Innovative Procedure Addresses Cancer of the Peritoneal Cavity

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Dear Colleagues & Friends:

This is an exciting time for Cleveland Clinic's Ob/Gyn & Women's Health Institute. Our commitment to clinical excellence, innovation, education and research has earned us recognition as the No. 4 program in the country, according to *U.S. News & World Report*. We are proud and humbled by the confidence our patients and colleagues have shown in our treatment of women, but we are not resting on our laurels. We continue to explore new approaches to obstetric and gynecologic care that will improve our outcomes.

While our main campus location has long been a national referral center for ob/gyn care, we are expanding throughout Northeast Ohio in regional hospitals and family health centers, bringing specialized care closer to home for our patients. Whether patients are referred from near or far, we work closely with their primary ob/gyn, offering treatment recommendations and follow-up care to the extent desired.

This issue of *Ob/Gyn & Women's Health Perspectives* highlights several examples of our innovative work. Among the advancements featured in the following pages is a promising approach to cancer of the peritoneal cavity, exciting progress toward developing a breast cancer vaccine, development of a robust menu of hysteroscopic office procedures and research that will help define the role of robotics. I also am pleased to share the work of our team members who are actively involved in international humanitarian efforts.

For more information on our work, please take a look at the recently released edition of our *Outcomes* book, available online at clevelandclinic.org/quality/outcomes.

I hope you find this edition of *Ob/Gyn & Women’s Health Perspectives* valuable. I look forward to continued collaboration with you. As always, I welcome your comments and feedback.

Sincerely,

Tommaso Falcone, MD
Professor & Chairman,
Department of Obstetrics and Gynecology
Chairman, Ob/Gyn & Women’s Health Institute
Clinicians and Scientists Collaborate on Promising Breast Cancer Research

For more than 30 years, the search for an effective breast cancer vaccine has eluded scientists throughout the world. However, a Cleveland Clinic researcher recently reported the development of a vaccine that provides safe and effective protection against the growth of breast tumors in mouse models. Remarkably, this protection occurs in the complete absence of any detectable side effects.

Scientists in the laboratory of Vincent Tuohy, PhD, Department of Immunology in the Lerner Research Institute, evaluated alpha-lactalbumin, a breast-specific protein over-expressed in the majority of human breast tumors but expressed only during lactation in the normal breast.

The research involved vaccination of mice with recombinant mouse alpha-lactalbumin. The team then assessed responses in normal mice and in several mouse breast tumor models, including autochthonous tumors in MMTV-neu and MMTV-PyVT transgenic mice, as well as transplantable 4T1 tumors in BALB/c mice. The data show a significant treatment effect when mice with established breast tumors are vaccinated and also show a highly significant inhibition of tumor growth when vaccination occurs prior to the appearance of palpable autochthonous tumors and prior to inoculation of 4T1 breast tumors.

“We are hopeful that this vaccine strategy will someday be used to prevent breast cancer in adult women in the same way that vaccines prevent polio and measles in children,” Dr. Tuohy says.

Derek Raghavan, MD, PhD, Chairman of Taussig Cancer Institute, expressed cautious optimism over Dr. Tuohy’s findings.

“This work is intriguing and the science is impressive,” says Dr. Raghavan. “If Dr. Tuohy’s early research is validated in clinical studies, it could potentially reduce the incidence of breast cancer. We’re currently designing trials here at Cleveland Clinic to test the vaccine in humans, but we’re five to 10 years away from being able to offer it to women.”

Financial support is now needed to continue the processes involved in moving this from the lab to the research venue to the patient.

Dr. Tuohy’s research is published in Nature Medicine, June 2010, “A prophylactic, autoimmune-mediated vaccination strategy for breast cancer,” and can be found at www.nature.com/nm/index.html.
Recent research has confirmed that hysteroscopic procedures such as sterilization and endometrial ablation performed in an office setting are safe, efficient and provide a high degree of patient satisfaction. With patient demand increasing for these services, gynecologists should be aware of important requirements that will enable them to provide office hysteroscopic procedures.

In the November 2008 edition of *Journal of Reproductive Medicine*, “Utility of in-office endometrial ablation: a prospective cohort study of endometrial ablation under local anesthesia” concluded that endometrial ablation can be performed successfully in a physician’s office under local anesthesia and oral anixolysis with low patient pain scores, high tolerability and high patient satisfaction. The study found 130 of 143 patients reported being very satisfied with the office procedure, while 13 patients said they were satisfied.

