

Outcomes²⁰⁰⁶

Obstetrics and Gynecology





Outcomes | 2006

Quality counts when referring patients to hospitals and physicians, so Cleveland Clinic has created a series of outcomes books similar to this one for its institutes and departments. Designed for a health care provider audience, the outcomes books contain a summary of our surgical and medical trends and approaches; data on patient volume and outcomes; and a review of new technologies and innovations. We hope you find these data valuable. To view all our outcomes books, visit Cleveland Clinic's Quality Web site at clevelandclinic.org/quality/outcomes.





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Chairman's Letter |



In the Cleveland Clinic Department of Obstetrics and Gynecology, a broad scope of clinical services, reflecting every phase of a woman's life – from adolescence through her reproductive, menopausal and postmenopausal years – is offered.

Our department is ranked No. 8 in the Nation and No. 1 in Ohio in the *U.S. News & World Report* physician polls and is known for clinical excellence and innovation, particularly in gynecologic surgery. We have found that a collaborative approach fostered in interdisciplinary care centers improves clinical outcomes, increases patient satisfaction and stimulates research. Our Centers of Excellence cover Fetal Care, Menstrual and Fibroid Treatment, Female Pelvic Medicine, Women's Health, and Reproductive/Infertility Research. Our oncologists are part of a large multidisciplinary Cancer Center.

Major research initiatives focus on reproductive biology, urogynecology and reconstructive pelvic surgery, robotics and gynecologic oncology. We are committed to educating the next generation of physician scientists at Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. Graduate education includes courses in surgery and operative endoscopy techniques for residents, and popular fellowships in Gynecologic Oncology, Urogynecology and Interdisciplinary Women's Health.

A longstanding national referral center, we now offer subspecialty Ob/Gyn services throughout Northeast Ohio at Cleveland Clinic hospitals and family health centers. Whether patients are referred from near or far, we work collaboratively with the primary Ob/Gyn on evaluation, offering treatment recommendations and follow-up care to the extent desired.

We hope this overview of our specialty services and quality outcomes proves useful.

Tommaso Falcone, M.D.

Professor and Chairman, Department of Obstetrics and Gynecology





Department Overview |

The Cleveland Clinic Department of Obstetrics and Gynecology, ranked No. 1 in the state of Ohio and No. 8 nationally according to *U.S. News & World Report*, is committed to providing world-class care for women. Within this context, we essentially offer all known subspecialty services in the field of obstetrics and gynecology. Services are available at Cleveland Clinic's Main Campus, Family Health and Surgery Centers, and systems hospitals. Sections within Obstetrics and Gynecology are listed:

Urogynecology and Pelvic Reconstructive Surgery / General Gynecology

Mission: To offer medical, behavioral and surgical management of pelvic floor disorders, to educate colleagues and physicians-in-training, and to advance the care of pelvic floor disorders through clinical and basic science research.

Physicians in this section have a wide variety of subspecialty interests: urogynecology and vaginal reconstructive pelvic surgery, advanced operative endoscopy, genital fistulas and bowel disorders, women's health, menopause and geriatric gynecology, pelvic pain, menstrual disorders and acupuncture for chronic pain. The professional staff aspires to remain at the forefront of advanced gynecologic surgery and to remain national leaders in surgical innovations and experience.

The Female Pelvic Medicine and Reconstructive Surgery Center provides a multidisciplinary approach to evaluation and treatment of patients with a variety of pelvic floor disorders. The Cleveland Clinic's Menstrual and Fibroid Treatment Center provides advanced care for women who are experiencing menstruation dysfunction and symptoms from uterine fibroids.

Gynecologic Oncology

Mission: To provide a full spectrum of state-of-the-art care for gynecologic malignancies, including streamlined access to clinical trials, and to research the biology of reproductive cancers.



The professional staff in this section employs a multidisciplinary approach to comprehensive management of gynecologic malignancies, incorporating surgery, radiation, chemotherapy and biologic therapy. They are members of the Gynecologic Oncology Group, the only national cooperative study group devoted exclusively to the investigation of gynecologic malignancies. Extensive clinical trials are available on the newest treatments and techniques. The section also encompasses the Familial Ovarian Cancer Registry and provides complete treatment of pre-invasive lower genital tract disease.

Pediatric and Adolescent Gynecology

Mission: To provide state-of-the-art diagnostic and therapeutic treatments to pediatric and adolescent patients with gynecologic conditions, utilizing an interdisciplinary approach with gynecologists, pediatricians, and other health professionals committed to pediatric-centered treatment and education.

The Section of Pediatric and Adolescent Gynecology works in conjunction with the Pediatrics Division and is responsible for the gynecological consultative and surgical care of pediatric and adolescent patients.

Reproductive Endocrinology and Infertility

Mission: To investigate and treat all aspects of infertility and recurrent pregnancy loss, reproductive endocrine disorders, and structural or functional developmental problems, using the safest, most cost-effective techniques, while attending to patients' needs for education and emotional support.

Reproductive Endocrinology and Infertility physicians provide comprehensive evaluation for infertile couples. Treatments encompass all assisted-reproductive technologies: artificial insemination, ovulation induction, intra-cytoplasmic sperm injection (ICSI), *in vitro* fertilization (IVF) and reproductive surgery, including microsurgery (sterilization reversal) and advanced endoscopic techniques for problems such as stage IV endometriosis.

In order to maximize patient convenience, the Cleveland Clinic Fertility Center has several locations throughout the Cleveland area. *In vitro* fertilization retrievals and



transfers are performed only at the Fertility Center at Beachwood. Initial fertility consults and testing are available at the main campus, Beachwood Fertility Center and the Solon and Strongsville family health centers. Consults and limited testing are also available in Youngstown and Wooster.

Developed in 2004, the Partnership for Families is a unique program designed for infertility patients. The program originally provided funding for a second *in vitro* fertilization (IVF) cycle for qualifying couples who completed one IVF cycle without success and cannot afford a second IVF cycle. Recently, the program was expanded to include grants for women to have oocyte and/or embryo cryopreservation before undergoing chemo- or radiation therapy. Thus far, this service has been provided to two women at no cost. As of October 2006, 59 couples had retrievals; 31 delivered or are currently pregnant.

Maternal-Fetal Medicine/Obstetrics

Our mission is to provide state-of-the-art care to pregnant women and their unborn children, to educate future physicians and to train prospective obstetricians, and to explore innovative treatment approaches through collaborative research.

Physicians and certified nurse midwives provide three levels of obstetrical care. Midwives offer a family-centered approach to low-risk prenatal care and delivery; general obstetricians provide care for low- and medium-risk pregnancies; and maternal-fetal medicine specialists provide diagnosis and treatment for more complicated, high-risk pregnancies. Available services include genetic counseling, ultrasound, chorionic villus sampling, amniocentesis, nuchal translucency ultrasound for early screening in pregnancy as well as sequential screening.

The Fetal Care Center involves a multidisciplinary team of perinatologists, neonatologists and pediatric surgeons whose goal is to achieve the best possible outcome in pregnancies complicated by complex congenital anomalies. Through collaboration and communication, accurate prenatal diagnosis is provided using state-of-the-art techniques such as high-resolution ultrasound, fetal MRI, and fetoscopy. That information is then applied in developing a management plan for pregnancy, delivery and newborn care.

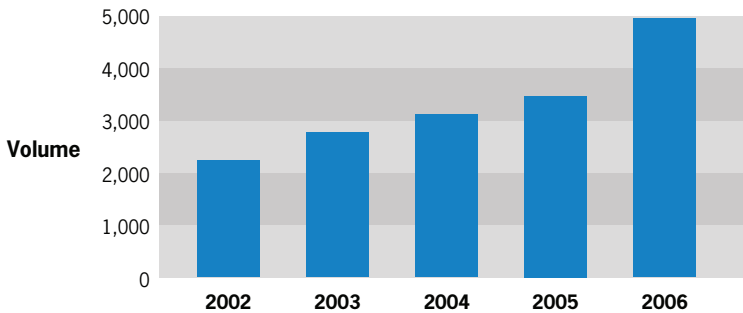


Quality & Outcome Measures

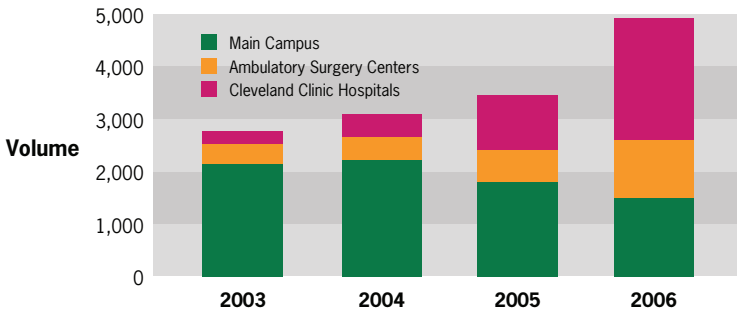
Gynecologic Surgery

Gynecologic surgery services continue to increase at a steady rate with 4,932 outpatient and inpatient procedures performed in 2006. Our gynecologic staff provides services in all areas of gynecological surgery: pediatric and adolescent gynecology, oncology, urogynecology and pelvic reconstructive surgery, infertility surgery, advanced laparoscopic and hysteroscopic robotic surgery.

