

# Aurora Cancer Care Connection

Your caring connection for  
support during cancer care

Winter 2013-2014  
Volume 2, Issue 1

## Aurora Health Care receives recognition for cancer care from largest oncology society in United States

By Carol Huibregtse, RN, BSN, OCN - Quality Oncology Coordinator

Aurora Cancer Care has been recognized by the Quality Oncology Practice Initiative (QOPI®) Certification Program, an affiliate of the American Society of Clinical Oncology (ASCO). The QOPI® Certification Program provides a three-year certification for outpatient hematology-oncology practices that meet the highest standards for quality cancer care.

"I am extremely pleased that Aurora Cancer Care Medical Oncology has received QOPI Certification. This certification reinforces the extremely high quality care provided to all of our cancer patients. This accomplishment is particularly notable as our group is one of the largest, if not the largest group in the country certified by QOPI," commented James Weese, MD, Vice President of Aurora Cancer Services.

"QOPI is designed by clinical experts in oncology to give practices the ability to continuously improve the quality of care they provide," said ASCO President Clifford A. Hudis, MD, FACP. "The QOPI Certification Program helps practices determine whether they are providing the best possible treatment and care to their patients and demonstrates their commitment to excellence and lifelong learning."

QOPI is a voluntary self-assessment and improvement program launched by ASCO in 2006 to help hematology-oncology and medical oncology practices assess the quality of the care they provide to patients. Through the QOPI program, practices abstract data from patients' records up to twice per year and enter this information into a secure database. More than 850 oncology practices have registered in the QOPI program.

The QOPI Certification Program (QCP) was launched in January 2010, with more than 180 practices already certified. This certification for outpatient oncology practices is the first program of its kind for oncology in the United States. Oncologists can achieve certification by demonstrating practice consistent with the highest standards of care. The QCP seal designates those practices that not only scored high on the key QOPI quality measures, but meet rigorous safety measures established by ASCO and the Oncology Nursing Society.

QOPI analyzes individual practice data and compares these to more than 160 evidence-based and consensus quality measures. The information is then provided in reports to participating practices. Individual practices are also able to compare their performance to data from other



# You've heard the words "You have cancer." So now what? Cancer Rehabilitation, that's what.

By Leslie J. Waltke, PT - Cancer Rehabilitation Coordinator

Congratulations on choosing Aurora Health Care for your cancer care. You are in the right place. All of our Aurora Hospital Cancer Programs, regardless of location, have been awarded the highest accreditation possible by the Commission on Cancer, which means we meet important quality patient care standards and offer multiple integrated services, such as Cancer Rehabilitation.

Being diagnosed and treated for cancer is difficult on so many levels: psychologically, physically and functionally to name just a few. But there is some very promising news.

Years ago, if you injured your back or had a heart attack, you were told to "take it easy." However, with time and research we have learned that "rest" is a very poor treatment tool. Today, those with cardiac problems or physical injuries are sent to physical therapy and encouraged to exercise.

Research is telling us the same thing about rehabilitation and exercise during and after cancer treatment.

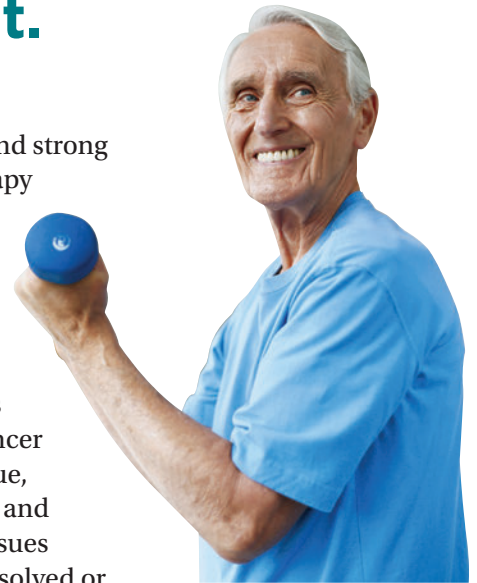
Aurora Health Care boasts one of the largest and highest quality cancer rehabilitation programs in the country. What is cancer rehabilitation? Aurora's Cancer Rehabilitation Team is made up of physical, occupational and speech therapists, as well as audiologists. Depending on the type of cancer diagnosed and the treatment prescribed, just like after a knee surgery or stroke, a Cancer Rehabilitation Therapist works to restore the body to a full pain-free recovery after surgery. Rehabilitation will continue with therapeutic exercise and a therapy program designed to

keep you healthy and strong during chemotherapy and radiation and assist in speeding recovery after treatment.