Cleveland Clinic gynecologists have found no clear advantage to performing hysteroscopic sterilization in a hospital operating room versus performing the procedure in a physician’s office.

Patient satisfaction, safety and efficiency drive demand for office hysteroscopic procedures.
**Strong Demand**

“Office endometrial ablation is very much in demand, and hysteroscopic sterilization is growing in popularity as more patients become aware of the common benefits of this minimally invasive procedure,” says Cleveland Clinic ob/gyn Jonathan Emery, MD. “Because demand for these services is growing, it is recommended that gynecologists consider certain steps that will help them establish safe and efficient office hysteroscopic procedures for their patients.”

Dr. Emery is among several gynecologists who perform outpatient hysteroscopic procedures at Cleveland Clinic locations throughout Northeast Ohio.

To develop the necessary technical proficiencies, Dr. Emery recommends that physicians perform at least 10 to 20 hysteroscopic procedures in a hospital operating room.

“I also recommend a minimal amount of proctoring to guide physicians through their first few cases in the office setting, which can enhance their comfort and confidence level when they begin to perform these procedures solo,” Dr. Emery explains. “Moreover, the companies that offer outpatient sterilization methods require some degree of proctoring for physicians.”

**New Methods**

Two sterilization methods that can be used in a physician’s office are Adiana and Essure. Adiana is a new hysteroscopic sterilization procedure that was approved for use by the U.S. Food and Drug Administration last year. This method utilizes radio frequency energy and a polymer microinsert that together result in tubal occlusion in the interstitial segment of the fallopian tube. Essure sterilization, which has been in use since 2002, is a coiled spring device that is inserted through the uterine cavity into the tubal opening utilizing a hysteroscope.

“These companies provide simulation training for physicians so they can develop a thorough understanding about how the methods work,” says Dr. Emery. “Following this training, companies also encourage physicians to have a proctor to guide them through the steps of one or two procedures in an office setting.”

Newer methods of endometrial ablation enable gynecologists to perform the procedure without special training. The methods utilize radiofrequency, freezing, heated fluid, heated balloon or microwave energy.

“These global methods treat the whole lining of the uterus, which theoretically provides a more uniform destruction of the endometrial lining,” explains Dr. Emery. “These methods are straightforward and have safety mechanisms, although they are not without risks. However, if physicians follow the prescribed recommendations and safety procedures, the outcomes are positive in terms of decreasing the patient’s menstrual cycle.”

**Necessary Protocols**

In addition to obtaining the necessary medical equipment such as a hysteroscope, fluid management system and other surgical tools, performing office hysteroscopic procedures requires protocols that typically involve a paracervical block, non-steroidal pain relievers and, in some cases, anti-anxiety medications.

“It also is important to have a well-trained office staff. You need a nurse or a medical assistant who can assist from the technical side and from the patient management side,” says Dr. Emery. “Although these procedures require only a local anesthetic and medications for pain management during and after the surgery, it may be helpful to train your staff to utilize ‘vocal local techniques’ to engage and distract the patient in conversation, which can help lower anxiety.”

**Patient Selection Critical**

“Not all patients are suitable candidates for an office hysteroscopic procedure,” explains Dr. Emery. “For example, a patient who can barely withstand a physical examination is clearly not ideal. Of course, qualifying a patient also requires a comprehensive review of her medical history, including whether she has had a C-sections or other prior surgeries or has an unusual uterine anatomy that may make the procedure too complex to perform in a physician’s office.”

In these cases, performing hysteroscopic procedures may be more appropriate in a hospital operating room.

To refer a patient to Dr. Emery or to discuss office procedures, call 440.943.2500 or email emeryj@ccf.org.
Innovative Procedure Addresses Cancer of the Peritoneal Cavity

Cancer of the peritoneal cavity that originates from primary colorectal cancer, ovarian cancer, gastric cancer, appendiceal cancer, mesothelioma and peritoneal carcinomatosis has been virtually incurable. For patients diagnosed with Stage IV peritoneal carcinomatosis, survival is approximately four months.

