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Summer 2006

Reducing Stress In Newborns Is Research Focus

Jeffrey Perlman, MD, has studied the neurologic problems than can affect newborns for over 25 years, focusing on the mechanisms of injury that contribute to these difficulties. There is increasing experimental data and experience with adult patients and adult evidence indicating that stress adversely affects the brain, causing a reduction in the hippocampus, a region important to such functions as memory and integrative thinking.

Dr. Perlman, the Division Chief of Newborn Medicine at NewYork-Presbyterian Hospital/Weill Cornell's Komansky Center for Children's Health, added, "Long-term studies at adolescence of premature infants compared to term infants show that the hippocampus is indeed smaller." Stress can be sensory, "as in noise, the presence of bright lights, or repeated interventions to check a lab or get vitals, for example." The problem is further compounded by the disruption of sleep patterns, "since it is believed sleep is important in terms of brain plasticity." This has led Dr. Perlman to research ways for reducing stress in the neonatal ICU, which in turn has led him to experiment with the effect music has on promoting sleep, either because it is in itself soothing or because it cancels

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Collaboration Across Specialties Is Hallmark of Innovative Center for Prenatal Pediatrics

Since its creation, the Center for Prenatal Pediatrics at Morgan Stanley Children's Hospital has demonstrated that a facility uniquely dedicated to complex pregnancies can dramatically improve the way medical care is delivered. Its strength is an integration of specialty management to keep everyone focused on the same goals, reassuring patients and maximizing the likelihood of an optimal outcome. No approach is better suited to putting together a plan for a successful outcome.

"In certain high-risk pregnancies, care in specialized centers provides the most

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This issue highlights the Center for Prenatal Pediatrics at the Morgan Stanley Children's Hospital of NewYork-Presbyterian/Columbia University Medical Center, and the Division of Newborn Medicine and the Program in Medical Genetics at the Komansky Center for Children's Health, NewYork-Presbyterian/Weill Cornell Medical Center.

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www.childrensnyp.org

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FASTER Trial Demonstrates Accuracy of First-Trimester Evaluation of Down's Risk

In an innovative program to provide a systematic and streamlined approach to early diagnosis of fetal abnormalities in pregnant women, Columbia University College of Physicians and Surgeons is pioneering a strategy in which women are tested non-invasively during the first trimester to determine who might benefit most from invasive testing. The approach promises to capture more than 90% of Down syndrome cases before delivery while reserving the cost, burden, and potential morbidity of invasive diagnostic tests for those who derive the greatest benefit-to-risk.

'This protocol puts screening tests to their best use. By this approach we miss very few Down syndrome cases and provide a very high rate of reassurance to women without excessive prenatal testing.'

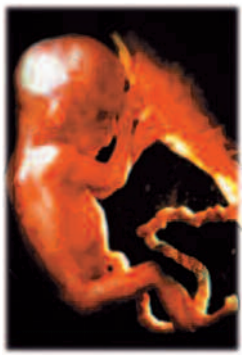
Todd Rosen, MD

The program, which will be employed at Columbia-affiliated satellite facilities, including one in New Jersey, has been fueled by results of the FASTER (First And Second Trimester Evaluation of Risk) trial, which was published in a recent issue of the *New England Journal of Medicine* (2005; 353:2001-2011). In that study, a protocol for first-trimester screening for Down syndrome was compared to a conventional second-trimester screening protocol. The study, led by Columbia investigators and funded by the National Institutes of Health and the National Institute of Child Health and Human Development, involved the participation of 38,167 pregnant women at 15 centers in the United States.

In the non-invasive first-trimester screening method used in FASTER, there were two independent steps. The first was a blood test to evaluate threshold levels of pregnancy associated plasma protein-A (PAPP-A) and free beta subunit of human chorionic gonadotropin (f, hCG), both of which are correlated with the presence of Down syndrome. The second was ultrasonography to assess nuchal translucency, a surrogate for skin thickness at the back of the neck that is a clinical marker of Down syndrome. When the two first-trimester results are combined, the FASTER study demonstrated a peak detection rate of 87% at 11 weeks' gestation. This compares favorably with the 81% detection rate achieved with conventional second-trimester screening. When both first- and second-trimester methods were used together, the detection rate was greater than 90%.