The most common physical symptoms associated with cancer treatment are fatigue, stiffness, weakness and pain. All of these issues can be lessened, resolved or prevented with rehabilitation. The American Cancer Society recommends 60 to 180 minutes a week of exercise during and after cancer treatment. Patients undergoing cancer rehabilitation have also been shown to have less pain, improved function, better strength and require fewer hospital stays. Rehabilitation and exercise have been shown to improve quality of life, lengthen life and in some cases reduce the risk of cancer recurrence.

So now what? If you are not feeling strong and well, call your doctor and get in to a cancer rehabilitation therapist soon and let's get you moving!

**For more information about our cancer rehabilitation program, please call 414-219-7193 or visit [Aurora.org/CancerRehab](http://Aurora.org/CancerRehab).**



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## **GOPI certification**, continued from page 1

practices across the country. Based on this feedback, doctors and practices can identify areas for improvement.

To become certified, practices must submit to an evaluation of their entire practice and documentation standards. The QCP staff and steering group members then verify through on-site inspection that the evaluation and documents are correct and that the practices met core standards in all areas of treatment, including:

- Treatment planning
- Staff training and education
- Chemotherapy orders and drug preparation
- Patient consent and education
- Safe chemotherapy administration
- Monitoring and assessment of patient well-being

## **About ASCO**

*The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds ground-breaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit [www.asco.org](http://www.asco.org). Patient-oriented cancer information is available at [www.cancer.net](http://www.cancer.net).*

# Breast cancer recurrence rates

By Wendy Mikkelson, MD, Ellen Zaija, MD, Danielle Greer, PhD, and Lisa Robinson, RHIA, CTR – Aurora Cancer Care

Decisions regarding breast cancer treatment options can be difficult for the person facing that diagnosis. Those with Stage I or II disease considering breast conservation surgery over mastectomy can be assured that the overall outcome is equivalent with either operation. This is based upon up to 20-year results from half a dozen prospective, randomized studies done in the mid '80s, including the NSABP B-06 trial (No. 1). While local recurrence rates are slightly higher with breast conservation (10-15%) than with mastectomy (5-10%), overall survival is not different.

Local-regional recurrence rates (LRR) were often found to be different between the two operations, with earlier studies finding that there is a 1-2% per year recurrence rate with breast conservation. LRR means breast cancer comes back in the treated breast or nearby area such as the axilla (armpit). An English study following patients treated with breast conservation from 1990-1997 observed a 1.4% per year LRR rate, or a 13.6% rate over 10 years (No. 2). A more recent study (No. 3) out of Edinburgh and Denmark found an ipsilateral breast tumor recurrence (IBTR) rate of 8.4% over 10 years. The NSABP 20-year results had a cumulative IBTR rate of 14.3%. IBTR means breast cancer comes back in the treated breast, but doesn't include axillary recurrences, so the rate will be less than LRR.

## So how do we at Aurora compare?

As part of a breast quality project, the Aurora Cancer Registry sponsored a study to determine the LRR of our patients treated with breast conservation. Danielle Greer, PhD, Aurora biostatistician, reviewed all analytical breast cancer cases in Aurora diagnosed at Stage 1 or 2 between 1990 and 2002. A total of 2,127 cases were included. Aurora system wide, the 10-year LRR for patients with stage 1 or stage 2 breast cancer treated with breast conservation surgery was 4.6% at 10 years. This is comparable or better than published national or international rates.

This review found that subsets of patients had different risks for LRR. For example, age at diagnosis, tumor grade and size, margin status, hormone receptor status, lymph node involvement with metastases, and patient ethnicity all had significant impact on the hazard ratio for LRR. This is not surprising, as other studies have also noted that young age (50 years or younger), ER/PR negative tumors, larger cancers (>2cm), higher-grade tumors, positive margins, lymph node metastases, and African American women all have an increased risk for local-

regional recurrence. For example, in the Aurora Health Care review, the risk of LRR over 10 years in a woman greater than 50 years of age at diagnosis is 4.0%, but the 10-year risk for a woman less than 50 years old is 7.36%. This is statistically significant, with p-value equal to 0.0013.

