ECHO Grants

NIH funds extensive project to gauge the impact of prenatal and early-life exposures

From conception through early childhood we experience critical developmental windows of susceptibility when we are especially vulnerable to the effects of pollutants, chemicals, stress, poor diet, and sleep deprivation. These exposures can alter a range of biological processes such as the expression of genes or development of the immune system—and the health effects of these impacts can be long-lasting.

To better understand how a wide range of environmental factors can affect a child’s future health, the National Institutes of Health has launched a seven-year, $157 million initiative, Environmental Influences on Child Health Outcomes (ECHO). Through ECHO the NIH plans to fund existing and new pediatric studies that will assess the health of more than 50,000 children from diverse racial, geographic, and socio-economic backgrounds. These studies will focus mainly on factors that may influence the health and development of the nervous system and the upper and lower airway, as well as the risk of obesity. Several CUMC researchers in Pediatrics and OBGYN are recipients of ECHO grants.

Under the aegis of the Columbia Center for Children’s Environmental Health (CCECH), Rachel Miller, MD, director of the Division of Pediatric Allergy, Immunology and Rheumatology, is the Columbia site principal investigator of an ECHO consortium of 12 asthma birth cohorts across the US. Members of the consortium will combine their data from approximately 7,000 children and young adults (plus new ones to be enrolled) to ask fundamental questions about the links between early exposure to environmental factors and specific types of asthma. “Through this consortium we’re bringing together national leaders in asthma research to ask basic questions about asthma in a united way, and that’s really very exciting,” says Dr. Miller.

Consortium members have data not only from 12 different geographic areas but also from different periods of time, from the late 1990s to more recently, which could enable them to understand asthma trends over time. “That variety will allow us to capture nuances and differences that we couldn’t capture from one cohort in one geographical area,” Dr. Miller says. “As individual researchers we’ve never had the numbers of patients to answer important questions about risk factors. We’ll be much better able to get the answers by teaming up.”

Through another ECHO grant, Ronald Wapner, MD, Professor and Vice Chair of Research in OBGYN, will be investigating the effects of prenatal and early childhood exposure to a variety of chemicals and nonchemical factors on two key health outcomes—obesity and neuroimpairment. Dr. Wapner and other investigators at the Medical University of South Carolina will use data from the National Fetal Growth Study (NFGS), which enrolled 2,397 racially and ethnically diverse women and children from 10 areas across the country between July 2009 to January
Message from the Editors

“Every baby should have the best opportunity to remain healthy and thrive throughout childhood,” Francis S. Collins, MD, PhD, Director of the National Institute's of Health (NIH), has said, “and ECHO will help us better understand the factors that contribute to optimal health in children.” ECHO (Environmental Influences on Child Health Outcomes), the NIH’s new $157 million research initiative, aims to explore the effects of prenatal and early-life exposures to different chemicals and air pollutants on the developing airway and brain, and the later risk of obesity. Several investigators in CUMC Women’s and Children’s Health are receiving ECHO funding to further their studies, and we highlight some of these projects in our page-one story. Nurses are critical players in research programs throughout CUMC. In this issue we profile Melissa Beauchemin, NP, in Pediatrics and Michelle DiVito, RN, MSN, in OBGYN who both are integral to their departments’ work (page 7). In his lab in CUMC’s Institute for Cancer Genetics Research Adolfo Ferrando, MD, PhD, is exploring the molecular mechanisms underlying T cell acute lymphoblastic leukemia (T-ALL) and is developing targeted therapies for this difficult-to-treat disease (page 6). Chief of the Division of Gynecologic Surgery Arnold Advincula, MD, outlines the work and goals of his division and the reason his team is setting a precedent in the region by releasing their outcomes data (page 8). And Meridith Sonnett, MD, talks about her work as Chief of Emergency Medicine and Chair of the joint Pediatrics/Morgan Stanley Children’s Hospital Quality Council—and about how those two roles intersect (page 10).

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Connections
Advances in Research

Planning a “Day Two” Talk about Palliative Care

Introducing palliation into the care of children with cancer, regardless of the stage of their disease and prognosis, substantially improves patients’ symptoms and suffering. But, barriers remain to fully integrating palliative care, including a shortage of trained pediatric palliative care specialists, the enduring perception that palliative care is synonymous with end-of-life care, and a lack of clarity among pediatric oncologists about how and when to integrate palliative care. CUMC pediatric oncologist Jennifer Levine, MD, and Elisha Waldman, MD, director of pediatric palliative care, proposed a way to address these failures with the concept of the “day two talk” in an article in the Journal of Clinical Oncology. They modeled the idea on a 2004 article, “The Day One Talk,” which presented an organized way for pediatric oncologists to approach the initial discussion of a child’s diagnosis, prognosis, and treatment with patients and their families. In discussing palliative care the authors recommend exploring each family’s understanding of their child’s illness and prognosis, their hopes, worries, and fears, their family and social supports, and spirituality or faith. By establishing a framework for these issues to be discussed throughout the course of a child’s treatment, and by touching on each domain from time to time throughout treatment, clinicians can provide care that remains consistent with the family’s goals and values. They can also set the stage for bringing in a pediatric palliative care team as the family’s hopes and worries, supports, and needs change over time, particularly if a child’s disease recurs or progresses.

### Studying the Complex Links Between Brain and Gut

The enteric nervous system (ENS), the complex mesh-like system of neurons that governs the function of the gastrointestinal system, can orchestrate gastrointestinal behavior independent of the central nervous system (CNS). An intact ENS is essential for life and its dysfunction is often linked to digestive disorders. It has also become increasingly evident that the ENS plays a role in neurological disorders. ENS structure and neurochemistry resemble that of the CNS, so the mechanisms that give rise to CNS disorders might also lead to ENS dysfunction, and nerves that interconnect the ENS and CNS can be conduits for the spread of disease. In a review article published in *Nature Reviews Gastroenterology and Hepatology*, pediatric gastroenterologist Meenakshi Rao, MD, along with neurogastroenterologist Michael Gershon, MD, reviewed evidence for ENS dysfunction in the development of autism spectrum disorder, amyotrophic lateral sclerosis, transmissible spongiform encephalopathies, Parkinson disease, and Alzheimer disease. Common pathophysiological mechanisms account for the frequency of gastrointestinal problems in these conditions, animal models suggest. Moreover, the herpesvirus varicella zoster (VZV), the virus that causes chicken pox, can establish latency in enteric neurons, recent studies show. When the virus is reactivated in these neurons it does not produce a rash and is therefore a clandestine cause of gastrointestinal disease, meningitis, and strokes.