"The FASTER study demonstrates that the first-trimester screen is sensitive," reported Todd Rosen, MD. "However, we do not have to confine patients to one or the other when the two together provide the best rates of detection. The question is how to combine the tests to provide patient's with information as early as possible while maintaining the highest detection rates for Down syndrome."

Although not all women wish to establish a diagnosis of Down syndrome or other fetal anomaly in advance of delivery, the answer for the majority is to screen first to determine if they are at high enough risk to warrant chorionic villus sampling (CVS) or amniocentesis. In those women who have a very low risk after the first-trimester screen, no further screening is recommended in the Columbia program. In those women who have a very high risk, CVS is offered to make an early diagnosis. In women who are determined to have an intermediate risk, they are offered second-trimester screening to further assess their risk before offering an invasive test. Eighty-five percent of women will complete their screening in the first trimester, and only 15% will require additional bloodwork in the second trimester.



"This protocol puts screening tests to their best use. By this approach we miss very few Down syndrome cases and provide a very high rate of reassurance to women without excessive prenatal testing," Dr. Rosen said.

The FASTER study was led by Fergal D. Malone, MD, and Mary E. D'Alton, MD, the chair of the Ob/Gyn department, who has emphasized the

importance of developing non-invasive screening tools because of the risks posed by invasive tests in women at low risk of carrying a child with Down syndrome. Yet, methods to define low risk, such as specific age cut-offs, offer little reassurance to the individual patient.

As all pregnancies are at risk, "all pregnant women should have the option of early screening for Down syndrome in their first trimester," Dr. D'Alton commented. "This newer screening protocol is a powerful tool for early detection of Down syndrome, which is the most common cause of retardation."

This opinion appears to be shared by the large number of physicians and sonographers nationwide who are pursuing training in the methodology described in FASTER in order to apply it in routine patient management. Information about training can be obtained at www.ntqr.org. While Dr. D'Alton has predicted that results of the FASTER trial "will undoubtedly change national practice," one of the best methodologies for routine screening is now in place at NewYork-Presbyterian/Columbia. By employing first- and second-trimester tests judiciously, the costs, inconvenience, and risks of diagnostic tests are minimized.

"In women with a positive first-trimester screen suggesting a high risk of Down, we can go on to provide a confirmatory test right away, which can be a big advantage over waiting until the second trimester. In those with a negative test and low risk, there is no good justification for a second-trimester test, and we can avoid the small but measurable morbidity of this study," Dr. Rosen explained.

A DVD explaining the program is now in late stages of development and will be available for distribution to physicians' offices and on-line for patients wishing to understand the options for prenatal testing for fetal anomalies.

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Medical Geneticists Now Improving Neonatal Clinical Care

The last decade has seen an explosion in genetic information and advances in genetic technology. With several hundred genetic disorders now diagnosable through some form of genetic testing, the field of medical genetics brings immediate benefits to clinical care.

"Genetics is a red thread through all of medicine," said Jessica G. Davis, MD, co-director of the medical genetics program at the Komansky Center for Children's Health at NewYork-Presbyterian Hospital/Weill Cornell.

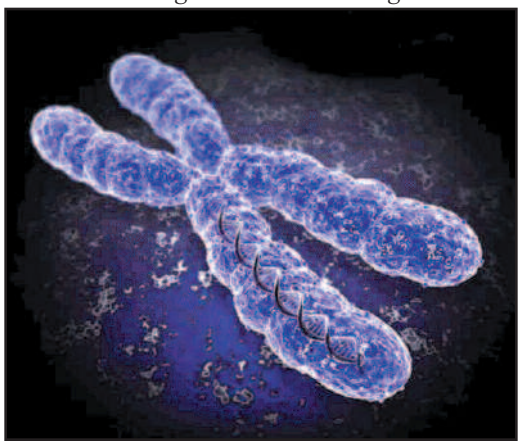
The Komansky Center's expanded medical genetics program, established in the 1980s, serves individuals at risk for genetic disease. Many people seek consultation with a medical geneticist when planning to conceive a child because of a family history of disease or because of increased risk of fetal abnormalities due perhaps to a mother's age or known exposure to chemicals or radiation. Sometimes a genetic diagnosis is suspected or diagnosed prenatally.

