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Stem Cells Hold Promise for Less Invasive Treatment

Treatments for pediatric cancers and autoimmune diseases are frequently traumatic, both physically and psychologically, to children. Chemotherapy, radiation, and bone marrow transplants all have side effects that can seriously disrupt a child's life. At The Pediatric Blood and Marrow Transplantation Program at the Morgan Stanley Children's Hospital of NewYork-Presbyterian, "a comprehensive program" is being developed that relies on stem cell transplants, promising less invasive therapy and milder side effects, according to director Mitchell Cairo, MD.

Reduced-intensity stem cell transplants for non-malignant diseases and a specialized program for pediatric cancers are the two main areas of treatment at the center. Physicians are able to treat autoimmune diseases and specific pediatric cancers, especially neuroblastoma, lymphoma, and leukemia.

To attack cancer cells, Dr. Cairo's team relies on the graft-versus-tumor effect, whereby grafted cells recognize tumorous cells as foreign and attack them. This process, dubbed adoptive cellular immunotherapy, relies on genetically engineering cells "so that

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Pediatric Heart Transplantation Center Makes Strides in Outcomes

By applying new surgical techniques and expanding the donor pool, Morgan Stanley Children's Hospital of NewYork-Presbyterian/ Columbia University Medical Center continues to make strides in pediatric heart transplantation. "Last year we performed more pediatric heart transplants than were performed by any other institution in the United States," noted Linda Addonizio, MD. "And we accept cases that many other institutions won't. The most notable of these are children with very high pulmonary vascular resistance. We were also the first hospital to perform heart transplants in an effective, single-lung physiology in children and also in adults."

Surgeons at Morgan Stanley Children's Hospital of NewYork-Presbyterian are using VADs to stabilize children pretransplantation.

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This issue highlights the Pediatric Transplantation Center of the Morgan Stanley Children's Hospital and the Komansky Center for Children's Health, both a part of NewYork-Presbyterian. The Center—an in- and out-patient center for treating children with solid organ failure—integrates medical and surgical pediatric transplant subspecialties, thereby providing focused care and dedicated resources for both patients and their families.

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Medical-Surgical Expertise Crucial To Liver Transplant Program Success

Liver transplantation in children is becoming an ever-safer procedure that is helping many young patients live normal healthy lives. A successful pediatric liver transplantation program requires an experienced staff of hepatologists, surgical excellence, and impeccable control of immunosuppression after transplantation—all of which come together at the Morgan Stanley Children's Hospital of NewYork-Presbyterian's Center for Liver Disease and Transplantation (CLDT), said Steven J. Lobritto, MD. "The beauty of this program is the med–surg marriage—patients will see both every time they come."

One of the most common causes for liver failure in children is biliary atresia, in which the ducts that drain bile from the infant's liver become blocked. The stagnant bile can quickly begin to damage the liver: "Instead of being a tube, the bile duct becomes a rod," Dr. Lobritto explained. The condition can sometimes be corrected by a surgical intervention known as a Kasai procedure, but most kids with biliary atresia will ultimately still require a liver transplant. Another major contributor to liver disease in children is intestinal disease with associated liver injury. The primary aim of the team is to manage these children's condition with medication and balanced nutritional support in order to permit organ recovery or adaptation, said Dr. Lobritto. "A lot of kids lose their liver unnecessarily because their small intestine is damaged," said Dr. Lobritto. For many patients, "if you can preserve their liver function, maybe they'll only need a small bowel transplant or in some cases recover without transplant at all."

The Center conducts about 20 pediatric liver transplants per year. "Although the volume is moderate, the global expertise of the team makes it an extremely successful program," said Dr. Lobritto, who also works with adult patients with liver failure. "One of my nurse practitioners has been caring for transplant patients for about 18 years."

As many as half of children at the CLDT who require a liver transplant receive it from a living donor—a technique pioneered in Chicago in the late 1980s by Jean C. Emond, MD, now the Clinical Vice Chair of Transplantation, and currently used extensively nationwide. Since the liver is one of a number of organs in the body with the ability to regenerate itself, the donor's liver will grow back to nearly its original size in a matter of weeks. Because of the wealth of the CLDT's experience, "we do a lot of things that other centers can't or don't do," said Dr. Lobritto. For example, in selected recipients surgeons are able to perform "bloodless" pediatric liver transplants to accommodate Jehovah's Witness patients, whose religious beliefs prevent them from receiving transfusions.