The gut–brain alliance is increasingly recognized as a contributor to good health, but a gut–brain axis that contributes to disease merits equal attention, the authors conclude.


### Postpartum Hysterectomy Is Sometimes Necessary: Hospitals Should be Prepared

Hemorrhage after childbirth is a leading cause of severe maternal morbidity and mortality worldwide: the risk of death ranges from 1-6%. Peripartum hysterectomy—a hysterectomy performed at the time, or within 24 hours, of delivery—can be a life-saving intervention when other medical and surgical treatment options have failed to halt hemorrhage. Research shows that maternal outcomes may be better at hospitals that perform peripartum hysterectomy more frequently and use a multidisciplinary approach in planning and delivery, so women at extremely high risk for peripartum hysterectomy, primarily those with suspected placenta accreta/percreta, are often referred to tertiary care centers. But to be most effective, hemorrhage safety policies at every hospital should include planning for the often unanticipated peripartum hysterectomies. To characterize the risk of hysterectomy among women at low and moderate risk for this procedure, a group of OBGYN researchers analyzed a large, nationally representative sample of delivery hospitalizations. In 55,214,208 low- and moderate-risk deliveries, they found 28,862 peripartum hysterectomies (1 in 1,913 deliveries), they reported in the *American Journal of Obstetrics and Gynecology*. Risk factors associated with significant risk for hysterectomy included cesarean delivery, stillbirth, placental abruption, fibroids, and antepartum hemorrhage. The authors concluded that, while certain obstetric factors are associated with increased risk, the need for hysterectomy is unpredictable and all centers providing obstetric care should be prepared to handle this clinical scenario.

Creating a Better Measure of Unplanned Pregnancy

In the United States, 45% of pregnancies in 2011 were unintended, while only 15% of pregnancies in Britain in 2010–2012 were unplanned. What’s behind the large difference in these numbers? A multi-institutional group that included OBGYN researchers Carolyn Westhoff, MD, and Paula Castaño, MD, set out to explore this question. Because unintended pregnancy is a benchmark for women’s reproductive health worldwide, the answer is of considerable interest. Using a binary timing-based measure of unintended pregnancy (TMUP), the US measure classifies pregnancies as unintended if they occurred sooner than wanted. It sub-classifies them further into unwanted (not intended at any time) and mistimed (intended sometime, but not when they occurred). Britain uses a different measure, the London Measure of Unplanned Pregnancy (LMUP), which assesses six different aspects of thoughts and behaviors prior to pregnancy; LMUP was developed in response to the observation that women often use different language than do researchers when talking about pregnancy intentions. The CUMC research team had some 220 women seeking pregnancy testing respond to three pregnancy measures: TMUP; LMUP; and a measure that combines women’s intentions and how they would feel about a positive pregnancy test with a statistical tool (receiver operating characteristic curves) to assess congruence. In this group TMUP indicated that 76% of pregnancies were unintended, while LMUP categorized 39% as unplanned. Expanding the range of scores for classifying pregnancies as unplanned on the LMUP would achieve greater congruence between the two measures, the authors report in Perspectives on Sexual and Reproductive Health. They conclude that a measure combining intentions and feelings may better predict pregnancy outcomes.

Lighting up the Dark

Adolfo Ferrando looks for causes of leukemia in unexplored DNA

Medical progress is made as basic science and clinical researchers gradually illuminate the unknown. For the past 15 years Adolfo Ferrando MD, PhD, has been uncovering the mysteries of leukemia, and showing why, despite huge gains in outcomes for most children with the disease, some still do less well and their disease recurs.

Dr. Ferrando is Director of the Lymphoid Development and Malignancy Program at the Herbert Irving Comprehensive Cancer Center, and heads up a 15-member lab in CUMC’s Institute for Cancer Genetics.

Using a combination of genomic and systems biology approaches, biochemical analyses, and experimental therapeutics, he and members of his lab are exploring the molecular mechanisms underlying acute lymphoblastic leukemia (ALL), the most common cancer in children.

Dr. Ferrando’s specific interest is T-ALL, a form of leukemia that develops in the progenitor cells that evolve into T-cells, one of the key cellular components of the immune system. T-ALL affects 15%-20% of children with ALL. Despite the introduction of highly intensified chemotherapy protocols, 20% of children and 50% of adults with T-ALL still relapse and ultimately die from the disease.

“This is a very aggressive, very difficult to treat hematopoietic tumor, and resistance to chemotherapy is a major challenge,” Dr. Ferrando says. “We are trying to find new targets for therapies to treat this disease, and we hope that the tools we are generating will be applicable very broadly across multiple different genetic variants of T-ALL.”

T-cell development is complex and orchestrated by many different signaling pathways and checkpoints, Dr. Ferrando explains. One key pathway in the evolution of stem cells into T-cells is called NOTCH. More than a decade ago, in a seminal study, Dr. Ferrando and colleagues showed that NOTCH1 is mutated in more than half of all T-ALLs. Their finding underscored the importance of NOTCH1 in the development of T-ALL and provided a strong rationale for targeted therapies that interfere with NOTCH signaling. Research has also shown that when NOTCH1 is activated, glucocorticoids—one of the mainstays of T-ALL therapy—is rendered less effective.

In subsequent work Dr. Ferrando and his team went on to define the mechanism of action of NOTCH inhibitors known as gamma-secretase inhibitors (GSIs) and identified drug combinations that maximize their anticancer effects while minimizing side effects. Several GSIs are now in clinical development for the treatment of high-risk T-ALL.

In their effort to map the genetic landscape of T-ALL and to define the mechanism of action of mutations linked to relapse, members of the Ferrando lab have identified, or worked with other teams to study, many other genes and pathways now known to interact with NOTCH1. These include the regulator gene MYC, which when altered plays a key role in T-ALL, and the pathway called PI3K-AKT, which is mutated in many types of cancer, and which may be also involved in the resistance of T-ALL cells to glucocorticoids. Importantly many drugs are now in development to target and block these molecules.

Most recently, his team focused their attention on the mechanisms that drive leukemia relapse. There they identified mutations that induce increased activation of NT5C2 a protein that helps cells clear themselves of chemotherapy drugs, thereby inducing resistance to chemotherapy. Much of the ongoing research in the Ferrando lab is dedicated to dissecting the mechanisms of NT5C2 function and developing inhibitors for the treatment of relapsed leukemia.

