A FOUNDATION OF strength

A FUTURE OF hope

Department of Gynecologic Oncology & Reproductive Medicine

Biennial Report FY15-FY16

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History™
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Cover photo: Pamela Soliman, M.D.
A foundation of strength, a future of hope.

This year, MD Anderson celebrates its 75th anniversary. Gynecologic Oncology has been an integral part of this Institution since 1954, when it was founded by Dr. Felix Rutledge. Our Department and its people have always embodied the best of MD Anderson, starting with our unwavering commitment to patients.

I am so pleased to present this biennial report to highlight the Department of Gynecologic Oncology and Reproductive Medicine’s faculty and progress. Some things never change – our drive for excellence, our commitment to cutting-edge, patient-centered research, and our commitment to educating the next generation of leaders in our field. What has changed is the scope and impact of our reach and accomplishments. Our clinical program now includes twenty gynecologic oncologists, three general gynecologists, one oncofertility specialist, thirteen basic science faculty and over 120 talented staff. In addition to the Main Campus, patients can now receive their care at six different Houston-area locations. Our surgery trials portfolio continues to impact our field by conducting practice-changing clinical trials, including many that are international in scope. Our developmental therapeutics program is developing a robust biologic and immunotherapy pipeline of trials. Our basic biology program is supported by NIH Specialized Programs of Research Excellence (SPORE) grants in ovarian cancer and endometrial cancer, as well as individual NIH, CPRIT, DOD and philanthropic grants. We are excited by the work that we are doing as part of the Ovarian Cancer Moon Shot and the HPV-Related Cancers Moon Shot, including prevention and policy work that will have an immediate impact in decreasing mortality from ovarian and cervix cancers.

As a department, we have inherited an extraordinary legacy from our predecessors: a legacy of leading our field, of bold discovery and distinguished patient care. With this report, we hope to share with you how this tradition continues to thrive in our clinical care, research and educational programs.

Karen H. Lu, M.D.
Chair, Department of Gynecologic Oncology & Reproductive Medicine
Facts & Figures

24 PHYSICIANS
- 20 Gynecologic Oncologists
- 3 General Gynecologists
- 1 Reproductive Endocrinologist

20 Advanced Practice Providers

13 DEDICATED research scientists

37 clinical research nurses, data coordinators & regulatory personnel

1,747 TOTAL SURGERY CASES IN FY15

4,887 NEW PATIENTS AND CONSULTS IN FY15

SURGERIES BY APPROACH
- ROBOTIC: 10%
- LAPAROSCOPIC: 48%
- OPEN: 42%

CLINICAL TRIALS
- 201 patients participating in 22 clinical therapeutic trials
- 159 patients participating in 9 surgical trials
- 375 patients participating in 12 HSR trials

Cancer disease site: New patients
- CERVIX: 22.3%
- UTERINE: 34.7%
- OVARIAN: 37.4%
- VULVA/VAGINAL/OTHER: 5.6%
TRAINING
Largest Gynecologic Oncology fellowship program in U.S.

12 fellows total, 3 per year

T32 grant funded 2005-2021

SERVICES PROVIDED
at the Texas Medical Center, Lyndon B. Johnson Hospital, The Woman’s Hospital of Texas, The Woodlands, Katy, Bay Area, Sugar Land and Memorial City.

• Gynecologic Oncology (Surgery & Chemotherapy)
• Developmental Therapeutic and Immunotherapy Clinical Trials
• Surgical Trials
• Suspected Cancer Diagnosis
• Acute Gynecology Care for Cancer Patients
• Colposcopy & Pre-invasive Disease
• Survivorship Follow-up
• Genetic Counseling
• High Risk Ovarian Cancer Screening
• Sexual Health Counseling
• Reproductive Endocrinology & Fertility Preservation

Research and Educational COLLABORATIONS Outside of Houston

Argentina • Australia • Bolivia • Brazil • Bulgaria • Canada • Chile • China • Colombia • Denmark • El Salvador • England • Guatemala • India • Italy • Korea • Mexico • Mozambique • Peru • Puerto Rico • Spain • Thailand • Uruguay • Zambia

Within the U.S.: Arizona • Florida • Illinois • Maryland • Massachusetts • Minnesota • Nebraska • Nevada • New Jersey • New York • New Mexico • Oklahoma • Puerto Rico • Tennessee • Texas • Washington • Wisconsin
research-driven
PATIENT CARE
The Anderson Algorithm shows encouraging results

A novel surgical decision tree, the Anderson Algorithm provides a personalized surgical approach to the treatment of deadly ovarian cancer.

Returning from a trip to Mexico in 2013, Leslie Medley Russell developed what she thought was a bad case of food poisoning. When treatment didn’t help, an emergency-room CT scan showed fluid in her abdominal cavity. Her diagnosis was far more frightening: ovarian cancer.

Like most ovarian cancers, hers was discovered after it had spread beyond her ovaries, “coating” other organs and structures in her abdominal cavity and making it difficult to define through imaging.

The result is one of the toughest malignancies to treat—as well as one of the most lethal.

Testing a new strategy

The standard treatments for ovarian cancer—surgery and chemotherapy—produce the best results for most women. But until very recently, oncologists had no clear guidelines about the best order for this dual therapy. If the cancer had spread to the patient’s liver or outside the abdomen, many physicians recommended chemo first—to shrink the tumor—followed by surgery to remove as much as possible. Still, no one really knew the best course of action.

Fortunately, by the time Russell was diagnosed, MD Anderson was conducting a quality improvement initiative based on the research of Anna Fagotti, M.D., and her colleagues at Catholic University of the Sacred Heart in Rome. The Italians offered an initial guideline for physicians based on a scoring system they developed.

Using a laparoscope inserted through a small incision in a patient’s abdomen, the researchers looked directly at the extent of her disease and scored it from 0 (least severe) to 14 (most severe). They showed that women with a score of 8 or higher had a better surgical result if they received chemotherapy first. Those who scored below 8 did well with surgery first.

MD Anderson doctors refined the guideline, having two doctors independently agree on the laparoscopic score. They began implementing the protocol, which they call
In 2013, MD Anderson launched the Moon Shots Program, inspired by President John F. Kennedy’s challenge to reach the moon half a century ago. This bold project focuses on dramatically accelerating scientific discoveries to reduce cancer deaths.

Focused on redefining treatment for patients with high-grade serous ovarian cancer, the flagship projects for the Ovarian Cancer Moon Shot team include:

- Minimally invasive surgery to determine best treatment practices
- Universal genetic testing, with active family outreach
- “Window of opportunity” drug trials
- New genetic paradigms for neoadjuvant chemotherapy
- New treatment agents that target ovarian cancer

“This program is meant to be ambitious and aggressive,” said Anil Sood, M.D., co-leader of the Ovarian Cancer Moon Shot.

Russell’s response to treatment was typical. Her laparoscopy indicated that she would better benefit from chemotherapy before having surgery to remove the cancer. After nine weeks of chemotherapy, a CT scan showed that Russell’s tumor had shrunk sufficiently to be removed through surgery. After surgery, she had nine more weeks of chemotherapy.

Outcomes of the quality initiative are impressive: Among all eligible patients, 59 percent scored below 8. Of the remaining patients, 86 percent had surgery to remove all visible disease. Of the cases scoring 8 or higher, 66 percent received three cycles of chemotherapy before surgery; surgeons were successful in removing all visible disease in 75 percent of these cases.

The protocol offers a second advantage: During the laparoscopy, doctors can collect a tumor specimen that they can compare, later, to a biopsy obtained during surgery. A before-and-after molecular analysis of these tumors could lead to new treatments that go beyond the limits of surgery and chemotherapy.

“I’m convinced that MD Anderson’s approach to my treatment saved my life,” said Russell, who is a teacher and avid triathlete. “Side effects were almost nonexistent, and I felt 100 percent during the entire process.”

Sood and his team have presented the Anderson Algorithm at medical meetings and to other institutions and say that doctors at both academic cancer centers and private providers have been enthusiastic about adopting it.

“Ovarian cancer is so deadly, and so much needs to be done,” Sood said. “Through our concerted efforts, I believe we can make real progress.”
When serendipity shows up, Dr. Pamela Soliman takes note

High blood sugar isn’t usually viewed as a positive, but it may have saved Janet Chapman’s life. And now it promises to save other lives as well.

When she was diagnosed with advanced-stage endometrial cancer in 2006, Chapman had a hysterectomy and chemotherapy, which was customary treatment then and now. It seemed to work—until 2010, when she had gall-bladder surgery, and her surgeon noticed spots that turned out to be cancer.

Chapman’s doctors in Kentucky recommended more chemotherapy, but she chose to visit MD Anderson for a second opinion. “This patient population doesn’t have a lot of good options. Standard chemotherapy is the norm, but the chances of response in cases like hers are low,” said Pamela Soliman, M.D., medical director for the Laura Lee Blanton Gynecologic Oncology Center at MD Anderson.