Surgical therapy is producing promising results for some patients. Cytoreductive (debulking) Surgery (CS) and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) are aggressive treatments that have been shown to increase life expectancy for well-selected patients with advanced abdominal cancers.

“Recently, a series of research studies has shown clear benefits for patients who have undergone CS and HIPEC surgeries,” says Cleveland Clinic hepato-pancreato-biliary and transplant surgeon Sricharan Chalikonda, MD, who performs approximately four CS and HIPEC surgeries every month. “For the right patients, we are starting to see survival rates increase by years.”

CS is a complicated surgical procedure that takes up to 10 to 12 hours to perform. It involves the destruction and/or resection of visible tumors within the peritoneal cavity. Depending on the size and location of the tumors, the procedure also may involve the partial resection of various viscera, such as the small bowel, large bowel, spleen and uterus.

Removing all visible tumors is crucial to the patient’s prognosis for long-term survival. The patient’s survival also depends on the volume of tumors within the abdomen and the aggressiveness of the carcinoma. The patient’s survival outlook decreases when all tumors cannot be eradicated or resected, unless they are less than 2.5 millimeters.

HIPEC facilitates the destruction of very small tumors that cannot be seen by the surgeon. HIPEC also eliminates cancer cells that may be hiding or those that may have been released during resections of visible tumors or when portions of visceral organs have been removed. The HIPEC procedure involves placing special catheters in the patient’s abdomen. Once the chemotherapy agent is heated to 42 degrees Celsius, it is distributed into the abdomen through the catheters for 100 minutes.

“HIPEC enables us to deliver higher concentrations of the chemotherapy agent into the peritoneal cavity, which facilitates the destruction of remaining cancer cells,” explains Cleveland Clinic gynecologic oncologist Pedro Escobar, MD, Director of Robotic and Minimally Invasive Surgery, who operates with Dr. Chalikonda on gyn cases.

HIPEC causes fewer side effects than IV chemotherapy because of the peritoneal plasma barrier, which prevents the high concentrations of the chemotherapy solution from invading the bloodstream.

Patients who may be candidates for CS and HIPEC are those with Stage IV cancer that is confined to the abdomen with no evidence of hematogenous spread of the disease. Other factors include comorbidities, the type of cancer, surgical history and the patient’s overall physical strength to withstand the CS and HIPEC procedures.

To make a referral or for more information, please contact Dr. Escobar at 216.445.8486 or Dr. Chalikonda at 216.445.0053.
While pregnant women represent just 1 percent of the U.S. population, they accounted for 5 percent of H1N1 flu deaths in 2009, according to a study by the Centers for Disease Control and Prevention. H1N1 is about as deadly as seasonal flu overall, but kills a higher proportion of those who are otherwise young and healthy, and is more deadly for pregnant women.

In February 2010, Cleveland Clinic launched a study of vaccination compliance in pregnant women who received their prenatal care in Cleveland Clinic outpatient clinics and planned to receive intrapartum care at Hillcrest Hospital, a busy (3600 deliveries per year) community hospital located in the eastern suburbs of Cleveland. Patients were asked to answer 18 questions while waiting for an office visit during the month of February. The questionnaire involved both seasonal and H1N1 vaccination. Descriptive statistics were applied, and comparisons were made using appropriate tests. A total of 328 questionnaires were collected at a gestational age of 23.5 weeks.

The study indicated that the major reason for refusal of both the seasonal and H1N1 vaccination was belief that the vaccines had not been studied enough. Despite reports from a recent review of the safety of the inactivated influenza vaccine verifying that no study has yet demonstrated an increased risk of either maternal complications or adverse fetal outcomes, the issue of vaccine safety remains an important barrier.

The three factors that produced the highest vaccination rate were having a discussion with the ob/gyn provider, the provider’s recommendation, and the belief that the vaccine had been studied enough.

It is clear from this study that to increase the vaccination rate of both seasonal and H1N1 influenza during pregnancy, there must be improvement in the information provided by the obstetrical providers to their patients. In a climate where more than 75 percent of the patients either strongly agreed or agreed that the advice by their providers was important to them, almost 30 percent reported that their ob/gyn providers did not discuss influenza or vaccination with them.

