

IUSCC PINK

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Dear Friends:

This issue of IUSCC Pink is devoted to our heroes—the breast cancer advocacy community. Breast cancer, among all the cancers we study, is the tumor whose biology is the best understood, the cancer which receives the most research funding, and the cancer that has seen the most impressive advances in therapy. It is also the cancer with the strongest advocacy community, bar none. A coincidence? I do not think so: breast cancer researchers, both in the lab and the clinic, have derived both resources, passion, and focus from the advocacy community.

This community serves multiple purposes: it educates, it raises funds at both a local and national level, it is active at a national level both in government and in national non-government organizations, and it provides a multitude of services and support for patients and scientists. It is hard to imagine the breast cancer program at Indiana University we have today without the many breast cancer advocates who have selflessly donated their time, energy, and financial support to our common task.

This issue attempts to share some (regrettably, only a few of the many) voices of the advocacy community. We owe these friends a great deal. At crucial points over the years advocates have provided the resources that have allowed our clinical and laboratory research to take wing. More importantly, though, on several occasions the advocates have provided us sound and timely advice that pointed us in new (and generally better) directions. Advocates bring their life experience to the breast cancer problem, and that experience time and time again has shone a new light on problems we have faced. I cannot begin to express my gratitude to our local advocacy community, but I trust that this issue gives you some idea of what that community has meant both to the breast cancer program at the IU Simon Cancer Center, and to the women of Indiana.

Sincerely yours,
George Sledge M.D.



Drs. Robert Hickey, Bryan Schneider and George Sledge are pictured with the graduates of the Research Advocacy Network's 2007 Advocate Mentor Program after receiving their white lab coats.

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Research Advocacy Network: Educating Advocates



In 2007, the Research Advocacy Network began its first Advocate Mentor Program. The goals were to increase the advocacy community's awareness and understanding of the mission and objectives of the Center of Excellence for Individualization of Therapy for Breast Cancer, a collaborative research project with Indiana University, the Hoosier Oncology Group, and research centers in the United States, Canada, and Peru and to use an intensive educational program to prepare and motivate cancer survivors to inform their communities about the importance of genomic research.

Eleven women who were recommended by eight different advocate organizations took on the challenge of this mentor program. The program, which lasted approximately three months, included Webinars on genomics and clinical trial design, a two-day educational program with hands-on lab experience and attendance to the 2007 ASCO (American Society of Clinical Oncology).

IUSCC Pink met up with some of the attendees and organizers to see how they were applying what they had learned in the program. Donna Threlkeld, Mary Studley, and Krysti Hughett -- all breast cancer survivors -- were so excited to share their experiences about the program. Each of these women has taken what they learned during their training and applied it to breast cancer advocacy in a different way.

The program gave Donna a way to "get involved" after completing her treatment for breast cancer. Prior to the Advocate Mentor Program, she wasn't sure where

or how to get started doing more for breast cancer. Now she has an irreplaceable network of advocates, mentors, and projects that keep her busy. The science training really helped Donna to better understand research. She now uses that training as an IUPUI Institutional Review Board (IRB) member where she assists in reviewing new research projects as a consentor and member of the Event Planning Committee for the Susan G. Komen for the Cure Tissue Bank at IU Simon Cancer Center, and as chair of the Pink Ribbon Connection, which promotes clinical trials. "I get very excited to see the advancements and potential cures," she said.

Mary was involved with the Wellness Community when she heard about the Advocate Mentor program. The incredible knowledge of science that the program provided gave her a leg up on other training in which she has participated. Mary has found many places to apply her new skills. She has attended lobbying events for the National Breast Cancer Coalition. Mary and others are also working to increase cancer research funding in Indiana by working for an income tax check-off that would benefit cancer research in the state. She has also helped to create a coalition to address community needs. Mary feels that her training has helped her "advocate for all cancer; everyone is a peer no matter what color their ribbon is," she said.