In their quest for new leads the Ferrando lab is constantly exploring new research lines. One of their most daring new projects is analyzing the function of critical as yet unannotated genomic sequences—the dark matter.

“For years we’ve been exploring the genetics of leukemia—what genes play a role in the pathogenesis of the disease, how they work, where are the mutations that cause the disease—to understand the machinery that drives it,” he says. “Yet, much of this effort has been focused on the space confined by boundaries of the annotated genome. Our hope is that looking beyond the space of the known genes we will uncover new mechanisms and targets to develop therapies.”

Research like Dr. Ferrando’s has a direct impact every day. “If we look back 10 to 20 years, it looks like we were actually playing a game without knowing the rules,” Dr. Ferrando says. “The amount of information we understand about the molecular and genetic basis of cancer today is really unprecedented. We are now able to play this game with the cards in our hands, and for the first time we are actually playing to win.”

— Beth Hanson
Melissa Beauchemin, NP

CUMC’s Division of Hematology, Oncology and Stem Cell Transplantation treats 150 new patients each year, many of whom have leukemia or lymphoma. Most pediatric oncology patients are enrolled in a clinical trial, Ms. Beauchemin says, “since it’s part of the culture, and we pass that on to our patients and families. I think they feel comfortable that they’ll receive either a treatment that is the standard of care or something slightly newer that may potentially be better. This is especially true if they’re are newly diagnosed and enrolled in a phase III study.”

Conversations with the families of newly diagnosed children about treatment options and trials are often extremely intense, Ms. Beauchemin says. Not only are they overwhelmed by their new situation, but a child may be eligible for up to five clinical trials at that time—a treatment trial, and three supportive care studies, and a registry study, for example. “Helping them navigate through that is really challenging, because they hear the word cancer and that’s all they hear. We do a good job explaining why research is important, why we believe in it, and that children in clinical trials do better than those who are not because of the extra layers of oversight by the clinical research team.”

Once a family agrees to enter their child in a trial, the most difficult part of the process is ensuring that the patient and family have reviewed and understand the informed consent document, which describes what their treatment options and trials are often extremely intense, Ms. Beauchemin says. Not only are they overwhelmed by their new situation, but a child may be eligible for up to five clinical trials at that time—a treatment trial, and three supportive care studies, and a registry study, for example. “Helping them navigate through that is really challenging, because they hear the word cancer and that’s all they hear. We do a good job explaining why research is important, why we believe in it, and that children in clinical trials do better than those who are not because of the extra layers of oversight by the clinical research team.”

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One of the pillars of academic medicine is to expand treatment options and understand disease through research. At CUMC nurses are critical players in this effort, helping families and colleagues wade through an increasingly complex research environment. Michelle DiVito, RN, MSN, CCRP oversees all of the administrative and operational aspects of clinical and basic science research in OBGYN, and Melissa Beauchemin, NP, and colleagues like her in Pediatrics help families and patients navigate the clinical trials process. Ms. Beauchemin and Ms. DiVito talk here about the rewards and challenges of their work.

Michelle DiVito, RN, MSN, CCRP

Michelle DiVito is Administrative Director of OBGYN’s Division of Research and Innovation, which supports all of the Department’s research activities. OBGYN has more than a hundred research projects at any time; about 80% are clinical studies and 20% are basic science projects. Ms. DiVito has worked closely with Maternal-Fetal Medicine specialist Ronald Wapner, MD, Professor and Vice Chair of Research, for many years, first in Philadelphia and over the past ten years at CUMC. They are true partners in this endeavour, she says. “We come with very different skills. I’m the detail-oriented person and he’s the visionary. And while he can see the details and I can see the vision, we really complement each other. And together we’ve been able to build quite an infrastructure.”

Each of OBGYN’s clinical divisions has a research manager who reports to Ms. DiVito, and these managers have research staff who do the day-to-day work—recruiting and consenting patients, collecting and entering data, and performing other research procedures. She also has an administrative team whose members do the accounting, payroll, contract management, quality assurance, and data security.

A major part of Ms. DiVito’s responsibilities includes, “ensuring that we’re following all the many, many rules and requirements of each study,” she says. “There are just layers of bureaucracy, and one of the hardest parts of my job is enforcing rules that may seem arbitrary, but that we need to abide by. That can be difficult because we’re trying to help our researchers get things done, but it’s these very things that sometimes stand in the way.”

Ms. DiVito started her career by caring for patients, then recruited and enrolled patients as a research coordinator, and is now a manager, and this wealth of experience enables her to understand every aspect of each study proposed in the Department. “I understand the complexity and the pieces needed to make each study work, so that helps me develop budgets and contracts and also enables me to give practical advice. Researchers often come to me when they’re formulating an idea and say, ‘Do you think this would work?’ I can help them find the best path to accomplish-
Arnold Advincula, MD, describes the division he’s led for the past three years as the only formalized, fully-organized GYN multispecialty surgery division in the tri-state region. “I have a dream team to specifically care for each gynecologic specialty surgery patient. If I don’t think I’m the best doctor for a particular patient, I know there’s someone on my surgical team who can manage her condition, and who can give her the best care possible to ensure the best outcome,” says Dr. Advincula. He is the Levine Family Professor of Women’s Health, the Vice-Chair of Women’s Health for the Department of OB/GYN, and the Chief of the Division of Gynecologic Specialty Surgery.

Members of the division include two board-certified female pelvic medicine and reconstructive surgeons, a pediatric and adolescent gynecologist who also treats infertility and congenital anomalies, and five other surgeons who perform the whole range of minimally invasive gynecologic surgeries. The surgical team operates at two locations, at NYP/Columbia University Medical Center and at NYP/Lawrence Hospital in Bronxville. “We’re able to offer all of the available options for women because we’re not just one or two individuals—we’re eight strong—and together we’ve got every procedure covered,” Dr. Advincula says.

The group treats benign gynecologic conditions, including fibroids, endometriosis, non-malignant pelvic masses, pelvic organ prolapse, and incontinence, and an array of other less common conditions. And, he says, they have developed a reputation as being able to handle the most difficult of these cases.

This year, for the first time, the division is releasing its annual outcomes data. “We know that medicine is moving towards greater transparency of outcomes, and this is something we’re really excited to share with our patients and with our colleagues across the country,” Dr. Advincula says. Surgeons in the division performed 299 hysterectomies, one of their most common procedures—using a minimally-invasively approach in 87% of cases. Division surgeons also performed 73% of 280 myomectomies (a procedure to remove fibroids) using a minimally invasive technique, “which is far ahead of national benchmarks,” he adds. This impressive outcomes data is a reflection of how important it is to have a team dedicated to gynecologic specialty surgery, leveraging each other’s strengths and coming up with the best plan for each patient.