After the transplant, the focus is on getting patients out of intensive care and onto a stable immunosuppressive regimen to prevent organ rejection. Nutritional issues that kids face after transplantation are different from those they faced pre-transplant and must also be managed. Before the procedure, many kids have a very hard time gaining weight, but afterwards, they are instead at risk for becoming obese if adjustments aren't made to their diet, said Dr. Lobritto.

The program's clinical work is closely intertwined with an extensive clinical trials program. Relatively few advances have been made in the surgical technique itself, said Dr. Lobritto, who noted that the real innovation is going to come from how to manage these diseases and improvements in immunosuppression." The Center has several ongoing trials aimed at defining doses and combinations specific to pediatric patients. "Kids are not just little adults," said Dr. Lobritto, and many immunosuppressants as well as other drugs that are approved for adults are not well studied in children.

Another important area of research focuses on pediatric treatment strategies for hepatitis B and C. "The liver injury in pediatric patients with hep B and C is not so extensive," said Dr. Lobritto, "but left untreated can progress to adults with huge problems." Finding more consistent ways for managing the disease in childhood would prevent a lot of health problems down the line. "Any patient I care for with hepatitis I prefer to treat on a clinical trial, so we can help the patient at the same time as we learn something new," he said.

The CLDT is also participating in a centralized long-term trial of over 1000 patients in the U.S. and Canada that aims to characterize the global experience of pediatric liver transplant patients. The trial, which began a decade ago, tracks kids' disease progression, techniques used for their transplants, and a number of post-transplant factors such as recovery time, acute and chronic complications, and drug therapy regimens. The idea, said Dr. Lobritto, is to pool all this information and to begin to build a coherent picture of what works best.

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they will be very specific about adapting to a patient's cancer." Although the knowledge and technology to do this have been explored in many research institutions, Dr. Cairo's center is one of the first to apply them to children.

Similarly, the graft-versus-autoimmune effect, whereby grafted cells attack autoimmune cells, is capitalized upon to create new treatments for autoimmune diseases such as lupus or arthritis. Stem cells transplanted from a donor attack the autoimmune system and prevent it from attacking the body itself.

The first step in these treatments is to collect stem cells. Depending on the disease, either an autologous or allogeneic transplant is performed. Of particular promise for collecting stem cells is the blood found in the placenta and the umbilical cord of a newly-delivered child: rich in stem cells, it can be collected, screened for diseases, and frozen for later use.

Once stem cells have been collected and are infused into the patient's blood stream through a central catheter, they instinctively migrate to the bone marrow by a process known as homing. Compared to bone marrow transplants, this process is non-invasive and much less traumatic.

As the cells are being transplanted, chemotherapy and immune therapy are used to deplete the patient's bone marrow and allow the grafted cells to replace it. An especially promising technique pioneered by Dr. Cairo's laboratory is the use of non-ablative or "mini" transplants, in which chemotherapy and immune therapy are used at minimal dosages, reducing dangerous side effects such as toxicity and growth failure. Non-ablative transplantation is used to treat autoimmune diseases and leukemias.

For other cancers, however, more aggressive therapy must be used, relying on the graft-versus-tumor effect. First, a fully ablating autologous transplantation is performed, with intensive chemotherapy, immune therapy and sometimes radiation, in order to reduce the cancer to minimal levels. A second, allogeneic transplantation is later performed to destroy remaining diseased cells.

While continuing to develop these therapies, Dr. Cairo's center is researching two areas he considers "hot." One is targeted therapy: the use of antibodies with radioactive

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Rehab and Transplant Best Options For Ped Small Bowel Disorders

Small bowel disorders can devastate pediatric patients—robbing them of nutrition, limiting their neural development, leading to infections, and damaging their livers. The answer, say specialists at the Morgan Stanley Children's Hospital of NewYork-Presbyterian, lies in an innovative program that combines intestinal rehabilitation with, if necessary, small bowel transplantation.