Gynecologic Surgical Case Volumes

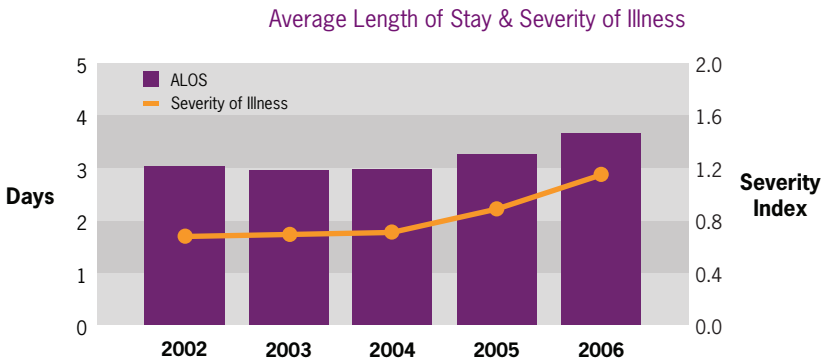


Surgical Cases by Location



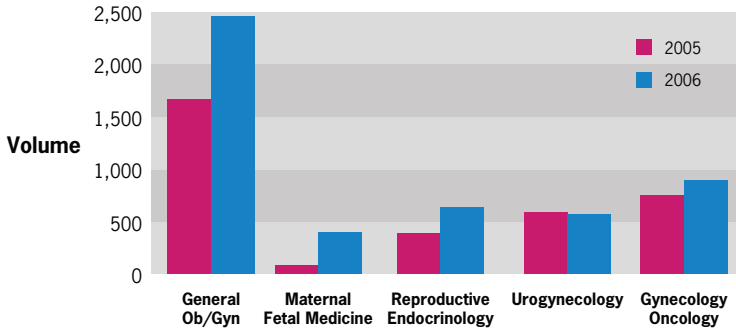


Average length of stay for total gynecology surgical cases at the main campus hospital remained low, despite an increase in case acuity. Case-per-case, compared to other tertiary care institutions, Cleveland Clinic manages the highest acuity cases in the United States.

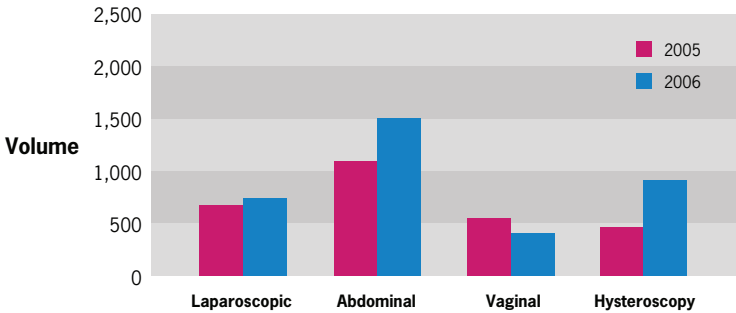


In 2006, more than half the total surgical cases were performed by the subspecialty areas of gynecology.

Surgical Procedure Distribution

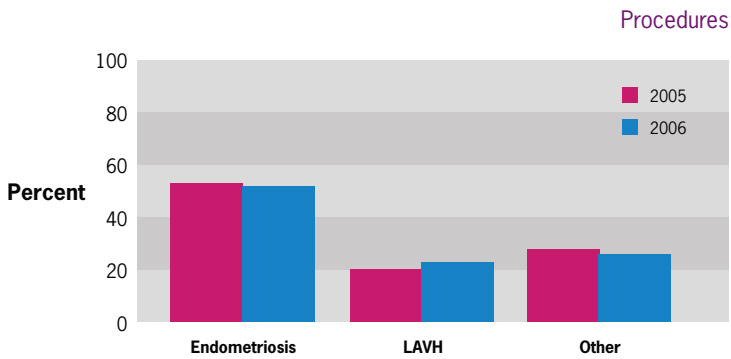


Surgical Approach



Advanced Laparoscopy

Many procedures are now performed via a minimally invasive laparoscopic surgical approach. Benefits to laparoscopy are a shorter hospital stay, smaller incisions, decreased blood loss and a shorter recovery time.



Surgical Risks – Endometriosis

Obstetrics and gynecology surgeons offer a minimally invasive surgical approach for most patients undergoing surgery for suspected endometriosis.

A four-year study was conducted to determine the incidence and risk factors for perioperative complications in women undergoing operative laparoscopy for endometriosis. During the study period, 705 women were reviewed.

- Overall incidence of developing ≥ 1 perioperative complication was 10.4% (95%CI 8.3 to 12.9).
- Conversion to laparotomy occurred in 0.7%.
- There were no cases of injury during the initial trocar entry.

Major Perioperative Complications (N = 705)

Complications	N	%
Transfusion	10	1.4
Abdominal wall hematoma	9	1.3
Wound infection	9	1.3
Bowel injury	6	0.9
Cystotomy	4	0.6
Ureteral obstruction	2	0.3
Ureteral fistula	1	0.1
Readmission	14	2.0
Reoperation	5	0.7

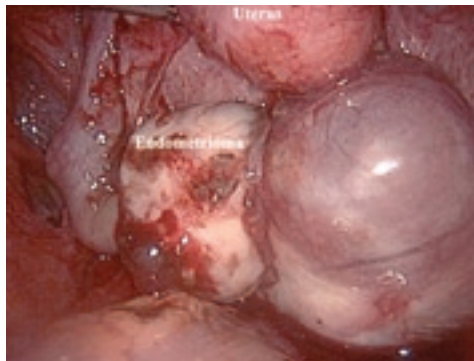


Risk factors associated with developing ≥ 1 significant perioperative complications.

	Risk Factors		
	Adjusted OR	95% CI	P
Prior laparoscopy	3.0	1.2-8.8	< .03
Stage IV endometriosis	3.7	1.6-8.8	< .03
Normal functional capacity (>7 METS)	0.26	0.11-0.62	< .002

Of the 705 patients in the study, endometriosis was confirmed in 77% of patients. The stage of endometriosis was classified using the ASRM Revised Classification.

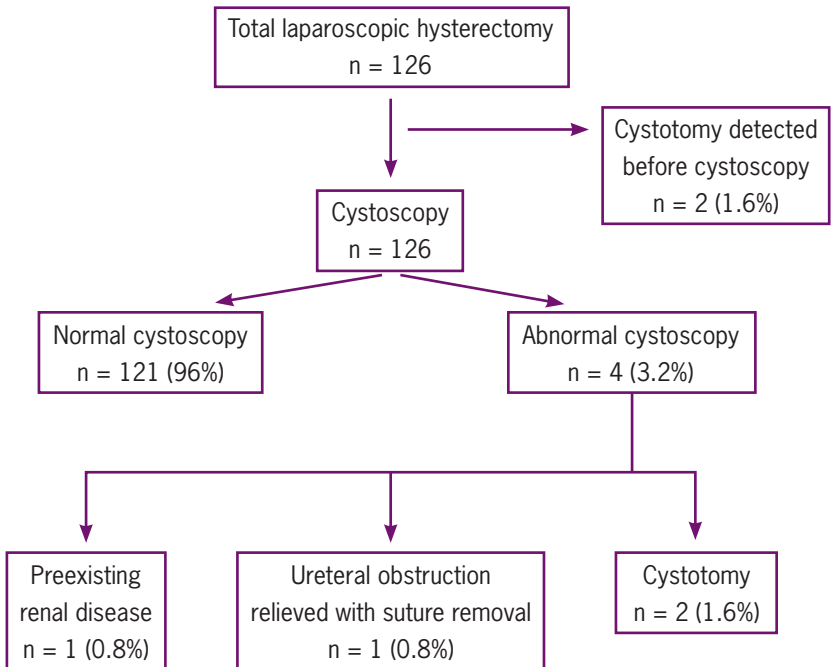
Endometriosis Staging (N=545)	
Stage	N (%)
I	217 (40)
II	144 (26)
III	66 (12)
IV	118 (22)



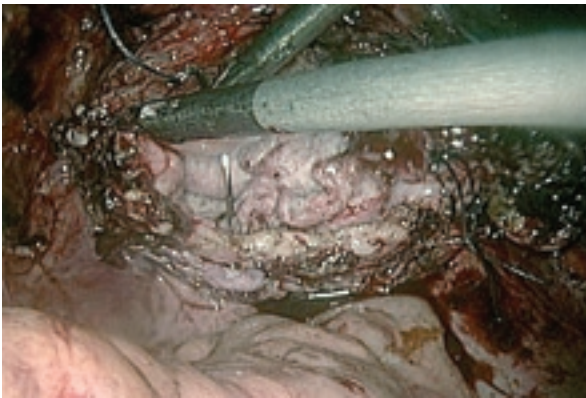
Surgical Risks – Total Laparoscopic Hysterectomy

Reducing intraoperative risks and postoperative complications are goals of the Department of Obstetrics and Gynecology.

Surgeons routinely perform cystoscopy at the time of total laparoscopic hysterectomy. A two-year study of 126 women undergoing total laparoscopic hysterectomy for benign disease indicated a 4% rate of lower urinary tract injury.



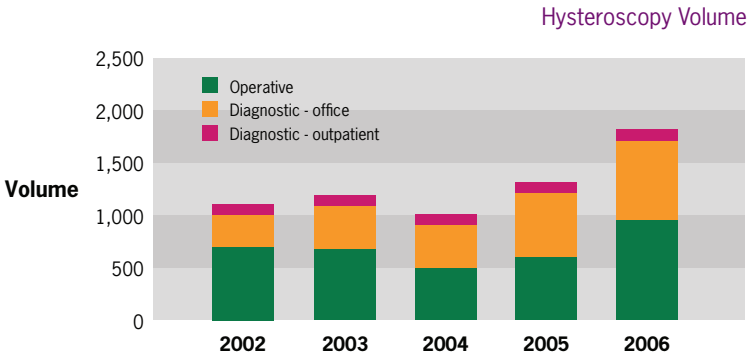
Surgeons were able to identify 40% of lower urinary tract injuries without using cystoscopy. All remaining injuries, however, were detected by performing cystoscopy. **This data suggests cystoscopy should be performed routinely during total laparoscopic hysterectomy procedures.**



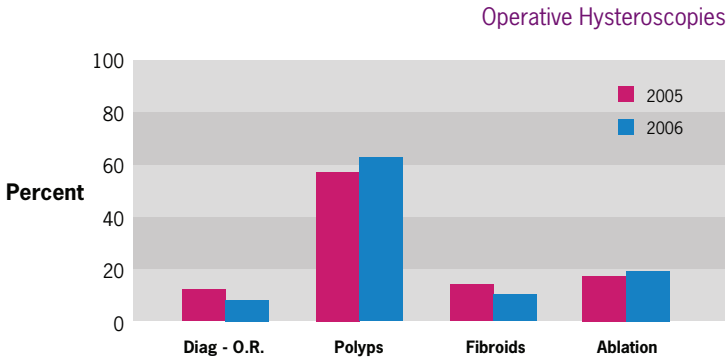
Closure of vaginal cuff after total laparoscopic hysterectomy

Hysteroscopy

Office based hysteroscopy is a viable technology. Its use minimizes the need for diagnostic hysteroscopy in the operating room. Advanced hysteroscopic procedures for intrauterine pathology and bleeding abnormalities are increasing as an alternative to hysterectomy.

