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Dear Colleagues:

Welcome to this issue of Ob/Gyn Perspectives. As 2011 draws to a close, we use these pages to reflect on some exciting — and controversial — times in our field.

This issue leads off with a story by J. Eric Jelovsek, MD, that explains the controversy surrounding the potential reclassification by the FDA of synthetic mesh for pelvic organ prolapse. As part of a national center for the correction of problems with transvaginal mesh, the staff at Cleveland Clinic’s Ob/Gyn & Women’s Health Institute continues to watch this debate closely.

We also provide information about two of our popular fellowship programs — one in Reproductive Endocrinology and Infertility, overseen by Dr. Jeffrey Goldberg, and another in Gynecological Oncology, run by Dr. Peter Rose. Both programs provide our next generation of doctors real-world and clinical opportunities not only to gather knowledge, but to apply that knowledge.

Also included in this issue is a story about our pathbreaking Center for Specialized Women’s Health. This unique center will celebrate its 10th anniversary in 2012.

In addition, we provide an in-depth review of the information contained in our recently released Outcomes book. The full edition of the book is available online at clevelandclinic.org/quality/outcomes.

I hope you find this edition helpful in your practice. As always, our team welcomes your comments and feedback, and continues to value our ongoing collaborations with you.

Sincerely,

Tommaso Falcone, MD
Professor & Chairman, Department of Obstetrics and Gynecology
Chairman, Ob/Gyn & Women’s Health Institute

Cleveland Clinic’s Gynecology program is ranked No. 4 in the nation by U.S. News & World Report.

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Special Delivery Unit to Open on Main Campus

Cleveland Clinic is opening a Special Delivery Unit (SDU) on the main campus in early 2012 for patients whose pregnancies are complicated by serious maternal or fetal conditions. The SDU adjoins a new Pediatric Cardiac Catheterization Laboratory.

Both the SDU and Cath Lab are key components of Cleveland Clinic’s Fetal Care Center, where maternal-fetal medicine specialists and neonatologists team up with pediatric surgeons and other specialists to offer diagnosis and management from initial consultation through delivery and the postpartum period. Advanced practice nurses offer families support and coordinated services throughout.

Both mother and baby also benefit from Cleveland Clinic’s Critical Care Transport (CCT) teams, who can transfer pregnant women with acute symptom onset to the SDU via fixed-wing aircraft, helicopter or mobile intensive care unit as needed. The CCT teams are on call 24/7 and can provide acute care staff when an aircraft transport is necessary.

Fetal conditions that would call for referral to the Fetal Care Center and delivery in the SDU include:

- Abdominal wall defects
- Congenital heart defects
- Open neural tube defects
- Congenital diaphragmatic hernia
- Hydrocephalus and other CNS lesions
- Kidney and urinary tract malformations
- Twin-twin transfusion syndrome
- Skeletal dysplasia

Expectant mothers with conditions such as adult congenital heart disease, cancer or autoimmune disease would benefit from delivery in the SDU. “The SDU is designed to equip Cleveland Clinic physicians to care for any potential complication, either maternal or fetal, that might occur during pregnancy,” said Jeffrey Chapa, MD, Head of Maternal-Fetal Medicine at the Ob/Gyn & Women’s Health Institute and one of the doctors who helped bring the new unit into service. “This unit will help us ensure the best possible outcomes for both mother and baby.”

The SDU has a labor and delivery suite, a large operating room for Cesarean sections and an advanced newborn resuscitation and treatment room. The adjoining Pediatric Cardiac Catheterization Lab offers immediate lifesaving intervention for newborns with Tetralogy of Fallot, hypoplastic left heart syndrome, transposition of the great vessels, or pulmonary atresia.

The state-of-the-art, minimally invasive Pediatric Surgical Suites across the hall from the SDU allow emergency procedures to be performed shortly after birth.

A Level III Neonatal Intensive Care Unit offers evidence-based care and 24/7 coverage by in-house neonatologists. Therapeutic hypothermia, nutritional support, continuous EEG monitoring and advanced modes of ventilation are offered, and ECMO is available. Parents appreciate the family-centered multidisciplinary rounds.

Other key services include a Neonatal Neurointensive Care service geared to newborns with intractable seizures, neurometabolic disease, neuromuscular disorders, hypoxic ischemic encephalopathy or other neurological/neurosurgical problems.

To refer parents to the SDU at the Fetal Care Center, please call 216.444.9706 or 866.864.0430. For emergency transfers, call 877.379.CODE (2633) for mothers with ST-elevated MI, acute stroke, intracerebral or subarachnoid hemorrhage, or aortic syndromes.
Transvaginal Mesh Controversy on to FDA for Review

By J. Eric Jelovsek, MD
Over the course of a lifetime, a woman has a 7 percent chance of surgery for pelvic organ prolapse (POP). In the recent past, synthetic mesh has become a popular option for surgical repair of prolapse. In 2004, the first commercially available trocar-guided mesh delivery system or “mesh kit” was introduced for repair of prolapse. With relatively little data, the kits were adopted into wide use; today, we as a profession are witnessing, and rectifying, the results of this fast-tracked adoption of the technology.