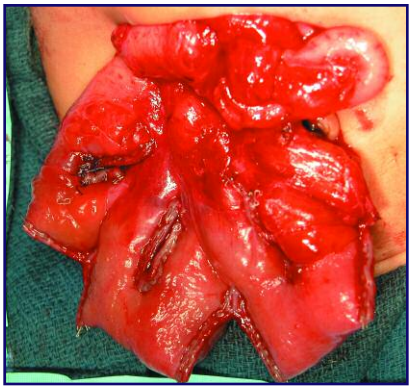
"One of the big pushes in the small intestine transplant field is to get involved with these kids early so that we can manage them with all our expertise," said Steven Lobritto, MD. "We'd like not to get them as late referrals when their options are already really limited and all we can offer them is transplantation. We want to partner with their physicians and lend our expertise in how to manage them. Then, if the kids get into trouble, we're their safety net should a transplant be necessary."

The intestinal rehabilitation team, which in addition to Dr. Lobritto includes surgical leader Dr. Dominique Jan and Drs. Lesley J. Smith and Robert A. Cowles, first works to optimize residual gut function by providing adequate nutrition and using medications to regulate motility and control acid output. They also employ surgical techniques to stop bleeding, to reconnect the colon and small intestine, to replace a damaged liver with a transplant, or to lengthen an intestine that has been shortened by previous surgery or disease. The preferred method at the Hospital for bowel lengthening is the novel STEP (serial transverse enteroplasty) procedure, Dr. Lobritto noted: "Basically, it turns a highway into Lombard Street by cutting the bowel from the side in a zig-zag pattern. You change a straight, dilated bowel into a tapered zig-zag bowel with twice the length."

Other treatments include physical therapy to overcome delayed walking or to teach swallowing. "A lot of these kids have never eaten so they have aversions to food. Giving someone food by mouth stimulates a number of hormonal reactions that favor adaptation," said Dr. Lobritto.

Typically, pediatric patients arrive with either a shortened bowel (commonly caused by necrotizing enterocolitis or intestinal volvulus) or one of several bowel disorders, including Tufting syndrome or intestinal pseudo-obstruction. They often rely on total parenteral nutrition to survive. Eventually, it becomes difficult to deliver nutrition, explained Dr. Lobritto: "You don't have an endless number of blood vessels that you can put I.V. lines into. When kids start to run out of those access points, it's time to start thinking about doing a transplant."

Pediatric patients, usually in the neonatal period, are too small to receive a bowel from an adult donor. Instead, they must wait an average of one year for an appropriate pediatric donor. Then, the transplantation must be scheduled for a time when the patient does not suffer from a systemic infection.



The STEP procedure elongates the bowel by a series of partial-width cuts.

The primary challenge for small bowel transplant recipients, according to Dr. Lobritto, is not to merely survive surgery but to avoid long-term risks. Physicians must be alert to cytomegalovirus infection or exposure to the Epstein-Barr virus, which can lead to a high risk of post-transplant lymphoproliferative disorder. Immunosuppressants, while helping prevent rejection, also impart their own side effects. "We're constantly looking for a better type of immunosuppressant. What revolutionized liver transplants was when cyclosporin and tacrolimus came around and the medicines got better. So we're looking at how we can manipulate the immune system in ways to benefit the patient, how we can minimize side effects of the medications by using combination protocols, and also how we can treat early viral complications," he said.

Dr. Lobritto is confident that productive research is on the horizon. "A lot of questions can't be answered by doing ten cases a year. The statistics won't have significance with these small numbers," he said. Each of the 1,200 small bowel transplants performed worldwide have been recorded in a registry; as the Morgan Stanley Children's Hospital expands its program, he hopes to pool data with leading institutions within the U.S. and internationally for clinical trials. "We have extensive clinical trial experience from our liver transplant program in pharmacokinetic, pharmacodynamic, multiple drug, and viral treatment studies.

"Five years from now," he predicted, "what we're doing now is going to seem like alchemy."