Perfect timing
In this case, however, Chapman’s timing was perfect: Soliman and other MD Anderson physician-scientists had just completed a study of the mTOR inhibitor, everolimus, as part of the MD Anderson Specialized Program of Research Excellence (SPORE). This drug blocks a key pathway, PTEN/AKT, that permits the growth and survival of endometrial cancer.

By the time Soliman saw Chapman, the investigators were beginning a follow-up study that added the anti-estrogenic agent, letrozole, to the everolimus. In contrast to chemotherapy, both of these drugs are pills which don’t require a hospital visit. The goal was to attack the cancer using two separate mechanisms. This approach had helped patients with breast cancer, another estrogen-sensitive cancer.

Fighting off the cancer
Chapman enrolled in this clinical trial and began the everolimus and letrozole treatment. But when her blood sugar soared—a known side effect of everolimus—her doctor prescribed the diabetes drug, metformin, to treat it.

Aided by the combination of therapies from the Phase II trial, Chapman’s body successfully fought off the endometrial cancer and, after two and a half years, she has no active cancer.

Chapman was one of several patients who responded well to the Phase II study. Overall positive response to the mixture of everolimus and letrozole was close to 30 percent better than everolimus or standard chemotherapy. Soliman noticed that other patients in the trial, also taking metformin for elevated blood sugar, likewise responded well, and she wanted to know why. Could it be the addition of metformin to all of these patients’ regimens?

Adding supplementary agents
Supported by the SPORE, scientists went back to the lab, using animal models to confirm the positive results they’d already seen in Chapman. They began a third clinical trial that now combines all three drugs. Enrollment for the trial is now complete and investigators are awaiting the final results to determine if three drugs will prove better than two.

In future trials, Soliman’s team will look at further supplementary agents, such as new cd4 and cd6 inhibitors, that may have even greater additive effects. “Most of the trials looking at options for endometrial cancer include targeted therapies,” Soliman said. “With each of these studies, we are still trying to determine if molecular tests can identify the patients most likely to respond to new therapies, sparing [the others ineffective] treatment.”
For 15 years, MD Anderson has been one of only two medical centers to be awarded the Specialized Program of Research Excellence (SPORE) grant for the study of endometrial cancer, a $10 million, five-year federal grant from the National Cancer Institute.
Putting an end to cervical cancer

MD Anderson clinicians and researchers are taking giant steps toward an ambitious goal

Ending cervical cancer will be one of the great medical success stories of our time. It is tantalizingly near, yet sometimes frustratingly far away.

The Pap test, introduced in the 1940s, detects abnormal cells in a woman’s cervix that, if left untreated, could lead to cancer. Its now-routine use in the United States has led to a 70 percent drop in cervical cancers since the 1950s.

Not only that, but prophylactic vaccines (GARDASIL® and CERVARIX®, introduced in 2006 and 2009, block transmission of the human papillomavirus (HPV), which causes almost all cases of cervical cancer. The Centers for Disease Control and Prevention said, in a 2013 news release, “HPV vaccine is an anti-cancer vaccine. Preteen [sic] and teens are relying on the adults in their lives to protect them.”

Tantalizingly near, yet frustratingly far away

Yet the vaccine, like the Pap test in the 1940s, has yet to be fully embraced by the medical community—or the parents whose children qualify (ages 9 to 21 for males and 9 to 26 for females).

HPV is the most common sexually transmitted virus in the United States. Almost all sexually active (unvaccinated) people will acquire HPV at some point in their lives. As a result, a small number will develop cancers of the cervix, vagina, vulva, penis, anus and oropharynx (back of throat or tonsils).

Underserved, underscreened and underinsured

In contrast to the 70 percent drop in cervical cancers nationwide, the cervical-cancer death rate in Texas’ Rio Grande Valley—the four southernmost counties along the border with Mexico—is 30 percent higher than in the rest of Texas. Even in Houston, many underserved, underscreened and/or underinsured women are dying unnecessarily from cervical cancer. And in Latin American, African and Caribbean countries, it’s one of the leading causes of cancer deaths in women. Globally, some 530,000 new cases of cervical cancer are diagnosed annually.

The culprit? Lack of resources, said Kathleen Schmeler, M.D., associate professor, Gynecologic Oncology and Reproductive Medicine. “Seventy percent of the population in the Rio Grande Valley is uninsured, and the number of public hospitals serving the uninsured in this area is zero,” said Schmeler. “Residents there are at a huge disadvantage.”

Too often, women in the Rio Grande Valley are unaware of the disease until they are diagnosed with advanced, incurable cervical cancer. Yet this cancer is almost always preventable when detected early with a simple Pap test—or another test, developed in 2011, which detects HPV.

“Without health insurance or public health care facilities, only a small number of women in these medically underserved counties receive these simple and lifesaving screening tests,” Schmeler said.

More screenings and treatments

To address this need, MD Anderson applied for and received a grant from the Cancer Prevention Research Institute of Texas (CPRIT) to increase cervical cancer screenings and preventive treatments for women in Cameron, Hidalgo, Willacy and Starr counties, which have 40 percent fewer physicians and half as many nurse practitioners as the rest of Texas.

The CPRIT grant has two goals: to educate the public to get screened and to educate/train health care providers to perform the necessary tests and procedures for women with abnormal results.

Project ECHO (Extension for Community Healthcare Outcomes), for example, uses videoconferencing to link MD Anderson faculty in Houston with Rio Grande Valley clinicians. Called “telementoring,” it bridges the treatment gap between Houston and the underserved areas by enabling real-time discussions of patient cases and medical techniques.

The Houston providers are teaching additional clinicians in the Rio Grande Valley—including nurse practitioners, physician assistants and midwives—to perform three medical procedures commonly indicated after an abnormal Pap or HPV test:

- Colposcopy—cervical examination using a special magnifying device
- Cervical biopsy—removing a small sample of tissue from the woman’s cervix for further examination
- LEEP (loop electrosurgical excision procedure)—using a thin, low-voltage electrified wire loop to remove precancerous tissue

“The CPRIT grant has allowed us to work more closely with our colleagues in the Rio Grande Valley to screen more women for cervical cancer, as well as educate and train additional local providers to better manage cervical dysplasia,” Schmeler said.
Global screening
A grant from the National Institutes of Health supports an MD Anderson partnership with Rice University to refine the use of a high-resolution microendoscope (HRME). This point-of-care diagnostic tool improves real-time diagnosis of cervical cancer in places where inadequate health care infrastructure hinders diagnosis.

“It gives providers an alternative way to diagnose cervical precancer and manage care efficiently,” said Schmeler. This improves outcomes by streamlining patient care and reducing return trips for patients who need further treatment.

MD Anderson and Rice are testing the HRME in Brazil, El Salvador, Houston and the Rio Grande Valley. And, in partnership with the nongovernmental organization Global Coalition Against Cervical Cancer, they are assisting low- and middle-income countries in their efforts to prevent and control cervical cancer.

Schmeler leads another global program, CONEP (Central America Oncology Education Program). Since it was launched in 2009, CONEP has connected with more than 100 Central American medical residents and faculty, bringing gynecological oncologists from MD Anderson and other institutions to see patients and train local doctors in Guatemala, Honduras, El Salvador, Costa Rica and Panama. The program is expanding to Mozambique and other areas of Africa through the International Gynecologic Cancer Society (IGCS) Education Committee, which Schmeler also leads as Chair.

In Houston and far beyond
Lois Ramondetta, M.D., professor, Gynecologic Oncology and Reproductive Medicine, said the department’s broader efforts include:

- An HPV-vaccination information-transfer program, in partnership with The University of Texas School of Public Health and 10 federally qualified clinics
- A Texas environmental scan identifying facilitators of and barriers to HPV vaccination
- Four annual Houston HPV summits and a two-day NCI Designated Cancer Centers HPV Summit in late 2015 that attracted representatives of 30 U.S. cancer centers to collaborate in addressing next steps
- Multilevel system interventions to Texas medical providers to raise vaccination rates
- An assessment of HPV knowledge among MD Anderson’s survivor clinics, seeking to identify and mobilize survivors as advocates for HPV vaccination
- A problem-based learning case, developed in collaboration with The University of Texas Health Science Center, to educate first- and second-year medical students about HPV beginning this fall
Responding to the growing threat of HPV, MD Anderson expanded its ambitious Moon Shots Program in 2015 to include HPV-related cancers.

“This is a unique and exciting opportunity,” said associate professor Kathleen Schmeler, who co-leads the effort with professor Lois Ramondetta, both in Gynecologic Oncology and Reproductive Medicine, along with Cathy Eng, M.D., professor, Department of Gastrointestinal Medical Oncology, and Erich Sturgis, M.D., associate professor, Head and Neck Surgery. “We’re working with our colleagues in gynecological surgery, head and neck surgery, medical oncology, anal and colorectal surgery, gastrointestinal medicine and urology.”

The moon shot’s goals include:

- Prevention and screening—dramatically increasing HPV vaccination rates and increasing access to early diagnosis
- Discovery—seeking new targets for therapy through an integrated genomics effort
- Immunotherapy and novel trials—working to influence the immune system to fight cancer

“The moon shot has spurred us to organize our efforts and move our work benefiting patients to the next level,” Schmeler said. “It’s not acceptable to make small, incremental improvements. We must do something big and innovative on their behalf.”
“We would love to see the curriculum project expand across the UT system,” she said. “HPV infection is part of being human today, and for doctors to fail to talk about it is substandard care—in the same way as failing to mention the need for colonoscopies or mammograms.”