It is estimated that 25 percent of all prolapse repairs now involve transvaginal mesh. In 2010, of the 300,000 procedures performed, 196,000 were traditional repair, 70,000 used vaginal mesh and 34,000 used abdominal mesh.

Soon after the kits began to be widely used, safety problems began to manifest themselves. In 2008, after about 1,000 reports from the nine surgical mesh manufacturers, the FDA issued a Public Health Notice regarding adverse events associated with the use of surgical mesh for both stress urinary incontinence (SUI) and POP procedures.

On July 13, 2011, the FDA released a safety communication regarding the building concerns about the mesh. One of the steps the FDA took in response to these concerns was to appoint an advisory panel, which presented an update to the FDA in early September. Panel members spoke on Sept. 8 about transvaginal mesh for POP; on Sept. 9, the panel took up the issue of mesh slings for SUI. Twelve of the 17 panel members were physicians: two urologists, five ob/gyns, four urogyns and one minimally invasive gynecologic surgeon. The panel was chaired by Dr. Tommaso Falcone, Chairman of the Ob/Gyn & Women’s Health Institute at Cleveland Clinic.

Multiple professional societies, including the American Urogynecologic Society (AUGS), the American Congress of Obstetricians and Gynecologists, the Society for Urodynamics and Female Urology and the Society of Gynecologic Surgeons, expressed concern about the groundswell of problems specifically with surgical mesh for POP repair.

In the presentations, representatives from these societies made it clear that two uses for mesh were being discussed — for SUI and POP — and that two separate histories for those two categories of products guided their recommendations. Presenters did not recommend the blanket withdrawal
of products from the market; rather, a case was made for conducting premarketing studies before approval of new products and postmarketing studies for existing transvaginal mesh products.

In cases of mesh use for SUI, the testimony reflected the belief that midurethral slings using synthetic mesh are the standard of care; considerable advances in and mature research of this application make it a continuing reliable and safe solution to a bothersome problem.

“AUGS is not recommending the removal of mesh for POP from the market,” said Matthew Barber, MD, President of AUGS. “Instead, we support the judicious use of transvaginal mesh for POP repair performed only by surgeons with appropriate training on patients who have been fully informed of the risks and benefits of all treatment options. Certainly, more data is needed on the long-term safety and effectiveness of these devices so surgeons and patients can make informed decisions. Alternatively, mesh slings for SUI are the standard of care, and AUGS does not feel any change in the current regulatory status of synthetic mesh for this use is warranted.”

The majority of the FDA Advisory Panel members advocated for the reclassification of the devices for POP from Class II (Special Controls) to Class III (Premarket Approvals). Members indicated that they believed that Class III will allow for appropriate comparison of method, for training concerns to be addressed and additional data collection. Reclassification would involve numerous steps and would take several years to complete. During that time, products currently in use would remain on the market. And, this would apply to products for POP only. The use of mesh slings for SUI has been studied thoroughly, and the only recommendation the panel made in this area is to better characterize the infrequent, life-altering adverse events that do occur.

Clinical studies are a necessity for premarket evaluation of vaginal mesh products, which would be required by Class III assignment. A minimum of one year of data is needed on clinically important outcomes, and three to five years of follow-up through post-market surveillance and registry information would be appropriate. Reclassification would also allow for assessment of reasonable assurance of safety and effectiveness via a RCT with non-mesh control arms.
Before placing surgical mesh, it is imperative to keep in mind that it is designed to be a permanent intervention for the condition. Placing the mesh could subject the patient to additional surgery for complications related to the mesh. In the event that mesh must be removed, it is many times necessary for the patient to endure multiple surgeries. In some cases, the mesh cannot be successfully removed, and even when the mesh can be removed, complications do not always resolve themselves.

In the hands of a skilled surgeon, mesh presents a good option for resolution of issues related to POP. Better outcomes may result from the abdominal placement of mesh for POP.

Prior to surgery the patient should fully comprehend the benefits and risks of all options, surgical and nonsurgical. If the mesh option is selected, the patient should be fully informed of the type of product used. The patient should understand that the limited long-term outcome data on these products should be an important consideration.

Cleveland Clinic is recognized as a center of excellence for the removal of troublesome synthetic surgical mesh placed for POP. We receive referrals of several patients a week, many coming from other institutions, for consultation and/or removal of mesh gone wrong.

In fact, the Ob/Gyn & Women’s Health Institute at Cleveland Clinic receives calls from patients on this topic on a regular basis. Our staff counsels and educates patients about what we know about this evolving issue, and informs patients about what symptoms to look for that would signal a mesh problem.

We do know that there are many women we don’t hear from — those women in which correct placement of mesh has been the right option in their case.