Why are our results so excellent? Because Aurora Health Care evaluates each patient with multidisciplinary input by surgeons, radiation oncologists, medical oncologists, pathologists, genetic counselors and clinical coordinators upon diagnosis, and then treatment is given according to evidence-based guidelines. High quality patient-centered standards are followed according to the Commission on Cancer accreditation requirements, and seven of our comprehensive breast centers are certified by The National Accreditation Program of Breast Centers, as being centers of excellence.

1. Fischer B, Anderson S, Bryant J, et al: Twenty year follow up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med* 2002; 347:1233-1241
2. Kontos M, Roy P, Rizos D, Hamed H: An evidence based strategy for follow up after breast conserving treatment for breast cancer. *J Surg Onc* 2011;104:223-227
3. Kunkler, I, et al: Impact of screening and risk factors for local recurrence and survival after conservative surgery and radiotherapy for early breast cancer: results from a large series with long-term follow-up. *Int J Rad Onc Biol Phys* 2012; Vol. 83, No. 3, pp 829-838



# What are clinical trials?

By Michael A. Thompson, MD, PhD – Medical Director, Early Cancer Research Program, Patient-Centered Research, Aurora Research Institute

## Aurora Health Care does research

Cancer clinical trial information at Aurora Health Care is available at [Aurora.org/Services/Research/Clinical-Trials](http://Aurora.org/Services/Research/Clinical-Trials) or via Sara Planton, BSN, at 414-219-4763.

Two quotes that deal with clinical trial myths include these tweets:

***I think a big misconception about clinical trials is that they are “last resort.” In many cases they may be best first option. RT @rsm2800***

***People who participate in clinical trials are not guinea pigs. They are trailblazers! Partners as we fight for better. #hcs HT @drdonsdizon***

Clinical trials are a type of research to determine what works and what doesn't work, usually with patients in a specific disease, such as cancer. Without a rigorous and systematic method to determine the efficacy (how well something works in a group) and effectiveness (how well something works in a “real world” community population), we can be deluded about medicine. Many examples were described by Dr. Prasad and colleagues in “A Decade of Reversal: An Analysis of 146 Contradicted Medical Practices”<sup>1</sup> The drugs we have available today are based upon laboratory research and clinical trial participation with patients. Dr. Sandra Swaim, recent American Society of Clinical Oncology (ASCO) president noted, “Only the 3% of patients who participate in clinical trials are able to contribute to advances in treatment...”<sup>2</sup>

## What are phase I, II and III clinical trials?

In nearly all trials, the goal is to help the patient (there are exceptions in which there is no chance of benefit). Statistically, the trials are designed to evaluate certain endpoints. These endpoints or concepts require increasingly larger studies as we move from safety to comparison against known drugs.

Phase	Designed to evaluate
1	Safety
2	Efficacy
3	Efficacy compared to the standard of care

## Preclinical research

**Cell lines (*in vitro*, *petri dish*)** – help us look at “proof of concept” (i.e., can it work in an artificial setting).

Scientists can try to understand why a drug works and how resistance occurs. Cells in petri dishes are less complicated than cancer cells in organisms with intact immune systems, so this method is not always predictive of clinical success.

**Animals (*in vivo*)** – extend the *in vitro* work to include organisms with tumor blood supplies. Many animal models are not like humans, such as “nude mice,” which lack an immune system. These cannot model human immuno-oncology treatments, such as cancer vaccines.

In pre-clinical studies, the doses of combinations of therapies can be closely controlled and we can look for synergy (an effect greater than the sum of individual effects) to determine combinations that might be useful in humans.

## Clinical research

While therapeutic intent is present in most studies, including phase 1, studies are statistically powered to evaluate the following:

**Phase 1** – Determine safety and the planned phase 2 dose for larger studies

**Phase 2** – Determine efficacy and safety in a larger number of patients

**Phase 3** – Compare efficacy vs. the “standard of care”

**Phase 4/Registry** – Post-marketing studies are studies done after the drug is approved by the Food & Drug Administration (FDA). These may be studies the FDA mandates for drugs approved by accelerated mechanisms. This type of study can also help evaluate comparative effectiveness, that is, how well does it work in a real population, not just in a clinical trial.