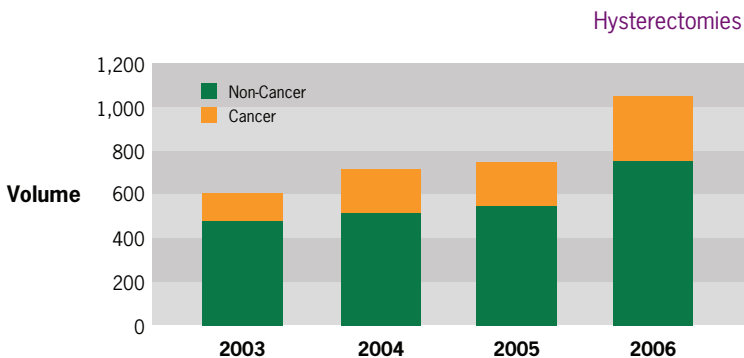
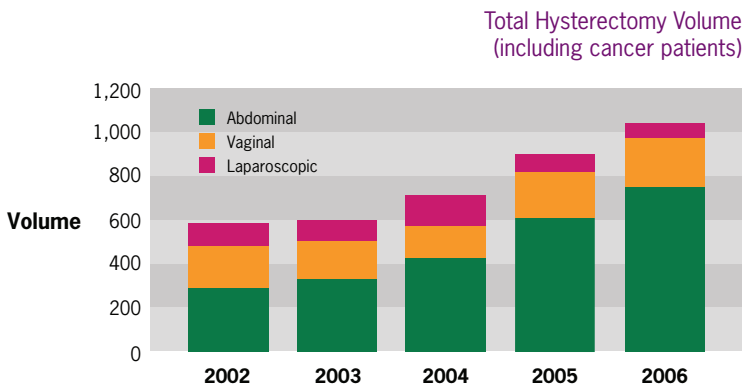


Various endometrial ablation techniques are available: Microwave, Rollerball and Thermal Balloon.

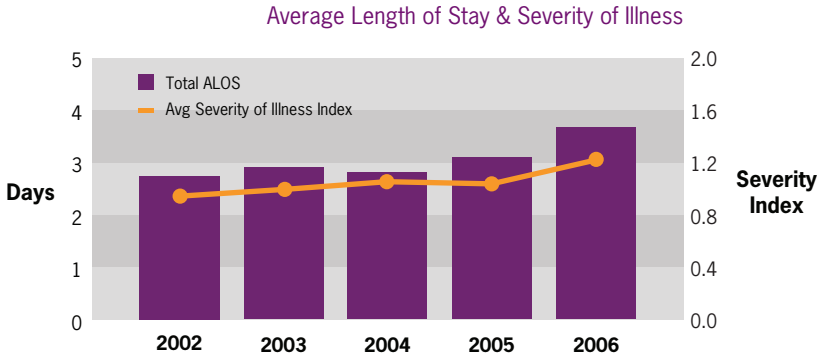


Hysterectomy

The number of hysterectomies performed is increasing due to an increase in gynecologic oncology surgeries. The number of laparoscopic and vaginal hysterectomies remains stable.



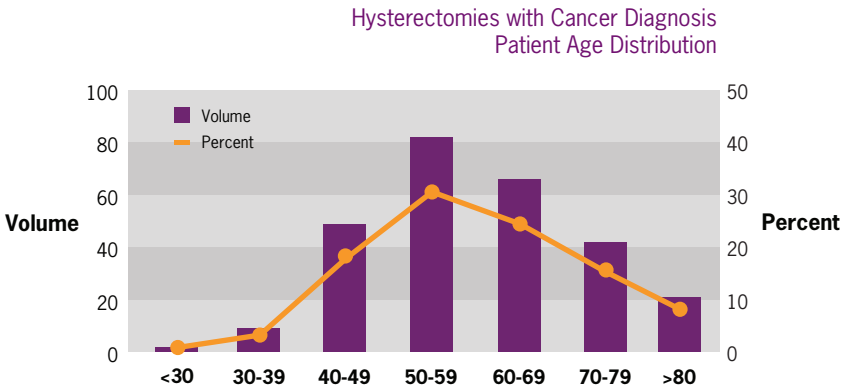
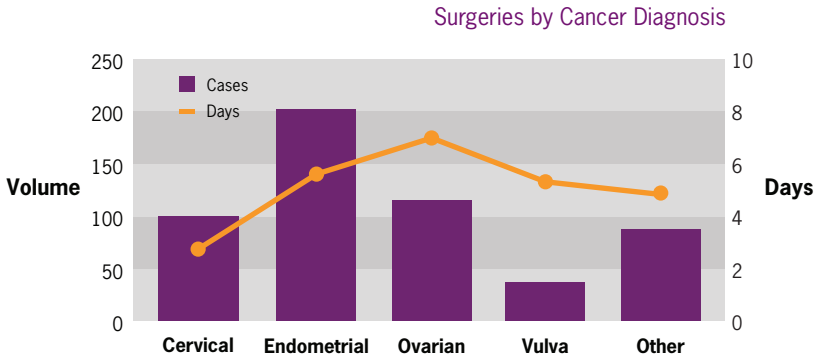
Average length of stay for hysterectomy increased slightly. This is attributed to increased patient acuity and increased number of gynecologic cancer surgeries at the main campus.



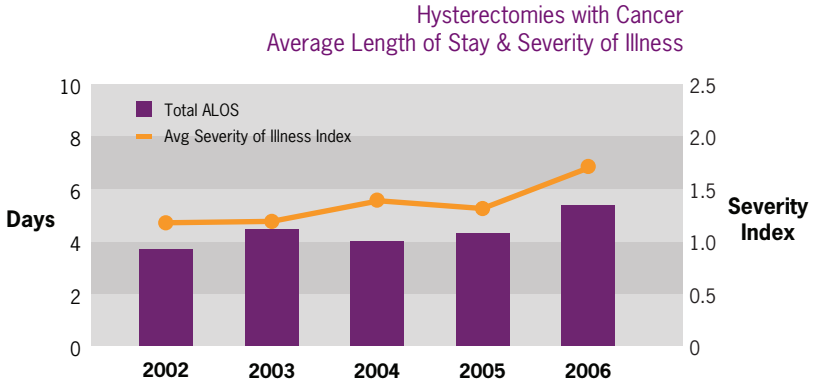
Gynecologic Oncology

Cleveland Clinic gynecologic oncologists are among approximately 600 gynecologists in the United States who are Board certified in gynecologic oncology and obstetrics and gynecology by the American Board of Obstetrics and Gynecology.

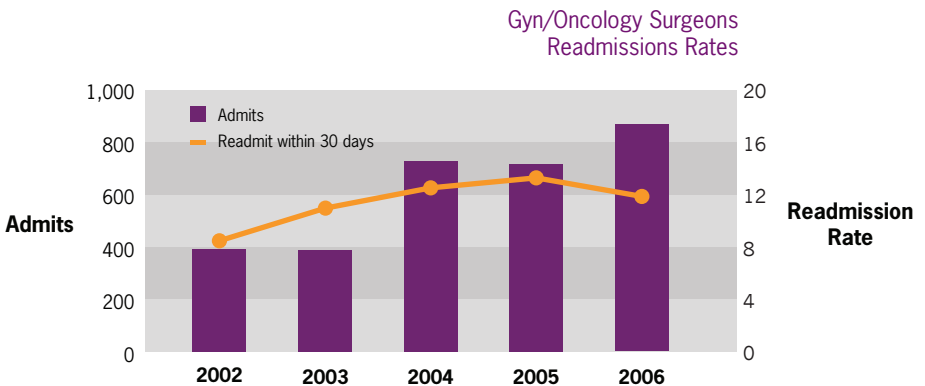
Most gynecologic malignancies are endometrial and ovarian. Patients undergoing surgeries for these conditions required longer hospitalizations.

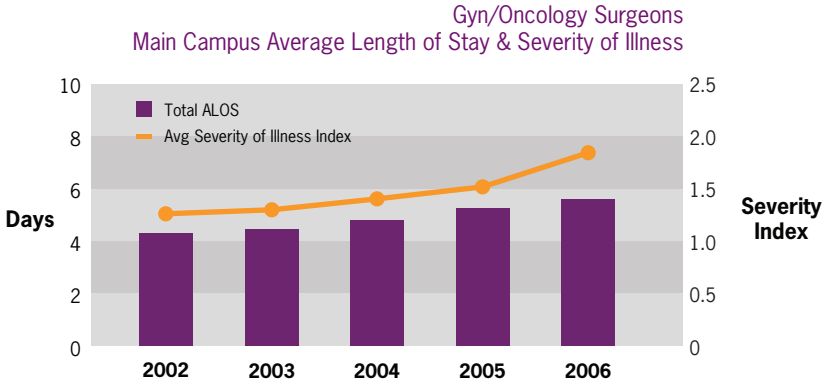


Increased acuity and volume of gynecologic oncology patients reflect the average length of stay noted in 2006.

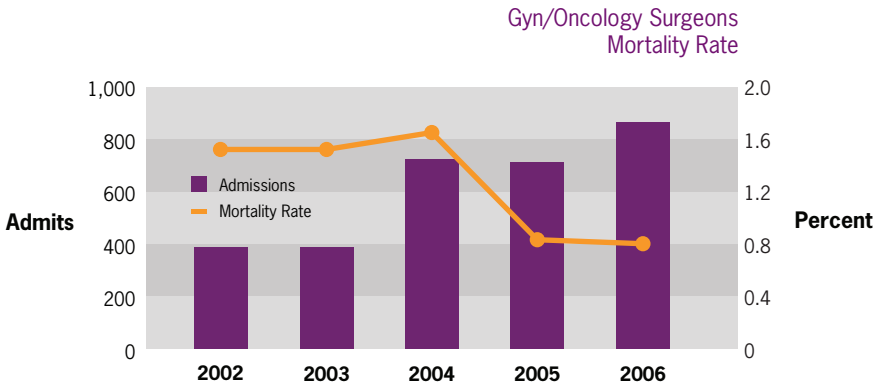


Readmissions within 30 days decreased, despite a 21% increase in gynecologic oncology surgeries.