It is clear that the potential benefits of transvaginal mesh placement to correct pelvic organ prolapse must be balanced against an increased rate of complications when considering treatment of POP.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Adverse Event</th>
<th># of MDRs</th>
<th>Percentile Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Erosion</td>
<td>528</td>
<td>35.1%</td>
</tr>
<tr>
<td>2</td>
<td>Pain</td>
<td>472</td>
<td>31.4%</td>
</tr>
<tr>
<td>3</td>
<td>Infection</td>
<td>253</td>
<td>16.8%</td>
</tr>
<tr>
<td>4</td>
<td>Bleeding</td>
<td>124</td>
<td>8.2%</td>
</tr>
<tr>
<td>5</td>
<td>Dyspareunia</td>
<td>108</td>
<td>7.2%</td>
</tr>
<tr>
<td>6</td>
<td>Organ Perforation</td>
<td>88</td>
<td>5.8%</td>
</tr>
<tr>
<td>7</td>
<td>Urinary Problems</td>
<td>80</td>
<td>5.3%</td>
</tr>
<tr>
<td>8</td>
<td>Neuro-muscular problems</td>
<td>38</td>
<td>2.5%</td>
</tr>
<tr>
<td>9</td>
<td>Vaginal scarring (41) / Shrinkage (2)</td>
<td>43</td>
<td>2.8%</td>
</tr>
<tr>
<td>10</td>
<td>Recurrence, Prolapse</td>
<td>32</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

Total number of adverse events is larger than total number of MDR reports because the majority reported more than one adverse event

Source: www.fda.gov

The panel recommendations have been forwarded to the FDA for its consideration. We believe that an official statement from the FDA, and perhaps recommended action, will be communicated to those in the ob/gyn field in the very near future. Until then, and as always, we recommend continued vigilance in the use of these products.

For additional information, contact Dr. Jelovsek or Dr. Barber at 216.444.2488.
The patient was referred to Cleveland Clinic gynecologic oncologists after a bilateral oophorectomy. Postsurgical pathology, however, revealed cancer in her Fallopian tubes.

The new cancer, coupled with the patient being identified as having mutations in her BRCA1 and BRCA2 genes, increased the complexity of her care. The genetic mutations increased the possibility of developing future gynecologic cancers. The decision was made to stage the patient via minimally invasive surgery through her umbilicus.

The patient is among an increasing number of gynecologic oncology patients at Cleveland Clinic who benefit from laparoendoscopic single-site (LESS) surgery. Pioneered at Cleveland Clinic, the technique enables surgeons to use several articulated devices through a single incision made in the patient’s umbilicus.

Cleveland Clinic’s team approach of involving multiple specialists can be the most important factor in long-term survival. Gynecologic pathologists, radiologists, medical oncologists and other Clinic specialists collaborate to provide a careful blend of accurate diagnosis, surgical skill with the newest technology and procedures, leading-edge radiation therapy and advanced chemotherapy.

“LESS surgery involves articulated high-definition scopes and flexible instrumentation. The ergonomics of the technology could be cumbersome for the surgeon because of wrist movements and discomfort,” said Pedro Escobar, MD, Director of Laparoscopy and Robotic Surgery at Cleveland Clinic’s Ob/Gyn & Women’s Health Institute.
Dr. Escobar uses the latest in miniaturized instrumentation. A 15-millimeter incision is made in the umbilicus, and a multichannel port is inserted to allow several devices to be used simultaneously. Organs and tissues are removed through the patient's vagina.

“LESS surgery is fairly new, but we already see several potential advantages of single-port over conventional multiport laparoscopy,” Dr. Escobar said. “We anticipate a possible decrease in morbidity related to visceral and vascular injury during trocar placement, as well as risk reduction of postoperative wound infection, hernia formation and elimination of multiple trocar site closures.” Studies also suggest improved postoperative pain profiles when compared to conventional laparoscopic surgery. This may be due to the use of the umbilicus as the single site of the incision, as it is one of the thinnest regions on the abdominal wall, containing few blood vessels, muscle or nerves.

Finally, LESS as well as other minimally invasive surgery modalities contributes to patients' postsurgical self-image because of superior cosmesis from a relatively hidden umbilical scar. “The Holy Grail of surgery is to leave little or no scars. Technology is finally catching up with the goal,” Dr. Escobar said.

LESS Oncologic Surgery

Future Robotic Platforms

Several devices operating through such a small incision creates a crowded condition that can hinder delicate surgery. A prime contributor has been the fiber-optic camera that surgeons need to see their work. Surgeons stop using the surgical instruments in order to work the camera controls, and merely redirecting the camera tip can bump the instruments.

“Ongoing research in MIS at our institute utilizing novel single-site robotic platforms (i.e. da Vinci® and ViKY® in the preclinical model) is very promising and essential prior to expanding and implementing novel robotic platforms to human trials,” Dr. Escobar said.
Cleveland Clinic gynecologic oncologists understand the fear and uncertainty a diagnosis of cancer can bring. Specialized services and supportive care, such as access to support groups and home care, arranged by clinical nurse specialists who also provide counseling, are available to help patients through a difficult time.

At Cleveland Clinic Taussig Cancer Institute, more than 250 cancer specialists, researchers, nurses and technicians are dedicated to developing and applying the latest and most effective medical techniques to achieve long-term survival and improve the quality of life for more than 10,000 new cancer patients every year. Because of the institute’s patient-centered care, leading-edge treatments, innovative research, access to clinical trials and state-of-the-art medical technologies, U.S. News & World Report has ranked Cleveland Clinic’s cancer program one of the top cancer centers in the nation.