At least half of the minimally invasive surgeries done by the team—particularly the more complex cases, such as surgery involving a large uterus, complicated endometriosis surgery, or myomectomy followed by a uterine repair—are done robotically, Dr. Advincula explains. “Members of my team have done robotics longer than anybody in the area.”

The division is training the next generation of minimally-invasive surgeons, and in 2017 will increase the number of fellows from two to three. “Because we’re the only three-year fellowship in the country, ours is one of the most comprehensive, and therefore, probably one of the most sought after,” says Dr. Advincula. Fellows learn not only the technical aspects of surgery, but also fundamentals in research, simulation, and new robotic technology.

Investigators in the division are conducting several studies of surgical devices and new pharmaceuticals, as well as conducting ongoing randomized controlled trials focused on various gynecologic surgical approaches. They have been presenting many of their studies at national meetings, and Dr. Advincula is preparing to recruit additional research assistants to help with this effort.

Other recently launched programs include a fibroid center and menstrual disorders program, and Dr. Advincula and his colleagues are preparing to open an endometriosis center this year. “We already offer our patients a ‘one-stop shopping experience’ in terms of the services we offer,” he says, “but we continue to take patient care to the next level in terms of comprehensiveness and innovation.”

—Beth Hanson

…”Members of my team have done robotics longer than anybody else in the region.”
Customized Care

Urogynecology team uses latest techniques to treat pelvic floor disorders

The pelvic floor is a network of supportive structures including muscles, ligaments, and tissues that form a kind of hammock to hold the pelvic organs—the uterus, vagina, bladder, urethra, and rectum—in place. If these structures become weakened, stretched, or damaged as a result of childbirth, age, or injury, the pelvic organs can prolapse, or drop down, and protrude into the vagina. Women who have pelvic floor prolapse can experience discomfort as well as incontinence, and their quality of life can be profoundly impacted. But the solutions to these disorders are not, “one-size fits all,” say Cara Grimes, MD, and Ladin Yurteri-Kaplan, MD.

Drs. Grimes and Kaplan are members of the Division of Gynecologic Specialty Surgery, and are specially trained and board certified in Female Pelvic Medicine and Reconstructive Surgery (FPMRS). Women with prolapse and resulting stress urinary incontinence, urgency urinary incontinence, or fecal incontinence account for two-thirds of the patients Drs. Grimes and Kaplan see. They also treat patients with other pelvic floor problems ranging from defecatory dysfunction to painful bladder syndrome to fistulas, says Dr. Grimes. Through their extensive training and experience they are able to offer patients an array of surgical and non-surgical options, and they tailor a treatment approach specifically for each patient based on her condition and goals.

Their advanced training and years of experience set them apart from most gynecologic surgeons. “A physician who is not FPMRS trained may be able to do only one surgery and will only offer every patient just that procedure,” Dr. Grimes says. “We may be able to perform four or five different procedures for that same condition, and can really do the right one for you.”

Drs. Grimes and Kaplan begin their work with each patient with a comprehensive office evaluation and discussion. “I spend time listening to my patients’ symptoms and understanding what bothers them the most,” says Dr. Kaplan, “so I can tailor my treatment to what they are most concerned with.” This collaborative approach ensures that each patient is a full partner in her treatment plan.

Some women may not require immediate treatment if their condition doesn’t bother them, and Drs. Grimes and Kaplan may suggest an approach called expectant management (also called watchful waiting). The team monitors these patients over time to determine if or when treatment is necessary. “We would track issues like whether their prolapse is affecting any other functions, and whether they’re voiding adequately,” says Dr. Grimes.

For women with more complex pelvic floor conditions, the team might provide a non-surgical solution such as a pessary (a supportive device worn inside the vagina), or pelvic floor therapy. This is a broad term for different ways to do Kegel exercises to strengthen the pelvic muscles using vaginal cones, biofeedback, or the help of a pelvic floor therapist—“a personal trainer for your pelvic floor,” Dr. Grimes adds.

For even more serious pelvic floor disorders there is a range of different surgical options. “The type of surgery we would offer depends on exactly what part of your pelvis is affected,” says Dr. Kaplan, “whether it’s the walls of the bladder, or the portion of the vaginal that is holding up the rectum or uterus that is prolapsing.” Both surgeons are skilled at performing minimally invasive cystoscopy, and vaginal, laparoscopic, and robotic procedures.

Drs. Grimes and Kaplan are both involved in clinical research at CUMC and collaborate with colleagues around the country. Dr. Grimes recently started a seven-center research network called the CoRPS (Collaborative Research and Pelvic Surgery) Consortium (cropsconsortium.org) to assess the effectiveness of different treatments, while Dr. Kaplan’s research focuses on improving operating room efficiency and teamwork. Dr. Kaplan notes that, “Because of our involvement in research we are continuously evolving our practice to provide the latest care.”

— Beth Hanson

“I spend time listening to my patients and understanding what bothers them most,”

Dr. Kaplan says.
Do no Harm

Leader of Pediatric ED Heads Quality Improvement Council

At a medical center where multidisciplinary care is the norm, Dr. Meridith Sonnett’s connections and collaborations may be among the most wide-reaching. Dr. Sonnett is the medical chief of the Division of Pediatric Emergency Medicine and oversees the care provided to more than 50,000 children each year, many of them with complex, urgent, medical problems requiring the input of a range of specialists and services. And as chair of the joint Pediatrics/Morgan Stanley Children’s Hospital (NYP/MSCH) Quality Council Committee for the past 15 years, she works closely with representatives from every sector of the hospital that touches children’s lives.

The Quality Council’s goals are to create and support a hospital culture that achieves optimal clinical outcomes, encourages efficiency while maintaining safety, and works toward, “getting to zero,” the concept that no patient should ever be harmed while at NYP/MSCH. Since its inception the very inclusive group has grown to nearly 50 members, with representatives from every hospital service including pharmacy, blood bank, patient services, information technology, patient families, nursing, and physicians from all divisions and departments that care for children. Physicians and nurses from pediatric surgery, anesthesia, radiology, urology, neurosurgery, as well as obstetrics are also members.

“This is a big hospital and every patient who comes here is invariably cared for by a whole host of different services and healthcare workers,” Dr. Sonnett says. “It’s important for the entire team to be part of our culture of safety and to understand how crucial every one of us is to ensuring that we deliver the highest quality and safest care to every patient, every day.”