More information and educational materials that are directed to both patients and providers addressing barriers to vaccination should be considered. This type of interventional strategy would improve antepartum care, have economic value and, most important, decrease the severity of H1N1 influenza and maternal deaths in this high-risk group.

Drs. Philipson and Emery recently presented their results at the annual meeting of the Central Association of Obstetricians and Gynecologists. For more information on the study, contact Dr. Philipson at 440.312.7774 or philipe@ccf.org or Dr. Emery at 440.943.2500 or emeryj@ccf.org.
Fetal Care Center Teams Up to Treat Infant with Eye Anomaly

When a maternal or fetal problem threatens a pregnancy, Cleveland Clinic’s Fetal Care Center facilitates diagnosis, offers counseling, and orchestrates delivery and immediate postnatal treatment to maximize patient outcomes.

Team members shift to meet the needs of each clinical situation. In the following case, the center’s maternal-fetal medicine specialists and neonatologists teamed with an ophthalmic oncologist, ophthalmic geneticist, pediatric neurosurgeon and fetal imaging specialist when an orbital cyst was diagnosed in utero. The entire process was coordinated by one of the center’s two advanced practice nurses, who also provide constant communication and support to the family.

**History:** An ultrasound for an unrelated obstetric concern revealed an orbital cyst in the fetus (at 27 weeks, 6 days estimated gestational age) of a 28-year-old, G2P0 woman. The 4-cm x 2-cm cyst behind the right eye occupied the right orbit, with a high likelihood of extensive damage within the eye. The left orbit appeared normal. The mother and father were advised of concerns about fetal brain development, although ultrasound findings appeared normal. Upon hearing this, they sought a second opinion in Cleveland Clinic’s Fetal Care Center.

**Maternal-fetal medicine consult:** The couple met the following day, Sept. 17, 2008, with maternal-fetal medicine specialist Jeffrey Chapa, MD, for a repeat ultrasound and consultation. Imaging revealed the cystic mass posterior to the right eye; however, the globe, including the lens and muscular attachments, appeared to be intact. The eye was severely proptotic, protruding from the orbit.

Cesarean section was planned to avoid potential trauma to the globe during passage through the birth canal. Left eye findings were unremarkable, as were intracranial anatomy and the remaining fetal anatomy.

**Fetal MRI:** Ultrafast fetal MRI, obtained the following day in our Fetal Imaging Center, showed an intraconal cyst involving the right orbit that produced marked proptosis but minimal globe deformity. Pediatric imaging specialists Janet Reid, MD, and Stuart Morrison, MD, believed that location and appearance suggested a lymphatic or venolymphatic malformation or, less likely, a colobomatous cyst. Because the finding was relatively recent, concerns were raised regarding rapid progression of the cystic structure. Follow-up MRI was planned in two weeks.

**Ophthalmology consult:** After a follow-up visit with Dr. Chapa, the couple had a prenatal consult on Sept. 23 with Arun Singh, MD, Director of Ophthalmic Oncology in Cleveland Clinic’s...
Cleveland Clinic has expert maternal-fetal medicine services in several locations in Northeast Ohio. Our high-risk pregnancy-related services include preconception planning, pregnancy management (primary or consultative) and delivery. Our goal is to get patients in to be seen in a timely manner, while keeping them close to home.

Ashtabula County Medical Center
2420 Lake Ave.
Ashtabula, OH 44004
440.997.6915

Beachwood Family Health and Surgery Center
26900 Cedar Road, Suite 210 South
Beachwood, OH 44122
216.839.3100

Elyria Family Health and Surgery Center
303 Chestnut Commons Drive
Elyria, OH 44035
440.204.7400

Fairview Medical Center
18099 Lorain Ave., Suites 320/345
Cleveland, OH 44111
216.476.7144

Hillcrest Medical Office
6770 Mayfield Road, Suite 426
Mayfield Heights, OH 44124
440.312.2229 (BABY)

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5001 Rockside Road, Crown Center II
Independence, OH 44131
216.986.4130

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1450 Belle Ave., Suite 310
Lakewood, OH 44107
216.529.2202

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850 Columbia Road, Suite 320
Westlake, OH 44145
216.476.7144

Strongsville Family Health and Surgery Center
16761 SouthPark Center
Strongsville, OH 44136
440.878.2500

Wooster Family Health Center
1740 Cleveland Road
Wooster, OH 44691
330.287.4930

Cole Eye Institute. Dr. Singh discussed the ultrasound and fetal MRI findings with them, describing potential diagnoses and treatments for the orbital mass, based on the findings at birth. The repeat fetal MRI on Sept. 30 showed relatively little change, and surveillance continued via ultrasound for the remainder of the pregnancy.

