologic handicaps. However, it is still better than anything else we have at this time."

Morgan Stanley Children's Hospital took the lead in developing the original cooling trials, and Dr. Polin was on the scientific advisory committee that designed the study. He has been using and advocating the Cool-Cap ever since. "We are one of the centers in the city—there have been two—that have offered cooling as routine therapy," he said. "We get referrals into Morgan Stanley of babies from other hospitals for cooling. It's an issue when they come from other hospitals because they absolutely must be started on cooling within 6 hours of birth. The sooner you begin cooling, the better off babies are."

Controlled reduction of body temperature has been shown to be beneficial in several areas. In the late 1990s, some reports were published that showed improvements in adults in cardiac arrest if their body temperature was lowered once they were admitted to a hospital. Separate research conducted at about the same time showed that brain injury in fetal sheep could be lessened by reducing body temperature. These results led to numerous animal studies that examined the mechanism of cooling and its effects on the body, particularly on the brain and on the central nervous system. Soon after, Olympic Medical developed the Cool-Cap system and organized an international randomized clinical trial of head cooling in infants with perinatal asphyxia. The results, which showed that cooling provided modest protection against adverse neurologic outcomes, were published in *The Lancet* (2005;365:663-670).

"The Cool-Cap didn't reduce the incidence of neurodevelopmental impairment for every baby in the study," Dr. Polin said. "It did for babies who were in the moderate severity group, but not the most severe cases. That made sense to us because the most severely affected infants probably had long-standing damage to the brain (ie, before birth), and the moderate severity group probably has had brain injury for a shorter duration. The moderate severity group was identified by doing some specialized studies using EEG, and it was that group of infants that showed a modest improvement in neurologic outcome."

> "The history of neonatology is made of small advances, and this is an advancement in a group of babies that we had no effective treatment for. It's not a panacea, but it does improve outcomes."
>
> —*Richard Polin, MD*

A second study on cooling was conducted by the National Institutes of Health. It differed from the first in 2 key ways: A mattress was used that provided whole-body cooling rather than a device specifically designed for head cooling, and the babies were not systematically evaluated with EEG. These differences make it difficult to directly compare the results of the 2 studies directly. Nonetheless, both showed that cooling led to a modest but definite improvement in outcomes and a reduction in death and moderate or severe neurologic disability. Only the Cool-Cap has acquired FDA approval so far.

Because studies have shown improvements only in certain situations, a strict set of criteria must be met for pediatricians to consider cooling a viable treatment option for newborns. "We identify the baby based on 3 different groups of criteria: history, physical examination, and an amplitude-integrated EEG," Dr. Polin explained. "If the baby meets those criteria and is less than 6 hours of age, we place him or her on the cooling device. The cooling device is a plastic cap that fits over the baby's head. Through that cap, cold water circulates and takes heat from the baby's body and provides more cooling directly to the baby's head. We lower the temperature down to 34.5°C, monitoring rectal temperature and other vital signs very closely. The baby is kept at that temperature for about 72 hours and then slowly brought back to a normal body temperature."

Two manuscripts on the cooling trials at Morgan Stanley Children's Hospital have been published thus far, and a third

Olympic® Cool-Cap System image courtesy of Natus Medical Incorporated

is under review. The results that have been published have patient follow-ups of just 18 months, and Dr. Polin is looking forward to re-evaluating the patients at the 5-year mark. Other trials are ongoing in Australia and the United Kingdom. Meanwhile, research on hypoxia and hypothermia continues to be a central part of Dr. Polin's work at NewYork-Presbyterian, and he hopes to conduct further studies in which cooling is combined with other treatments. "As I look at the future of cooling," he said, "one of the main benefits is that it probably will allow us to go in with a second drug, which will further improve the outcomes of babies who have had asphyxia. There are animal data to suggest that the combined use of hypothermia and other drugs may offer greater benefits."

Although Dr. Polin urged caution in interpreting the results of the cooling trials, especially pending the publication of 5-year results, he also acknowledged that being able to offer hypoxic infants any hope of improvement at all is a big change from past years, when no real treatment was available. "The history of neonatology is [made] of small advances," he said, "and this is an advancement in a group of babies that we had no effective treatment for. It's not a panacea, but it does improve outcomes."