Dr. Sonnett works closely with Dena Goffman, MD, Quality Officer at NYP/MSCH Hospital, who is equally committed to reducing serious safety events and improving patient and family experiences. As a testament to the hospital’s commitment to quality improvement efforts, the hospital recently joined The Children’s Hospitals’ Solutions for Patient Safety (SPS), a quality and patient safety organization made up of more than 100 US and Canadian childrens’ hospitals. Its mission is to “eliminate serious harm” in every setting where children receive medical care, says Dr. Sonnett.

While quality and patient safety work at NYP/MSCH is ongoing 24/7/365, Dr. Sonnett explains, the monthly quality council meetings are crucial to this mission. Items on the monthly agendas include a comprehensive comparison of MSCH process and outcomes data to national benchmark data, updates on regulatory issues, a review of any serious safety events, and a discussion of opportunities to implement improvement strategies. The group’s ongoing improvement efforts include implementing standardized best practice strategies to reduce rates of central line bloodstream infections, catheter-associated urinary tract infections (CAUTI), and surgical site infections in children.

When a safety event does occur, says Dr. Sonnett, it is rarely because of a single person’s actions, but rather the result of system failures. “A comprehensive investigation of a safety event gives us an opportunity to look at the whole system, to identify the junctures where the system has failed, as well as to ensure accountability on the individual level. This approach has really allowed us to transform how we take care of patients,” she says. “We encourage staff and faculty to openly share errors and safety concerns, since each and every one of these is an opportunity to address and remediate serious safety events.”

One of the institution’s recent major successes was reducing CAUTI, Dr. Sonnett explains. “We recognized that our CAUTI rates were higher than the national benchmark, and we aspired to be at zero, so we established a multidisciplinary group to address this issue.” The group focused on improving processes by adopting a standardized approach to inserting and maintaining indwelling urinary catheters. By complying with data-supported standards the medical center has significantly improved outcomes, and reduced CAUTI rates to near zero.

Like Dr. Sonnett there are many physicians involved in quality and patient safety roles at children’s hospitals around the country who are pediatric emergency medicine physicians, she says, because they, too, interact with nearly all subspecialties and services that care for children in the hospital. In turn, Dr. Sonnett is supporting several junior faculty members in her Division who are passionate about quality control and who want to be part of the leadership team for the center, she says.

— Beth Hanson
A new volunteer council at Columbia is focused on advancing clinical and research programs dedicated to women’s health. Led by chair Sarah Billinghurst Solomon, a long-time champion of women’s health at Columbia and member of the CUMC Board of Advisors, the Women’s Health Care Council launched earlier in 2016 with 39 members.

“The Women’s Health Care Council is composed of women from all walks of life—the law, the media, the arts, and other professions,” says Mary D’Alton, MD, chair of the Department of Obstetrics and Gynecology. Dr. D’Alton describes the group’s mission as threefold: to provide the department with feedback and advice; to build and circulate knowledge about Columbia OBGYN across the city and beyond; and to support the department’s philanthropic efforts.

“It is important to have outside eyes on what we’re doing,” says Dr. D’Alton. “Sometimes I think we can get too focused in our own jobs, and we benefit tremendously from other perspectives. We take their feedback very seriously.”

On October 19, the council met to introduce one of the department’s young faculty members, share some recent accomplishments and updates, and discuss areas that need input and support from council members. The evening was hosted by long-time Columbia supporter Diana Vagelos, who is also a member of the council, and featured a presentation by Margo Harrison, MD, assistant professor of OBGYN.

Dr. Harrison is an expert on global maternal health whose career has focused on protecting women during childbirth and equipping them with the tools to enable conscious family planning. Her research began on urogenital fistula, a potentially debilitating tissue tear that is usually the result of neglected childbirth complications or poor-quality surgery.

“Each woman with an obstetric or gynecological problem that results in urogenital fistula is a symbol of societal failure,” says Dr. Harrison. “These women needed some kind of clinical help and they either never got it, or when they did, they received such poor-quality healthcare that it left them damaged for life.”

That realization led Dr. Harrison to a wider investigation of healthcare systems in low- and middle-income countries, and the effects they have on women’s health. She is currently pursuing funding for a study on the quality of cesarean section in low-resource settings.

The Women’s Health Care Council has prioritized new strategic and fundraising efforts to support this kind of high-impact research, as well as programs that support training for young physician-scientists and faculty recruitment—always with the goal of ensuring that Columbia’s Department of OBGYN continues to elevate the standard of women’s health care locally and globally. — John Uhl
Hospital Leadership Aims to Further Enhance Performance and Outcomes

NewYork-Presbyterian Morgan Stanley Children’s Hospital (NYP/MSCH) and Sloane Hospital for Women are world-renowned for providing pediatric services and obstetric/gynecology care, including treatment of the most complex disorders and diseases in children and advanced maternal-fetal medicine expertise. Each year, the hospital ranks in multiple specialties in U.S. News & World Report and is a major referral center for patients and families from across the globe. As an institution that maintains high standards, the hospital is continually seeking to raise the bar, enhancing its delivery of top-quality patient care and further improving patient outcomes.

Hope Copperstone, MBA, MSN, RN, has worked at NewYork-Presbyterian for 30 years and knows what it takes to keep an institution moving forward. After starting her career as a cardiac nurse and later assuming leadership roles in Patient Access/Transfer, the Vascular Service Line, Radiology, Oncology, and Cardiology, Ms. Copperstone took the helm as Vice President of Operations for NYP/MSCH and Sloane Hospital for Women in January 2016 to shepherd programmatic growth and development. “As we continue to make progress in advancing pediatric and obstetric care, opportunities have been identified to launch innovative initiatives,” says Ms. Copperstone. “We’re refining the hospital’s infrastructure and developing the clinical and operational teams which will make those advances happen.”

Among the most recent efforts: the expansion of magnetic resonance imaging services at NYP/MSCH, the addition of two new state-of-the-art operating rooms, enhanced partnering with physicians, and even stronger integration between Columbia University College of Physicians and Surgeons and NewYork-Presbyterian Hospital. Ms. Copperstone also encourages hospital employees at every level to be the best they can be—supporting front-line staff, finding ways to promote staff engagement, and increasing efficiency throughout the hospital.

“We want to challenge everyone to be as effective as they can be, always asking: What do they need from us to get there?” she says. “Great things happen when we work together and support each other to move initiatives forward.”