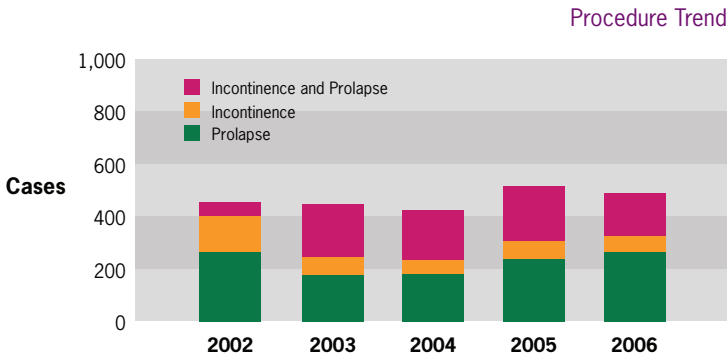


Mortality rates remained low even with an increase in gynecologic oncology surgical volumes.

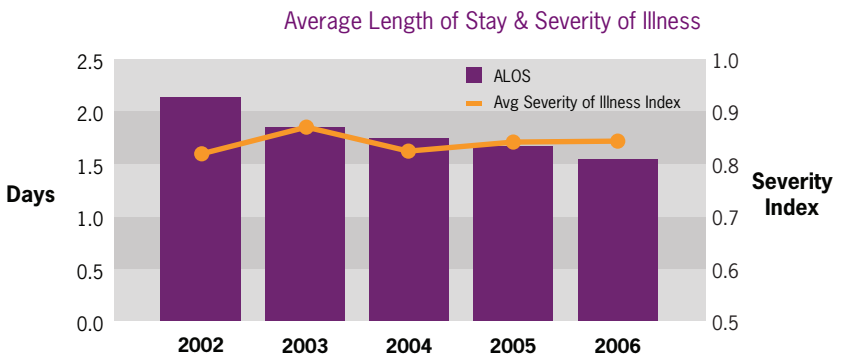


Incontinence & Prolapse Surgeries

It is estimated 11% of all women will have at least one surgery for pelvic organ prolapse or urinary incontinence during their lifetime. The number of patients treated for prolapse or incontinence has increased since 2004.



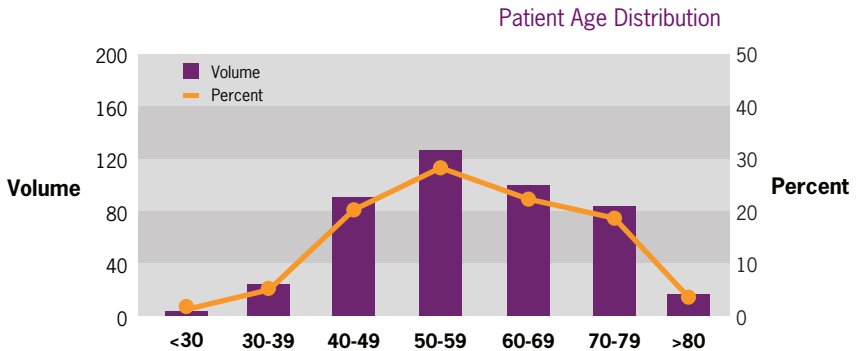
Eighty-seven percent of patients with pelvic floor disorders at the main campus undergo complex pelvic organ prolapse reconstruction with or without an anti-incontinence procedure.



The average severity of illness remains high but the average length of stay for patients undergoing incontinence and prolapse surgeries has decreased steadily since 2002.



Studies show 20% to 40% of women in their mid-to-later years of life have some incontinence.



There has been a 0% mortality rate for patients who underwent incontinence and prolapse surgery between 2000 and 2006, although over 20% of patients were greater than 70 years of age.



Surgical Risks - Rectocele Repair

Approximately 200,000 women undergo prolapse surgery annually in the United States. An estimated three-fourths of women with prolapse have a rectocele. The Section of Urogynecology and Pelvic Reconstructive Surgery conducted a study to compare outcomes of three different rectocele repair techniques: posterior colporrhaphy, site-specific rectocele repair and site-specific rectocele repair augmented with porcine graft.

Intraoperative Complications*

	Posterior Colporrhaphy	Site-specific Rectocele Repair	Site-specific Rectocele Repair with Graft	P
	(n = 37)	(n = 37)	(n = 31)	P
Mean operating time (mean ± SD)	150 ± 68	151 ± 69	169 ± 62	0.61
Median estimated blood loss (mean [range])	150 (50-950)	150 (50-600)	200 (50-3500)	0.14
Mean change in hematocrit (%) (mean ± SD)	8 ± 4	8 ± 3	9 ± 3	0.6
Median length of hospital stay (days) (mean [range])	2 (1-19)	2 (1-7)	2 (1-6)	0.57
Intraoperative complications:				
Blood transfusion	1 (3)	0 (0)	1 (3)	0.67
Bladder injury	0 (0)	2 (5)	0 (0)	0.15
Ureteral injury	0 (0)	0 (0)	1 (3)	0.3
Bowel injury	0 (0)	0 (0)	0 (0)	1

*Data presented as n (%) unless otherwise stated.

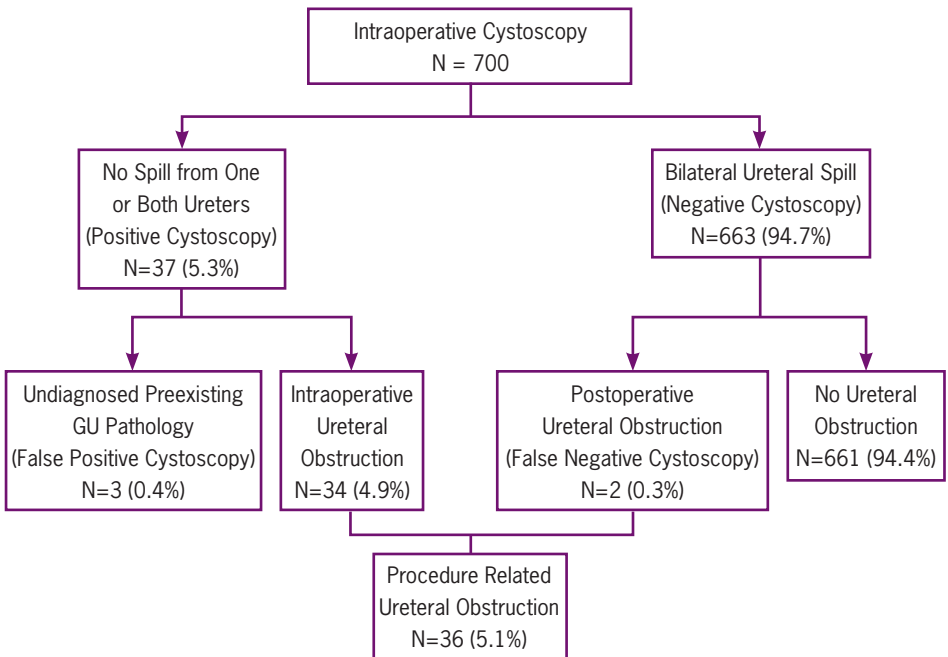


Traditional surgeries for rectocele repair with and without graft augmentation significantly improved bowel and sexual function as well as quality of life. Augmentation of traditional posterior colporrhaphy and site-specific rectocele repair porcine graft did not appear to improve surgical outcome.



Surgical Risks – Vaginal Surgery For Pelvic Organ Prolapse

Because of anatomic proximity, ureteral injury and obstruction are risks associated with pelvic organ prolapse surgery using a vaginal approach. Unrecognized ureteral injury can lead to additional procedures and significant short- and long-term morbidity.



Seven hundred patients who underwent vaginal reconstructive surgery for anterior and/or apical pelvic organ prolapse were evaluated for ureteral injury and obstruction. All patients had intraoperative cystoscopy with intravenous indigo carmine dye for the assessment of ureteral patency. The rate of ureteral obstruction was 5.1%. Ureteral injury was most common in patients undergoing uterosacral vaginal vault ligament suspension and McCall culdeplasty.



Ureteral Obstruction and Injury During Vaginal Surgery for Pelvic Organ Prolapse

	# Procedures Performed	<u>Ureteral Obstruction</u>			<u>Ureteral Injury</u>		
		N	%	(95% CI)	N	%	(95% CI)
Uterosacral vaginal vault ligament suspension	355	21	5.9	(3.9-8.9)	3	0.9	(0.2-2.6)
Proximal McCall culdeplasty	204	9	4.4	(4.4-8.2)	3	0.9	(0.2-2.6)
Colpocleisis	48	2	4.2	(1.2-1.4)	0	-	
Distal McCall culdeplasty	185	1	0.5	(0.1-1.3)	0	-	
Anterior colporrhaphy	574	2	0.4	(0.1-1.3)	0	-	
Indeterminate		1	1.0		0	-	
Overall	700	36	5.1	(3.7-7.1)	6	0.9	(0.4-1.9)

Cystoscopy accurately detects intraoperative ureteral obstruction and allows relief of obstruction in the majority of cases, reducing the ureteral injury rate to 0.9%.



Surgical Risks – Vaginal Surgery and Obesity

A 2 ½ year study compared the incidence of perioperative complications in obese and normal weight patients undergoing vaginal urogynecologic surgery.

Perioperative Complications*

Type	Obese (n = 194) (BMI ≥ 30 kg/m ²)	Non-Obese (n = 194) (BMI > 18.5 kg/m ² , < 30 kg/m ²)	P
Intraoperative complications	14 (7%)	8 (4%)	NS
Any vaginal or pelvic infection	7 (4%)	1 (1%)	0.03
Any operative site infection	13 (7%)	3 (2%)	0.01
Readmission	12 (6%)	4 (2%)	0.04

*Values are number of patients (%).

Although obese patients were more likely to develop an operative site infection when compared to normal weight patients, risk of developing perioperative complications at the time of vaginal surgery was not significantly increased in obese patients.



Pelvic Organ Prolapse & Quality Of Life

Women who suffer from pelvic organ prolapse, a condition that results from loss of support structures around the uterus, vagina and rectum, also suffer from a lower body image and decreased quality of life. Women who seek treatment for pelvic organ prolapse may see improvement in both body image and quality of life.