**Orchestrating delivery:** The Cesarean section was scheduled for Dec. 1, 2008. Standing by were Dr. Chapa and maternal-fetal medicine colleagues (to facilitate care for the mother) and neonotologists Ricardo Rodriguez, MD, and Sabine Iben, MD (to care for the newborn). Dr. Singh and his ophthalmic surgical team, ophthalmic geneticist Elias Traboulsi, MD, and pediatric neurosurgeon Mark Luciano, MD, were ready. Side-by-side operating rooms were reserved. The father was present for delivery, and the baby was promptly assessed. The father then carried his daughter to the adjoining OR for further assessment.

**Prompt team assessment:** Drs. Singh, Traboulsi and Luciano were concerned that the proptosis worsened when the baby cried. They quickly decided that further imaging was needed to determine the cyst’s possible etiology prior to any invasive procedure. Dr. Singh placed several stitches (a temporary tarsorrhaphy) to protect what appeared to be the functional left globe.

**Surgery and follow-up:** Imaging revealed that the cyst had no communication with any intracranial structures. Under the care of Drs. Singh and Traboulsi, the baby underwent two surgeries for partial cyst removal, with histopathologic confirmation of a benign squamous epithelial cyst.

By the time the baby reached 6 months of age, she was growing and thriving. The cyst had not recurred, and she had good use and function of her right eye. She required continued follow-up to check for cyst recurrence and would likely need surgery, including a procedure to shorten her right extra-ocular muscles and cosmetic surgery for her eyelids.

To refer families to Cleveland Clinic’s Fetal Care Center, please call coordinator Donna Patno, RN, CNM, DNP, at 216.444.9706 or 866.864.0430.
Cleveland Clinic Medical Students and Staff Provide Care in Peru

A group of students and staff from Cleveland Clinic Lerner College of Medicine traveled to Peru’s impoverished area of Lamay in the summer to staff a clinic established by the town’s mayor to attract medical personnel.

Their preparation took place over about a year and a half and included taking Spanish classes every Sunday, as well as jumping legal hurdles and acquiring support, supplies and advisers.

“They believed in it enough to make it happen,” Dr. Franco says. “They were extremely respectful and concerned for those who do not have the healthcare we receive in this country.”

Student Shares Snapshot

While the clinic was clean and spacious, it lacked some key details. For example, it has a lead-lined room for X-rays but no X-ray machine, and an operating room but no lights or equipment.

Roth says the team expected a slow start the day it arrived because local radio stations announced they were coming a day later, but those expectations were soon cast aside. “We were planning on getting organized in the morning and starting to accept patients at 1 p.m. By 8:45 a.m., there was a line,” Roth wrote in her blog. “As we watched people trickle in steadily, it became obvious that the longer we waited to see people, the longer we would be at the clinic.

“By 9:15, I was taking stitches out of a woman whose bull had impaled her. It was only her leg, but there was an entry wound and exit wound, and it was infected and ulcerated of course, and why are the stitches still in three weeks later? Plus, do you have any idea of the kind of logistics necessary to treat even the smallest thing? First, just a place to sit. She sat in a spare dentistry chair. I squatted on the floor. Second, light. We left the door open for the hallway light, and I used my penlight to spot the stitches amongst the scab and the healing tissue. Third, water. Even if it was running somewhere in the clinic, it’s not clean, so I used lots of iodine and alcohol ... she took 45 minutes. There were 10 people in the waiting room when I came out at 10 a.m.”
The team adjusted quickly, though, and two days later saw about 80 patients in the same amount of time that 40 were seen the day before.

Future Directions
Surprised by the number of domestic violence problems it saw, the team initiated plans for a women’s health clinic and domestic violence shelter, as none in the region allows women to stay with their children. (The children are sent to orphanages.) The mayor is developing a rehabilitation and education program for alcoholics to complement this effort. The team hopes to repeat the trip annually for Cleveland Clinic and Case Western Reserve University students as an elective clinical rotation.