New patient Handbook

The Breast Care and Research Center staff is working on a handbook to help new patients better understand our practice. We hope this book will help our patients to know who to call in times of need, our schedules, and general treatment knowledge. We would also like to hear suggestions from you. Please send an e-mail to Casey at calallen@iupui.edu with suggestions of things that would have been helpful for you or things that you found confusing. We would love to hear from our current patients in order to make improvements.

Krysti is a four-year survivor of inflammatory breast cancer. She says the program has given her an opportunity to get to know the researchers and to better understand breast cancer. She realizes that breast cancer isn't as easy to cure as she once might have thought. Since her completion of the program, she has gone on to participate in Project LEAD (the National Breast Cancer Coalition Fund's science training course for activists) and review grants for the Susan G. Komen for the Cure and the DOD. Krysti's favorite thing about participating in the program was the hands-on experience in the lab.



The commitment these women made to learning more is really paying off. If you are interested in participating in the Advocate Mentor Program, send an e-mail to info@researchadvocacy.org or visit the web site at www.researchadvocacy.org.

If you would like to participate in current advocacy projects, the Advocate Mentor Program graduates recommend the following projects:

- Women and men are needed to advocate for state-wide cancer research donation box on tax returns. Forty-one other states provide this option to tax payers. It is a great way to raise funds for cancer research. For more information, contact Mary at 317-919-0983.
- Consider contacting your Indiana House and Senate representatives and ask them to support House Bill 1382-legislation requiring insurance companies to cover the basic patient costs of clinical trials. Many insurance companies will provide coverage for "approved" chemotherapy, but will not cover the same costs in a clinical trial, inhibiting many Hoosiers from participating in clinical trials. For more information, visit the Indiana Cancer Consortium at www.indianacancer.org.
- Join the American Cancer Society's Cancer Action Network. Receive e-mails about advocacy issues and

contact your U.S. and Indiana House and Senate representatives to support legislative action. Issues that will be up for debate in Indiana and around the country:

Insurance Coverage

- Defeat attempts to gut laws that guarantee insurance coverage for lifesaving cancer screenings
- Guarantee insurance coverage for the routine costs incurred by patients in clinical trials

Breast Cancer

Protect state funding for the national program that helps ensure uninsured and underinsured women have access to mammograms

Colon Cancer

- Require health insurance companies to cover the full range of colon cancer screenings
- Create programs to ensure everyone has access to colon cancer screenings

Tobacco

- Pass comprehensive smoke-free laws at the state and local level
- Increase the tax on cigarettes and other tobacco products
- Increase funding for tobacco control, prevention and cessation programs, including additional coverage for these programs through Medicaid

Health Care Reform

Enact health care reform legislation that will provide people with greater access to cancer screenings and treatment

Other Important Issues

- Enhance nutrition and physical activity policies
 - Improve pain and palliative care policies
 - Help Make Casinos Smoke-Free
- The National Council of Legislators from Gaming States has formally adopted the Smoke-free Gaming Resolution. This resolution calls for states to make all gaming workplaces, such as casinos, smoke-free. ACS CAN testified in support of the resolution and encourages everyone to use this victory in their efforts to protect everyone's right to breathe smoke-free air
- Raise breast cancer research funds by participating in the Indianapolis Susan G. Komen Race for the Cure or host your own fundraising event and donate the proceeds to breast cancer research at the IU Simon Cancer Center. For more information, contact the IU School of Medicine Office of Gift Development at 317-274-7409.



Advocacy at work

By: Ginny Mason RN, BSN Executive Director
Inflammatory Breast Cancer Research Foundation
and IU Simon Cancer Center Patient

In 1994, when I was diagnosed with inflammatory breast cancer, I was working as a nurse in an outpatient mental health clinic. My job involved providing medical services to a variety of mental health clients and often serving as an advocate for those patients. Little did I know how that job would prepare me for my current work.