Locally, Ramondetta and her MD Anderson colleagues in information technology, nursing and health policy are working with the State of Texas and Harris Health System to ensure that the 50,000 age-eligible, but low-income boys, girls, young men and women in Harris County receive HPV vaccinations through the Adult Safety Net Program.

“We still see so many advanced cancers in this population, and it has to stop,” she said. “Historically, Harris County couldn’t afford to vaccinate everyone. But we have recently been approved by the state as an Adult Safety Net provider (for the first time), and we will be able to vaccinate 19- to 26-year-olds, as recommended by the Centers for Disease Control.”

**Within our own walls**

“We have a goal to ensure that, by 2020, 80 percent of 11- to 15-year-olds in the United States will be fully vaccinated against HPV,” said Ramondetta, who stresses education, advocacy and policy in her fight against HPV and its six associated cancers.

“We started small, by surveying our own campus to learn how MD Anderson employees deal with the threat of HPV,” she continued. “We discovered, after reviewing 4,000 employee responses, that they were no better informed than the community around us.”

The survey spurred a multidepartmental effort involving pediatrics, information technology and education. It seeks to educate MD Anderson health care providers, as well as age-eligible employees and their children, about the urgent need to be vaccinated.

“The pilot employee-vaccination program began June 11 with the intent to increase vaccination rates in our own ‘cancer-center family’ by providing convenient vaccinations on site. We will offer the clinic monthly for one year and re-evaluate,” said Ramondetta. “Depending on the need, we may offer quarterly clinics thereafter.”

‘A powerful force for change’

Ramondetta, working with MD Anderson government relations, is advocating for statewide HPV vaccinations through the Texas Department of Health and Human Services. “This is a partnership with the Texas Pediatric Society, and that has been a big help, enabling us to work with state leaders in pediatrics,” she said. Among other activities, they have produced educational videos, now available on the web.

“It’s a very exciting time for us,” she continued, “especially as MD Anderson prepares a large marketing campaign tied to an educational message for all of the cancer moon shots.

“It takes a village to do this, and we are building a village; it includes our health-policy specialists, head and neck oncologists, anal oncologists, urologic oncologists, Texas professional societies, the Centers for Disease Control and Harris Health System, as well as gynecologic oncologists.

“Working together, we are a powerful force for change.”
Setting a new standard of surgical care

Large clinical trials aim to prove that ‘less is more’

In the recent past, cervical cancer meant a one-way ticket to hysterectomy, lengthy hospitalization and recovery times, and potentially high rates of complications. But the Innovative Surgery Working Group in the Department of Gynecologic Oncology and Reproductive Medicine, led by Pedro Ramirez, M.D., professor, promises to change that. Its groundbreaking slate of clinical trials is bringing minimally invasive and fertility-sparing surgery to women with cervical and other gynecological cancers.

Several trials are multi-institutional, including three international collaborations. “These trials explore important questions of research in patients with early-stage cervical cancers,” said Ramirez. “They foster great academic relationships and support the MD Anderson mission to eradicate cancer, not only nationally, but also internationally.”

**International surgical trials**

The ConCerv Trial, led by Kathleen Schmeler, M.D. and associate professor, explores whether or not it is safe and feasible to perform conservative surgery (conization or simple hysterectomy) in certain patients with low-risk, early-stage cervical cancer. It will very likely change the surgical approach to such patients and significantly improve the rates of complications associated with the more traditional approach: radical hysterectomy.

A collaboration with 11 other institutions in the United States, Colombia, Peru, Brazil, Mexico, Argentina, Thailand and Australia, the ConCerv Trial already has accrued 80 of the total 100 patients it will evaluate. “We expect it to be the new standard of care for patients who are considered ‘low risk,’” Ramirez said.

Ramirez leads the large LACC Trial, in which early-stage cervical cancer patients are selected at random for either radical hysterectomy through a laparotomy (open surgery) or minimally invasive surgery. It studies overall survival, quality of life, feasibility of lymphatic mapping, pelvic-floor dysfunction and overall cost. This multi-institutional trial is underway in 26 centers around the world and has accrued 490 of the total 740 patients planned.

“We’re hoping to set minimally invasive surgery as the new standard for these patients, reducing complications while improving their recovery times and overall quality of life,” he said.

The working group also is studying:

- Outcomes of radical trachelectomy (removal of the cervix while keeping the uterus), which is intended to treat early-stage cervical cancer while preserving fertility
- Ovarian function after radical trachelectomy

**Promising new treatments for endometrial cancers**

“In addition to our trials for cervical cancer, we’re also studying several important questions in patients with endometrial cancers,” Ramirez said.

“The biggest risk factor for endometrial cancers is obesity, and it used to be found mostly in postmenopausal women,” he said. “But, in today’s population, we find a lot of obese young women who have never had children. If they develop endometrial cancer, they generally want to preserve their fertility. But this was not considered feasible because standard treatment has been a total hysterectomy.”

However, new studies are evaluating the role of conservative management in patients with low-risk endometrial cancer—with the goal of treating the disease without the need for a hysterectomy.

Ramirez attributes the success of the Enhanced Surgical Recovery Program to the integration of a large group of collaborators: surgeons, anesthesiologists, research data coordinators, statisticians, pharmacists, nurses and dietitians.

One trial is exploring the use of intrauterine devices (IUDs) to safely treat these cancers. This novel approach, led by Shannon Westin, M.D. and associate professor, treats patients who have low-grade endometrial cancer by inserting the Levonorgestrel IUD. Patients whose disease is stable after three months of this treatment are randomly selected to either continue their use of the IUD alone or use it along with everolimus, a targeted agent that appears to reduce the cancer’s resistance to progesterone therapy.

Ramirez and his colleagues also are evaluating the role of sentinel lymph-node mapping for low- and high-risk endometrial cancers. “Today, this is the standard of care for breast cancers and melanomas, and we hope it can become the standard for endometrial cancers.”

Typically, these cancers are treated with the removal of all the patient’s lymph nodes in the pelvis and lower abdomen. Classified as major surgery, it has the potential for significant intraoperative (during surgery) complications, plus long-term complications associated with disruption of the lymphatic drainage system of the pelvis and lower extremities.
Sentinel lymph-node mapping enables surgeons to identify the “sentinel” lymph node, defined as the first lymph node into which a tumor drains. “Instead of taking lots of lymph nodes and sending them to pathology for a standard study, we’re identifying one lymph node that is sliced by a pathologist into many, many thin layers and studied very, very thoroughly,” Ramirez explained.

Pamela Soliman, M.D., associate professor and medical director for Laura Lee Blanton Gynecologic Oncology Center at MD Anderson, has completed an important trial evaluating the role of sentinel-node mapping in patients with high-risk endometrial cancer. She will present the results of her trial at the International Gynecologic Cancer Society Meeting in October 2016. The results are highly anticipated and may set a new standard of care.

Westin is leading a novel trial that is evaluating the role of sentinel-node mapping in low-risk endometrial cancers and also identifying molecular biomarkers that may predict recurrence.

Enhanced Surgical Recovery Program
In addition to the major trials, Ramirez is equally enthusiastic about the Enhanced Surgical Recovery Program (ESRP), which he leads with Larissa Meyer, M.D., assistant professor. “This is a fabulous program that is already showing remarkable results,” he said.

Begun in November 2014, the program is a prime example of evidence-based medicine. “We took an extensive look at the surgical literature and critically evaluated it, working to identify what we could do to improve the entire perioperative experience,” said Ramirez. “Perioperative” generally refers to the three phases of surgery: preoperative, intraoperative and postoperative.

“We saw inconsistency in all three surgical stages here at MD Anderson, so we set 22 standards that all of our surgeries must meet. It’s had a tremendous impact.” He cited:

- Shorter patient stays
- Much improved patient-reported outcomes
- An 80 percent reduction in the amount of opioids used for pain (Twenty percent of the patients in the new program required no opioids at all)
- Reduced costs to the hospital system

“And we achieved all this without increasing our complication rate or our readmissions, both of which often happen when you try something new,” he said.

Ramirez attributes the success of the program to the integration of a large group of collaborators: surgeons, anesthesiologists, research data coordinators, statisticians, pharmacists, nurses and dietitians. Nearly 1,000 patients have been treated in this groundbreaking program.

“It’s had a truly amazing positive impact on both the hospital system and our patients,” said Ramirez.
Developmental therapeutics and immunotherapy

Advancing the standard of care through innovative clinical trials

Providing exceptional research-driven patient care is central to the mission of the Department of Gynecologic Oncology and Reproductive Medicine. The department’s pioneering clinical research focuses on developing innovative approaches to the treatment of gynecologic cancers. Taking a new treatment from the lab to the clinic doesn’t happen overnight. Researchers in developmental therapeutics and immunotherapy are steadfastly focused on translating scientific discoveries into clinical practice through the design and implementation of clinical trials.