This provides some basic background. Additional information in the links below and in future articles will aim at improving understanding of clinical research and look at some of the cancer clinical trials available at Aurora Health Care.

## Links

NIH

<http://clinicaltrials.gov/ct2/about-studies/learn>

Cancer.net

<http://www.cancer.net/all-about-cancer/clinical-trials>

## How to read health news

Health care headlines often seems like a yo-yo with substances such as coffee and chocolate going from bad to good week by week. Often the actual research articles are not the same as the over-hyped headlines. An article from Dr. Alicia White from 2009 is still very valuable today.<sup>3</sup> Reading the full article is very useful, but bullet points include:

- Does the article support its claims with scientific research?
- Is the article based on a conference abstract?
- Was the research in humans?
- How many people did the research study include?
- Did the study have a control group?
- Did the study actually assess what's in the headline?
- Who paid for and conducted the study?
- Should you shoot the messenger?
- How can I find out more?

Part of being an informed and engaged health care participant (either as a patient or a provider) includes being both curious *and* critical. Explore the news, but realize more information is not needed. This brings us to another commonly asked question ...

## Why don't you just give us the good drug?

Tomasz Beer, MD, FACP, notes that "Without clinical trials, cancer treatment would always remain the same." The drugs we have available today to treat cancer are only here based upon patients participating in clinical trials. We also know that theory is not proof. That is, good ideas need to be tested initially in petri dishes, but eventually in human beings. We can't use cell, animal or computer models to completely predict what will happen when we give drugs to human cancer patients. The reason we test drugs is that we predict they will be better but aren't sure.

John Mandrola, MD, notes in the *Kevin.MD* blog "The hubris of medicine has to end" and "Our interventions should never be eminence-based, but rather, evidenced-based." The evidence is based on clinical trials (<http://www.kevinmd.com/blog/2013/09/hubris-medicine.html>).

## Myths and truths about cancer clinical trials

Conspiracy theories may make for good summer blockbuster movies, but aren't helpful for making nuanced medical decisions. Here is a collection of clinical trial myths:

*Learn About Cancer Clinical Trials – Myths & Facts About Cancer Clinical Trials*

Coalition of Cancer Cooperative Groups  
<http://ow.ly/qg1hG>

*Myths and Truths About Cancer Clinical Trials*  
Tom Beer and Larry Axmaker, 2012  
<http://ow.ly/qg2oN>

*Clinical Studies –Myths vs. Facts*  
Seattle Cancer Care Alliance

*Busting Clinical Trials Myths*  
American Cancer Society - Katherine Sharpe, MTS

*Cancer Treatment Myths: Any Truth to These Common Beliefs?*  
Mayo Clinic  
<http://www.mayoclinic.com/health/cancer/HO00033>

## FDA priority/Fast track/Accelerated/Breakthrough designations

The FDA is often criticized for not approving cancer drugs fast enough. A recent Forbes article by Matthew Herper noted "The FDA's Cancer Czar Says He Can't Approve New Drugs Fast Enough." In fact, in 2012 the FDA approved 39 new drugs, the most in 16 years. The article detailed a few FDA drug designations that are commonly in the lay and physician press. A drug can get one or more of the designations at once.

### FDA drug designations

**Priority Review** – Created by Congress in 1992, cuts the targeted review time from ten to six months

**Fast Track status** – Streamline the review process for drugs that meet an unmet medical need

**Accelerated Approval** – Allows approval based on preliminary data pending the completion of larger studies

**Breakthrough** – FDA Safety and Innovation Act of 2012 – catalyzes communication between companies and the FDA

These designations are designed to improve the drug approval process. In future issues, we will discuss specific cancers and available clinical trials available at Aurora Health Care.

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1. Prasad V, Vandross A, Toomey C, et al: A decade of reversal: an analysis of 146 contradicted medical practices. *Mayo Clin Proc* 88:790-8, 2013

2. ASCO: ASCO Completes Prototype for CancerLinQ™, Marking First Demonstration of a "Learning Health System" to Transform Cancer Care, 2013

3. A. W: How to read health news, 2009  
Retrieved from <http://www.nlm.nih.gov/hsrinfo/cer.html>

# Special attention for special medication needs

For cancer patients, few things are higher priority than managing medications properly – and not just cancer drugs. Typically, you may be on complex drug therapies for symptoms, complications and chronic conditions beyond the actual cancer. And with multiple physicians prescribing for you, coordinating all your medications can be a challenge.