To contact Pedro Escobar, MD, please call 216.445.8486 or email escobap@ccf.org. To make a referral, please call 800.553.5057.
Endometriosis Symptom Relief Methods Described in New Article

The clinical management of endometriosis is complex and somewhat controversial. Most gynecologists have patients with recurring endometriosis-associated pain. The American College of Obstetricians and Gynecologists has released an updated Practice Bulletin (Management of Endometriosis — Bulletin #114, published July 2010 in Obstetrics & Gynecology) that deals with these issues.

A recent review article by Falcone and Lebovic published in the Green journal this year (Falcone T, Lebovic DI. Clinical management of endometriosis. Obstet Gynecol. 2011 Sep;118(3):691-705) expands on these ideas. The article confirms the common notions that diagnosis can be definitively made only by laparoscopy, and that transvaginal ultrasound remains the imaging technique of choice for investigating pain symptoms thought to stem from endometriosis. Both fertility and pain can be improved with surgery, but medical suppressive therapy will help relieve pain but not improve fertility. If surgery does not improve fertility, then assisted reproductive technology is the next step.

Evidence is clear that postoperative suppressive therapy with oral contraceptive can prevent the recurrence of pain and ovarian cysts (endometriomas). Surgical management of endometriomas is particularly difficult because resection may decrease ovarian reserve. Techniques for achieving hemostasis in these patients should minimize the use of electrocautery.

Recurrence of pelvic pain is common after medical and surgical treatment. Hysterectomy with bilateral salpingo-oophorectomy will help these patients, but recent evidence shows that conservation of normal ovaries is an acceptable option in these women. There is no contraindication to the use of postoperative hormone replacement therapy in young women who have undergone definitive surgery.

Tommaso Falcone, MD
Chairman, Ob/Gyn & Women’s Health Institute

Severe endometriosis involving the rectum, the ovary and the Fallopian tube.
Ethics and the Maternal-Fetal Dyad:
Unique Challenges for Patient and Provider

The ethical challenges that arise in obstetrics are unique because this field is so different from other areas of medicine. Medical professionals are responsible for two patients at the same time: the pregnant woman and the developing fetus. “That’s what separates obstetrics from other medical specialties; you have to consider the health of the mother and the baby,” said Jeffrey Chapa, MD, Head of Maternal-Fetal Medicine in Cleveland Clinic’s Ob/Gyn & Women’s Health Institute. Dilemmas and challenges can arise while trying to safeguard the well-being of both.

In many instances, there is agreement between what a physician or midwife recommends for a pregnant woman and what she feels is an appropriate healthcare plan. But difficulties can arise when the choices of the pregnant woman do not align with the recommendations of her healthcare provider or, in the case of high-risk pregnancy, the multidisciplinary healthcare team. “In such cases, ethics and ethics consultation play a key role in patient care,” said Ruth Farrell, MD, MA, Assistant Professor of Surgery at the Cleveland Clinic Lerner College of Medicine and a staff member in the Department of Bioethics and the Ob/Gyn & Women’s Health Institute. “The term ‘maternal-fetal conflict’ does not adequately describe the unique interaction in the maternal-fetal dyad. This is an ever-changing and unique state in which the well-being of the mother and the fetus are intertwined. Conflict introduces the notion that the interests of the mother and fetus are in direct contest — something that is rarely the case.” Dr. Farrell said that using the term “maternal-fetal dyad” instead more effectively communicates the special state of pregnancy.

New advances in prenatal care can present unique challenges for providers in balancing the health of the pregnant woman and the fetus. Examples include procedures performed either during pregnancy (such as maternal-fetal surgery) or at the time of delivery. Such procedures, while intended to mitigate the effect of a genetic condition or developmental abnormalities on the fetus, do carry important risks for mother and fetus. “Potential conflicts between the provider and the patient can arise for any procedure, but particularly so when there is no or scant evidence-based data to demonstrate positive outcomes with the procedure,” said Dr. Farrell. Debate also can arise when evidence demonstrates therapeutic promise for the newborn but potentially serious medical complications for the mother, as in the case of in-utero repair of neural tube defects. As technology advances, it’s important for providers to constantly reconsider the consideration of what data are available about outcomes and how such procedures affect the health of both mother and fetus.

One example is the EXIT (Ex-utero Intrapartum Treatment) procedure — a surgical procedure performed on a newborn while still attached to the umbilical cord to maintain utero-placental gas exchange. The procedure was developed to reverse tracheal occlusion in severe congenital diaphragmatic hernia; it has been expanded to treat other indications such as congenital high airway obstruction syndrome, large fetal neck masses, and lung and mediastinal tumors.
While the EXIT procedure can be lifesaving for the newborn, it poses serious short-term and long-term risks for the mother. Like fetal surgery, the EXIT Procedure has a direct impact on a woman’s reproductive and overall health. “Any procedure performed on the fetus is performed on the woman, so she must be able to make an informed decision about whether the procedure is right for her and her child,” said Dr. Farrell.