Gynecologic Oncology and Reproductive Medicine’s research is supported by a robust infrastructure that includes 37 research nurses, data coordinators and regulatory staff who help coordinate and run our portfolio of trials. As the program expands, the department continues to develop collaborative relationships with other academic institutions and the pharmaceutical industry through strategic alliances, and is prioritizing its commitment to the Moon Shot programs and SPOREs (Specialized Program of Research Excellence).

**Bench to bedside**

Robert L. Coleman, M.D., professor, spearheads the department’s developmental therapeutics program. Coleman has dedicated his career to driving innovative research through clinical trials. He works closely with the department’s researchers as they assess discoveries made in the lab for clinical trial potential.

“It’s very collaborative,” said Coleman. “Brainstorming with the labs as they work to move assets into the clinic, designing and running the trials...it’s exciting to help build a bridge between the lab and the clinic and see the process through from beginning to end.”

Coleman is the principal investigator for a first-in-human Phase I trial that explores the use of gene silencing to treat cancer. The trial is a collaboration with Anil Sood, M.D., professor, and builds on findings made in his lab.

“Dr. Sood identified a specific gene called EphA2 that seems to be very important for solid tumor biology, including ovarian and endometrial cancer,” said Coleman. The gene is responsible for invasion, metastasis and angiogenesis. The researchers did a series of experiments developing a short interfering RNA sequence (called siRNA), which could silence the gene’s activity in the tumor. The challenge was to develop a delivery mechanism that could deliver this product throughout the body.
I think the idea that during my lifetime there may be significant changes in the way we treat cancer is very exciting.”

—Amir Jazaeri, M.D.
The team developed a nanoparticle liposome which would self-assemble around the siRNA sequence, enabling the agent to be delivered in the blood safely and efficiently. Once in the tumor, the liposome would break down in the tissue, releasing the sequence. “The animal models were very impressive, both as a single agent and in combination with chemotherapy agents we commonly use in gynecologic cancers,” said Coleman. This led the team to develop a human drug candidate they call EPHARNA – which is the siRNA sequence for EphA2 packaged in a liposome.

The trial launched in late 2014 and is funded by the Uterine Cancer SPORE and CPRIT (Cancer Prevention Research Institute of Texas). Fifteen patients have been infused to date as the trial evaluates the agent’s safety through a number of dosing levels. As the study progresses, the team will assess the drug’s effect on tumor size, and then expand the trial to assess chemotherapy versus chemotherapy-plus-EPHARNA to see if the drug is augmenting the effect normally seen in chemotherapy.

“It’s exciting because it’s all home-grown; it came out of our lab,” said Coleman. “We’ve got an army of people who have worked on this, including most of the fellows who have come through this lab.”

Coleman emphasizes the importance of innovative research to improve outcomes for patients. “I live by the mantra ‘research cures cancer.’ The only way we’re going to move the needle is with research.”

**Early drug development**

Shannon Westin, M.D., associate professor, is also aiming to move the needle through her research in developmental therapeutics.

Westin focuses her research on early drug development, novel window of opportunity studies and utilizing biomarkers to predict response and resistance to therapeutics.

With her training as a fellow in Investigational Cancer Therapeutics and participation in the FDA Investigators Course, Westin brings considerable expertise to the conduct and design of Phase I studies. She is leading the department’s efforts to create a sustainable business plan for the creation of a Phase I unit within the Gynecologic Oncology Center.

Currently, Westin is conducting an early drug development Phase Ib trial for patients with ovarian, breast and endometrial cancer which evaluates the combination of a PARP inhibitor with one of two different drugs targeting the PI 3-kinase pathway. Researchers perform biopsies before and after treatment to understand which patients respond and what changes occur in the tumor.

Westin points out the trial is one of the first to evaluate on a large scale the impact of these drugs in endometrial cancer. The research will not only help identify who
should get this combination of drugs, but could also lead to the discovery of new drug combinations.

The trial, which combines efforts with the breast cancer team, is both a Moon Shot and SPORE protocol. It is a large-scale, multidisciplinary effort that fuses the unique expertise of its collaborators.

“Our collaborator in Systems Biology, Gordon Mills [M.D., Ph.D., professor and chair], has a platform that allows us to really understand resistance to therapy,” said Westin. “By testing a tumor before it gets treated and then after treatment, we can really see what’s changing, what’s driving that tumor to either respond or not respond. Nobody really has access to anything like that, except here at MD Anderson.”

Westin underscores the potential benefits clinical trials have for patients: “For these early phase trials, patients have exhausted a lot of their standard of care opportunities, or their standard of care opportunities have shown dismal response rates,” said Westin. “There’s a huge opportunity for the patient to be on the front line and get the benefit of the new drug before anyone else. I think it’s an exciting opportunity, and that’s the reason why you come to a place like MD Anderson.”

**Immunotherapy**

In addition to developmental therapeutics, the Department of Gynecologic Oncology and Reproductive Medicine has a strong focus on immunotherapy, a new way of fighting cancer that stimulates the body’s own immune cells to attack cancer cells.

Cancer cells take advantage of the pathways (or “checkpoints”) that turn immune cells off, allowing them to circumvent immune cells. A new class of drugs, called immune checkpoint inhibitors, interfere with these checkpoints and reactivate the immune cells.

In 2014, Amir Jazaeri, M.D., associate professor, joined the faculty to lead the department’s immunotherapy research. Jazaeri, who had been studying the molecular genetics of ovarian cancer, was intrigued by the potential use of immunotherapy to treat patients with gynecologic cancers.

“Initial success with checkpoint inhibitors was seen in melanoma,” said Jazaeri. “I work very closely with Dr. Patrick Hwu’s research team, who are melanoma immunologists and physicians, and we’re trying to translate their experience in melanoma into gynecologic cancers. Because the drugs are not melanoma-specific drugs, but immune system-specific drugs, there was an immediate hope we could get these drugs to produce beneficial results in other types of cancer as well.”

In ovarian cancer, some of the early results of a drug affecting one major pathway, the PD1 pathway, are showing response rates of about 10-15%. With a lower response rate than is typically seen with melanoma, Jazaeri’s research seeks to better understand what the barriers to immunotherapy are in ovarian cancer.

“If single agent checkpoint inhibitors produce a 10-15% response rate, by using drugs that affect two different immune checkpoints, can we get an increased benefit, or a larger portion of patients to respond?” Jazaeri asked.

To this end, Jazaeri is leading a clinical trial to evaluate the effect of two immune checkpoint inhibitors in platinum-resistant ovarian cancer. Platinum resistance refers to patients whose cancer has now become resistant to the most effective drugs currently available, which are platinum-based chemotherapies.

“Patients with platinum-resistant ovarian cancer are particularly in need,” said Jazaeri, “because despite decades of research with various chemotherapies and biological therapies, this patient population still has very low response rates to any treatment, and a median progression-free survival of only 3 to 4 months.”

Jazaeri is driven by the impact immunotherapy research could have for patients. “I think the idea that during my lifetime there may be significant changes in the way we treat cancer is very exciting.”

Jazaeri, Westin and Coleman, along with all the department’s dedicated researchers, know improving cancer diagnosis and treatment is only possible through continued innovative research. Finding a cure is the long-term goal, but on a day-to-day basis the department focuses on providing exceptional patient care.

“Patients are at the center of everything that we do,” said Westin. “We always make the patient our top priority. We’re always going to do what’s right for them.”
Terri Woodard, M.D.
Preserving fertility after cancer

MD Anderson’s oncofertility program increases its influence

The decision to have a baby is daunting for many. When you’re a cancer patient of reproductive age, it can be overwhelming.

Will you still be fertile after treatment? “Doctors often are scared of this conversation because the patient is sick and doesn’t seem to be a good candidate for parenthood,” said Terri Woodard, M.D. Woodard is an assistant professor and reproductive endocrinologist at MD Anderson with a joint appointment at Baylor College of Medicine who focuses on oncofertility: fertility after cancer.

“We doctors tend to make a lot of assumptions about who the patient is and what she or he wants,” said Woodard, who counsels women and men of reproductive age who have cancer. “But we shouldn’t make assumptions, regardless of the stage of their illness, their age, their fertility history or the number of children they already have.”

Instead, Woodard encourages MD Anderson oncologists to refer their patients to her for consultation. “I want them to give patients the opportunity to tell us their desires, and I can educate them about their options,” she said.

Many options for fertility after cancer

The options may include assessments of their fertility and streamlined access to fertility-preservation methods: egg freezing, sperm banking and embryo freezing through MD Anderson’s partnership with Baylor College of Medicine.

These methods have been used for many years and offer fairly good success rates. Others, such as testicular- and ovarian-tissue freezing, are considered experimental, and their success rates are unknown.

“There are so many ways to build families today, and talking about the future is therapeutic,” said Woodard. “One patient said, ‘I came here knowing that I was not a good candidate for parenthood. But thanks for giving me the opportunity to talk about the part of me that wants to be a mother.’”