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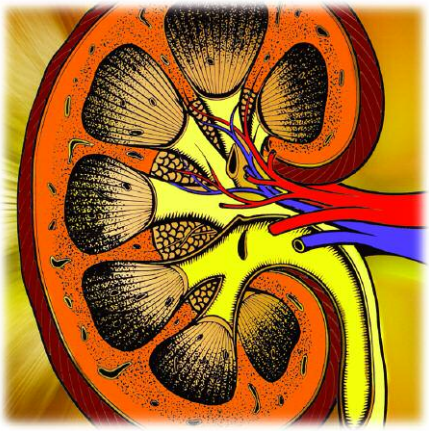
Kidney Transplantation Buys Time For Those With Pediatric Renal Disease

For most children with end-stage kidney failure, a kidney transplant is the best option for treatment that can help them achieve a normal quality of life. Renal disease in kids has very different causes from those in adults. Most kids require transplants because they are born with structural abnormalities in their kidneys, bladder, or urinary tract, explained Valerie L. Johnson, MD, PhD. Older children present with diseases such as hemolytic uremic syndrome, which is often caused by an infection in the digestive system, and focal and segmental glomerular sclerosis, in which scar tissue forms in the kidneys.

Growth is an especially important factor in pediatric kidney transplantation, Dr. Johnson said, and this is particularly tough in newborn patients. A child must achieve certain growth milestones before being able to receive a transplant, which can be performed from about the age of two. In addition to the constant treatments they receive, their illness can cause a taste in the mouth than can make certain foods unpalatable. "Kidney failure causes kids not to want to eat well—often they are anorexic," she said. A research project is currently under way to study exactly how chronic renal insufficiency affects the rate at which kids grow. Meanwhile, a major focus of any transplantation program is keeping kids healthy through dialysis and maintaining their growth through nutritional management until they are old enough and large enough to undergo the procedure.

The Komansky Center's pediatric kidney transplant program is part of the Rogosin Institute, a non-profit treatment and research center for kidney disease. The renal transplantation program is one of the oldest in the country, conducting the first kidney transplant in the New York City area in 1963. It now conducts about ten pediatric kidney transplants per year, with transplant outcomes well above the national average. Because adult donor kidneys have better long-term survival than those from cadaveric child donors, about 75% of the center's pediatric kidney transplants come from living donors—usually the parents, said Dr. Johnson. Unless their blood type is incompatible, parents are almost always a good match. But in some cases, the medical risks may be too high. "We have a little girl whose mom is healthy but has an extremely strong history of diabetes," said Dr. Johnson, explaining why the team decided that she should not provide the kidney.



Advances in surgical technique over the past decade have made the procedure much simpler. Since 1998, almost all the surgeries at NewYork-Presbyterian Hospital to remove kidneys from the donor are done using a new minimally invasive technique called laparoscopic nephrectomy, greatly speeding recovery.

Meticulous follow-up treatment is crucial for children who receive kidney transplants, Dr. Johnson stressed. Many kids continue to have bladder problems even after their transplant, and her team works closely with the urology department to monitor their bladder function and detect any problems. "None of the other centers in the city has the level of sophistication of our urodynamic program," she said.

Chronic rejection of the organ also remains a problem. "Unfortunately, many of our children develop problems because they don't take their medicine," she said. "But no matter how good one is with medicine, the organ is partly not you, so there will always be some element of rejection over time." Although the program has an excellent five-year survival rate of over 80%, "you have to look at a pediatric patient probably needing another transplant down the line."

The pediatric kidney transplant team now keeps kids' post-transplant medication steroid-free, a technique that many other centers nationwide are beginning to adopt.

Much of the program's ongoing clinical research focuses on improving techniques for immunosuppression, with a particular area of interest being regimens that do not use steroids. In the past, steroids have been central to immunosuppressive therapy, but they can also put a heavy damper on kids' growth as well as lead to hypertension. The pediatric kidney transplant team now keeps kids' post-transplant medication steroid-free, said Dr. Johnson—a technique that many other centers nationwide are beginning to adopt.

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Lung Transplantation Team Readies Children's Program

The NewYork-Presbyterian Transplant Institute conducted a major reorganization of its adult lung transplantation program five years ago. Since then, the program has almost doubled its volume to over 40 transplants per year and has maintained a one-year survival rate of over 90%—one of the highest nationwide. With these changes in place, the Institute has now laid the groundwork for a lung transplant program for children.

"Lung transplantation is difficult and really needs a dedicated program and team to get these kids through the procedure," said Joshua R. Sonett, MD, the program's surgical director, and few hospitals in the country have such programs in place. Even at the largest centers, surgeons' experience with the procedure in pediatric patients is necessarily more limited. Fortunately, with the recent addition of a pulmonologist to direct the pediatric lung program, the Center is ready to accept young patients in the coming months, said Dr. Sonett. "The pieces of the program are coming together."