Whether a procedure is experimental or established, informed decision making and communication with the patient is critical. “You’ve got to spend time talking with the patient, especially when explaining complicated procedures,” said Dr. Chapa. “It’s important to give the patient detailed information and allow her to choose.”

In addition, Dr. Farrell emphasized the importance of informed decision-making. “It is not enough to give the patient a laundry list of risks and expect her to make a decision. The process of informed decisionmaking involves having important data and also being able to align that information with personal values and beliefs. As healthcare providers, we must help our patients make informed decisions that meet their needs because they are the ones who must carry on after the delivery.”

Practitioners need to be vigilant in how they frame information so they don’t bias the patient’s decision in a way that does not meet her healthcare goals. “Many times, there may be the hope of ‘doing something’ to try to improve the health of the child. However, in these instances, there is the risk that information could be framed in a way that places undue burden on the pregnant women to go ahead with a procedure. It is vital that healthcare providers present patients with the scientific evidence, including risks and benefits, the knowns and unknowns, in a meaningful way and support the woman in making a decision that reflects her values and beliefs,” said Dr. Farrell.

“One of the challenges in obstetrics is that, in many cases, we don’t have the luxury of time. While it is critical that patients be prepared to make informed decisions, we have to recognize that the clock does not stop ticking because we are in the midst of an ethical or medical dilemma.”

Sometimes, when a patient is uncertain about a recommended procedure, Dr. Chapa may refer her for a second opinion. “It may help the patient to hear another perspective,” he said.

When a patient’s choices appear to not be in agreement with the clinical plan or recommendations, the provider may uncover the reason by asking questions and getting to know the patient better. “There may be something the patient isn’t telling you. You don’t know all the circumstances,” said Dr. Chapa. When he learned that one of his patients wasn’t taking her medication because it was too expensive, Dr. Chapa was able to switch her to a less expensive formulation.

Dr. Farrell advocates for giving patients the time and opportunity to gather information and make an informed decision. “Timing is everything in pregnancy. Each gestational week brings with it new challenges as the fetus comes closer to viability and the mother’s body changes in ways that can make her more susceptible to medical complications of pregnancy. One of the challenges in obstetrics is that, in many cases, we don’t have the luxury of time. While it is critical that patients be prepared to make informed decisions, we have to recognize that the clock does not stop ticking because we are in the midst of an ethical or medical dilemma.”

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Public reporting of hospital outcomes data has been making headlines recently as more and more facilities publish their first editions. The Ob/Gyn & Women’s Health Institute is one of 16 institutes at Cleveland Clinic that has reported its outcomes for physicians and patients since 2008 as part of the organization’s commitment to transparency.

The vast data collection involved in releasing outcomes books every year allows the organization to uncover strengths that are then cultivated, and also weaknesses that warrant increased attention.

The extensive amount of data included in the Outcomes book each year serves as an excellent resource for both care providers and patients. The institute applies what it learns from this data to continue on the constant path of care improvement and innovation.

The report provides data in a multitude of areas, from bone density to hysterectomy rates to patient experience.

As procedures have become less invasive due to technological advances in robotics and laparoscopic surgery, the duration of patient stays has decreased. Patients can expect hospital discharge in less than one week from their surgery — an average decrease of about two days since last year.

Cleveland Clinic takes a minimally invasive approach to breast cancer diagnosis. The majority of breast biopsies performed were nonsurgical. Because of the advent of robotic-assisted laparoscopy, minimally invasive procedures have increased nearly fourfold since 2006 in gynecologic subspecialties, while invasive procedures have stayed relatively stagnant. Following the same general trend, the rate of surgical treatments for women with endometriosis has decreased nearly 10 percent, while medical treatments have risen in treating those patients.

When it comes to routine obstetric care, which is offered at Cleveland Clinic community hospitals, improvements have been made in vaginal deliveries. The use of episiotomy in vaginal deliveries has decreased by more than 5 percent. Additionally, the rate of successful Vaginal Birth After Cesarean (VBAC) has significantly risen while that of failed VBAC has dropped.

Reproductive endocrinology continues to see improvement. While the success rates for in vitro fertilization (IVF) continue to improve over time, the patient's age is the strongest predictor of success. Cleveland Clinic’s In Vitro Fertilization Laboratory employs cutting-edge technology to achieve fruitful outcomes.

In urogynecology, strides have been made in reducing postsurgery small bowel obstruction. This past year, there were zero incidences of small bowel obstruction following urogynecologic surgery. While the surgical severity index has remained constant, the 30-day readmission rate has been reduced by nearly half. Patients’ length of stay in urogynecology has continued to be less than expected at all severity levels.

As part of the Surgical Care Improvement Program (SCIP), Cleveland Clinic has tracked process measures showing how consistently recommended care was provided to adult patients. In all but one measure, Cleveland Clinic far surpassed the national benchmarks. “Patients First” is the guiding principle of Cleveland Clinic, and the results of patient surveys illustrate how well this mission is being carried out. The overwhelming majority of outpatients of the Ob/Gyn & Women’s Health Institute rated their care and services and their outpatient provider as very good, and cited the likelihood of recommending that care provider as very good. Additionally, there have been improvements in the Ob/Gyn & Women’s Health Institute’s HCAHPS assessment. In the past year, significant increases have been reported in patients’ overall ratings of the hospital and the percentage of patients who would recommend the hospital to others.
Cleveland Clinic’s Ob/Gyn & Women’s Health Institute is committed to providing world-class care to women of all ages. The institute offers a full complement of subspecialty services in the field of women’s health, from general obstetric/gynecologic care and screenings for breast disorders to complex oncologic surgery for breast and gynecologic malignancies, management of fetal anomalies and cryopreservation of gametes.