A study was conducted by the department which compared body image and quality of life in 47 women with advanced pelvic organ prolapse to a control group of 51 women. The control group consisted of women with normal pelvic floor support without urinary incontinence who visited the Clinic for an annual visit.

Abnormal Body Image for Subjects with Stage 3 or 4 Prolapse Versus Controls

	Patients with Stage 3 or 4 Prolapse (%)	Patients with Normal Pelvic Floor Support (%)	Adjusted OR (95% CI)
Self-conscious	29 (62)	28 (55)	4.7 (1.4-18.4)
Less physically attractive	30 (64)	19 (37)	11 (2.9-51)
Dissatisfied with appearance	18 (38)	29 (57)	0.7 (0.2-2.2)
Less feminine	25 (53)	13 (26)	4.0 (1.2-15)
Difficult to see self naked	22 (47)	27 (53)	1.1 (0.4-3.6)
Less sexually attractive	28 (61)	19 (38)	4.6 (1.4-17)
Avoid people	6 (13)	12 (24)	0.6 (0.1-3.2)
Dissatisfied with body	34 (72)	38 (75)	1.1 (0.3-4.1)



The study suggests women with advanced pelvic organ prolapse are more likely to feel self-conscious. They are also likely to feel less physically attractive, feminine, and sexually attractive than women with normal pelvic floor support.

Based on this data, a woman's quality of life (both condition specific and generalized) suffers as her perceived body image decreases. This illustrates the domain of body image, along with quality of life, should be considered as an outcome measure when determining efficacy of therapy for pelvic organ prolapse. Surgery for pelvic organ prolapse is likely to improve a patient's body image, quality of life and overall well-being.



In Vitro Fertilization

2004 IVF Pregnancy Rates*

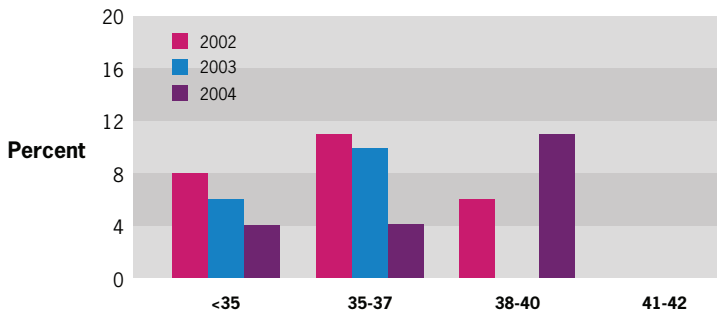
Age of Women	<35	35-37	38-40	41-42
Number of retrievals	230	111	75	33
Number of live births	118	47	21	5
Percentage of retrievals resulting in live births	51%	44%	30%	15%

*A comparison of clinic success rates may not be meaningful because patient medical characteristics and treatment approaches may vary from clinic to clinic.

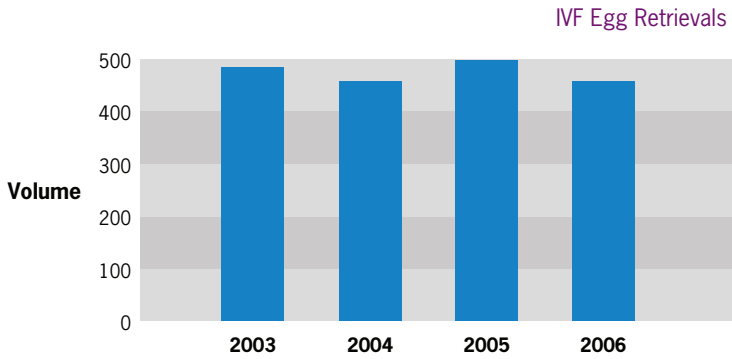
Multiple Pregnancies

Complications of *in vitro* fertilization (IVF) are often related to multiple pregnancies. A goal of IVF programs is to maximize pregnancy rates while minimizing multiple pregnancies.

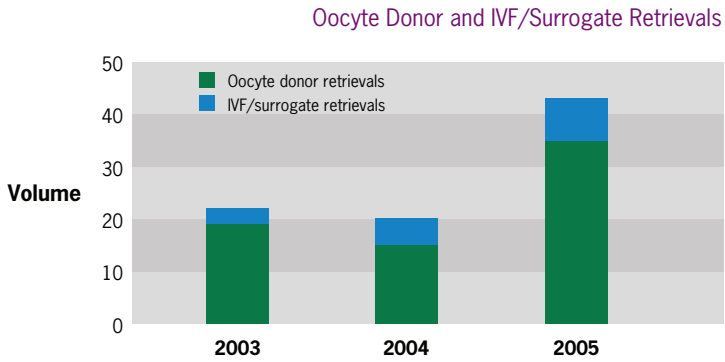
Pregnancies with Triplets or More Patient Age Distribution



IVF Egg Retrievals*



*Does not include oocyte and IVF/surrogate cycles

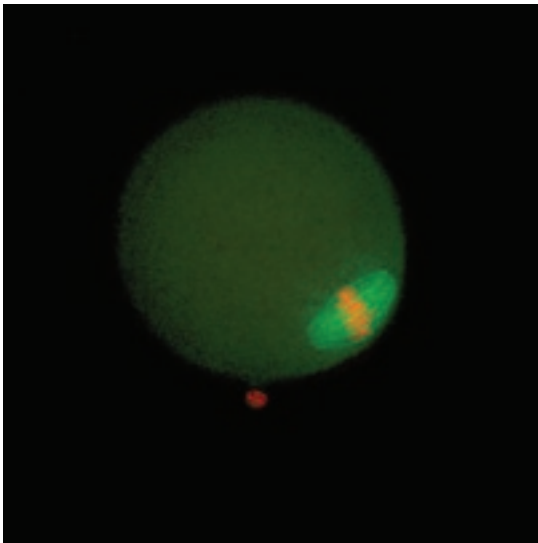


In addition to providing convenient, cutting-edge infertility care, Cleveland Clinic has research labs that specialize in infertility.

Research done in these labs tends to be in areas that have potential to be rapidly integrated into new innovative infertility treatments.

Examples of research includes:

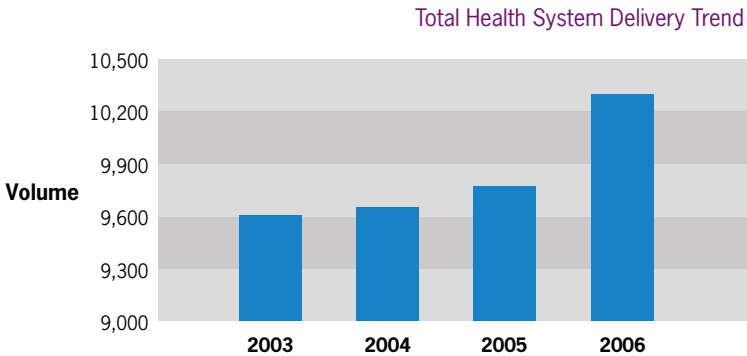
- Oocyte freezing
- Vitrification of embryos and sperm (a very rapid freezing technique)
- *In vitro* maturation of oocytes
- Assessment of secretions of HLA G by embryos
- Role of oxidative stress in fertility



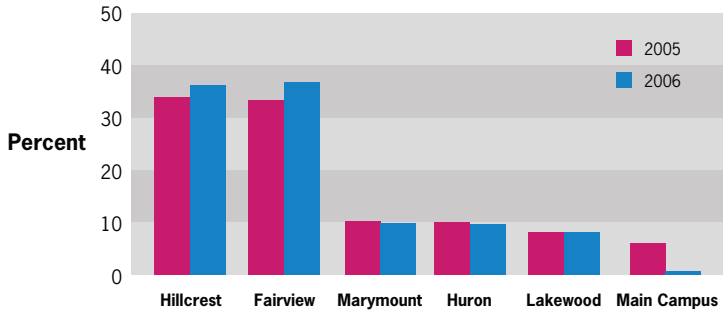
Obstetrics

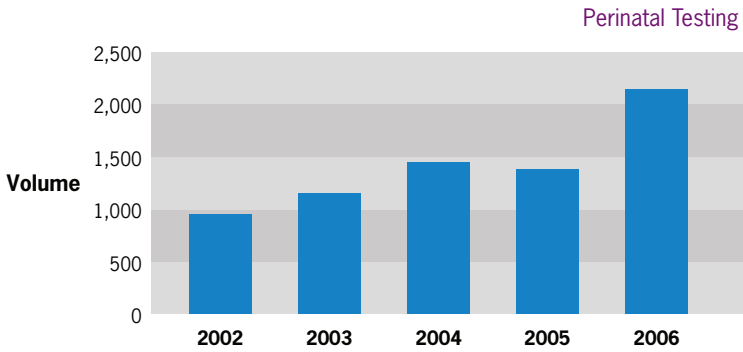
Cleveland Clinic's approach to obstetrics is to integrate its systems hospitals. Patients are transferred, if necessary, to specific hospitals if they require a level III nursery or subspecialty surgical care.