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"NewYork-Presbyterian Children's Health"
is a publication from the Morgan Stanley Children's Hospital of NewYork-Presbyterian/Columbia University Medical Center and the Komansky Center for Children's Health/Weill Cornell Medical Center. NewYork-Presbyterian Hospital/Columbia University Medical Center and NewYork-Presbyterian Hospital/Weill Cornell Medical Center are respectively affiliated with Columbia University College of Physicians and Surgeons and the Weill Cornell Medical College.

NewYork-Presbyterian Children's Health Editorial Board

Longitudinal Study Tracks Preterm Infants: Accurate Prediction Is Goal

Preterm infants are at high risk of brain injury and attendant neurological and developmental deficits. Several years ago, doctors at the Division of Newborn Medicine at the Komansky Center for Children's Health/Weill Cornell Medical Center began a program in which MRIs are conducted just prior to discharge for infants whose birth weight is less than 1,000 g, in an attempt to determine which specific or global areas of the brain are affected by preterm birth.

When new algorithms enabled them to use MRI data to measure the volume of different areas of the brain, Jeffrey M. Perlman, MD, Professor of Pediatrics and the Division Chief, and his colleagues initiated a longitudinal study to correlate brain volume measurements with neuropsychological evaluations of those same children as they aged and developed. The results of this study may eventually lead to a greater understanding of the neurological, psychological, and cognitive difficulties that these children are likely to face, which in turn will allow developmental problems to be predicted based on MRI data and pave the way for early interventional programs that may even begin before the infant leaves the hospital.

"We evaluate the children at 18 months [corrected age], at 3 years, and, in time, beyond that," Dr. Perlman said, "and we perform different psychological and psychometric tests. The primary goal is to examine the MRI volumes that we are measuring and try to predict, based on those volumes, what the outcome will be at 3 years. Then, as a second goal, if specific areas of the brain are affected more than other regions, we will try to determine the mechanisms accounting for these differences. As a third goal, we want to determine what factors and/or events during the neonatal intensive care course could account for the specific abnormalities that may be seen on the MRI."

> "I am becoming more of a believer that you can actually induce plasticity and get recovery far in excess of what one may have anticipated."
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> —*Jeffrey M. Perlman, MD*

Gail Ross, PhD, Associate Professor of Psychology in Pediatrics and Psychiatry, noted that she and the other testers are blind to the MRI results and other perinatal data on the children they evaluate. "We maintain a database of our results, while Dr. Perlman maintains a database of the perinatal variables and the results of the MRIs taken at birth," she said.

At the 18-month visit, the children are tested in 3 areas: cognitive abilities separate from language, ability to understand language, and ability to communicate using language. Parents also complete a checklist that describes the child's behavior at home and in everyday situations, and the child's behavior during test-taking is described and rated by the tester. "When children are 3 years old, we administer the Wechsler Preschool and Primary Scale, which is a standardized measure of intelligence, as well as measures of language and behavior," Dr. Ross said. "We hope to see the same children again at 6 years old, at which time we can do more complete assessments of neurocognitive functioning and learning abilities."

Dr. Perlman, who has been studying neonatal brain injury for 25 years, noted that from his research he has come to appreciate the brain's ability to "repair" itself if the conditions are right. "I am becoming more of a strong believer that you can actually induce plasticity and get recovery far in excess of what one may have anticipated, unless the brain injury is very severe," he said. "The moderate cases may become mild and the mild may actually develop normally or be near normal. Those are the aspects that we're focusing on, and as we identify these deficits, we'll begin to implement early targeted intervention strategies as early as possible. We're beginning to raise questions about potential interventions even within the unit before discharge that may improve cognitive outcomes, though more data are still needed."

The longitudinal study began in 2004. Now 18-month (and in some cases 3-year) results are in for the first 40 study participants, and some very interesting patterns are beginning to emerge. "For example, we have already begun to identify certain patterns of consistent early abnormalities related to speech," Dr. Perlman said. "That's not a big surprise, but it's something we really need to focus on. These babies appear to understand but they have difficulty expressing themselves. We've got to try to understand the reasons for that. We're trying to understand where we're falling short, and we're trying to fix it."

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Focus on Nutrition for Improving Long-Term Development In Very-Low-Birth-Weight Babies

Advances in neonatal care have yielded vast improvements in infant survival: Whereas 25 years ago babies weighing less than 1,000 g rarely survived, today the neonatal intensive care unit may be called on to care for infants weighing as little as 500 g.