In 2010, the Department of Obstetrics and Gynecology was ranked No. 4 in the nation by *U.S. News & World Report*. Cleveland Clinic offers 26 locations at which Obstetrics/Gynecology, Breast Services and Women’s Health staff provide comprehensive care. With more than 200,000 outpatient visits in 2010, the Ob/Gyn & Women’s Health Institute strives to continue this legacy with continuing innovation and transparency of information, as demonstrated by the annual report of clinical outcomes.

To provide informational transparency, Cleveland Clinic Outcomes books are offered both in print and online. The Ob/Gyn & Women’s Health Institute Outcomes booklets are available at clevelandclinic.org/OutcomesOnline.

Clinical Trials

Cleveland Clinic Ob/Gyn & Women’s Health Institute offers an online tool for physicians, patients and caregivers to search for open clinical trials. At any given time, there are hundreds of clinical trials under way at Cleveland Clinic.

To search for a clinical trial, go to clevelandclinic.org/obgynclinicaltrials.
REI Fellowship Program Offers Exposure to Medical and Surgical Infertility Management

The Cleveland Clinic Reproductive Endocrinology and Infertility (REI) Fellowship is a relatively new program aimed at preparing fellows for an academic career in reproductive endocrinology and infertility, according to Jeffrey Goldberg, MD, who is the program director.

The program, which began in 2009, is a three-year fellowship, approved by the American Board of Obstetrics and Gynecology (ABOG), leading to board certification as a subspecialist in reproductive endocrinology and infertility. One new trainee is accepted each year following completion of an ABOG-approved Ob/Gyn residency.

Fellows gain clinical experience in the full spectrum of reproductive endocrinology and infertility. During the first six months, the fellows rotate in pediatric endocrinology, medical endocrinology, medical genetics, male infertility, pediatric/adolescent gynecology, and menopausal medicine, in addition to infertility and reproductive surgery. The next year and a half are protected to allow the fellow to focus on research.

“We can offer the fellows tremendous research opportunities,” Dr. Goldberg said. “They have all the resources of Cleveland Clinic available to them. Depending on their particular area of interest, they may conduct their work in the IVF research laboratory, the Center for Reproductive Medicine Research or the Learner Research Institute.”

During the final year, the fellows are involved in every aspect of the infertility practice. Working with five board-certified reproductive endocrinologists, all with different educational backgrounds, the fellows gain a varied exposure to the
medical and surgical management of infertility patients.

The practice has a high-volume IVF program with excellent success rates, Dr. Goldberg said. Approximately 600 IVF cycles are performed each year, encompassing every permutation including ICSI, donor gametes, gestational carriers, embryo co-culture, embryo and oocyte cryopreservation, assisted hatching, preimplantation genetic testing, percutaneous sperm aspiration and testicular sperm extraction.

A great strength of this program is the very large volume and variety of surgical cases. The fellows will develop competency to independently perform microsurgical reversal of sterilization and surgical correction of congenital malformations, myomas, tubal disease and all stages of endometriosis utilizing laparotomy, laparoscopy, hysteroscopy and robotic surgery. In fact, Drs. Falcone and Goldberg performed the world’s first fully robotic surgery, a tubal anastomosis, in 1998. The fellows will also gain experience teaching residents in the clinic and operating room.

Highly regarded as a top hospital, Cleveland Clinic was ranked No. 4 in the nation in U.S. News & World Report’s Best Hospitals 2011-2012. The Department of Obstetrics and Gynecology at Cleveland Clinic was also ranked No. 4 in the nation, and is also noted as the top Ob/Gyn department in Ohio.◆

Fellows who are interested in taking advantage of this program are encouraged to visit the Society for Reproductive Endocrinology and Infertility’s website at www.socrei.org where they can get more information and apply online.

Gynecologic Oncology Fellowship Program Shapes Leaders

Cleveland Clinic’s Ob/Gyn & Women’s Health Institute is a proud partner in a pathbreaking gynecologic oncology fellowship program. Four or five fellows are enrolled in the three-year Cleveland Clinic Gynecologic Oncology Fellowship program at any given time. There are currently 16 alumni from this program dating back to 1996. The program offers a wide range of superior training, education, research and writing experiences.

Fellows receive broad training in management of gynecological cancers via in-depth exposure to surgery, chemotherapy and palliative care. The fellowship also has a robust program at the main campus, and Fairview and Hillcrest Hospitals in minimally invasive surgery using robotics and both standard and single-port laparoscopy.

For the past four years, fellows in this select program have had the distinct opportunity to follow a track where they can explore a research thesis based on clinical questions and have the additional option to obtain a master’s in public health during their research year.