One important way to enhance hospital care is to focus attention on the quality of care, patient safety, and outcomes. In Sloane Hospital, simulation training is improving team readiness and expertise by engaging doctors, nurses, and other members of the maternity team to learn how to handle obstetric emergencies they may rarely encounter in clinical practice.

One example is shoulder dystocia, a rare but serious childbirth emergency in which the baby’s head is delivered outside the mother’s body, but a shoulder remains stuck in the birth canal. The hospital has a special simulator called PROMPT Flex that replicates shoulder dystocia, with an artificial baby in the simulated birth canal. Trainees are able to practice delivering the baby safely, and sensors inside the baby send signals to an iPad letting the doctor know if too much pressure is being applied to the simulated infant. “This tool allows our doctors build their delivery skills in a safe, standardized and reproducible environment,” says Dena Goffman, MD, Associate Chief Quality Officer for NYP/MSCH and Sloane Hospital for Women and a maternal-fetal medicine specialist.

The simulator can be programmed to replicate other obstetric emergencies, such as a breech birth, hemorrhage, and forceps/vacuum delivery. Simulation is one way maternal-fetal medicine experts at Sloane Hospital for Women are improving quality and patient safety. Through the Safe Motherhood Initiative, the hospital has standardized care and preparedness for three obstetric emergencies: maternal hemorrhage, hypertension, and blood clots (venous thromboembolism).

Quality control and patient safety initiatives abound in Pediatrics as well. Through Solutions for Patient Safety, a national learning collaborative, NYP/MSCH staff are learning how to reduce surgical site infection, catheter-related urinary tract infections, and hospital readmissions. The effort is part of a larger hospital-wide program to promote a positive culture of error prevention—one which will be expanded in 2017. “We want to get everyone speaking the same language and practicing evidence-based error prevention techniques,” says Dr. Goffman.

Through the KEEPSAFE system, staff in both Obstetrics and Pediatrics can report errors or “near misses,” which are discussed on a daily conference call to address systematic improvements to further enhance patient safety. “As physicians, we go into medicine to help patients and improve outcomes,” Dr. Goffman adds. “Through patient safety and quality programs, we can make an impact on an even larger scale.” — Rosie Foster
Everything you need to know about how our doctors make a difference in the lives of children is now a go-to digital resource that fits in your pocket. At ColumbiaChildrensHealth.org, all of our pediatric specialties are found in one place, including programs and medical services that cut across disciplines. The robust content is packaged in an appealing design that scales across devices, from desktop computers to tablets to smartphones.

“The new website is a welcoming resource for patient families and captures the spirit of Columbia’s inspired care for kids,” says Karen A. Kennedy, MD, chair of the Children’s Board at Columbia and P&S alumna. “As a pediatrician, I know how dedicated our doctors are to providing the best care and latest advances in medicine to the families of our youngest patients, through any illness or injury and across all specialties. The website showcases our commitment to children’s health in an accessible design with comprehensive information about our programs, treatments and conditions, specialties, and our many convenient locations in the tristate region.”

The Columbia Children’s Health website has profiles for nearly 400 doctors who treat children and conveys our brand of compassionate care with new photos and videos, showing the warmth of interactions between our specialists and kids of all ages.

Our website content is also optimized for online search, with concise, clearly organized information presented in lay terms. The first thing many people do when looking for health care information is to type their questions into Google. In 2015, 1 in 20 Google searches were for health-related information, according to the search engine giant.

Developing and launching the website was a collaborative effort and included teamwork among the Department of Pediatrics, the Children’s Board at Columbia, the ColumbiaDoctors faculty practice organization, and the Columbia University Medical Center Web Services team.

Explore ColumbiaChildrensHealth.org and let us know what you think. We welcome your comments at feedback@cumcweb.org.

— Rose Spaziani

ColumbiaDoctors Launches Children’s Health Website

columbiachildrenshealth.org
Media Mentions

**NPR**

**Rush on IUDs Following Presidential Election**

The election of Donald Trump has a lot of women wondering how much longer their birth control will be available without copays, as is required under the Affordable Care Act. So some women are on the hunt for reversible birth control that could last through his presidency, OB/GYN Anne Davis, MD, told NPR. Normally her office receives one call a day to book an IUD insertion, but the day after the election six women called “in a panic” to schedule IUD appointments, said Dr. Davis, who is also consulting medical director for Physicians for Reproductive Health, a nonprofit that works to improve access to comprehensive reproductive health care, including contraception, and abortion. “These women weren’t just looking for an appointment somewhere in the future. They wanted one right now,” Dr. Davis said. “Between last week and this week, my talking with patients has completely changed. Last week, it was all about, ‘Let’s talk about what’s best for you,’ and it was all about the patient. This week, politics is in the chair next to me.”

http://n.pr/2eYovtW

**U.S. NEWS & WORLD REPORT**

**Setting Kids up for Success**

Parents can play an important role in helping their children make a healthy and happy transition from home to college, but parents and even doctors often don’t talk to high school seniors about how to prepare to care for themselves and take full charge of their physical and mental health. There’s a lot of information students need to know, adolescent medicine specialist Karen Soren, MD, told U.S. News & World Report. “They should be told, ‘These are your medical issues, these are your prescriptions, these are your allergies … this is your insurance card, it will cover this or not this,’” she said. “Now is the time to have adult conversations on tough subjects they’ll encounter at college, like sex, drugs, alcohol, peer pressure and the meaning of ‘no means no.’ It’s really important,” Dr. Soren said, “for a parent to make clear to their young adults what their expectations are.”

http://bit.ly/2cJmJtg

**NEW YORK TIMES**

**Cancer Among Children in Retreat**

Children are dying less often from cancer, with substantial declines in all races and age groups: overall deaths from childhood cancer fell 20 percent from 1999 to 2014, according to a new report from the National Center for Health Statistics. Pediatric oncologist Julia Glade Bender, MD, told the New York Times that the reductions in death rates were the result of lessons learned in clinical trials that had led to small changes in practice. “Many hope for cancer breakthroughs, or cancer moonshots,” she said, “But it’s a series of well-conceived trials where we’ve studied minor changes in standards of care which add up over decades to substantial gains in survival.” Doctors are better at prognoses, she added, ramping up treatment for children with high-risk disease while easing off chemotherapy, and its side effects, for children with milder conditions.

http://nyti.ms/2dPaO11

**SCIENCE**

**First Child With Three Genetic Parents Reportedly Born in Mexico**

A couple who lost their first two children to Leigh syndrome, an inherited mitochondrial disorder, are reported to be the first to have a baby created with DNA from three different adults. A US infertility doctor, prohibited by the FDA from performing the procedure in the US, performed it at a Mexican clinic instead. Commenting on the minimal information available about the procedure, called a spindle nuclear transfer, stem cell biologist Dieter Egli, PhD told Science, “Right now it’s just, ‘We have done it.’ It’s a claim.” Dr. Egli said it’s possible that there are abnormalities in the embryos created, which reinforces why the FDA should be overseeing such experiments. “For me, the lesson here is that it’s very important that regulatory agencies like FDA move forward,” he said, “This could have been done in the United States by groups that have many years and decades of research [experience].”