According to Sudha Kashyap, MD, neonatologist and infant nutrition specialist, "although survival has been increasing appreciably for preterm, very-low-birth-weight [VLBW] infants, addressing the nutritional needs of this group has lagged behind. Yet optimizing nutrition is key to proper growth and development of fetal organ systems. In premature infants, who are still undergoing rapid cellular proliferation and development, failure to address these needs can lead to long-term physiologic deficits and irreversible functional damage."

The American Academy of Pediatrics' dietary goals for preterm infants recommend nutrition adequate to mirror the growth of a fetus of similar gestational age. Yet achieving this goal is complicated, Dr. Kashyap explained, because although enriched diets have proved effective at increasing weight gain to mimic intrauterine rates, the nutritional make-up of these regimens has led to a disproportionate increase in body fat.

Dr. Kashyap believes that proper nutrition for these infants requires specific definitions of the macronutrient content of their diets, taking into consideration not only overall weight gain but also lean body mass gain.

Over the past several years Dr. Kashyap and colleagues have been studying the effects of varying amounts of dietary protein and energy on the growth of VLBW infants. The investigators have reported that the proportion of weight gain stored as fat versus protein is a direct function of the protein-to-energy ratio of the diet. As a result, Dr. Kashyap said, "You cannot prescribe protein or energy requirements for VLBW infants separately. Protein requirements are dependent on concurrent energy intake and, conversely, energy needs must be determined in light of the protein content of the diet."

Evidence from Dr. Kashyap's studies and the work of others indicates that VLBW infants (<1,250 g) incur a deficit in protein stores during the early days and weeks of life as a result of inadequate protein availability and/or retention. Given the uncertain neurodevelopmental outcome for these small infants and the likelihood that some of this deficit may be attributable to nutritional factors, Dr. Kashyap is studying the effects of aggressive protein supplementation during the first days and weeks of life on macronutrient retention, growth rate, and neurodevelopmental performance at 18 months. Preliminary results indicate that higher protein intake in the first days and weeks of life is tolerated by these small infants and results in improved growth.

Working within the hypothesis that posits fetal origins of adult disease, which suggests that programmed changes in fetal metabolism and development due to poor nutrition in the womb predicts later health, Dr. Kashyap hopes to expand her research to determine the impact of early aggressive protein supplementation on later health status (at age 7-8 years).

"If," Dr. Kashyap predicted, "the nutritional environment of VLBW preterm infants determines later health, one might expect to see improved central nervous system function over time among preterm infants fed fortified diets compared with their nutritionally compromised counterparts."

Dr. Kashyap emphasized that breast milk has many advantages over formula, and remains the best source of nutrition for neonates. However, to better meet the nutrient requirements of VLBW infants, breast milk should be supplemented with a human milk fortifier. "Ideally with early, aggressive nutrition," she explained, "we can help preterm VLBW infants to better reach their physiologic, neurologic, and developmental potential."

"Protein requirements are dependent on concurrent energy intake and, conversely, energy needs must be determined in light of the protein content of the diet."

—Sudha Kashyap, MD

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High-Density EEG

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tioning from measurements of other things, like blood pressure or oxygen saturation. There really isn't a direct monitor of brain well-being."

Dr. Grieve uses high-density electroencephalography (EEG) to study brain function and development in infants. The 128-electrode array of the high-density device covers a larger portion of the scalp, and thus the brain, than do the 20 to 30 electrodes used in traditional EEG. With the large number of electrodes, an average of the voltages from across the scalp can be used as a reference and to provide more accurate readouts.

In addition, the multiplicity of sensors furnishes sufficient detail for sensitive spatial maps of brain function. Recent studies have shown that if electric activities in 2 regions of the brain are highly correlated over time, then these 2 regions are likely pursuing related activities. The high-density device is ideally suited to measures of brain synchrony, the sensitivity and precision of which are dependent on the number of electrodes and their spacing along the patient's scalp.

Dr. Grieve and his group measure the presence or absence of normal infant sleep state cycling; babies who do not cycle properly through sleep states often have undergone significant stress during labor, delivery, and/or the early newborn period that in turn may lead to functional problems later in life. Other brain responses, including changes in synchronous activity, can also be measured. Dr. Grieve has good reason to believe that analyses of these measurements will soon help him and his colleagues to discriminate between normal and stressed term infants, and between premature babies who will continue to develop normally and those who will encounter problems later in life.