Working closely with Weill Cornell's in-vitro fertilization center, the Komansky Center's medical genetics team also offers counseling about preimplantation genetic diagnosis for couples undergoing assisted reproduction.

Prenatal counseling may also be referred by such diverse sources as the program on Maternal-Fetal Medicine, whose director is Frank A. Chervenak, MD, or the Center for Reproductive Medicine and Fertility, headed by Zev Rosenwaks, MD.

In some cases, said Dr. Davis, she and her colleagues step in postnatally. "Often I'm called straight to the nursery," Dr. Davis said. The center sees children born with a variety of problems, including metabolic diseases, congenital malformations (cleft lip/cleft palate, club foot), neurologic disorders, connective tissue conditions such as Marfan's syndrome, and skeletal dysplasias, to name a few. Older children as well as adults are also evaluated through this program.

The first goal of the medical geneticist is to arrive at a diagnosis and provide accurate information, including the natural history, prognosis, availability of genetic tests and recurrence risks. Equally important is providing access to the wide range of medical and social services each genetic condition requires. "Each disorder has its own set of issues," Dr. Davis said. "What's more, people have a lot of misconceptions about genetics, and they may not know anything about their condition." Allaying fears and creating a pressure-free environment in which a family can accurately assess an affected member's needs is another key element of a genetic consultation.



Chromosomal analysis can pinpoint genetic abnormalities

Individuals or their families are asked to provide as much information as possible, including any available medical records and photographs of family members with a suspected similar condition. The geneticist then constructs a family tree going back three or four generations and performs a physical exam.

"Then I try to put it all together, like a detective, identifying any missing pieces that would help in a diagnosis, coordinating any testing needed, and updating the family's physician about what's been done." She then counsels about her impressions and conclusions.

Laboratory and diagnostic testing are offered as needed. By the time she sees a family for their second appointment, she has done extensive research on the clues to the condition. One young boy, she recalled, presented with a strange symptom: a black substance accumulating on his teeth. By contacting experts in dentistry, she was able to identify this symptom as part of a specific disorder.

Being diagnosed with a genetic disorder has a major impact on patients and their families. One woman who wished to get pregnant sought consultation because of a family history of developmental delay. She arrived for her consultation with members of her extended family together with the obstetrician who had delivered her and her siblings 30 or more years ago. Dr. Davis eventually was able to identify the cause of the developmental delay within the family. "For the first time every one understood what the condition was, and everybody cried," she said. The woman and her siblings have subsequently gone on to have healthy children.

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Immaturities in Neonatal Cellular Immunity Provide Opportunities For Stem Cell Transplantation

The use of umbilical cord blood for stem cell transplantation is a major area of research at NewYork-Presbyterian Hospital/ Columbia University Medical Center. Cutting-edge work there has examined the regulation of cord blood immunity and how it affects the use of cord blood for transplantation. This research also has relevance on the basic understanding of neonatal immunity.

"Our research has identified unique and profound immaturities in neonatal cellular immunity that predispose the newborn to overwhelming and potentially lethal infections," explained Mitchell S. Cairo, MD. Research by Dr. Cairo and colleagues has focused on subpopulations of cellular immunity, including T cells, dendritic cells, natural killer cells, monocytes, and regulatory T cells.

The regulation and function of T cells depends on immunoregulatory proteins called interleukins—most critically, interleukin-12, -15, and -18. "Our group has demonstrated that neonatal immune cells are incapable of producing normal amounts of interleukin-12, -15 and -18 compared to older children or adults with similar populations of immune cells," Dr. Cairo said. "Furthermore, the genes associated with each of these three interleukins are also dysregulated and are in part responsible for the decrease in the production of each of these three proteins. This predisposes the neonate to an immaturity in their T cell immunity and increases their risk of intrauterine and postpartum infections."