To learn more, visit http://www.lamayclinic.org/ or email info@lamayclinic.org.

Gynecologic Oncologist Earns Prestigious Award in China

Jerome L. Belinson, MD, professor of surgery in Cleveland Clinic Lerner College of Medicine and founding director of Preventive Oncology International, recently received the esteemed Friendship Award from the People’s Republic of China. Chinese Vice Premier Zhang Dejiang recognized Dr. Belinson in a ceremony during this year’s National Day celebrations in Beijing.

The Friendship Award, established in 1991, is China’s highest award given to a foreign expert who has made outstanding contributions to China’s economic and social progress.

For more than 14 years, Dr. Belinson has worked to bring gynecologic cancer screening integrated with clinical trials to rural China, an area of the world with a high prevalence of female cancers. Through his efforts and the work of his POI colleagues, almost 40,000 women who participated in the studies received screening for cervical cancer, often for the only time in their lives. Dr. Belinson and his team have been recognized for their careful adherence to human values and the proper conduct of studies involving human subjects in the Third World.

“After more than 30 years in the full-time practice of gynecologic oncology, my work in China has been the highlight of my professional life,” said Dr. Belinson. “Our mission is far from done, and it is my sincere hope that this award will draw attention to the continuing need for support for our efforts.”
Trial Compares Traditional and Robotic-Assisted Laparoscopic Sacrocolpopexy

Cleveland Clinic Director of Urogynecology and Reconstructive Pelvic Surgery Marie Fidela Paraiso, MD, recently reported results from the first randomized clinical trial comparing traditional laparoscopic sacrocolpopexy to robotic-assisted laparoscopic sacrocolpopexy. The study was the largest randomized controlled study comparing the two surgical approaches in any field to date. While the primary outcome measured was operating time from incision to closure, the trial also addressed other operative parameters, anatomic, functional and quality-of-life outcomes.

Dr. Paraiso’s team enrolled 76 patients, 67 of whom were randomized and underwent surgery (32 traditional, 35 robotic-assisted). Inclusion criteria included post-hysterectomy vaginal apex prolapse at POPQ stages 2-4; age over 21 years; and a desire for laparoscopic surgical management. Patients were excluded based on contraindication for general anesthesia; history of prior sacrocolpopexy; suspicious adnexal masses or other factors that could increase risk of pelvic malignancy; history of pelvic inflammatory disease; morbid obesity (BMI over 40); or history of prior or concomitant need of rectopexy for rectal prolapse. There were no differences in demographic and preoperative anatomic and functional data between groups.

Surgical experience (analyzed per surgeon) showed that there was no significant association between the number of cases a surgeon performed and any of the surgical times recorded.

“Both approaches led to significant improvement in anatomic outcome and pelvic floor function at six months,” says Dr. Paraiso, an internationally recognized pioneer in laparoscopic sacrocolpopexy. “We found no differences in length of stay, hospital pain medication requirement, or pelvic floor six-month functional or anatomic outcomes between groups.”

However, total operating room time, anesthesia time, total procedure time, total sacrocolpopexy time and total suturing time were all significantly longer in the robotic-assisted group. Similarly, the robotic group reported significantly higher pain scale scores at rest and with activity during weeks three through six after surgery and required non-steroidal anti-inflammatory drugs longer (19.5 vs. 9.5 days).

Dr. Paraiso says that although robotic surgery greatly improves surgeon dexterity and ergonomics and has enabled surgeons to overcome some of the limitations of conventional laparoscopy, this study provides valuable insight regarding future application of the technology.

“One of the barriers to widespread adoption of robotics is the lack of high-quality data such as this. Certainly, insurance companies are asking for this kind of quantifiable data to determine reimbursement,” she says. Her team currently is engaged in a similar study of conventional vs. robotic-assisted laparoscopic hysterectomy with Brigham and Women’s Hospital in Boston.

Dr. Paraiso specializes in laparoscopic surgery, vaginal reconstructive surgery, prolapse and incontinence in the Ob/Gyn & Women’s Health Institute and the Glickman Urological & Kidney Institute. Physicians may contact her at 216.444.3428 or paraism@ccf.org.
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– Delos M. “Toby” Cosgrove, MD, CEO and President, Cleveland Clinic