**NPR**

**Hormonal Contraceptives Linked to Depression**

Women who use hormonal contraceptives—especially teenage girls—may be at a significantly higher risk of experiencing depression, a new study in JAMA Psychiatry showed. Women who used the combined birth control pill, a mix of estrogen and progestin, were 23 percent more likely to be prescribed anti-depressants than nonusers, and progestin-only pills raised the likelihood by 34 percent. With the patch, antidepressant use doubled; risk increased by 60 percent for vaginal rings and 40 percent for hormonal IUDs. Catherine Monk, PhD, director of research at the Women’s Program in OB/GYN, told NPR, “There are some women who are just much more sensitive to these hormone changes … You need to know yourself and be really informed. If I were of an age and reading this article right now, I would want to be thinking, ‘Who am I? Am I someone who has moodiness around my periods?’ Each woman should consider these findings in conjunction with what she knows about her own body and circumstances,” she said.

http://n.pr/2gSYEa5

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**ALLURE**

**Active City Kids Show Higher Rates of Pollution Exposure**

City-dwelling kids who were physically active are more likely to be exposed to black carbon, a pollutant most commonly associated with high-trafficked areas, a recent CUMC study showed. “Black carbon is a indicator of diesel exhaust pollution exposure, so exposures can be high near traffic areas,” pediatric pulmonologist and the study’s lead author Stephanie Lovinsky-Desir, MD, told Allure. Over the six-day-long study, 129 children, aged nine to 14, wore wrist motion detectors to measure physical activity. Nearly 60 percent of the children were considered active during that time, and of that number, 25 percent were exposed to a greater concentration of black carbon compared to the non-active children. “There are also indoor sources of black carbon, including residential heating and cooking,” Dr. Lovinsky-Desir said. “In New York City, depending on the season, indoor sources can be greater than outdoors. So it is still unclear if indoor or outdoor activity is better.”

http://bit.ly/2h8qOLW
Honors & Awards

Shweta Antani, MD, (Child and Adolescent Health) received a loan repayment award from the New York State Department of Health’s Doctors Across New York program, for physicians who are training and practicing in underserved communities in the state.

Emilio Arteaga-Solis, MD, PhD, (Pulmonology) will receive a three-year grant from the National Heart, Lung, and Blood Institute for his research on “Hormonal Regulation of Airway Diameter by Bone and Its Implication to Asthma.”

Tamar Baer, MD, (Endocrinology Fellow) received the Pfizer 2016 ASPIRE Young Investigator Research Award in Endocrinology.

Julia Glade Bender, MD, (Hematology, Oncology and Stem Cell Transplantation) received a grant from the Pediatric Cancer Foundation to support the Developmental Therapeutics Program.

Joel Berezow, MD (Emergency Medicine) received the 2016 Medical Hero Award from the R Baby Foundation for his work through the Pediatrics for Emergency Physicians (PEP) Network.

Sudesha Chatterjee-Paer, MD, (Obstetrics & Gynecology) was awarded the Society of Gynecologic Oncology Buck and Betsy Peters Award for “Analysis of Platelet Function and microRNA-mRNA Profiles in Neonatal Cardiac Patients.”

Richard J. Deckelbaum, MD, (GI, Hepatology & Nutrition) will receive a two-year award from the Beijing Scieure Pharmaceutical Company for “Characterization and Effects of an MCT-Fish Oil Intravenous Lipid Emulsion.”

Adolfo Ferrando, MD, PhD, (Hematology, Oncology, and Stem Cell Transplantation) mentored a summer intern in his laboratory, Sarah Romanelli, who is a senior at Oceanside High School. Sarah was selected as a semi-finalist in the Siemens Competition in Math, Science, and Technology.

Joji Fujisaki, MD, PhD. (Hematology, Oncology and Stem Cell Transplantation) received an American Society of Hematology Junior Faculty Scholar Award, one of the society’s most prestigious honors.

Anne Gershon, MD. (Infectious Diseases) received the International Society for NeuroVirology Steinman/Gilden Lectureship Award in recognition of her exemplary scientific achievements.

Nancy Green, MD, (Hematology, Oncology, and Stem Cell Transplantation) gave a keynote lecture at the 2016 convention of the Sickle Cell Disease Association of America on the use of community health workers to improve outcomes in sickle cell disease.

Caro Grimes, MD, (Obstetrics & Gynecology) was invited to join the Society of Gynecologic Surgeons. Meyer Kattan, MD, (Pulmonology) will receive a five-year award from the National Heart, Lung, and Blood Institute for his work on “Oral Bacterial Extracts (ORIBEX): Primary Prevention of Asthma and Wheezing in Children.”

Steven Kernie, MD, (Critical Care Medicine) has been promoted to Professor of Pediatrics.

David Kessler, MD, and John Babineau, MD, (Emergency Medicine) received an MCIC Risk Reduction Award for their Quality Improvement Project, “Stress-Testing the System for Sepsis Recognition.”

Sivan Kinberg, MD, (GI, Hepatology, and Nutrition) received a “posteer of distinction” award at the Ninth International Pediatric Intestinal Failure and Rehabilitation Symposium for her research, “Beneficial Effects of Enteral Fat Supplementation on Essential Fatty Acid Profiles of Pediatric Patients with Intestinal Failure.” (Additional authors include Susan Brodlie, RD, Julie Klevner, MD, Esi Lamoussé-Smith, MD, PhD, Maeghan Overly, RD, Steven Lobritto, MD, and Mercedes Martinez, MD.)

Usha Krishnan, MD, (Cardiology) was nominated to the Committee of Congenital Cardiac Diseases, a sub-committee of the American Heart Association Council on Cardiovascular Diseases of the Young.

Rachel Miller, MD, (Allergy, Immunology and Rheumatology) is the principal investigator on a NIH grant, “Children’s Respiratory and Environmental Workgroup (CREW).” This newly funded multi-center, multi-study initiative is under the auspices of the NIH Environmental influences on Children’s Health Outcomes (ECOH) initiative (see article on page 1).