"Studies in the lab have demonstrated that when we add increased amounts of each of these interleukins alone or in combination, we can increase neonatal T cell function to levels that are normal in adults and older children," Dr. Cairo said. These results give hope to the idea that the treatment of a subset of serious neonatal infections by administration of interleukins may be possible.

Dr. Cairo and colleagues have also found that regulatory or suppressor T cells regulate normal T cell immunity, and have demonstrated in the laboratory that an increased amount of regulatory T cells in activated cord blood suppresses normal T cell immune response. "These findings have profound implications on normal regulatory responses in cord blood T cells and potentially predispose the neonate to further increased risks of infection."

NewYork-Presbyterian/Columbia has been a pioneer in the use of umbilical cord blood as a stem cell source, which has been used for a variety of childhood diseases, including leukemias, lymphomas, aplastic anemia, immune deficiencies, and sickle cell disease. The research in neonatal cellular immunity has identified a number of weaknesses in the cord blood cellular immune system that provide guidance on how best to use cord blood for stem cell transplantation.

"While these developmental immunodeficiencies in cord blood T cell immunity predispose the neonate to increased risk of serious infection, they also provide a unique opportunity to use these stem cells in a *positive* way as a source for stem cell transplantation," Dr. Cairo said. "These immunodeficiencies provide an opportunity to use umbilical cord blood that is not genetically matched to the recipient. The major limitation in doing a stem cell transplant is the prevention of graft-versus-host disease. The significant decrease in the production of these interleukin proteins and the increased function and number of regulatory T cells allow the use of umbilical cord blood in mismatched donor-recipient pairs, with no increased risk of serious graft-versus-host disease."

Dr. Cairo's lab is also investigating the possibility of taking subsets of cord blood immune cells, including T cells, natural killer cells, and regulatory T cells, and giving them after a cord blood transplant in order to amplify immune response, "either specifically directed against the child's cancer or to prevent or treat graft-versus-host disease."

'While these developmental immunodeficiencies in cord blood T cell immunity predispose the neonate to increased risk of serious infection, they also provide a unique opportunity to use these stem cells in a positive way as a source for stem cell transplantation.'

Mitchell S. Cairo, MD

Umbilical cord blood collection.

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Prenatal

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comprehensive approach, from prenatal diagnosis to neonatal management," said Lynn Simpson, MD, Director of the Center, a NewYork-Presbyterian Hospital facility. "These are complex pregnancies managed best when there is a strategy in place to keep specialist care coordinated for both the mother and her baby, who may have a significant birth defect. I don't think that this level of care could be achieved in any other way."

The management of each case proceeds rapidly after the first contact with the Center. A clinical care coordinator gathers the history and patient data to set up a preliminary work-up that will provide or confirm a diagnosis and define therapeutic options. The patient will leave the facility with answers and information about the likely route of care through the prenatal period, delivery, and newborn period. The goal is not only to provide a plan of management for prenatally diagnosed anomalies, but also to provide reassurance to the mother and her family.

"Knowing what is ahead can make all the difference. We put the puzzle pieces together when everyone—the physicians and patients—can calmly evaluate the options and agree on what comes next," Dr. Simpson explained. "The patient has an opportunity to become fully informed by the experts who specialize in the relevant issues. We find the patients extremely grateful."

Not all patients who come to the Center for an evaluation return for delivery. Sometimes the diagnostic work-up determines that the risks of an adverse outcome are low. Whether they return or not, referring physicians are kept in the loop about all aspects of the patient's diagnosis and medical needs. A system has been developed specifically to ensure that reports are circulated to all those involved in care, including staff at the Center and every healthcare professional with an interest in the patient's outcome.

"We think it is important to maintain communication with physicians who will continue to be involved in the patient's care after they leave the Center. We prepare a package of material on each case to provide to referring physicians, and we typically follow up with a phone call. This is a system that we put in place at the beginning, which ultimately provides the best care for patients returning to their referring physicians," Dr. Simpson said.