That's where **Aurora Specialty Pharmacy** does what no other pharmacy can do: work in close collaboration with the rest of your care team to help manage your medications.

*Smart Chart*, Aurora's electronic health record, connects all the providers within Aurora's integrated system. So when the pharmacist is filling or refilling your prescription, there's no waiting for someone to "fax over" the latest lab results or imaging report. And when the pharmacist needs to talk with your doctor, there's no delay. For you, coordinated care means quicker, smoother service and a better experience all around.

## Ongoing support

If you have medication questions or concerns at any point in your treatment, Aurora Specialty Pharmacy is there to offer reliable information and support, coordinating with your doctor as appropriate. Coordinated care gives you a higher level of assurance that you are receiving the best treatment based on your total health picture.

In addition to providing the highest clinical quality and safety, Aurora Specialty Pharmacy can help with benefit coordination and preauthorization, and even connect you with special copayment programs that may be available. It's one more way we work hard to keep the best care affordable.

**To learn more about Aurora Specialty Pharmacy, ask your Aurora physician or Aurora pharmacist, or please call 262-252-5600.**

# Upright stereotactic breast biopsy unit

One reason a breast biopsy is recommended is when a mammogram shows a breast abnormality that could be cancer. Obtaining this tissue sample is very important because the result will guide the surgeon in how to proceed if surgery is indicated and could reduce your need for additional operations.

Minimally invasive breast biopsy (MIBB) is the procedure of choice for sampling a breast abnormality to determine if it is cancerous or not. MIBB can be performed either using ultrasound guidance (most commonly) or stereotactic guidance. During stereotactic breast biopsy, the patient lays in the prone position (on her stomach with the breast falling through an opening) on the special procedure table. The skin is locally anesthetized and a tissue sample is taken with a needle. The physician is guided to the correct location with mammographic images. The procedure takes about one hour.

Some patients find it difficult to lie on their stomach for one hour. Aurora St. Luke's has a special upright stereotactic breast biopsy unit that allows the patient to sit upright for this procedure. Your physician can place the order in your electronic medical record for the upright biopsy to be done in the radiology department at Aurora St. Luke's Medical Center. Biopsy results are available usually within 1-2 working days. When the procedure is complete, you return to your local physician for follow-up care.

Obtaining tissue prior to surgery is very important. The availability of the upright stereotactic machine at Aurora St. Luke's makes it possible to undergo a minimally invasive breast biopsy when you cannot tolerate prone positioning in the standard stereotactic device.

**For more information about the upright stereotactic breast biopsy unit, please call Aurora St. Luke's Medical Center Breast Imaging Center at 414-649-6095.**

## Did you know?

Michael Mullane, MD (Aurora Advanced oncology and hematology) has been named best doctor in the health care category by the Journal Times of Racine in their annual Best of Racine County feature. Community members are encouraged

to nominate those in various service categories (for example, health care, etc.). Nominees are published, and the community has a chance to vote via ballot for their choices. Dr. Mullane, who works at the Aurora Cancer Care facility in Racine, won first place in the best doctor category.



Michael Mullane, MD

# After autologous stem cell transplant, business leader wants to “make people’s lives better”

By Erica Weber – Donor Communications Specialist Senior, Aurora Health Care Foundation

Dan Kwiecinski can vividly remember the Christmas of 1990. “I had just gotten out of the hospital after my transplant. The lights were so beautiful and the snow was so crisp. It was just wonderful. There is so much you appreciate after going through all that.”

On Oct. 29, 2013, Dan shared his story and memories at the *Celebration of Life* at Discovery World in Milwaukee. This survivorship event honored those who received treatment from the Autologous Stem Cell Transplant Program at Aurora St. Luke’s Medical Center.

Dan received the eighth stem cell transplant of the program in Nov. 1990, after being diagnosed with stage 4 Hodgkin’s lymphoma and experiencing a recurrence after nine months of chemotherapy. Dan admits that 23 years later, he has lost a bit of the wonder he had back then, because he has gone on with his life without cancer.