While continuing to work in mental health, I began getting involved in local breast cancer advocacy work. During that time, I started a local support group, did television spots to raise awareness of breast cancer, and shared with local church and civic groups. In 1999, the Inflammatory Breast Cancer Research Foundation (IBCRF-www.ibcresearch.org) was just getting started when I had the opportunity to meet its founder and president, Owen Johnson. We had been in communication via e-mail for some months. Through our conversations, it was obvious we shared a passion to both facilitate research of inflammatory breast cancer and raise awareness of the disease. I began volunteering for the organization immediately, and then joined the board in 2001. As my foundation work "took over my life," the board called me to my current position as executive director in 2003.

Because inflammatory breast cancer is a less common form of breast cancer, it can be difficult to find others dealing with the disease. Since the time of my diagnosis, I had wanted to be involved in research but couldn't find a suitable project. Having survived the disease, I thought someone would want to study my case but no one seemed interested. Through my volunteer work with the foundation, I've found a way to use my experi-

ence as a patient and my medical background to make a difference for others. When I share my survivorship with a newly diagnosed patient, I can often hear hope return to their voice. Through the foundation's BioBank and Clinical Data Base, I am an active participant in research that will improve diagnosis, treatment, and survival from this disease.

Over the years, my role with the IBCRF has grown, and as a result, I too have grown. I've gotten involved in the broader cancer community through involvement in the American Society of Clinical Oncology, Oncology Nurses Association, American Association for Cancer Research, and the National Breast Cancer Coalition. Attending major cancer conferences has provided opportunities for education and expanded my network of colleagues in the field. In addition, I've served as a consumer

"Because inflammatory breast cancer is a less common form of breast cancer, it can be difficult to find others dealing with the disease."

reviewer for the Department of Defense Breast Cancer Research Program and California Breast Cancer Research Program, contributing a consumer perspective on research grant proposals. Each new experience provides knowledge and resources that make me a more effective patient advocate.

For too long, inflammatory breast cancer was either overlooked or considered a locally advanced breast cancer. Through our advocacy efforts there is now a

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specific National Comprehensive Cancer Network Breast Cancer Treatment Guideline specifically for inflammatory breast cancer. This is a significant step in establishing inflammatory breast cancer as an independent disease. We hope this action will also encourage clinical trials and other research that is inflammatory breast cancer specific so that treatment decisions can be evidence-based.

"My advocacy work is a way to give back for these years of survivorship I never expected to have."

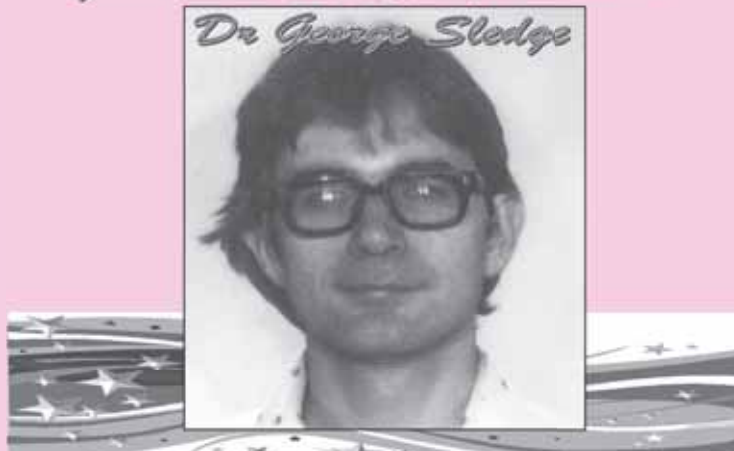
There is a large breast cancer advocacy network in the United States that does a good job of providing general breast cancer information. The IBCRF started to fill a unique niche not covered by the others. We don't need to duplicate the services and information provided by other groups; instead we focus on inflammatory breast cancer specific needs. Through an extensive Web site, two e-mail discussion lists, an e-letter, the BioBank, and other initiatives we seek to provide education, information, and facilitate research.