> 'From the beginning, our goal was to pioneer a better way of taking care of complicated pregnancies.'
>
> *Lynn Simpson, MD*

The degree of coordination of care may be unmatched anywhere. If multiple specialists are involved, the clinical care coordinator organizes appointments so that the patient and family members can complete all the appointments in a single visit to the Center. When appropriate, this includes geneticists to counsel about the hereditary nature of the condition and risks for future pregnancies as well as various pediatric specialists that may become involved with care of the child after delivery.

While the organization of the Center is a key strength, it is also important to emphasize that patients benefit from the physicians who are defining today's standards of care. The Center for Prenatal Pediatrics draws on the deep roster of leading specialists working at NewYork-Presbyterian/Columbia, where several research initiatives are ongoing.

The staff has a regularly scheduled meeting to discuss cases, providing a systematic and consensus approach. "Everyone affiliated with the Center is invited to the meetings, which are important to fostering a collaborative approach. Creating a time to discuss cases and work together is part of what makes the management plan fairly seamless for the patient," Dr. Simpson observed. "The Board of Directors of the Center includes representatives from every specialty involved in managing complex pregnancies, including maternal–fetal medicine specialists, geneticists, pediatric surgeons, pediatric subspecialists such as cardiologists, and neonatologists."

There is no complication or fetal anomaly that the Center is not prepared to handle. Patients have access to still-emerging interventions performed in few hospitals around the world, including in utero procedures and therapies. While other hospitals attempt to provide this level of care, few will be able to provide the one-stop opportunity for the management of high-risk pregnancies, particularly for those with rare complications. The strength of the program is further fostered by the proximity of the new Carmen and John Thain Labor and Delivery Unit, located on the top floor of Morgan Stanley Children's Hospital.

"From the beginning, our goal was to pioneer a better way of taking care of complicated pregnancies. We want to provide the best of care, and I think this is what we are achieving," Dr. Simpson reported.

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Specialized Surgical Expertise Is Vital Part of Center's Fully Integrated Management Approach

At the Center for Prenatal Pediatrics, the surgical program is integrated into the full management strategy from the outset, often months or even years before a planned procedure. The Center promotes education, planning, and collaboration among the obstetrician, the maternal–fetal medicine physician, the neonatologist, the pediatric surgeon, and any other members of the team assembled to produce a healthy child.

"The Center provides an opportunity to gather under one roof all of the clinical expertise needed to improve the likelihood of a good outcome in a complicated pregnancy," said Charles J.H. Stolar, MD, Chief of Pediatric Surgery, who was an important force behind the creation of the Center in 2004. "This comprehensive, multidisciplinary, integrated approach is unique in the New York region. It allows the team to identify potential problems long in advance of delivery and enlist all the skills that will be needed in difficult situations. Most importantly, it allows us to give parents a comprehensive education regarding the challenges they are facing so they can make the most informed decisions possible."

Integration of care is the critical concept and founding principle of the Center. While similar centers have skilled physicians, the mission of the Center for Prenatal Pediatrics has been to provide a single destination where potential complications are not divided among specialists, but managed as part of a comprehensive plan. According to Dr. Stolar, the Center is among the first of a very few facilities for complicated pregnancies that is designed to address the needs of both the mother and the child in one building. The goal is seamless care from initial counseling to discharge and beyond.

"Because the recently opened Morgan Stanley Children's Hospital is fully integrated with the Carmen and John Thane Labor and Delivery Unit as well as existing peripartum services, we offer a physical plant that is just as fully integrated as the clinical program," Dr. Stolar said. "This is an approach that makes a lot of sense. We think it is the best way to achieve a good outcome in difficult patients. The documented growth and success of the Center over the last 2 years speaks to the wisdom of its development. I am not sure any other women's and children's center is better equipped or staffed to optimize the likelihood of a healthy baby."

Surgery can be considered before, during, or after delivery.