Selected residents from respected U.S. and international universities have participated in the program. Applications are accepted each year and will be accepted beginning March 2012 for the next class, which starts in July 2013.

A one-month Gruber Fellowship in Gynecologic Oncology is also offered for third-year residents from other institutions who would like to gain additional exposure to the field.◆

For more information, contact Dr. Chad Michener at michenc@ccf.org or 216.445.0226.
Center for Specialized Women’s Health:
A Special Answer to Women’s Unique Health Concerns

By Holly L. Thacker, MD, FACP, NCMP, CCD

Hormone therapy. Perimenopause. Menstrual disorders. Osteoporosis. Menopause. Incontinence. Breast concerns. “Bioidentical hormone therapy.” Sexual problems. These are areas of special concern to women — not only because they affect their physical health, but also because they impact their entire well-being.

Cleveland Clinic’s Center for Specialized Women’s Health, located within the Ob/Gyn & Women’s Health Institute, offers specialty care to meet women’s unique health care needs — from routine health screenings to complex problems that cross multiple disciplines.

Established in 2002 with a generous grant of $2 million from the Avon Foundation, the Center for Specialized Women’s Health offers comprehensive female-focused care that includes the services of Cleveland Clinic’s Ob/Gyn, Endocrinology, Internal Medicine and Breast Services, including Imaging. The center also features the popular Shared Medical Appointments, follow-up care in a shared setting with other previously evaluated women who may share similar health concerns and who want more time with their physician. The Center for Specialized Women’s Health houses one of the oldest and most respected interdisciplinary women’s health fellowships. Education of physicians including those in the fields of medicine, Ob/Gyn, and Reproductive Endocrinology and Infertility fellows learning about menopause, hormone therapy, and osteoporosis are the core of the center’s educational mission.

Every day, the center has among its staff on-site women’s health specialists, gynecologists, breast imaging radiologists, nurse practitioners, bone density technicians and caring nurses. Rotating into the center are physicians in different disciplines from various women’s health specialty clinics who provide additional services in our one-stop, female focused environment.

In fact, our center has distinguished itself as a practice model such that we frequently host medical professionals from around the globe who seek to replicate our model of patient care in their home countries.
Several Cleveland Clinic staff members also participate at the leadership level in the North American Menopause Society (NAMS). Many of our providers have been certified by NAMS as Certified Menopause Practitioners, and the center has the highest concentration of menopause-certified specialists in the world. This important certification demonstrates that these practitioners have met national standards for menopause practice, and exposes both our patients and our trainees to leading-edge menopause-related healthcare at midlife and beyond. The Center for Specialized Women’s Health enjoys the distinction of having a staff that includes the Executive Director of NAMS — Marjory Gass, MD — who is also the Deputy Editor of *Menopause*, which is one of the most-cited women’s health journals.

We also offer women leading-edge and reliable tests to identify and prevent potential health problems. Bone mineral density (BMD) tests, also known as dual energy X-ray absorptiometry (DXA) scans, are offered to determine the bone density of the spine, hip and wrist. We have suggested a national benchmark of 50 percent of women with abnormal DXAs returning for repeat scan in two to three years. On-site mammography, pelvic ultrasound, office hysteroscopy, breast ultrasound and thyroid ultrasound are also available, along with a breast-only dedicated MRI. We are increasingly caring for women who have identified genetic mutations that put them at higher risk for female malignancies.

When a woman is not sure what type of physician to see for a particular women’s health concern, it can be difficult for even the most savvy to determine what type of women’s health specialist to see. That’s why the Center for Specialized Women’s Health has a strong commitment to lay outreach, education, and physician and allied health collaboration. One of the ways this commitment is put into practice is through the Cleveland Clinic Women’s 4HER Health Line® at 216.444.4HER (216.444.4437). Staffed Monday through Friday from 8 a.m. to 4 p.m. ET, the 4HER line offers a nurse advocate who has special training in women’s health issues.

The centerpiece of our outreach programs is the national Speaking of Women’s Health program which includes a vibrant website (www.speakingofwomenshealth.com) monthly e-newsletter, tweets and blogs containing important health messages, and national and regional uplifting health and wellness conferences exclusively for women. The Cleveland-area Speaking of Women’s Health conference just celebrated its 10th anniversary in September and inducted 10 honorees into the Speaking of Women’s Health Hall of Fame, which included Tommaso Falcone, MD and Wulf Utian, MD, and our 4HER nurse, Mary McDonnell, RN.

Cleveland Clinic’s Center for Specialized Women’s Health has operated the national Speaking of Women’s Health program since 2008. The Speaking of Women’s Health motto is “Be Strong, Be Healthy, Be in Charge.” Speaking of Women’s Health also includes the brands of Universal Sisters, a program for women of color, and Hablando de la Salud, a program for Latinas.

For more information about the services offered by and the philosophy of Cleveland Clinic’s Center for Specialized Women’s Health, visit our website at clevelandclinic.org/WomensHealthServices.

For additional information, contact Dr. Thacker at thackeh@ccf.org, or the Center for Specialized Women’s Health at 216.444.4437.
Cleveland Clinic is pleased to announce the recent addition of three new breast surgeons to the staff of the Ob/Gyn & Women’s Health Institute. The three doctors will practice at the main campus and at regional locations.