My advocacy work is a way to give back for these years of survivorship I never expected to have. I feel a sense of urgency to push research ahead in an effort to improve the prognosis for those diagnosed with inflammatory breast cancer. When my daughter was diagnosed with aggressive, early-stage breast cancer at 27, I became even more dedicated to this mission. With no family history of breast cancer, having us both diagnosed with pre-menopausal, aggressive breast cancer was a shock. While my daughter is doing well, her diagnosis is a reminder that there is more work to be done.

I certainly wouldn't have volunteered for this disease and I'm not sure I'd want to call it a blessing, but it is clear that my diagnosis and treatment for inflammatory breast cancer have helped me find a unique way to use my nursing education. I do consider myself blessed to be doing something I care about deeply and hope makes a difference for others.

Your 2010 ASCO President

Dr. George Sledge



Congratulations to Dr. Sledge, or should we say President Elect Sledge! Dr. Sledge has been elected to become president of the American Society of Clinical Oncology (ASCO) for a one-year term beginning in June 2010. He will take office as president-elect during ASCO's 45th Annual Meeting in Orlando in June 2009.

"Being elected to serve as ASCO president is an honor and a privilege. I look forward to working with my colleagues on the board of directors to support all types of cancer research and address the challenges of the modern-day practice of oncology," Dr. Sledge said. "ASCO institutes real change by uniting all members of the oncology community with the common goal of improving cancer care and prevention and ensuring that all patients with cancer receive the highest quality care."

As we all know, Dr. Sledge currently serves as the Ballve-Lantero Professor of Oncology and Professor of Pathology and Laboratory Medicine at the Indiana University Melvin and Bren Simon Cancer Center. He joined IU in 1983 (see picture above), after completing his residency at St. Louis University and his fellowship at the University of Texas, San Antonio. He received his undergraduate degree from the University of Wisconsin and his medical degree from Tulane University. His research interests include molecular and tumor biology, growth factors, and anti-angiogenic therapy related to breast cancer.

"Every new member that is elected to ASCO's board of directors brings a unique perspective that will shape the society's future goals and practices," Allen S. Lichter, MD, chief executive officer of ASCO, said. "I am particularly looking forward to working with Dr. Sledge and watching how his 25 years as an ASCO member will define the legacy that he leaves on the society's efforts to improve cancer care."

Yoga Therapy at IUSCC



Yoga has become so very popular, and for good reason. It's an effective means of stress and anxiety reduction, and provides balanced and complete exercise. It is safe, inexpensive, and at some 3000 years old, has certainly withstood the test of time. Practitioners report feelings of increased peace of mind and an opening of the heart that lead toward personal growth and a spiritual blossoming. Once the basics are learned yoga can be practiced from the comfort of one's own home. A regular yoga practice confers all the benefits that support successful cancer treatment and long time survivorship.

With this in mind, IUSCC'S CompleteLife Program welcomes Heartland Yoga Therapy as another facet to the complementary care the program offers patients and their caregivers. Heartland Yoga Therapy (HYT) is a well-trained and highly experienced group of yoga enthusiasts who aspire to bring the nurturing and empowering therapeutic yoga practices to all at the IUSCC; those receiving cancer treatment, as well as their families, caregivers, and all the staff. HYT sees yoga practice as an ideal complement to the exceptional medical treatment offered at the IUSCC.

The IUSCC Heartland Yoga Therapy project involves three main facets:

- Clinical-offering individual and group instruction in appropriate yoga practice, free of charge, to all at the IUSCC. This may include the familiar "asanas" ~ the physical postures, as well as meditation, breathing practices (pranayama), deep relaxation (yoga nidra), and support for prayer.

- Education-conducting a nationally recognized Yoga Therapist Training to develop a team of highly skilled yoga therapy technicians to provide yoga instruction in a variety of settings and capacities at IUSCC.