Preplanning is the hallmark of the Center. Its aim is to produce a calm delivery room where well-informed parents are part of a team engaged in a common goal. Surgeons are not on the periphery at any stage of management, particularly during deliberation of treatment options. Patients referred to the Center for Prenatal Pediatrics are scheduled to consult with multiple specialists, including surgeons, often at a single visit. Dr. Stolar added, "There is a very deep talent pool from which to draw" when specific surgical skills are needed, such as procedures involving the cardiac, neurologic, orthopedic, or urologic systems.

"Columbia [University Medical Center] does not just have accomplished specialists—many are leaders in their fields," Dr. Stolar said. "In complex cases, we are lucky to be able to access these unique skills. There may be no center in the world better positioned to handle these challenging situations."

Depending on the circumstances, surgery can be considered before, during, or after delivery. Currently, indications for intrauterine surgery remain very limited and largely investigational, but Dr. Stolar reported that the surgeons at the Center have been innovators in the use of surgical approach at the time of delivery called EXIT (EXtra-uterine IntraparTum). EXIT permits surgery to be performed on children who remain on maternal support for vital functions.

Dr. Stolar recounted one recent case in which a large tumor was completely obstructing the airway of the newborn. "The tumor was diagnosed at 16 weeks of gestation, and it produced some challenges for the obstetrician and maternal-fetal medicine specialist, Dr. Todd Rosen, to bring the pregnancy to term. At the elective C-section, the placenta was left intact, while the child's head was exposed so that a tracheostomy could be performed to get control of the airway. The delivery was then completed and a procedure was initiated to remove the tumor," Dr. Stolar reported. The 17-hour procedure was successful, "and the baby is fine and destined to develop into a normally difficult adolescent."

Dr. Stolar reported that many complicated pregnancies are referred by community obstetricians, although parents can contact the Center by dialing 1-877-THE-BABY. He noted that the Center strives to provide a collaborative relationship with the referring physician, who is invited to participate in the antenatal discussion and is kept informed by the Center's staff.

"In our experience, it has been very much a two-way street. The community physician is reassured by having our facility available to allow them to get help for the most difficult cases, while clearly we depend on the referring physicians in achieving good delivery of care once the mother and child leave our center," Dr. Stolar reported.

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Newborn Stress

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out background noise.

The Komansky Center has created a developmental room where the intensity of lighting is adjusted depending upon the time of day, and speaker systems have been installed to pipe in relaxing music. Mozart (since it has been studied in other populations) and Miles Davis, among others, have been used to reduce the newborns' stress. "Interestingly enough, it also calms the parents down," Dr. Perlman added.

Dr. Perlman has also borrowed a technique a colleague of his at Stanford successfully employed, which involves the use of simulation centers to mimic real-time situations in the delivery room. "We are training providers to respond to resuscitation events—for example, use of CPR, placement of a breathing tube, etc.—by creating virtual situations, videotaping them, and then afterwards reviewing them with the providers." For instance, the heart rate on a simulated neonate can be decreased or increased to create a realistic environment and then "normalized" as the emergency is resolved. "All of these efforts are related to the great attention to detail we place at the time of delivery."

As part of their research efforts, Dr. Perlman and colleagues are currently expanding their follow-up program to be more longitudinal than most pediatric programs, which follow babies through 18 months. Dr. Perlman plans "to take them longitudinally through adolescence and beyond—particularly those born weighing less than 2 lbs or so—because you may think things are going well, but, for example, if a child can't talk properly, we need to know that."

"To summarize, we are trying to integrate clinical conditions and the basic science together with concern for the family so that we can provide a more comprehensive overall approach."

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Neonatal care includes an extensive newborn screening program that is dictated by the New York State Department of Health and administered by Jacqueline T. Gomez, RN, for NewYork-Presbyterian Hospital. One blood test performed at discharge is sent to the state's health department. "Both negative and presumptive positive test results come back to us," said Ms. Gomez, who then organizes follow-up care, "either through the child's pediatrician or designated physicians covering such areas as hemoglobinopathy and genetic or endocrine disorders." The program started simply back in the 1960s, but has grown as new after-birth screens for genetic, endocrine and infectious diseases have become available—at last count, 44. "The state expanded their panel greatly at the end of 2005, becoming one of the most comprehensive in the country."

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