Since 2012, oncofertility program grows

MD Anderson established its oncofertility program in December 2012. During the first year, Woodard saw 200 patients. In 2015, she saw twice that many, and the number of new consults continues to grow. To date, more than 100 men and women have taken advantage of the fertility-preservation options offered by the program.

Woodard describes the program’s four main objectives: to offer access to comprehensive reproductive health care for cancer patients and survivors, to conduct research in this area, to educate health care providers and their patients, and to advocate for these services at institutional, local and national levels.

Advocating for change

As improvements in cancer treatment have permitted longer lives for cancer patients, the importance of fertility preservation has grown. But huge barriers remain—primarily financial ones, as neither the preservation procedures nor the needed psychological support is typically covered by health insurance.

Woodard, representing the oncofertility program at MD Anderson, is working hard to change insurers’ minds. “It is a travesty that fertility treatment is not covered by insurance for most of these patients,” she said. “It is not their fault that we give them chemotherapy, and they become sterile.”

In pursuit of that goal, Woodard spends an increasing share of her time advocating for change. “I speak to departments and sections at MD Anderson, participate in awareness activities, speak at national meetings, write articles and consult with groups who likewise advocate in this category.”

It’s all part of her passion for helping to free cancer patients to make their own decisions about parenthood.
Braving the obstacles to fertility

One woman’s story of conceiving after cancer

Angela Jorge Gilchrist, 38, is glowingly pregnant with her first child, a girl due in February. That is miracle enough for her, but her story—like most cancer stories—is more complicated than that.

It begins with a family history of ovarian and breast cancer and continues through Gilchrist’s genetic testing, her double mastectomy, a serious automobile accident, her wedding, hypothyroidism, in vitro fertilization, genetic testing of the embryos, a Zika scare, and embryo implantation. And it will continue past the birth of her baby in late February, with more decisions—and more surgery.

Gilchrist’s mother Gloria Esther Diaz died in 2000 of ovarian cancer, when Angela was 21. Her aunt also died of ovarian cancer. Another aunt and her grandmother had breast cancer. When Gilchrist’s blood count dropped in 2011 due to a cold, a specialist recommended that she be tested for the BRCA gene mutation.

BRCA 1 and BRCA 2 mutations account for 5 to 10 percent of all breast cancers, as well as 15 percent of ovarian cancers. The mutation can come from the mother or father. A child of a parent with the mutation has a 50 percent chance of inheriting it.

“It took seeing a genetic counselor and some serious consideration before I agreed to testing for the BRCA gene. My thought was ‘If I’m going to test, I need to be ready to make a change—a double mastectomy and removal of my ovaries—or the test would be worthless,’” she said. But after more thought, she decided to go through with it. “I finally made the decision that I would have the test and, if it was positive, I would have the double mastectomy.”

The test was positive: She carries the BRCA 2 mutation. According to the American Cancer Society, some 50 to 65 percent of women with either of the BRCA mutations will develop breast cancer, and 35 to 45 percent will develop ovarian cancer before age 70.

A double mastectomy reveals cancer cells

“My father is from Portugal and very old school, so it was hard for him to accept my decision. I was literally sitting on the table, waiting for the mastectomy, when my dad said he didn’t think I should do it. But I knew in my heart that this was God’s plan.” She went ahead. “Having the mastectomy was one of the best decisions I’ve made,” she said.

Gilchrist had breast reconstruction, with which she is very pleased. The next step was to consider an oophorectomy—removal of her ovaries.

An automobile accident—and her own wedding

“Six months after the 2011 surgery, when I was scheduling ultrasounds of my ovaries every six months, I traveled to Massachusetts for my sister’s bachelorette party. On the way to the party, our SUV was struck head-on by another vehicle. It was crushed and rolled over several times, landing upside down in a ditch. The first thing I did was feel for my breasts—were they all right?”

They were, but Gilchrist had a lacerated liver, a broken thumb, fractured ribs, a head contusion, multiple bruises and whiplash. She spent a week in the hospital and a month at her sister’s home in Massachusetts, unable to travel back home to Texas. “I stayed until my sister got married—and tried to hide my cast in the pictures,” she laughed.

Fortunately, within a few months she was no longer in pain. In March 2012, she married her fiancé Colin Gilchrist and became a loving stepmother to his two children. “Colin is the most amazing man. He has been at my side for everything,” she said.

Pushing her ‘new’ body

Devoted to health and fitness after a disturbing weight gain in her thirties, Gilchrist got even more serious in February 2013, when she joined a team of women who train for and compete in bodybuilding competitions. In her first competition a month later, she placed third in her class and qualified for national competition. By August 31, she stepped on the national stage for the first time and placed first in one category and third in another, qualifying for a pro card with the International Federation of Bodybuilding and Fitness.

“One of the most important things bodybuilding did for me was help me feel comfortable with my ‘new’ body,” she said.

Now, at 37, she felt the pressure of her “biological clock.” Adding to that pressure were the repeated recommendations from her doctors that she have her ovaries removed.

Discussing fertility options

“My husband and I wanted to have a baby, but we weren’t conceiving naturally,” she said. “And of course we were worried that my child would inherit the BRCA mutation.”

Gilchrist had repeated conversations with Woodard about her options and ultimately brought her husband into the conversation. “After talking with Dr. Woodard, Colin came on board,” she said. They decided to try in vitro fertilization (IVF) with a pre-implantation genetic diagnosis of the embryos so they could identify the ones without the BRCA mutation.
They began the IVF process in February 2016, but had to delay the embryo implantation after their March vacation to Mexico raised concerns about the Zika virus. “The doctor harvested 13 of my eggs. Eight embryos made it to day five for genetic testing. Six had other chromosome issues, and one had the BRCA mutation. There was just one healthy embryo left that did not have the BRCA mutation. I was so sad and scared because I knew I only had one shot.”

As it turned out, one shot was all she needed, as Angela soon learned she was pregnant with a healthy child.

‘Telling my story’

“I know my story doesn’t compare to someone who has had cancer and had to undergo treatment. In no way can I relate to that and, after watching my mom go through it, I feel for anyone who has it. It’s a scary disease, and I wish they would find a cure for all cancer.

“But I do hope that my story can help those that have family who have suffered from cancer and may be carrying the gene.

“When I tested, I never thought it would be positive, and it was scary finding out. But I think finding out was the best decision I’ve ever made. Not only does my risk decrease, but I know that I am able to bring into this world a beautiful, healthy little girl—with no worries that she may carry the same gene.”

Gilchrist intends to wait two years after her daughter’s birth to schedule her oophorectomy, which is expected to reduce her risk for ovarian cancer to 1 percent—on par with the risk of women who don’t have the BRCA gene mutation. Dr. Woodard has told her she has the option to freeze embryos if she chooses, but she has not decided if she will.

In the meantime, she hopes to find a way to speak to other women facing the same decisions she did. “Having a doctor tell you something and speaking with someone who has been through it herself are two different things,” she said.

The Gilchrist family eagerly awaits the arrival of their newest addition, a baby girl due in February 2017.

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**MYTHS:**

1. **A consultation is only useful prior to cancer treatment.** Although Woodard acknowledges that it’s best to discuss fertility before cancer treatment, she stresses that patients can benefit from the conversation during or after treatment. “The conversation matters,” she said.

2. **Fertility isn’t that important for someone who is diagnosed with cancer.** Although it may not seem to be a priority at the time of diagnosis, many survivors report that they wish they had at least learned about options to preserve their fertility.

3. **Not many options exist for preserving fertility.** Patients can benefit from many proven and emerging technologies.

4. **Pursuing fertility preservation will delay the patient’s cancer treatment.** Some methods have never required much time, and newer protocols have shortened the time required for other methods.

5. **Fertility treatment is unattainable due to cost.** Yes, these services can be expensive and often are not covered by insurance. But there are payment options, too.

6. **It is dangerous for a cancer survivor to conceive.** Generally, this is not true.
Training tomorrow’s giants in gynecologic oncology

“I have only one way of thanking my mentors in the fellowship program at MD Anderson, and that is by paying it forward,” said Amanda Bruegl, M.D., a graduate of MD Anderson’s Gynecologic Oncology fellowship program and the first Native American gynecologic oncologist.

Bruegl, from the Oneida tribe in Wisconsin, set out to become a primary-care physician for her tribe when she entered the University of Washington School of Medicine in 2003. “I still believe in that model, but it was not a good fit for me,” she said. “Instead, at the end of my intern year, I did my gynecologic oncology rotation and loved it!”

Now an Assistant Professor of Gynecologic Oncology at Oregon Health & Science University, she’s a voice for Native American women, educating the community about issues such as HPV and diabetes, as well as caring for gynecologic oncology patients. “I call myself a ‘women’s cancer doctor,’” she said.

Oldest, largest and most successful gynecologic oncology fellowship program

Bruegl was recently one of 12 fellows in the world-renowned Gynecologic Oncology Fellowship Training Program at MD Anderson—the largest program in the world.

Initiated in the 1950s by Dr. Felix Rutledge, the program has been continuously accredited by the American Board of Obstetrics and Gynecology since the inception of subspecialty certification in 1973. Three new fellows are accepted each year, with a total of 12 fellows in the program at any one time. Since its inception, 171 fellows have graduated from the internationally acclaimed program.