Many children who require lung transplants suffer from cystic fibrosis, the inherited disease in which thick mucus forms and clogs up the lungs. Others suffer from lung diseases, such as pulmonary fibrosis, or congenital heart diseases, such as Eisenmenger's syndrome, which can also affect the lungs. Although in the past kids with cystic fibrosis generally did not survive their teens, advances in techniques, new drugs for clearing or thinning accumulated mucus, novel antibiotics to prevent lung infections, and other medical innovations are allowing these patients to live fuller lives well into adulthood.

Surgical transplantation is just one part of treating these patients, stressed Dr. Sonett, and the key to a successful transplant program is the ability to provide a wide array of integrated clinical services, from psychiatric counseling to medical management to stave off the need for a new set of lungs. One of the closest partners of the Institute's pediatric lung transplant program is its cystic fibrosis center, the largest in the Northeast and ranked one of the best in the country. "In fact, the cystic fibrosis program is so good at managing patients that it's rare for any patient who has been through our program to need a lung transplant as a child," said Dr. Sonett.

> "Lung transplantation is difficult and really needs a dedicated program and team to get these kids through the procedure."
>
> — *Joshua R. Sonett, MD*

Children who ultimately do require lung transplants face a difficult road ahead. In addition to a regimen of immunosuppressive medication to prevent the rejection of their new lungs, these children will require frequent lung function monitoring using bronchoscopy. Lungs are the only organs open to air, making them particularly susceptible to infection—which can be deadly for kids taking immunosuppressants, noted Dr. Sonett. "This is especially important for the pediatric population, who will have smaller airways than adults," said Dr. Sonett. "We have a very low threshold to do bronchoscopy in these kids, to try to differentiate between infection and organ rejection." The Center recently committed to building a new bronchoscopy suite dedicated to the memory of cystic fibrosis patient Laura Rothenberg, who received national acclaim for her two-year audio diary chronicling her experiences of living with the disease for National Public Radio before her death at age 22 in 2003. It will open in spring 2006.

Alongside its program in clinical care for transplant patients, the Institute also conducts numerous clinical trials to investigate new techniques in immunosuppression. Even under ideal conditions, every lung transplant will have episodes of rejection, particularly in the first year, and up to half of all lung transplants will begin to fail within five years, Dr. Sonett explained. Another key research area soon to get off the ground is the study of ex-vivo lung perfusion—a system for supporting donor lungs outside the body to extending the length of time during which they remain viable. "When any person dies, the lungs are often damaged," said Dr. Sonett. "Only 20% of donors in general are acceptable transplants." With kids, the problem of availability is further compounded because the organs must be matched for size, and the ability to transplant organs from donors to recipients over long distances could mean the difference between life and death.

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The mortality rate of pediatric patients awaiting transplantation at the Hospital was 5% to 6% in 2004, compared to about 20% nationwide, according to Jonathan M. Chen, MD. One explanation for this improved survival rate may be that Hospital physicians are aggressive in getting young children into surgery as soon as possible. A shorter waiting time often means a lower mortality.

Once children have undergone heart transplant, evaluating long-term survival is crucial. Today, according to Dr. Chen, many patients have survived 20 years with palliative surgery, and some have undergone an additional 4 or 5 heart operations. Many researchers question how well these patients fare when they are reconstructed or need new transplants. Dr. Chen and his colleagues evaluated data (*Ann Thorac Surg* 2004;78: 1352-1361) that showed congenital heart disease patients who underwent transplant surgery years later had outcomes similar to those with cardiomyopathy. This may be due to technical improvements such as the ability to reconstruct pulmonary arteries and route blood back to where it should be flowing.

Morgan Stanley Children's Hospital is the first institution in the United States to perform ABO-incompatible heart transplants (meaning that donors and recipients have different blood types) in pediatric patients. Dr. Chen noted that when surgeons follow protocol, survival is the same as in children who receive ABO-compatible hearts (*N Engl J Med* 2001;344:793-800).

Prior to transplant surgery, physicians exchange the patient's blood, washing away any preformed antibodies that may be present. The patient also receives immunosuppressant drugs. "We almost trick the body into not making antibodies against the incompatible blood type," said Dr. Addonizio. "This doesn't mean that they won't experience rejection, but they won't make antibodies against that blood group."