Deliveries				
Hospital	2003	2004	2005	2006
Hillcrest	2,864	2,733	3,336	3,734
Fairview	3,101	3,132	3,264	3,814
Marymount	697	707	960	969
Huron	900	851	947	982
Lakewood	686	794	754	787
Main Campus	1,352	1,436	541	10
Total	9,600	9,653	9,772	10,296



Delivery Distribution by Location





Perinatal testing includes:

dopplers, amniocentesis, biophysical profiles, chorionic villus sampling (CVS), and nuchal translucency



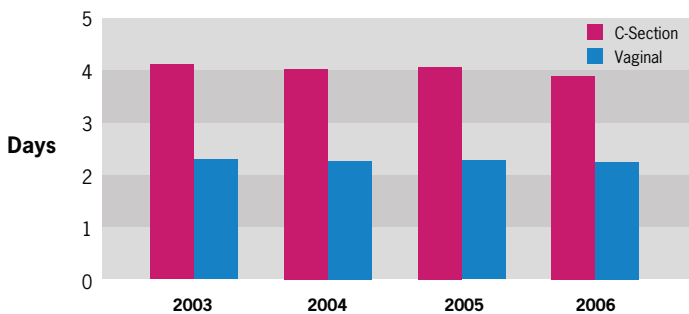
Nuchal Translucency



Average Length of Stay by DRG

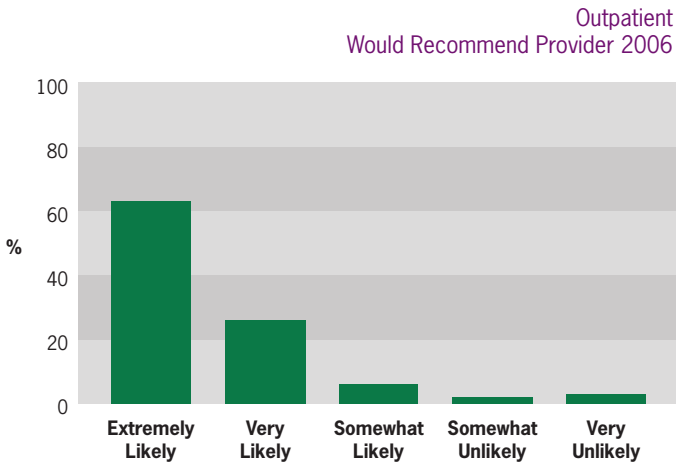
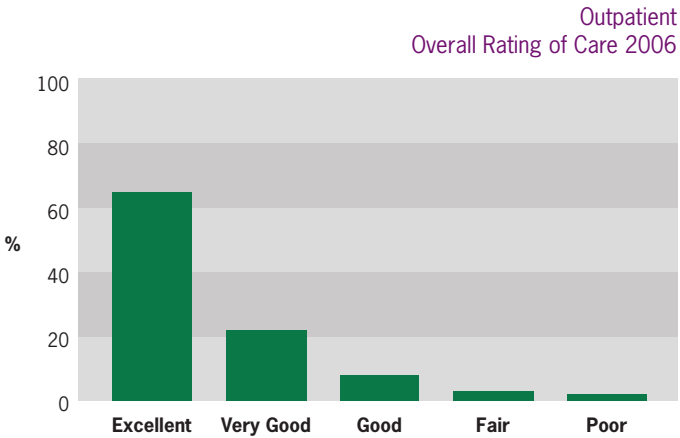
DRG Description	DRG	2003	2004	2005	2006
Cesarean Section with Complicating Diagnoses	370	4.88	4.74	5.05	4.53
Cesarean Section without Complicating Diagnoses	371	3.93	3.86	3.82	3.76
Vaginal Delivery with Complicating Diagnoses	372	2.63	2.52	2.61	2.65
Vaginal Delivery without Complicating Diagnoses	373	2.25	2.22	2.23	2.20
Vaginal Delivery with Sterilization and/or D&C	374	2.36	2.37	2.54	2.31
Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C	375	5.33	2.50	4.00	2.71
DRG Total		2.81	2.78	2.86	2.80

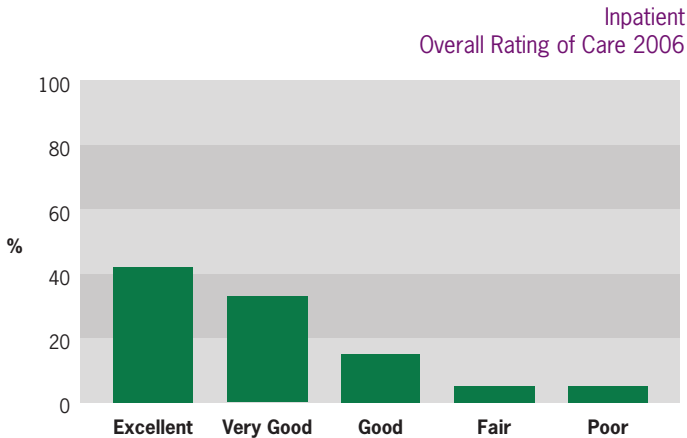
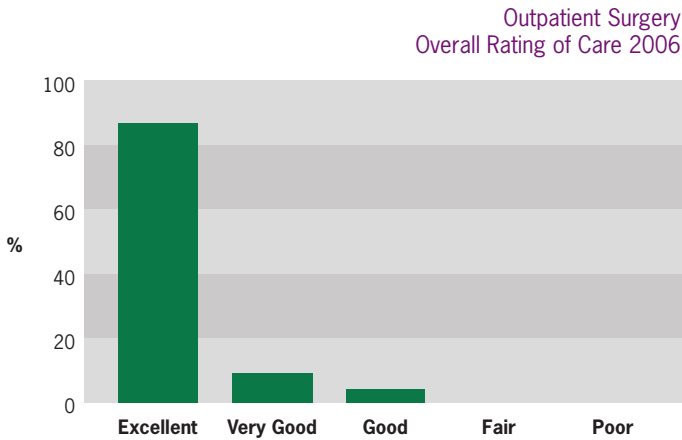
Average Length of Stay by Delivery Type



Patient Experience |

We ask our patients about their experiences and satisfaction with the services provided by our staff. Although our patients are already indicating we provide excellent care, we are committed to continuous improvement.





A Note regarding H-CAHPS, the New National Standard for Reporting Hospital In-Patient Experience of Care:

The service excellence data displayed above shows results from an external patient experience survey administered for Cleveland Clinic.

A new national standard patient experience survey instrument called H-CAHPS was instituted across the country on October 1, 2006. Public reporting of initial results on CMS's Hospital Compare website is anticipated in late 2007. Accordingly, Cleveland Clinic outcomes booklets will transition to reporting H-CAHPS inpatient service excellence results in 2007.



Innovations |

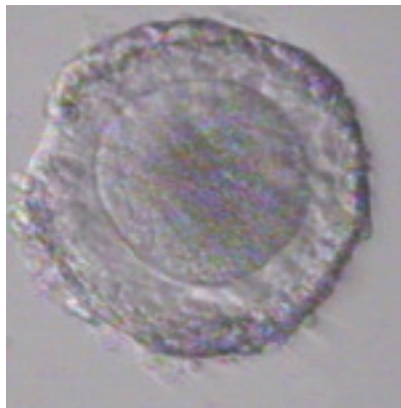
Reproductive Endocrinology and Infertility

***In Vitro* Maturation (IVM)**

While conventional *in vitro* fertilization (IVF) is the most popular treatment choice for the vast majority of women who are seeking advanced fertility techniques, *in vitro* maturation (IVM) is an option for specific subsets of women who are unable or unwilling to undergo controlled ovarian hyperstimulation utilized with conventional IVF.

IVM offers a shorter treatment time frame with, at most, only a few days of gonadotropin injections prior to egg retrieval. The oocytes are removed from the ovary while they are still immature. The immature oocytes are cultured in a complex medium until they have undergone extrusion of the first polar body, signaling the oocytes are mature metaphase II eggs. At this point, the eggs are ready for fertilization by intracytoplasmic sperm injection (ICSI).

The Cleveland Clinic Fertility Center is among the few centers in the nation offering *in vitro* maturation. Patients who may benefit from IVM are women who are at increased risk of severe ovarian hyperstimulation, women who respond poorly to gonadotropin stimulation, and women who are unable to complete a cycle of controlled ovarian hyperstimulation (e.g. oncology patients who wish to cryopreserve eggs and/or embryos prior to chemotherapy or pelvic irradiation).



Ovarian Transplantation

Although many patients of childbearing age can survive cancers and lead normal lives, they are at increased risk of impaired reproductive functions. Consequently, fertility preservation is an important quality-of-life issue for them. Cleveland Clinic reproductive endocrine and infertility specialists have introduced strategies to help preserve fertility in women of childbearing age who are undergoing chemotherapy or radiotherapy for cancer treatment. Ovarian tissue cryopreservation, ovarian tissue transplantation and oocyte cryopreservation are services offered to patients who cannot delay treatment for their disease but who wish to preserve fertility.

Obstetrics

Early Screening in Pregnancy Program

The new Cleveland Clinic Early Screening in Pregnancy (ESP) Program allows fast, accurate and noninvasive screening for Down syndrome and trisomy 18 at 11 to 12 weeks gestation. Cleveland Clinic maternal-fetal medicine staff members performed more than 300 first-trimester combined screenings. These consist of a Nuchal Translucency (NT) ultrasound and maternal blood work: pregnancy-associated plasma protein A (PAPP-A) and beta human chorionic gonadotropin (HcG). Cleveland Clinic maternal-fetal medicine staff are trained and certified to perform NT ultrasounds.

First-trimester screening provides patients earlier reassurance when results are normal and extra time to plan when a chromosomal abnormality is detected. Studies have also indicated first-trimester combined screening helps identify obstetric and pediatric risks, including premature rupture of membranes, preeclampsia and congenital heart defects, and detects multiple fetuses. Results can be ready in three to four days.

Chorionic villus sampling and amniocentesis are available for definitive diagnosis and for the 7% to 10% of patients in whom NT screening cannot be performed due to fetal position or movement.

Another noninvasive test, the Sequential Screen, has recently become available for women. The Sequential Screen takes advantage of the first-trimester combined screening with quadruple screening and evaluates risks for trisomy 21 (Down



syndrome), trisomy 18, and open neural tube defect (ONTD). The Sequential Screen has a 90% detection rate for Down syndrome and trisomy 18 and an 80% detection rate for open neural tube defect. The false-positive rate is low (1.2%).

Gynecologic Surgery

Interstim Procedure

Sacral nerve stimulation for urinary urgency, frequency, urge incontinence, and urinary retention refractory to conservative therapy is greatly improving quality of life for many patients. The patient undergoes stage I implantation of a quadripolar lead at the third sacral nerve root under fluoroscopic guidance. The patient is then hooked up to an external device to see if there is adequate improvement of voiding function. Stage II is implantation of the pulse generator, or bladder pacemaker. These bladder pacemakers are a wonderful option for patients who cannot tolerate, do not respond to, or cannot afford medication. (Currently, Botulinum toxin A is injected intramuscularly into the bladder, but is not FDA approved and, thus, not often reimbursed by insurance companies.) The Interstim Device requires two outpatient surgeries but can ultimately change a patient's quality of life.