Dan explains what he appreciated most about the approach Dr. Robert Taylor and the Aurora St. Luke’s team took with his cancer treatment, saying, “Their message to me was the sooner we can get you back in your life, the better.”

Living is definitely what Dan has done since his transplant. Now a married father of three and executive vice president at Hays Co. in Wauwatosa, Dan wants to make people’s lives better. “And I can do that because of what Aurora St. Luke’s has done for me,” Dan says.



*Dan Kwiecinski and his family.*  
Left to right: Katie (daughter, 16), Maureen (wife), George and Sam (sons, 12), Jim and Darlene Kwiecinski (parents).



*Dan Kwiecinski reconnects with Dr. Robert Taylor, who performed his stem cell transplant in 1990.*

“What began as a bucket list so many years ago has now been checked off multiple times over,” says Dan. He and his friends began an annual golf outing a number of years ago and have always donated the proceeds to the transplant program at Aurora St. Luke’s. Over the years, they have donated nearly \$100,000 to impact patient care. This year, their gift will help support the patient experience for the patients and families who are in the transplant unit at Aurora St. Luke’s.

The first autologous stem cell transplant was performed at Aurora St. Luke’s in 1990. Dr. Robert Taylor and his team have now performed over 700 transplants.

Dan shared the sentiments of everyone gathered in thanking Dr. Robert Taylor and his team for their care and support for the past 23 years. “I hope you truly see how you have grown families. Just look at what you have contributed to life.”

**To join Dan and his friends in supporting Cancer Care at Aurora St. Luke’s Medical Center, contact Bridgette Frommell, Foundation Development Officer, Aurora Health Care Foundation at 414-649-3636.**

# Female-focused care

By Mira Ketzler, RN, MSN – Women’s Health Program Director

As individuals, we can all attest to the fact that who we are and how we experience life can be influenced by many things, such as our families, social experiences, and cultural and spiritual beliefs. There is one more key variable that may influence our life experience and that is gender. When talking about our own individual health, we know that sex does matter.

Women have unique health needs, and many diseases affect women differently than men. There are diseases that are unique to women, such as gynecologic cancer; occur predominately in women, such as breast cancer; and then there are those that are biologically and physiologically different in women, such as cardiac disease. There is an entire new field of scientific inquiry called “sex-based biology,” which is “committed to identifying the biological and physiologic differences between men and women. There are biological differences at every level, from a single cell to the entire body” (Society for Women’s Health Research, [www.womenshealthresearch.org](http://www.womenshealthresearch.org)).

It is important to note that prior to 1990, women were not included in clinical trials or adequately represented in research studies. This recognition sparked several actions by the National Institutes of Health to form the Office of Research on Women’s Health, as well as pass additional regulation requiring the inclusion of women and minorities in clinical research (National Institutes of Health Revitalization Act of 1993). In addition, expert organizations such as the Society for Women’s Health Research were also formed. Though there are many specifics yet to be answered, we do have sound scientific evidence to support that there are many health conditions that are different in women, due to either a higher incidence, different symptomology than men, and/or different risk factors.



The Women’s Health Program at Aurora Health Care strives to recognize these differences and implement best practices to support health care to all women. By combining what our female patients have shared regarding their desired health care experience and our clinical expertise, we’ve created programs and services that address the unique health care needs of women. One such program is our Incontinence and Pelvic Reconstructive Surgery program. We bring together a group of highly trained experts in the field of urogynecology, pelvic floor rehab and pelvic reconstructive surgery who work together with our patients to develop their optimal plan of care. Integrated with this program are experts in Behavioral Health and Sexual Health and Medicine, to provide additional support and treatment as needed. We partner with our cancer colleagues in a similar fashion, to develop a female-focused cancer program that addresses the unique needs of women. Our programs in gynecologic oncology and breast health combine the expertise of women’s health care providers with the expertise of our medical, surgical and radiation oncologists, to provide the excellence in the entire spectrum of care from screening and early detection through treatment and cancer survivorship.

**For more information about women’s health at Aurora Health Care, please visit [Aurora.org/WomensHealth](http://Aurora.org/WomensHealth).**

*The information presented in this newsletter is intended for general information and educational purposes. It is not intended to replace the advice of your own physician. Contact your physician if you believe you have a health problem.*

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