"We're focusing on very premature infants, born after maybe 25 weeks and weighing less than 1,000 g," Dr. Grieve said. "When they get to 40 weeks of age, there appear to be differences in brain function between these babies and those who are born at around 40 weeks."

"We're focusing on very premature infants, born after ... 25 weeks and weighing less than 1,000 g."

—Philip Grieve, PhD

While research in this area is itself in its infancy, the differences in brain function found in premature babies measured by high-density EEG appear to parallel differences in brain anatomy that other researchers have found while using magnetic resonance imaging. Correlations have been established between anatomic differences defined by MRI and differences in intellect and behavior defined by a low IQ and attention deficits. The goal of Dr. Grieve's group is to establish functional EEG measures at term age that correlate with longer-term outcomes.

"We're looking backward in time through the nursery stage to understand what, if anything, has caused the deficiencies we see at term age," Dr. Grieve said. "Or, we may find that they have had those deficiencies since they were born."

Another method Dr. Grieve's group uses involves visual- and auditory-evoked potentials. The auditory method involves playing a series of tones to the baby; at some point, an odd note or set of notes is played. Even during sleep, a normal brain will demonstrate a different response to the odd note, called the "oddball" response. Although this has so far been done only in normal babies, Dr. Grieve said that, "because premature babies' brain anatomy is different, we think they may respond differently. Right now we're not exactly sure what the difference will be."

Currently, an increasing number of nurseries are using an EEG device with a restricted sensor array of 2 or 4 electrodes for the continuous monitoring of brain activity. In the future, high-density EEG may provide insight into the specific locations in the brain that should be monitored as premature babies develop. "We hope to find the regions of the brain that will give us information of a more complex and useful nature," Dr. Grieve said. "Instead of these 2-wire monitors, we may have 8- or 10-wire long-term monitoring devices placed in critical locations. Hopefully, these would give us the kind of information from which we could make crucial care decisions."

In the future, high-density EEG may provide insight into the specific locations in the brain that should be monitored as premature babies develop.

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Novel Delivery Room Procedures, Including Use of Plastic Wrap, Improve Preterm Outlook

Contrary to popular wisdom, recent research has shown that resuscitation with 100% oxygen can often lead to detrimental effects in full-term newborns, presumably because of oxygen toxicity. According to Jeffrey M. Perlman, MD, the same is true for preterm infants. "What we do now in the delivery room is put on a pulse oximeter," he said, "and that allows you to measure the saturation of oxygen in the skin. We try to maintain the saturations between 85% and 95% in accordance with the recommendations of the Neonatal Resuscitation Program. Using that approach, we have by and large lowered the starting oxygen concentration down from 100% to approximately 30%. We have seen no side effects from this approach at all."

It's not an exact science, noted Amy Presti, MD, Assistant Professor of Pediatrics, who works closely with Dr. Perlman on improving the procedures used after delivery of preterm infants. "Now that the toxicities of oxygen have been acknowledged, we are trying to assess the best oxygen level with which to start a resuscitation," she said. "We currently use 30% most of the time, and if the baby's not responding to that, we increase as needed. If the baby does well with 30% we dial it down. We've been able to bring babies down to the ICU on very minimal oxygen, and get them extubated quickly."

Another major issue for these babies, who are often born weighing less than 1,500 g, is rapid drops in body temperature, which can lead to hypothermia and significant attendant side effects. "Due to their small size and very high surface areas relative to their volume, premature babies are at a high risk for heat loss and water loss," Dr. Presti said. "The baby needs to be put into a humidified environment as soon as possible. Until then, we have to keep the baby warm and prevent heat loss. The best way to do that is to wrap the baby's body in plastic wrap while they're on a warmer, to reduce conductive and evaporative heat loss."

The idea of using plastic wrap—the type found in the kitchen—in the delivery room may sound outlandish, but both Drs. Presti and Perlman report that this technique has worked wonders. "When I first got here," Dr. Perlman said, "the mean body temperature of babies less than 1,000 g was about 34.5°C when they reached the NICU. We implemented plastic wrap and the temperature has increased to a current mean value of 36.2°C, a huge difference. The key is that the wrap is high diathermacy, which allows radiant heat from the warmer that we place them under to cross through but stops evaporative temperature losses."