- Research-writing and executing clinical trials to document our results and make our greatest impact.

The director of the program, Nancy Schalk, is seeking input as she establishes the optimal schedule and types of classes that will be offered. Please contact Nancy at nancy@heartlandyogatherapy.com to share your thoughts and suggestions on the following:

- Would you attend group yoga classes at the IUSCC?
- What days and times would be ideal for you to attend a class?
- Which areas of yoga are you most interested?
- Do you feel you'd benefit most from private instruction, at least to get started or because of special needs or circumstances?

The program also needs your tax deductible donations to assist in building their permanent space at the IUSCC. Contact Nancy if you'd like to help financially, or be involved in any way.

If you have any questions or comments about this or other CompleteLife programs, please contact Mary Lynn Hoffmann, CompleteLife Program Coordinator, at 278-4630 or hoffmaml@iupui.edu.

We look forward to watching this cutting edge project take form in our IUSCC as a blessing for all.

Would you like to hear more from our doctors?

You can listen to them anytime on Sound Medicine, www.soundmedicine.iu.edu. You may have heard Sound Medicine on WFYI-FM, but you can also listen online. Host Barbara Lewis interviews medical experts on a wide range of current medical issues, ranging from Alzheimer's disease research to the West Nile virus. Joining Ms. Lewis each week are faculty co-hosts from the IU School of Medicine: Drs. Steven Bogdewic, David Crabb, Eric Meslin, Kathy Miller, and Ora Pescovitz. Specific cancer topics can be found at www.cancer.iu.edu/news/SoundMedicine.php.

Breast Cancer



Why don't we have a cure?

We do cure some case of breast cancer with our current treatments that include any combination of surgery, radiation therapy, chemotherapy, hormonal therapy, and biologic therapies. Unfortunately not all cases are cured, because some cancer cells are resistant to these therapies.

What part of the body does breast cancer recur?

Most often breast cancer recurs in the breast itself (local recurrence) or at distant sites like the bones, lungs, liver, and brain. We use a variety of therapies to attempt to prevent this from happening.

If chemotherapy throws your body into menopause, is it safe to take a compounded form of progesterone?

This is a question that you should speak with your doctor about. The risks and benefit are different for each person.

What is the current research for lobular carcinoma?

We know that lobular cancers are commonly ER+ and tend to be very responsive to hormonal therapy. Lobular cancers also tend to be somewhat more resistant to tradition chemotherapies. Having said this, many patients probably derive some benefit from chemotherapy depending on other factors present in the tumor.

Is it advisable to have your unaffected breast removed and have both sides with reconstruction after 5 years? (has not had genetic testing done) If there is a reoccurrence would it be easily detected?

The risk of recurrence after breast reconstruction is the same as the risk without reconstruction. Most of these recurrences are of the skin and soft tissue (72%) but about 1/3 of them can be deep. The superficial recurrences are detectable by clinical examination alone. The deep recurrences are more difficult to detect.

Many patients worry about the risk of developing a cancer in the breast opposite their cancerous breast. Overall the risk of developing a contralateral cancer is about .7% per year and the chance of death from that cancer is even smaller at 0.2% per year. There are special circumstances such as BRCA 1/2 abnormalities where the risk of a contralateral cancer with in 5 years can be as high as 20% however. Contralateral malignancy is a great concern for younger women who have the potential of prolonged survival and subsequent contralateral cancer. Having said this, I believe that the accuracy of emerging imaging modalities like digital mammography and contrast enhanced breast MRI will provide us with excellent means of detecting breast cancers when they are treatable. My practice is to present the facts to my patients and allow them to decide the risks they are will to assume as they move forward.