The Department of Breast Services will now be staffed by eight highly skilled surgeons, the greatest number of dedicated breast surgeons in the region.

The Ob/Gyn & Women’s Health Institute is committed to providing world-class cancer care to women of all ages. The institute offers a full complement of subspecialty services that fall within the field of women’s health, from general gynecologic care and screenings for breast disorders, to complex oncologic surgery for breast and gynecologic malignancies. Services are available on main campus, as well as in family health centers and hospitals throughout the region.

The department’s staff includes breast surgeons, medical breast specialists, midlevel providers and nurses. The staff works closely with the Imaging Institute, which has 10 dedicated breast imaging radiologists who perform and read our screening and diagnostic mammograms and perform breast ultrasounds, ultrasound-guided core biopsies, stereotactic core biopsies and breast MRIs.

The department also collaborates with Medical and Radiation Oncology and Plastic Surgery. About half of the department’s mastectomy patients receive immediate breast reconstruction performed as a combined procedure. Plastic surgery options include the complex DIEP and Tram procedures.

Michael Cowher, MD, will practice at Cleveland Clinic’s main campus and the Beachwood Family Health and Surgery Center, Mita Patel, MD, will practice at Fairview Hospital, and Stephanie Valente, DO, will see patients at the main campus and the Strongsville Family Health and Surgery Center.

To reach the Breast Center and the Center for Specialized Women’s Health appointment line, call 216.444.3024.
Selected Publications
From Cleveland Clinic’s Ob/Gyn & Women’s Health Institute

Journal Publications


Rose PG, Brady MF. EORTC 55971: Does it apply to all patients with advanced state ovarian cancer? *Gynecol Oncol*. 2011 Feb;120(2):300-301.


**Book Chapters**


**Book, Whole**

Resources for Physicians

Physician Directory
View all Cleveland Clinic staff online at clevelandclinic.org/staff.

Referring Physician Center
For help with service-related issues, information about our clinical specialists and services, details about CME opportunities, and more, contact the Referring Physician Center at refdr@ccf.org, or 216.448.0900 or 888.637.0568.

Track Your Patient’s Care Online
DrConnect is a secure online service providing our physician colleagues with real-time information about the treatment their patients receive at Cleveland Clinic. To receive your next patient report electronically, establish a DrConnect account at clevelandclinic.org/drconnect.

Request Medical Records
216.445.2547 or 800.223.2273, ext. 52547

Critical Care Transport Worldwide
Cleveland Clinic’s critical care transport teams and fleet of mobile ICU vehicles, helicopters and fixed-wing aircraft serve critically ill and highly complex patients across the globe. Transport is available for children and adults. To arrange a transfer for STEMI (ST elevated myocardial infarction), acute stroke, ICH (intracerebral hemorrhage), SAH (subarachnoid hemorrhage) or aortic syndromes, call 877.379.CODE (2633). For all other critical care transfers, call 216.448.7000 or 866.547.1467, or visit clevelandclinic.org/criticalcaretransport.

Outcomes Data
View clinical Outcomes books from Cleveland Clinic institutes at clevelandclinic.org/quality/outcomes.

CME Opportunities: Live and Online
Cleveland Clinic’s Center for Continuing Education’s website offers convenient, complimentary learning opportunities, from patient simulations, webcasts and podcasts to a host of medical publications and a schedule of live CME courses. Physicians can manage CME credits using the myCME.com Web portal available 24/7. Visit ccfmce.org.

Resources for Patients

Medical Concierge
For complimentary assistance for out-of-state patients and families, call 800.223.2273, ext. 55580, or email medicalconcierge@ccf.org.

Global Patient Services
For complimentary assistance for national and international patients and families, call 001.216.444.8184 or visit clevelandclinic.org/gps.

MyChart®
Cleveland Clinic MyChart® is a secure, online personal health-care management tool that connects patients to portions of their medical record at any time of day or night. Patients may view test results, renew prescriptions, review past appointments and request new ones. A new feature, Schedule My Appointment, allows patients to view their primary physician’s open schedule and make appointments online in real time. Patients may register for MyChart through their physician’s office or by going online to clevelandclinic.org/mychart.
Cleveland Clinic
Ob/Gyn Doctors
Lead National Groups

Linda Bradley, MD recently completed her first term as President of the American Association of Gynecological Laparoscopists

Matthew Barber, MD
President of the American Urogynecologic Society

Jeffrey Goldberg, MD
President of the Society for Assisted Reproductive Technology

Mark Walters, MD
President-Elect of the Society of Gynecologic Surgeons (President in April 2012)

Register for Infertility eNews

The latest information on infertility — delivered to your inbox!

Infertility eNews is an online publication that includes timely and practical health information from Cleveland Clinic. Designed for primary care physicians as well as obstetricians and gynecologists, Infertility eNews will serve as a clinical resource for your practice by featuring our institutional perspective on stories making medical headlines and highlighting new services and technology that impact clinical care.

Register at clevelandclinic.org/ObGynNews.