Anne Moscona, MD, (Infectious Diseases) has been promoted to Professor of Pediatrics, Microbiology & Immunology, and Physiology and Cellular Biophysics, with tenure.

Elvira Parravicini, MD, (Neonatology and Perinatology) has been promoted to Associate Professor of Pediatrics.

Beth Rackow, MD, (Obstetrics & Gynecology) was elected as a member-at-large to the Board of Directors of the North American Society for Pediatric and Adolescent Gynecology.

Rini Ratan, MD, (Obstetrics & Gynecology) was appointed to the governance board of the National Board of Medical Examiners. Dr. Ratan has also been named Vice Chair of Education in OB/GYN.

Erika Berman Ronsenzweig, MD, (Cardiology) was appointed chair of the Scientific Leadership Council of the Pulmonary Hypertension Association.

Minna Saslaw, MD’s, (Child and Adolescent Health) workshop, “Provider Engagement and Communication Training: 3 Years Later. Lessons Learned” was accepted for the Beryl Patient Experience Conference in Colorado in March 2017.

Arunjot Singh, MD, (third-year fellow in Gastroenterology, Hepatology, and Nutrition), along with his mentors Ben Tycko, MD, PhD, (Genetics), Peter Green, MD, (Medicine), and Joel Lavine, MD, PhD (Gastroenterology), received a poster of distinction award from the World Congress of Pediatric Gastroenterology & Hepatology for his work on epigenetic regulation of genome-wide association studies-related genes in celiac disease.

Jason Wright, MD, (Gynecologic Oncology) has been named Vice Chair of Academic Affairs in OB/GYN.

Shan Zha, MD, PhD, (Hematology, Oncology, and Stem Cell Transplantation) has been promoted to Associate Professor of Pediatrics and Pathology & Cell Biology with tenure (in the Institute for Cancer Genetics and in the Herbert Irving Comprehensive Cancer Center).

Zhiguo Zhang, PhD, (Molecular Genetics) has been promoted to Professor of Epigenomics and Molecular Biology (in Pediatrics, Genetics & Development, and in the Institute for Cancer Genetics), with tenure.
ECHO Grants

CONTINUED FROM PAGE 1

DR. CANDE V. ANANTH

2013. They plan to follow up and re-contact study participants to assess the children’s current neurobehavioral and metabolic health.

During the initial study period the NFGS collected detailed serial assessments of fetal health, using 2D and 3D ultrasounds and analyses of maternal stress, diet, and blood samples for several factors including persistent environmental pollutants (POPs). “There are extensive gaps in our understanding of the mechanisms by which these exposures are linked to a child’s future risk of obesity and neurological impairment,” Dr. Wapner says, “so our main goal is to capitalize on the NFGS data to fill these gaps. This is a unique opportunity to gain insight into how the fetal in-utero environment can impact later life,” he adds.

Epidemiologist and biostatistician Cande V. Ananth, PhD, MPH, the Virgil G. Damon Professor in the Department of OB/GYN is working with CCCEH on a third ECHO grant to look at the long-term effects of prenatal exposure to air pollutants, particularly polycyclic aromatic hydrocarbons (PAH). The CCCEH has been following 900 children from predominantly African-American, Latino, and low-income households in New York City from before birth to age 17. The researchers have collected a large database and biospecimen bank, as well as MRI brain imaging data, and have already demonstrated that prenatal PAH exposure is associated with cognitive and behavior problems, obesity, asthma, and MRI brain changes in childhood.

Under the ECHO grant the researchers plan to use their in-depth prenatal data to develop a novel biomarker for PAH exposure in cord blood. This biomarker could then be used to screen newborns based on their likelihood of developing PAH exposure-related neurodevelopmental problems and obesity. The CUMC researchers will then cross-validate and test their risk marker in children from across the US, in populations with varying PAH exposure. “If we can identify newborns who are at risk of later neurodevelopmental problems or obesity,” says Dr. Ananth, “it might be possible to prevent those adverse outcomes with targeted educational and preventive measures instituted at birth or earlier.”

The research collaborators also plan to add another layer to their already detailed exposure data by collecting New York City air pollution data by residence for the past 15 years. This will provide information about the levels of air pollution each study participant has been exposed to over that time period. “We are going to backward extrapolate and link the CCCEH data with air pollution data by residence,” says Dr. Ananth. “This kind of study is unique.”

Research Nurses

CONTINUED FROM PAGE 7

clinical trials are available to the community surrounding the hospital. NCORP participants recently met to discuss barriers to participation in clinical trials. Not surprisingly, the consent forms were cited as one of the major barriers, she says. “To get through one consent, and then probably another for a second trial, is a lot to expect for families who have a good understanding of English and a higher education level, never mind the families who don’t.”

Ms. Beauchemin says her exposure to the many interesting studies and pathways in clinical research inspired her to pursue a PhD. “As a nurse you’re part of the team but you’re not always able to ask your own questions. With a PhD I’ll be able to conduct my own research and work within a multidisciplinary team to ask questions and get answers about many of the things that I’ve seen over the past 10 years.” — Beth Hanson

CONTINUED FROM PAGE 7

ing what they want while staying within the guidelines. I like helping people find ways to do things that aren’t so easy to do,” she adds.

Conducting a really well-designed clinical trial is hugely expensive, Ms. DiVito says, because there are so many regulations. “We have to monitor and document things in a certain way, and we have to make a lot more effort than in years past to cross all the T’s and dot all the I’s. And to do that we have had to add more staff to get the job done right.” The rollout of HIPAA for example, with its requirements about data security and protecting patients’ information, has had a huge impact on the research process, she adds. “There’s more paperwork now—with HIPAA, we often have two consent forms instead of one form. Additional rules have really increased the cost of doing research.”

While the high cost of research is discouraging some investigators, others are designing studies in more cost-effective ways than in the past, she says. But the obstacles are especially challenging for young researchers who don’t have funding support and are doing their research on a shoestring. “We spend a lot of time trying to help fellows who don’t have any extra funding get their projects done,” she says. “As much as we can, we make our large research infrastructure available to help them so they have a good research experience and are not frustrated and overwhelmed by the practical aspects of doing a study.”

Despite the obstacles and challenges, at the end of the day Ms. DiVito says her job is extremely rewarding. And, she adds, “many of the trials I’ve helped implement and execute have resulted in improvements in care for our patients.”

— Beth Hanson