Chicken, Barley, & Bow-Tie Soup

2 ½ pounds Chicken breasts
(skinless and boneless) cut into
1-inch pieces
1 cup Celery chopped
1 ½ cups Onion chopped
2 cups Carrots thinly sliced
1 Bay leaf
12 cups Water
½ cup Pearl barley
Salt and Pepper to taste
½ teaspoon Basil leaves dried
3 Chicken bouillon cubes
1 (16 oz) package Bow-Tie Pasta

Place the chicken, celery, onion, carrots, bay leaf, and water in a large pot. Bring to a boil and add the barley. Reduce the heat, cover, and cook until the chicken and barley are done, about 30 minutes. Season with salt and pepper, and add the basil and bouillon cubes. Meanwhile, cook the pasta according to the package directions, omitting oil and salt. Drain and set aside. Remove the bay leaf and add the pasta. Makes 10-12 servings.

This recipe is wonderful to make and eat on the day of your chemotherapy treatment. It is low in fat (2g), yet will fill you up with all the protein (28g) and fiber (3g) in each serving. Try adding additional vegetables and whole wheat pasta to make this dish extra healthy.

Source: Eating Well Through Cancer, Easy Recipes & Recommendations During & After Treatment, Holly Clegg & Gerald Miletello, M.D.

Understanding News Headlines

Being a wise consumer is always necessary, especially in these difficult economic times. We should shop for information no less carefully than goods when keeping up to date on the latest advancements in cancer. This is no easy task for there is voluminous publishing on cancer every year. In fact the medical research published in just scholarly journals in one year alone would look like a skyscraper of dizzying height if stacked in one pile. This primary source of information sent out to medical communities is then compounded by its play in the many mainstream media outlets, the constant quest for headlines of the ravenous 24 hour broadcast news cycle and the internet with its tsunami of information. How is one to sift through the many claims and declarations of this kaleidoscope of sources?

An article in a scholarly journal is like the head of a dandelion that has gone to seed and its many detailed findings are launched into the wind to be planted in other research, media, medical schools, conferences, Wall Street and ultimately patient's conversations with their doctors. These wisps of important information, that were once part of a whole, are acted upon by competing forces as they scatter and finally find their home taking root. Some pieces of that information take on a life of their own to become another flower that provides food and shelter and contribute to the surrounding ecosystem, some fall among the rocks and die and some fall on manicured lawns and become pests. Like a dandelion in a lush lawn information can be difficult to eradicate unless it is dug up by the roots. In today's information age these seeds have the potential to proliferate wildly in headlines.

One such example is "Secondhand Smoke Causes Breast Cancer in Young Women" this was repeated in 2005 headlines and paired with a variety of modifiers like: study says, researchers find, evidence says... The work referenced in these 2005 news articles was a review of existing scientific literature by the California Environmental Protection Agency. The report, "Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant," was compiled for the purpose of declaring second hand smoke a pollutant – mind you this is a very necessary step in important regulation but it was not a study on the causes of cancer. This causal relationship has since been the subject of numerous studies; one study in June of 2008 found "the strength of the Evidence in the 2005 review by the California EPA stronger than for (second hand smoke as a cause for) lung

cancer in 1986" which is when the US Surgeon General declared it a cause for disease in non-smokers.

Navigating scientific material in the media is a complex task. It is very important to seek out the scientific source of information one reads in mainstream media by digging to the roots of the original research. Sylvia Nasar, author of *The Best American Science Writing* 2008, refers to these competing forces as sand. "Uncertainty, anxiety and conflict (in science journalism are) sand in an oyster's shell: they inspire pearls of reporting and writing. This task is especially difficult when reading about causes of cancer but navigating information is also challenging when reading about screening, diagnosis and treatments." How exactly does a reader find the pearls?