Robotic Surgery

Robotic assistance has been applied to many laparoscopic procedures in urogynecology, gynecologic oncology and reproductive endocrinology and infertility. In fact, the first gynecologic surgery in the world performed with robot assistance was a microtubal reanastomosis at Cleveland Clinic. Other robot-assisted procedures performed to date include laparoscopic myomectomy, total laparoscopic hysterectomy, laparoscopic bilateral salpingo-oophorectomy, laparoscopic sacral colpopexy and uterosacral vaginal vault suspension, and laparoscopic pelvic and para-aortic lymph node dissections.

Despite the advantages of a shorter hospital stay, decreased postoperative pain, reduced narcotic use, a more rapid recovery and earlier return to work, most advanced laparoscopic procedures are not widely adopted. This could be secondary to the steep learning curve associated with certain laparoscopic techniques such as suturing and a potentially longer operative time compared with an open approach. Some surgeons, therefore, have advocated using robotics to perform these laparoscopic procedures.



Robotic systems were developed with the rationale of enhancing laparoscopic movements by making them more ergonomic, easier to perform and more precise. They also offer depth of perception by providing a three-dimensional monitor which compensates for some of the loss of tactile sensation with conventional laparoscopy.

Specifically, the da Vinci Surgical System's (Intuitive Surgical Inc., Sunnyvale, Calif. USA) endo-wrist instruments are capable of 7 degrees of movement (versus 3 degrees with conventional laparoscopy) that mimic the human wrist and are controlled intuitively at the surgeon's console. The problems of grasping, cutting or suturing at awkward angles during conventional laparoscopy are essentially eradicated.

Additional advantages of robotic assistance include surgeon comfort and probable increased longevity of a surgeon due to lack of fatigue and bodily stress, a means to bypass the learning curve of conventional laparoscopic suturing, less need of skilled assistance in the operating room for advanced laparoscopic procedures and future ability to operate from remote sites if capable assistance is present at the patient's side.

Robotic assistance for advanced laparoscopic procedures is a win-win situation for the patient and the surgeon.

We are in the midst of a trial comparing robotic laparoscopic sacral colpopexy to conventional laparoscopy and a similar trial for total laparoscopic hysterectomy. Additional uses for robot-assisted procedures in gynecologic surgery are being pursued, including radical hysterectomy for cervical cancer.



New Knowledge |

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New Knowledge: Research Initiatives |

Research on Ovarian Transplantation - Cryopreservation

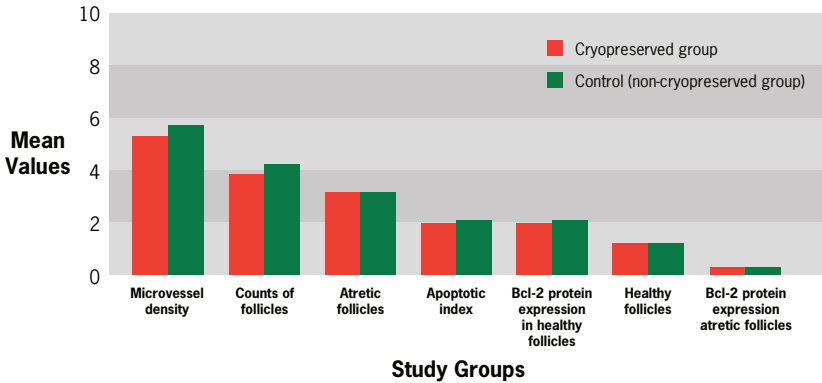
Our first trial of intact whole human ovary cryopreservation was performed. The aim of this study was assessment of the immediate post-thawing injury to the human ovary – cryopreserved as a whole with its vascular pedicle – rather than ovarian cortical strips.

The intact ovary was cryopreserved with its vascular pedicle. After thawing seven days, follicular viability, histology, a terminal deoxynucleotidyl transferase (TdT)-mediated dUTP-digoxigenin nick-end labelling (TUNEL) assay to detect apoptosis and immunoperoxidase staining to define Bcl-2 and p53 protein expression profiles of the ovarian tissue, were performed.

Overall viability of the primordial follicles was 75% and 78% in intact cryopreserved-thawed (C-T) ovaries and 81% and 83% in ovarian cortical strips in 46- and 44-year-old patients, respectively. Comparable primordial follicle counts, absence of features of necrosis, mean values of apoptosis and weak Bcl-2 and p53 protein expressions were observed both in the intact C-T ovary and in the C-T ovarian cortical strips.

We conclude that cryoperfusion and cryopreservation of the entire human ovary can be achieved with the maintenance of excellent viability of the superficial and the deeper tissues, using a slow-freezing protocol. Cryopreservation injury is associated with neither significant alteration in the expression pattern of Bcl-2 and p53 proteins in the ovarian tissues nor with significant follicular damage.





Research on Stress Urinary Incontinence

A randomized trial was undertaken to compare the Monarc Subfascial Hammock procedure with the Tension-Free Vaginal Tape procedure for the surgical treatment of stress urinary incontinence. This is a multi-center clinical trial conducted by members of the Department of Obstetrics and Gynecology. Other sites include the Greater Baltimore Medical Center (Baltimore, MD) and Good Samaritan Hospital (Cincinnati, OH).

The goal of this study is to compare two different surgical techniques for treatment of urinary incontinence in women. Both the Tension-Free Vaginal Tape (TVT) and the Monarc Subfascial Hammock methods are minimally invasive mid-urethral slings using a synthetic tape; however, the Monarc uses a transobturator approach rather than the TVT retropubic approach.

The primary research question is: is the Monarc equivalent to (not inferior to) the TVT in the treatment of stress urinary incontinence?



The second question is: does concurrent prolapse surgery (reconstructive surgery on the vagina due to a uterine/vaginal vault, or bladder or rectal prolapse) have any effect on the efficacy of these two procedures?

Women were considered for enrollment if they had bothersome stress urinary incontinence confirmed by urodynamics and a desire for surgical correction. Outcomes, including a bladder diary, health-related quality of life measures, and sexual function, were assessed before surgery and six months-, one- and two years after surgery.

One hundred eighty women were enrolled in this study and all subjects will have completed one-year follow-up by April 2007.

Role of Ovarian Cancer Immunoreactive Antigen (OCIAD1) in LPA-Induced Ovarian Cancer Metastasis and Recurrence of Metastasis

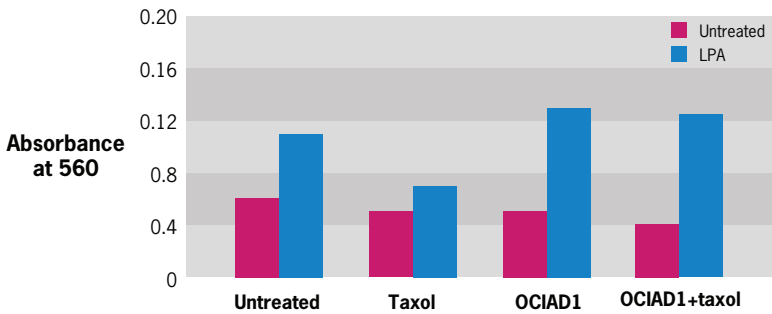
Using mass spectroscopy, immunocytochemistry and western blotting strategies, we observed OCIAD1 has significantly higher expression in metastatic sites than in the primary ovarian tumors. The role of OCIAD1 was then studied in the metastatic process. Several important cell-signaling molecules (*i.e.*, phosphoinositide 3-Kinase (PI3K), protein kinase C (PKC) and Erk kinase and p38 MAP kinase) were inhibited. We found blocking the function of PKC or PI3K decreases OCIAD1-induced cell adhesion, an important event in the development of metastatic disease.

Since lysophosphatidic acid (LPA) has been shown to significantly increase tumor cell migration and adhesion to specialized proteins, such as collagen I and laminin, we evaluated the role of OCIAD1 in LPA-induced metastasis. Migration assays revealed OCIAD1 did not alter the migratory properties of ovarian carcinoma cells *in vitro*, even in the presence of LPA. Overexpression, however, of OCIAD1 in cells attached to collagen I did prevent Taxol-induced cell detachment *in vitro*. This



raises the possibility that select cells overexpressing OCIAD1 in the peritoneal cavity may be protected from detachment and, therefore, protected from cell death, even in the presence of Taxol-based chemotherapy.

Work is currently ongoing to further dissect the role of OCIAD1 in ovarian cancer metastases and to evaluate whether or not inhibition of OCIAD1 expression can be used as a therapeutic molecular target in advanced or recurrent ovarian cancer.



Cell adhesion assay in presence of insult from Taxol; (note: HEY cells are an experimental ovarian cancer cell line). Cell adhesion is increased by OCIAD1 overexpression and resists detachment following exposure to Taxol.



CME Courses Hosted by Cleveland Clinic

2006 Women's Healthcare Across the Lifespan

Jan. 29 - Feb. 1, 2006

San Jose, Costa Rica

Second Annual Hysterectomy: Minimally Invasive Approaches and Alternatives

Jan. 20 - 23, 2006

Fort Lauderdale, Florida

5th Annual Update on Gynecologic Endoscopy

March 9 - 10, 2006

Cleveland, Ohio

2006 Update in Female Urology and Urogynecology

October 27 - 28, 2006

Cleveland, Ohio

Courses Planned for 2007

Third Annual Hysterectomy Conference: Tricks, Tools and Alternatives

Jan. 25 - 29, 2007

Fort Lauderdale, Fla.

Fourth Annual Advances in Surgical Gynecology and Female Sexuality

Jan. 27 - Feb. 3, 2007

San Jose, Costa Rica

Sixth Annual Update on Gynecologic Endoscopy

March 1 - 2, 2007

Cleveland, Ohio

For additional information regarding current Ob/Gyn publications, CME courses and other newsworthy events, please visit our Web Site at clevelandclinic.org/obgyn



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Tommaso Falcone, M.D.

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Professor, Cleveland Clinic Lerner College of Medicine

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surgery, surgery for endometriosis, infertility surgery



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 Gita P. Gidwani, M.D.



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and Gynecology Residency Site Director*

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Michael Anderson, M.D.
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Michael Bloomfield, M.D.
Linda D. Bradley, M.D.
Deborah Clark, M.D.
Amelia Cleveland, M.D.
Jonathan Emery, M.D.
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Gretchen Fisher, M.D.
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Kristina Sole, M.D.
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Cynthia Cover, CNM

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For more information about our staff,
visit www.clevelandclinic.org/staff.