Michael Frumovitz, M.D., professor and a 2005 graduate of the program, is now its director. He calls it “one of the most prestigious gynecologic oncology fellowships in the country.”

“It has traditionally been the kingmaker, and many, many of the leaders in our field are graduates,” Frumovitz said. These include both clinical investigators and physician-scientists: 32 alumni are division heads, 16 are OB/GYN department chairs, and 13 have served as president of the Society of Gynecologic Oncology.

Frumovitz says the cornerstone of the fellowship program is recruitment of the best people, who are attracted by the department’s renowned faculty, strong commitment to mentorship, proven research record and high-volume, highly complex clinical environment. “When our fellows graduate, they’ve already started their careers,” he said. “We give them support and guidance, and what they do when they leave is a continuation of the strong foundation they built here.”

Bruegl, for example, feared that she would have to set aside her dream of specializing in native women’s health care. Instead, she was encouraged and given appropriate tools. As a fellow, she was elected to the board of the Association of American Indian Physicians, and is now actively practicing gynecologic oncology in Portland.

“When I came to MD Anderson, the faculty told me: ‘Follow your passion. Do it now. There’s no reason to wait.’ No other place in the country would have been so willing to give me the opportunity to develop my career goals,” she said.

Teaching leadership in patient care, education and research

Intent on producing leaders in patient care, education and research, it is one of the few NCI-funded training programs dedicated to gynecologic oncology. The program is in year 11 of a multyear, multimillion-dollar NIH T32 training grant to address the national shortage of academic gynecologic oncologists. The T32 grant was recently refunded for the next five years.

The four-year program requires two years each of research and clinical duties, with the goal of training academic gynecologic oncologists who are highly skilled and knowledgeable surgeons, fully capable of establishing new academic gynecologic oncology programs at other teaching institutions.

During the research years, the fellows complete two courses and earn a master’s degree in public health or biomedical science. This versatility in academic training increases the likelihood that MD Anderson’s fellows will be offered an academic position upon graduation.

Fellows are drawn to the unparalleled flexibility of the program, as well as its broad range of research-training disciplines: cancer biology, molecular therapeutics, quality, tumor immunology, health disparities, epidemiology and health services. No routine patient responsibilities distract them from their laboratory and research activities.

Upon completion of the two-year research period, fellows begin in-depth clinical training in surgery, chemotherapy, radiation therapy, intensive care and terminal care, as well as outpatient evaluations and follow-up. They learn the techniques of treating gynecologic malignancies with chemotherapeutic and biological agents, including planning, dosing and administration.

Mentors, mentors, mentors

But what sets the program apart is its faculty mentors—physician-scientists and research scientists with active research programs supported by external, peer-reviewed funding.

“Our faculty is completely devoted to the fellows,” said Frumovitz. “Basically, each fellow has 20 mentors, not just one.”
We give [our fellows] support and guidance, and what they do when they leave is a continuation of the strong foundation they built here.”

—Michael Frumovitz, M.D.
Fellowship Program Director
Celebrating a legend in gynecologic oncology
An interview with David M. Gershenson, M.D.

On the occasion of his retirement, we take a look back at the distinguished career of David M. Gershenson, M.D., former chair of the Department of Gynecologic Oncology and Reproductive Medicine, and celebrate his immeasurable contributions to the field.

An international leader in the field, Gershenson also is a prolific writer who has edited six major gynecology textbooks and published more than 375 peer-reviewed articles, as well as 167 book chapters and invited articles.

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<tr>
<th>Year(s)</th>
<th>Achievement</th>
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<tbody>
<tr>
<td>2014</td>
<td>International Gynecologic Cancer Society Award for Excellence in Gynecologic Oncology (with William J. Hoskins, M.D.)</td>
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<tr>
<td>2010-2016</td>
<td>Co-chair, NCI Gynecologic Cancer Steering Committee</td>
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<td>2009</td>
<td>Chairman, Foundation for Women’s Cancer</td>
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<td>2006-2014</td>
<td>Director, American Board of Obstetrics and Gynecology</td>
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<tr>
<td>2005</td>
<td>Member, NCI Gynecologic Cancer Steering Committee</td>
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<tr>
<td>2005</td>
<td>Chair, Gynecologic Oncology Group’s Rare Tumor Committee</td>
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<tr>
<td>2002-2005</td>
<td>Chair, ABOG Division of Gynecologic Oncology</td>
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<td>2000-2001</td>
<td>President, American Radium Society</td>
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<td>1999-2015</td>
<td>Co-principal Investigator, MD Anderson’s NCI-funded ovarian cancer SPORE, and co-project leader of the Personalized Therapy for Women with Low-Grade Serous Carcinoma of the Ovary Project</td>
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<tr>
<td>1996-2007</td>
<td>Director, MD Anderson Blanton-Davis Ovarian Cancer Research Program</td>
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<td>1996-1997</td>
<td>President, Society of Gynecology Oncology</td>
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<td>1994-1995</td>
<td>President, Felix Rutledge Society</td>
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What would you count as some of your major accomplishments?
During my tenure as chair, we increased the number of department faculty by 300 percent, making a point of enhancing transitional research by recruiting top physician-scientists. We also expanded the fellowship program to four years and won a T32 grant.

We established a section of general gynecology for MD Anderson patients with benign gynecological conditions. As a foundation for an oncofertility program in collaboration with other departments, we recruited a reproductive endocrinology infertility physician, Terri Woodard, M.D..

What are some highlights of your research?
Early in my career, I became interested in rare ovarian cancers—principally malignant ovarian germ-cell tumors and sex cord-stromal tumors. In the late ’80s, I began to focus on serous tumors of low malignant potential, as well as low-grade carcinomas of the ovary. As chair of the Rare Tumor Committee of the Gynecologic Oncology Group since 2005, I have led the effort to develop national and international clinical trials for rare types of cancer, especially rare ovarian cancers. The guiding principle for this work is personalized medicine based on advances in molecular biology.

Since 2005, I have led a multidisciplinary research team focused primarily on enhancing our understanding of the biology of low-grade serous carcinoma of the ovary and peritoneum, defining its clinical course, and developing better therapeutic options. Improving the outcome of patients afflicted by this rare tumor is an unmet need, and I have learned immensely from the examples set by these courageous women. This work was the foundation for a project focused on low-grade serous carcinoma, Personalized Therapy for Low-Grade Serous Carcinoma, which was funded within MD Anderson’s NCI-sponsored SPORE (Specialized Program of Research Excellence) grant in Ovarian Cancer beginning in 2010.

In addition, I am privileged to serve as the international Principal Investigator of an NCI-sponsored clinical trial, A Randomized Phase II/III Study to Assess the Efficacy of Trametinib in Patients with Recurrent or Progressive Low-Grade Ovarian Cancer or Peritoneal Cancer (GOG281). This exciting trial uses Trametinib, a targeted agent that inhibits MEK, a primary driver of this disease. Contrary to what it sounds like, low-grade serous carcinoma is a cancer that is difficult to treat and that responds to little. To date, we have treated 23 patients at our center alone.

What sets the department apart?
Our philosophy has always been to have a broad, not narrow, focus on how to treat gynecologic malignancies. We’re not just pigeonholed into surgery, as in some departments. We’re expected to be experts in all treatment modalities. This allows our patients to remain with us throughout their journey with cancer.

From its inception, our department has been a leader within the institution in both innovation and openness to change. And our group is populated by extremely bright, innovative and talented individuals.

Recently, we were named No. 9 in U.S. News & World Report’s “Best Hospitals” rankings for gynecology, even though our primary focus is gynecologic cancer. I believe this is a reflection of our dedication to our patients.

Dr. Gershenson continues his important research and clinical work in a post-retirement part-time position within the Department.

“It is very clear that David is a giant in the field of gynecologic oncology, both in the United States and in the international community. David’s record of scholarly publications and leadership positions in national and international organizations is without equal.”

—William J. Hoskins, M.D.
retired chief,
Gynecology Service,
Memorial Sloan Kettering Cancer Center
commitment
TO COMMUNITY
MD ANDERSON LOCATIONS

- Houston-area locations
- Texas Medical Center
- Lyndon B. Johnson Hospital in Harris Health System (cancer care)
Taking MD Anderson care to the outskirts of Houston—and beyond

Regional locations offer multidisciplinary care across Greater Houston

“When my gynecologist told me there was a strong probability I had ovarian cancer, I was so scared that I could only see through a pinhole,” said Barbara White, 52, of Lake Jackson, Texas.

White’s reaction is not uncommon. Cancer is the most-feared disease among Americans, according to a 2011 study conducted for MetLife Foundation. Adding to MD Anderson patients’ anxiety is learning to navigate the Texas Medical Center for their treatment. The traffic, parking and population around MD Anderson’s main campus can be overwhelming—not only for the cancer patient, but also for her friends and family who want to support her emotionally and logistically. This is especially true for people who live outside of central Houston—in the Houston suburbs and the smaller Texas cities within reasonable driving distance.