One such tool is www.patientinform.org. "patientINFORM is a collaborative effort by trusted and experienced patient health organizations, medical societies, health information professionals, and scholarly and medical publishers patientINFORM is a free online service that provides patients and their caregivers access to some of the most up-to-date, reliable, and important research available about the diagnosis and treatment of specific diseases. Here, consumers have the ability to not only read the latest research, but also to find help interpreting that information and accessing additional materials. By making it easier to understand research findings, patientINFORM empowers healthcare consumers to have improved discussions with their physicians and make informed decisions about care." (this is directly from www.patientinform.org)

A new book published this fall by the University of California Press by Woloshin, Schwartz and Welch is "Know Your Chances: Understanding Health Statistics" can help us be informed consumers of health statistics. It teaches the skills necessary to interpret the numbers behind health claims.

Another free online source is www.thecochranelibrary.com. "The Cochrane Library is a collection of databases that contain high-quality, independent evidence to inform healthcare decision-making." Use these tools and be a good shopper for information.

-Mary Studley-Patient Advocate and Breast Cancer Survivor

Today's Research Tomorrow's Cure:

Highlights from the San Antonio Breast Cancer Symposium 2008

The 2009 San Antonio Breast Cancer Symposium (SABCS) continues to showcase the amazing researchers and scientists from around the world. Every year the symposium demonstrates the progress that has been made in diagnosing and treating breast cancer. This year not only demonstrated how much drug research can make a difference, but how important the science of human biology is in treating breast cancer now and will continue to be in the future.

Early cancer drug research focused on whether a drug could shrink a tumor. Most of the time, these early drugs would be approved for use without clearly knowing why or how the drug worked. Today drug research has changed as the science that goes into understanding a drug is as important as shrinking a tumor.

AI superiority

With the approval of Aromatase Inhibitors (AIs) to treat hormone receptor positive breast cancer, there have been many trials to debate which AI is better or which combination is better. This year's symposium opened with results from multiple AI trials. All the trials demonstrated a superiority for AIs-Exemestane and letrozole to tamoxifen. What do these results mean for women who are taking tamoxifen? These results should be discussed with your physician and the benefits and side effects of switching to an AI should be considered. Women who switched from tamoxifen to an AI in these trials were shown to quickly have a reduction in their recurrence risk. Although, these drugs can reduce the risk of breast cancer recurrence they are not without side effects. Ironically, a recent report from the ATAC trial suggests that patients with the most complaints in the first three months of treatment (and possibly at increased risk for noncompliance) tended to have the most benefit.

While the majority of the focus during this session of the symposium was breast cancer risk reduction, symptoms, and quality of life were not forgotten. Women who participated in the N-SAS BC 03 trial received tamoxifen and then were randomized to continue tamoxifen or switch to an AI. These women were asked to take surveys to better understand their health-related quality of life (HRQOL). Many of the differences between these groups were not significant, but there were a few items that differed quite dramatically. Hot flashes and vaginal discharge were worse in the tamoxifen group, while

dizziness, diarrhea, and headache were worse in the anastrozole group. These results indicate that patients continuing on tamoxifen may have a slightly better HRQOL than patients switching to anastrozole. Despite being better at reducing the risk AIs do have side effect that should always be considered an important part of any treatment plan.

HER2 Better regimes

HER2 (Human Epidermal growth factor Receptor 2) positive breast cancer has been known for its aggressive nature. In recent years, the treatment options for this type of breast cancer have changed tremendously. The second day of the SABCS focused on HER2 treatment. The NOAH trial is the largest neoadjuvant (chemotherapy before surgery) study to evaluate the addition of trastuzumab (Herceptin®) to the standard anthracycline- and taxane-based chemotherapy for patients with HER2-positive locally advanced breast cancer, including inflammatory breast cancer. The average survival time for local advanced disease is very low, and ranges from three to six years. The NOAH study compared women in this group by treating them with standard chemotherapy or standard chemotherapy plus trastuzumab (Herceptin®). For HER2-positive patients who received chemotherapy and trastuzumab, the event-free survival (the length of time during and after treatment in which a patient is living with a disease that does not get worse. Also known as progression free survival.¹) was significantly improved compared with HER2-positive patients who only received chemotherapy. Overall survival, a secondary endpoint, was also improved in patients receiving trastuzumab, but the difference was not significant.