Since these techniques were implemented, Dr. Perlman said his team has become as efficient as a racetrack pit crew. "When a baby is born in the delivery room," he said, "we immediately put on the plastic wrap or equivalent in about 5 seconds. We slap on a pulse oximeter immediately, and we have blenders in the delivery room so that you can blend the amount of oxygen we want to administer. As long as the heart rate is good, you're in good control." He added, "We presented our data at the Society for Pediatric Research meeting in Toronto this May, and several other institutions have indicated that they will follow our approach."

Dr. Presti said the improvement was due in great part to the use of pulse oximetry. "Now we're more efficient in everything else," she said, "and we can pay more attention to things like the baby's temperature and heat and evaporative losses. In the past, many of the smaller babies were hypothermic because we just couldn't get them down to the NICU fast enough or get them warm enough. We've now almost eliminated the hypothermia, just in this past year. Hopefully, this reduction in hypothermia will give these little babies a better transition into extra-uterine life."

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Mannequins

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Vital signs are visible and audible to the team in the room, and can also be detected by standard diagnostic equipment, allowing for highly realistic simulations unbroken by the voices of the instructors.

"We don't have to yell out what the heart rate is; it's there to be heard by auscultation and seen on the monitor," said Amy Presti, MD, Assistant Professor of Pediatrics. She has been practicing with the new mannequin, making sure she knows all the controls and is familiar with the ways it differs from previous models she has used for simulations. "We're going through multiple scenarios," she said, "just to get us used to the mannequin and using the remote and everything else, and also to see if there are any problems with it, since we're beta testers. It is really exciting to be working with something so lifelike."

Calling the model a "mannequin" or "doll" doesn't really begin to convey its complexity or the realism of working with it. Perhaps most telling is that everyone who works with it simply calls

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Mannequins

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it "the baby." According to Dr. Perlman, it has a seemingly endless array of features. "You can put intravenous lines into the belly button, and you draw back and you get what resembles blood," he said. "If you have to administer fluid through the bone, you can put a specific needle into the bone. You can change the size of the pupils. You can change the heart rate or rhythm. If the team asks for an X-ray because of a discrepancy in breath sounds, we can display a chest radiograph on a computer screen that will show a pneumothorax, and if they react appropriately then we can allow the breath sounds to improve by controlling it on the computer console. We're just getting underway with all this, but eventually it is our goal to make it so realistic that the resuscitation team will forget that it is a simulation and think they're actually in the delivery room."

"We want to make sure everybody is the best they can be at their resuscitation skills and ready for anything in the delivery room," Dr. Presti said. "We want to get everyone prepared for any kind of scenario. We do mock codes where we run a whole team through different scenarios, and it has been shown to be very effective in teaching and retention of resuscitation skills. It has also been shown to be as good as the real thing as far as getting people prepared and their adrenalin pumping." The obstetricians have a similar model for deliveries, she said, so they run mock deliveries and then hand off the "baby" to the pediatric team for simulated resuscitation.

Dr. Perlman stressed the importance of simulating the hospital environment as closely as possible. "They need to be in scrubs," he said. "We don't tell the doctors and nurses when this is going to happen; they just get called through the regular call mechanism. We've got a warmer where the baby is placed, we've got a tray with all the medications that you would use, and we've got the electronic chart where one of the team members will record what's happening. If they need blood, we'll give them red-colored fluid. If they need a medication, it's there. They have to draw it up, they have to call out the dose."

To make it fully realistic, the simulated delivery room is right next to the real ones, so teams being called in don't know until the last minute whether to expect an actual delivery or a simulated session. Following the simulation, all the team members review video of the completed scenario and critique their performance.

Is this the future of intensive training? Drs. Perlman and Presti believe it is. In fact, starting in July, physicians and nurses will be required to train and become proficient with the mannequin before being allowed to set foot in the real delivery room. The future is expensive—$15,000 for a baby doll and $250,000 for an adult—but those costs can be offset by setting up hospital training centers and conducting lessons for outside practitioners.

"Weill Cornell recently built a simulation center in a new building close to the hospital," he said, "and we'll eventually want to utilize that area as well, hopefully, and use it as a model to train people from other institutions. You can train 10 or 12 people in a day in a way they've never been trained before. When they go into a real delivery room situation, they will remember all the mistakes they made during the simulation. You never forget: 'Did I actually do that? I called out the wrong dose? Whoa!' Next time they won't make that mistake."

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NEWYORK–PRESBYTERIAN CHILDREN'S HEALTH

Advances in pediatric care from NewYork-Presbyterian's Morgan Stanley Children's Hospital and the Komansky Center for Children's Health.

Summer 2007

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