That’s why, 20 years ago, the Department of Gynecologic Oncology and Reproductive Medicine began its expansion into MD Anderson’s other Houston-area locations. Today, our physicians offer multidisciplinary care and clinical trials at multiple locations throughout the greater Houston area: Michael Bevers, M.D., section chief of the gynecologic oncology regional program, sees patients in The Woodlands and Memorial City; Nicole Fleming, M.D., in Sugar Land; Jennifer Burzawa, M.D., in Katy; and Behrouz Zand, M.D., in Bay Area.

Lois Ramondetta, M.D., and Ralph Freedman, M.D., see patients at Lyndon B. Johnson (LBJ) Hospital, where Kathleen Schmeler, M.D. and Andrea Milbourne, M.D. staff a colposcopy clinic. The LBJ Hospital Oncology Service, in partnership with Harris Health System, serves low-income and medically underserved patients who otherwise might not have access to specialized cancer services such as oncology therapies and surgeries, colposcopy, inpatient care, research participation and education.

A more convenient, intimate care environment

White saw Nicole Fleming, M.D., at MD Anderson’s Sugar Land location. “Her surgery took place at the main hospital, but she had all of her chemotherapy in Sugar Land,” said Fleming. “This environment is smaller and a little more personal, and we notice that the patients are a lot happier with that. They’re not as stressed, and that makes our job easier, too.”

White couldn’t agree more: “I wanted to see Dr. Fleming for every appointment because of her wisdom, knowledge, aggressive treatment and bedside manner. The whole staff is just as good as she is—from Misty White, her physician assistant, and Dr. Shen, my surgeon, right down to the infusion nurses.”

White’s was a rocky road that included anxiety, depression and the discovery that she carries the BRCA-1 gene, increasing her chance of developing breast cancer to a scary 80 percent.

“When I got that news, the room became a pinhole again—just like my first diagnostic conference,” she said. But with the support of her MD Anderson genetics counselor, her nurturing husband John, family, friends and church members, she chose a double mastectomy and encouraged her parents and three grown sons to undergo genetic testing as well.

Regional access to clinical trials

White also participated in the groundbreaking beta-blocker research that prompted widespread media coverage in August of 2015. The research concluded that women who were being treated for ovarian cancer, who also took generic beta blockers, lived more than twice as long as women who didn’t. That research, led by Anil Sood, M.D., professor, continues today.

“Dr. Sood’s research is a great demonstration of the level of care we offer in our regional centers,” said Fleming. “Our goal was to bring MD Anderson’s level of care for all gynecologic cancers to as many patients as possible. We decided that the best way to deliver that care was to find a way to be closer, geographically, to the patients.

“Today, our patients can get their clinical visits, consultations and even surgery in our regional centers and nearby community hospitals. This reduces the time they have to spend away from their homes and families, the stress of navigating a hospital the size of MD Anderson, and gives them the comfort of our ‘small family’ of clinicians, who are also happy about working closer to their own homes.”
Sprint For Life

Founded in 1998 by Judith K. Wolf, M.D., Laura Lee Scurlock Blanton and Sandra G. Davis and hosted by the Department of Gynecologic Oncology and Reproductive Medicine, Sprint For Life is a 5K run/walk that raises funds for ovarian cancer research and awareness.

To date, the annual event has raised more than $4.6 million for the Blanton-Davis Ovarian Cancer Research Program at MD Anderson. The multidisciplinary program was the first official, comprehensive ovarian cancer research effort in the U.S., which is now under the direction of Anil K. Sood, M.D., professor of the Department of Gynecologic Oncology and Reproductive Medicine.

“Funding innovative studies is critical to advancing research,” said Sood. “Given the current funding climate, Sprint For Life continues to have a meaningful impact on promoting research.”

Sprint For Life funds also support $50,000 grants awarded annually to ovarian cancer researchers, to further their explorations in the early detection and treatment of the disease that is the leading cause of death among gynecologic cancers.

United in their determination to educate the public and advance ovarian cancer research, the 2016 event brought together more than 2,000 race participants, 500 guests and 200 volunteers. The 2017 Sprint For Life race will be a milestone celebration of the event’s 20th anniversary.

To participate, volunteer or donate, please visit sprintforlife.com.

Peach Outreach

Marcy Kurtz, founder of the nonprofit Peach Outreach, was a tireless advocate for uterine cancer awareness and research. Her legacy of strength and perseverance lives on through the organization she founded to help others.

After beating breast cancer diagnosed in 2005, Kurtz came to MD Anderson for treatment for uterine (also known as endometrial) cancer in 2010. Inspired by the support communities of more widely-recognized types of cancer such as breast and ovarian, Kurtz decided she wanted to do something to support uterine cancer awareness.

There was just one small issue: “How do you raise money for this, when nothing rhymes with uterus?” Kurtz joked. But as breast cancer has pink and ovarian cancer has teal, uterine cancer is associated with the color peach, and that’s how Peach Outreach was named.

Peach Outreach raises awareness through a number of community events, including a ladies-night-out fundraising event called “Peaches ‘n Dreams,” and an annual “Rooftop Yoga” event for men and women, to educate attendees about uterine cancer.

Peach Outreach donates the funds to MD Anderson’s uterine cancer research program. To learn more about Peach Outreach, visit peachoutreach.com.
Eddy and Kelli Blanton: A tradition of giving

Eddy S. Blanton, Sr. and his wife Kelli are no strangers to philanthropy. The Blanton family has a long history of charitable giving, which became an important part of Eddy’s life from a young age.

“Ever since I was little, my parents always instilled in my brother, sister and me that we were very fortunate, and we needed to do what we can to help people,” said Eddy. “We’ve all taken that attitude and instilled it in our children as well.”

When Eddy’s mother, Laura Lee Scurlock Blanton, was diagnosed with ovarian cancer twenty years ago, the family knew they wanted to direct their philanthropic efforts toward finding a cure. The Blantons (along with the Davis family) provided seed money for the formation of the Blanton-Davis Ovarian Cancer Research Program, which strives to find a cure for ovarian cancer by advancing innovative research in the diagnosis and treatment of the disease.

Today, Eddy and Kelli continue to drive ovarian cancer research forward with their commitment to the program, and to the Laura Lee Blanton Gynecologic Oncology Center at MD Anderson.

“You can’t find anybody who hasn’t been affected by cancer in their lives one way or another,” said Eddy. “Although finding a cure for ovarian cancer is personal for me because of my mother, we know that anything they find could also potentially help with other cancers.”

“It is a critical time in the juncture of cancer research,” added Kelli. “Everyone who is able needs to step up to the plate; every dollar counts.”

As longtime supporters of MD Anderson, the Blantons have witnessed firsthand the life-changing advances in cancer treatment.

“There are types of cancer that are treatable now that would have been a death sentence twenty years ago,” said Eddy. “Many people don’t realize how much money and effort go into it; it doesn’t just happen. It wakes you up to why supporting research is so important.”

Through their generosity and unyielding commitment to improve the diagnosis and treatment of ovarian cancer, the Blantons are a supportive voice in the cancer community and a powerful driving force in MD Anderson’s mission to end cancer.

If you are interested in supporting our research efforts through a donation, please contact the MD Anderson Development Office at 713-792-3450 or 800-525-5841, or visit www.mdanderson.org/gifts. Please specify that you would like to direct your donation to gynecologic oncology.
Top Publications

The following is a list of high-impact and practice-changing publications from the Department of Gynecologic Oncology and Reproductive Medicine.

**BASIC BIOLOGY**

**EXOSOMAL TRANSFER OF STROMA-DERIVED MIR21 CONFER PACLITAXEL RESISTANCE IN OVARIAN CANCER CELLS THROUGH TARGETING APAF1.**

Exosomes were identified as a key vehicle of “communication” in the ovarian cancer microenvironment, which transfer miR21 from the stroma to cancer cells. Upon receiving miR21, cancer cells show suppressed apoptosis and increased chemoresistance. Inhibiting this transfer is a novel modality for treating advanced and recurrent ovarian cancer.

**ERYTHROPOIETIN STIMULATES TUMOR GROWTH VIA EPHB4.**

Concerns have recently emerged regarding a potential adverse effect of recombinant human erythropoietin (rhEpo), a common treatment for anemia in cancer patients. EphB4 was identified as an alternative Epo receptor that mediates signaling through STAT3 to increase tumor growth and progression. Expression of EphB4 is associated with decreased survival in rhEpo-treated patients.

**PREVENTION, EARLY DETECTION AND BIOMARKERS**

**UNDERESTIMATION OF RISK OF A BRCA1 OR BRCA2 MUTATION IN WOMEN WITH HIGH-GRADE SEROUS OVARIAN CANCER BY BRCAPRO: A MULTI-INSTITUTION STUDY.**

Researchers evaluated the accuracy of BRCAPRO, a model that is widely used to estimate likelihood of carrying a germline BRCA1/2 mutation based on family history. They found that BRCAPRO significantly underestimates risk of BRCA1/2 mutations in women with high-grade serous ovarian cancer.