> "We accept cases that many other institutions won't. The most notable of these are children with very high pulmonary vascular resistance."
>
> — *Linda Addonizio, MD*

According to Dr. Chen, an evolving area of surgery is the use of ventricular assistance devices (VADs) in pediatric pretransplant patients. Currently, surgeons at the Hospital use VADs in 1 or 2 patients a year. Dr. Chen envisions that 5 years from now, surgeons will be using the procedure in 25 to 50 children annually. VADs support the heart and stabilize the pretransplant patient, a process called "bridging." This becomes important as younger patients "will wait quite a while before surgeons can locate a heart that is the right size," he explained.

Overall, the outlook for pediatric transplant patients has improved in the last 20 years. With Dr. Addonizio as co-founder, the Morgan Stanley Children's Hospital Pediatric Cardiac Transplant Program has been at the forefront in the management of children after heart transplantation. The Hospital also has a leadership role in the Pediatric Heart Transplant Study Group, which consists of 23 institutions across North America and is responsible for a significant proportion of multi-institutional research related to pediatric heart transplantation today. The Hospital plans to expand its organ transplant initiative in pediatric patients with the creation of the Morgan Stanley Children's Hospital Pediatric Transplantation Center, which will house transplant teams for all types of solid organs, as well as specialists in immunosuppression, rehabilitation, and neurocognitive development.

"There's no reason why we can't be the biggest transplant center for children in the United States," said Dr. Chen. "We're almost there."

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tags that attach only to cancerous cells, allowing the diseased cells to be specifically targeted. Also on the horizon is research into how natural killer cells, the most aggressive lymphocytes in the immune system, may be harnessed to attack specific cancers. This research is focused on better understanding the biology of these cells and how they can be isolated and expanded to attack specific cells. With protocols for almost any type of pediatric transplant and several fronts for further research, Dr. Cairo hopes that his laboratory will be able to develop treatments that can, in the future, be applied to larger numbers of patients in new ways. "The research in children today will touch the lives of the children with cancer and lethal blood disorders in the future," he said.

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Additions of Diacovo and Presti Boost Neonatology Acumen

The Morgan Stanley Children's Hospital of NewYork-Presbyterian has recruited Thomas G. Diacovo, MD, formerly of Washington University School of Medicine in St. Louis, as Director of Neonatal-Perinatal Research at the Hospital and as Assistant Professor of Pediatrics at Columbia University College of Physicians and Surgeons.

"Dr. Diacovo is trained in pediatrics and neonatal-perinatal medicine, and had several years of additional training in research laboratories at Harvard University. We're very excited to have him as a member of the Division," said Richard A. Polin, MD.

Diacovo's research focuses on cell trafficking, much of it aimed at understanding the von Willebrand factor (vWF), the plasma protein that allows platelets to aggregate on injured vascular endothelium. In his new position, Diacovo will have both research and clinical responsibilities. He will dedicate the majority of his time to his laboratory, where he will train graduate students and fellows, and also serve as an attending physician.

Diacovo's research focuses on cell trafficking, much of it aimed at understanding the von Willebrand factor.

Also, the staff of the Komansky Center at Weill Cornell has welcomed a new neonatologist to its faculty. Amy Presti, MD, who received her medical degree in 1999 from Georgetown University School of Medicine and has just finished her fellowship at Columbia University Medical Center, joined in July as Assistant Professor of Pediatrics.

The focus of Presti's research is clinical studies in neonatal resuscitation. This includes the investigation of how babies are resuscitated in hospital settings and the elements of its education in a medical institution. Her responsibilities at the Komansky Center will be divided 50/50 between teaching and training residents and as clinical attending in the hospital's newborn intensive care unit.

Based on interviews with **Amy Presti, MD,** and **Richard A. Polin, MD,** who is Director, Division of Neonatology, Morgan Stanley Children's Hospital of NewYork-Presbyterian/ Columbia University Medical Center, and Professor of Pediatrics at Columbia University College of Physicians and Surgeons. Email: rap32@columbia.edu.

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NEW YORK-PRESBYTERIAN Children's Health

Important news from NewYork-Presbyterian's Morgan Stanley Children's Hospital and the Phyllis and David Komansky Center for Children's Health—leading the way in pediatric research and treatment.