Department Contacts | How to Refer Patients

For Physician Consults or Hospital Transfers to Main Campus

800.553.5056

24 hours a day, seven days a week

Hillcrest Hospital/Cleveland Clinic Obstetrics Program Hospital Transfer

440.312.2229

24 hours a day, seven days a week

(Hospital transfer requests for obstetrics patients will be handled by the physician on call.)



Locations |



Main Campus

9500 Euclid Ave./A81
Cleveland, Ohio 44195
Appointments: 216.444.6601

Hillcrest Hospital

Obstetrics & Gynecology Suite
440.312.2229

Hillcrest Hospital

Gynecologic Oncology Suite
440.312.5560

Fairview Hospital

Gynecologic Oncology Suite
at the Moll Center
216.476.7540

Beachwood Family Health and Surgery Center

216.839.3100

Independence Family Health Center

216.986.4130

Lorain Family Health and Surgery Center

440.204.7400

Marymount Medical Center

216.986.4000

Solon Family Health Center

440.519.6960

Strongsville Family Health and Surgery Center

440.878.2500

Willoughby Hills Family Health Center

440.943.2500

Cleveland Clinic Wooster

330.287.4930

Cleveland Clinic Fertility Center in Youngstown

330.702.1950

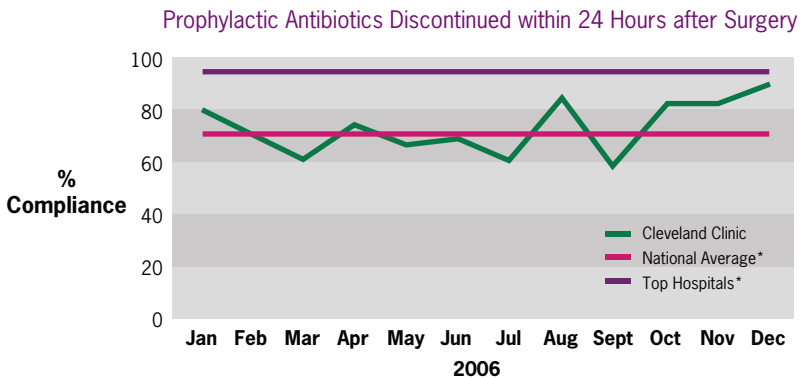
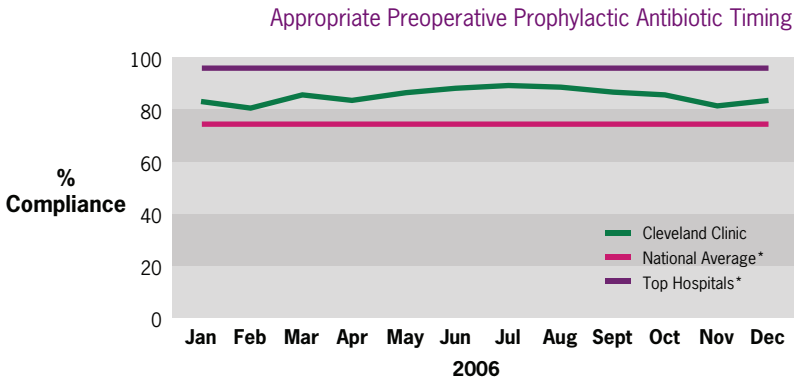
Visit us online at clevelandclinic.org/maps for maps and location information.



Division of Surgery Overview |

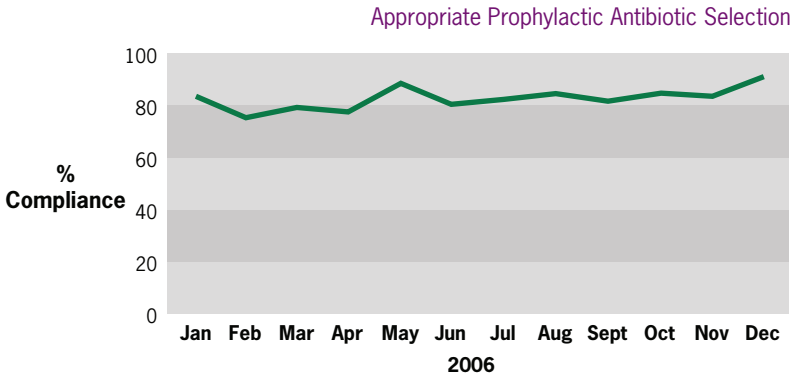
Surgical Infection Prevention

Surgical site infections contribute to surgical morbidity and mortality in all specialties. The timely administration and the appropriate selection of antibiotics prior to surgery in appropriate patients have been shown to reduce surgical site infections. A multidisciplinary team, involving Surgery, Infectious Disease, Anesthesia, Nursing and Quality has been working to ensure that our patients receive their antibiotics in a timely fashion. Data collected show our successful results:



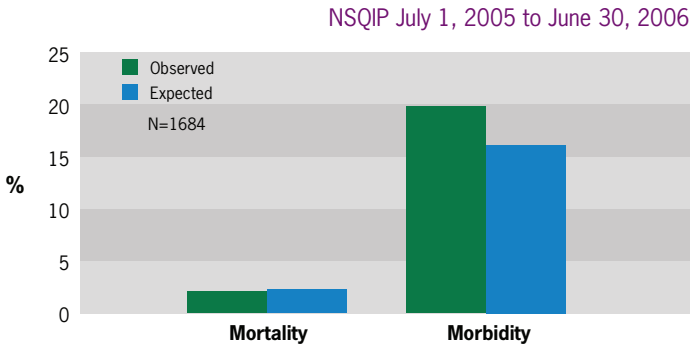
* Source: United States Department of Health and Human Services, Hospital Compare
Most current reported discharges April 2005 to March 2006.





National Surgical Quality Improvement Program

The American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) is a national program that objectively measures surgical outcomes. It reports risk-adjusted 30-day mortality and morbidity outcomes. Currently, the program includes surgical cases from Cleveland Clinic's departments of Colorectal Surgery, General Surgery and Vascular Surgery. As this program continues to grow at a national level, Cleveland Clinic is committed to expanding it to all surgical departments. We view NSQIP as the most valid, independent way to document our surgical outcomes and provide a basis for ongoing performance improvement.



Cleveland Clinic Overview |

Cleveland Clinic, founded in 1921, is a not-for-profit academic medical center that integrates clinical and hospital care with research and education. Today, 1,700 Cleveland Clinic physicians and scientists practice in 120 medical specialties and subspecialties.

Cleveland Clinic's main campus, with 41 buildings on 130 acres in Cleveland, Ohio, includes a 1,000-bed hospital, outpatient clinic, subspecialty centers and supporting labs and facilities. Cleveland Clinic also operates 13 family health centers, eight community hospitals, two affiliate hospitals, and a medical facility in Weston, Florida.

At the Cleveland Clinic Lerner Research Institute, hundreds of principal investigators, project scientists, research associates and postdoctoral fellows are involved in laboratory-based research. Total annual research expenditures exceed \$150 million from federal agencies, non-federal societies and associations, and endowment funds. In an effort to bring research from bench to bedside, Cleveland Clinic physicians are involved in more than 2,400 clinical studies at any given time.

In September 2004, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University opened and will graduate its first 32 students as physician-scientists in 2009.

For more details about Cleveland Clinic, visit clevelandclinic.org



Online Services |

eCleveland Clinic

eCleveland Clinic uses state-of-the-art digital information systems to offer several services, including remote second opinions through a secure Web site to patients around the world; personalized medical record access for patients; patient treatment progress access for referring physicians (see below); and imaging interpretations by the Department of eRadiology's subspecialty trained academic radiologists. For more information, please visit eclevelandclinic.org.

DrConnect

Online Access to Your Patient's Treatment Progress

Whether you are referring from near or far, our new eCleveland Clinic service, **DrConnect**, can streamline communication from Cleveland Clinic physicians to your office. This new online tool offers you secure access to your patient's treatment progress at Cleveland Clinic. With one-click convenience, you can track your patient's care using the secure **DrConnect** Web site. To establish a **DrConnect** account, visit eclevelandclinic.org or e-mail drconnect@ccf.org.

MyConsult

MyConsult Remote Second Medical Opinion is a secure, online service providing specialist consultations and remote second medical opinions for more than 600 life-threatening and life-altering diagnoses. **MyConsult** remote second medical opinion service allows you to gather information from nationally recognized specialists without the time and expense of travel. For more information, visit eclevelandclinic.org/myconsult, e-mail eclevelandclinic@ccf.org or call 800.223.2273, ext 43223.



Cleveland Clinic Contact Numbers |

How to Refer Patients

24/7 Hospital Transfers or Physician Consults
800.553.5056

General Information

216.444.2200

Hospital Patient Information

216.444.2000

Patient Appointments

216.444.2273 or 800.223.2273

Medical Concierge

Complimentary assistance for out-of-state patients and families
800.223.2273, ext. 55580, or email: medicalconcierge@ccf.org

International Center

Complimentary assistance for international patients and families
216.444.6404 or visit www.clevelandclinic.org/ic

Cleveland Clinic in Florida

866.293.7866

www.clevelandclinic.org



Cleveland Clinic is determined to exceed the expectations of patients, families and referring physicians. In light of this goal, we are committed to providing accurate and timely information about our patient care.

Through participation in national initiatives, we support transparent public reporting of healthcare quality data and participate in the following public reporting initiatives:

- Joint Commission Performance Measurement Initiative (www.qualitycheck.org)
- Centers for Medicare and Medicaid (CMS) Hospital Compare (www.hospitalcompare.hhs.gov)
- Leapfrog Group (www.leapfroggroup.org)
- Ohio Department of Health Service Reporting (www.odh.state.oh.us)

In addition, this publication was produced to assist patients and referring physicians in making informed decisions. To that end, information about care and services is provided, with a focus on outcomes of care. For more information, please visit the Cleveland Clinic Quality Web site at clevelandclinic.org/quality.



9500 Euclid Avenue, Cleveland, OH 44195

Cleveland Clinic is a not-for-profit multispecialty academic medical center. Founded in 1921, it is dedicated to providing quality specialized care and includes an outpatient clinic, a hospital with more than 1,000 staffed beds, an education division and a research institute.

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Cover photograph by Stephen Travarca