**INNOVATIVE SURGERY**

**THE ROLE OF SECONDARY CYTOREDUCTION IN LOW-GRADE SEROUS OVARIAN CANCER OR PERITONEAL CANCER.**

The authors showed that secondary cytoreductive surgery improves clinical outcomes in women with recurrent low-grade serous ovarian or peritoneal cancers, which had not previously been evaluated in this patient population. They also reported that patients with no gross residual disease have improved progression-free survival.

**A FRAMEWORK FOR A PERSONALIZED SURGICAL APPROACH TO OVARIAN CANCER.**

Advanced-stage ovarian cancer patients undergoing complete gross resection (R0) have the best clinical outcomes, yet previous methods to determine if disease could be optimally debulked are inaccurate. The authors propose an algorithm to score the likelihood of achieving R0, in order to improve the quality of surgical care.
DEVELOPMENTAL THERAPEUTICS AND CLINICAL TRIALS

PHASE II STUDY OF EVEROLIMUS AND LETROZOLE IN PATIENTS WITH RECURRENT ENDOMETRIAL CARCINOMA.

The addition of everolimus (mTOR inhibitor) to letrozole resulted in a clinical benefit rate of 40% in recurrent endometrial cancer patients, a significant improvement over previous treatment options. In addition, the objective response rate was 32%, including several prolonged responses.

A PHASE II EVALUATION OF THE POTENT, HIGHLY SELECTIVE PARP INHIBITOR VELIPARIB IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER IN PATIENTS WHO CARRY A GERMLINE BRCA1 OR BRCA2 MUTATION - AN NRG ONCOLOGY/GYNECOLOGIC ONCOLOGY GROUP STUDY.

Veliparib is a potent inhibitor of PARP enzymes, which induces cell death in tumor cells with BRCA1/2 defects. In this study of ovarian cancer patients with inherited BRCA1/2 mutations, veliparib was found to be effective and well-tolerated as a single agent.

HEALTH SERVICES RESEARCH, QUALITY IMPROVEMENT AND SURVIVORSHIP

PERIOPERATIVE TRAJECTORY OF PATIENT REPORTED SYMPTOMS: A PILOT STUDY IN GYNECOLOGIC ONCOLOGY PATIENTS.

The investigators showed that assessing symptom burden longitudinally (from a preoperative time point to 8 weeks postoperatively) is feasible in women undergoing laparotomy. Collection of this data will enable more meaningful comparisons of surgical procedures and perioperative care, which can transform clinical practice.

PERIOPERATIVE BLOOD TRANSFUSION IN GYNECOLOGIC ONCOLOGY SURGERY: ANALYSIS OF THE NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM DATABASE.

Data from 8,519 gynecologic cancer patients, including clinical and perioperative variables, showed that blood transfusion was associated with higher morbidity, surgical site infection, mortality, and length of hospital stay. These findings indicate that transfusion practices must be re-evaluated and the creation of new guidelines could significantly improve clinical outcomes for these patients.

IMPACT OF AGE AND PRIMARY DISEASE SITE ON OUTCOME IN WOMEN WITH LOW-GRADE SEROUS CARCINOMA OF THE OVARY OR PERITONEUM: RESULTS OF A LARGE SINGLE-INSTITUTION REGISTRY OF A RARE TUMOR.

This registry study of rare tumors included 350 patients with stage I to IV low-grade serous (LGS) ovarian or peritoneal cancer and was the first to conduct a robust analysis of clinical outcomes in these patients. Younger age of onset and persistent disease after primary therapy were associated with worse outcomes. Women with LGS peritoneal cancer have a better prognosis than women with LGS ovarian cancer.
Faculty Awards of Distinction

Shannon Westin, M.D.
— Andrew Sabin Family Fellowship

Shannon Westin, M.D., associate professor of Gynecologic Oncology and Reproductive Medicine, was selected as one of eight faculty members for the inaugural 2016 Andrew Sabin Family Fellowship Program, a prestigious program that recognizes faculty who have demonstrated outstanding independent research in their early years and are poised to become future leaders in their field. Dr. Westin completed her fellowship at MD Anderson in 2010, after which she stayed on in the department. Her major area of interest is early drug development and targeted therapy for gynecologic malignancies, as well as the development of biomarkers to predict the response and resistance to therapy.

Dr. Westin will receive the $100,000 award over two years to build a platform in which to evaluate P53 targeted agents. “If we can create a platform in which we can evaluate who should get treated with what therapy, that could have potentially very far-reaching consequences,” said Westin. “This is an award that can be spent to support novel trials that aren’t necessarily easy to fund through traditional means. It’s an honor to receive it, and it’s very exciting that we can move our studies forward.”

Kathleen Schmeler, M.D.
— R. Lee Clark Fellow

Kathleen Schmeler, M.D., associate professor, was selected among MD Anderson’s first R. Lee Clark Fellows in 2014 as a Clinical Innovator awardee. Dr. Schmeler’s research interests are primarily focused on the prevention and treatment of cervical cancer, particularly in underserved women both in the U.S. and globally. Following a pilot study in Brazil, she received this $100,000 award to further test a high resolution microendoscope (HRME) in collaboration with Rice University as a low-cost point-of-care diagnostic tool for cervical cancer prevention in the Rio Grande Valley, along the Texas-Mexico border.

Dr. Schmeler’s research was unique among the awardees for its focus on prevention and its low-resource setting. “I think it’s really exciting that the institution finds it of value and worth funding,” said Schmeler. “We’re taking what we’re learning globally with the HRME and bringing it to underserved populations in Texas.”

Charles Levenback, M.D.
— The University Cancer Foundation Faculty Achievement Award in Patient Care

Charles Levenback, M.D., professor of Gynecologic Oncology and Reproductive Medicine and MD Anderson’s Chief Quality Officer, received the 2015 University Cancer Foundation Faculty Achievement Award in Patient Care. Recognizing those who have made important contributions in their area of expertise, this award was given to Dr. Levenback for his achievements in the care of patients with gynecologic cancer. In addition, his key role advancing surgical and chemotherapy safety has benefited patients throughout MD Anderson.

Dr. Levenback has been driven by a patient-centered focus on quality throughout his 26 years at MD Anderson. For him, it all comes down to providing the best patient experience. “Being the recipient of the Patient Care award is something I consider a really big honor,” said Levenback. “The core of my identity is being a bedside physician and gynecologic oncologist, so this recognition is really special.”
Pamela Soliman, M.D.
— UT Regents’ Outstanding Teaching Award

Pamela Soliman, M.D., associate professor and Center Medical Director, was selected as a recipient of the 2015 University of Texas Regents’ Outstanding Teaching Award for her innovation and top-tier quality of health education instruction. After completing her fellowship at MD Anderson in gynecologic oncology, Dr. Soliman joined the department’s faculty in 2007, where she has focused on her passion for education. Among her many contributions, Dr. Soliman has worked on developing the surgical curriculum, started an education committee to give fellows the opportunity to have more influence on the education program, and serves as co-director of the multidisciplinary surgery group MINTOS (Minimally Invasive New Technologies in Oncologic Surgeries).

This award is meaningful to Dr. Soliman because it recognizes excellence in an area that is difficult to quantify. “My favorite moments are the ‘ah-ha!’ moments,” said Soliman, “when you teach someone who has been struggling with something, and then all of a sudden they get it. It’s great to know that you’re contributing to more than just the patient care that you give individually.”

Larissa Meyer, M.D.
— NIH K07 Award

Larissa Meyer, M.D., assistant professor, was awarded the National Institutes of Health’s K07 grant in June 2016 to further her health services research. The five-year grant helps young investigators develop new skillsets in research by providing protected time for the awardee to dedicate to their research project. Dr. Meyer’s project aims to develop a shared medical decision tool for patients and providers to help guide their decisions regarding primary therapy for ovarian cancer. She aims to build a decision analytic model based on large data sets and incorporate patient reported outcomes and preferences to build the computer-based tool, which will also include an interactive part for patients.

“The work that will be done in order to build the decision aid will help me develop skills in analyzing large data sets, qualitative research, and the collection and analysis of patient reported outcomes. In a larger context, I hope to gain expertise in the process of shared medical decision making,” said Meyer. “Cancer treatment isn’t one-size-fits-all, and I think this tool can help facilitate important conversations between the patient and the provider.”

Anil Sood, M.D.
— American Cancer Society Research Professorship

Anil K. Sood, M.D., professor, was awarded a prestigious Research Professorship by the American Cancer Society. The five-year renewable grant will support Dr. Sood’s research in the tumor cell microenvironment, exploring how tumor cells are able to block the immune system and aiming to identify new targets which will support the development and effectiveness of immunotherapies.

“This award means a lot in terms of recognition of our group’s research from the cancer research community,” said Sood. “The additional funding will support our projects and hopefully help us develop better therapies for our patients.”
Clinical Faculty

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Clinical Cancer Genetics
Deputy Division Head for Research
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Instructor

Samuel C. Mok, Ph.D.
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Charlotte C. Sun, Dr.P.H.
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Instructor

Kwong K. Wong, Ph.D.
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