The newest FDA-approved HER2 treatment, Tykerb (Lapatinib) a drug that targets the HER2 receptor on positive breast cancer cells, continues to prove its effectiveness in treating HER2+ cancer. The EGF30008 trial in which IUSCC participated, hypothesized that adding lapatinib to the aromatase inhibitor letrozole would improve outcomes in postmenopausal women with hormone receptor-positive metastatic breast cancer. The trial included 1,286 patients randomized to daily treatment with lapatinib and letrozole or letrozole and placebo. The results of this trial were so clearly significant that the trial was stopped early. For women with HER2+ receptors

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on their cancer, the average progression-free survival (time without disease progression) was significantly increased in the patients receiving lapatinib in addition to letrozole, 8.2 months vs. 3.8 months until disease progression. The overall response was also significantly increased in the HER2-positive population receiving lapatinib plus letrozole, but there was no difference between treatment arms in the HER2-negative patients.

New drugs

T-DM1, also known as Trastuzumab-DM1, is very similar to the drug Herceptin, but this drug takes the antibodies that target HER2 receptors (as in Herceptin) and combines them with DM1, an anti-microtubular drug that targets the microtubules of cancer cells and prevents the tumor from growing. The trial of T-DM1 showed that almost half the patients experienced a response on the drug alone. Patients also experienced very few side effects for this drug. IU Breast Care and Research Center is one of the centers continuing the research on this drug. We are currently conducting a phase II trial to learn more about the effectiveness of this drug and will be starting a trial combining T-DM1 with chemotherapy in a few months. Our researchers are very excited about the possibilities that this drug holds for HER2 positive breast cancer patients.

IGF1-R inhibitors and "pro-apoptotic" drugs are the possible new drugs of the future. The insulin-like growth factor receptor (IGF-1R) is a relative of HER-2. In laboratory studies presented at SABCS, the IGF1-R inhibitors prevented metastases. Unfortunately, the inhibitor drugs had no effect on metastases that had already developed. The IGF1-R inhibitors also showed promise for overcoming resistance to hormonal therapy drugs. Many new IGF1-R inhibitor drugs are in clinical trial testing currently. The results of these trials should be very exciting for the future of breast cancer treatment.

Diagnostics & Screening

The debate over the use of MRI to detect breast cancer continued at the 2008 SABCS. The Saturday morning plenary lecture opened the day with a discussion of the role of MRI in breast cancer patients. Although MRI is a useful tool in specific cases such as: axillary disease with unknown primary tumor, assessing response to neoadjuvant therapy in patients desiring breast sparing surgery, and when there is discrepancy among clinical and mammogram or ultra sound findings, these

are the few proven uses for MRI. It has also been shown to lengthen pretreatment time by more than three weeks and delay surgery an average of 14 days, without any clear benefit. MRI can be useful in finding breast cancer in high-risk patients, but the reliability and where to fit this imaging tool into practice is in flux.



Contradictory studies using MRI were also presented at SABCS. The first, the COMICE Trial of MRI, looked at whether adding an MRI scan to the standard mammogram, ultrasound, and biopsy routine assisted with staging and thereby reduced re-operation rates for patients with primary breast cancer scheduled for excision. People were randomized into two groups: one receiving MRI, the other not receiving MRI. The results of the trial demonstrated no reduction in the need for additional surgery between the two groups. This study adds to the confusion about MRI. On the other hand, a poster presentation of a study from M.D. Anderson demonstrated a significant benefit to alternating mammography and MRI every six months for high-risk patients. Overall during the study, nine cancers were detected in seven of the 86 women who underwent a screening MRI. Of these nine cancers, five (55%) were found by MRI but not by mammography, three (33%) were found by both modalities, and both mammography and MRI missed one cancer (11%) 1mm in size that was found by mastectomy. This alternating method of screening will need further study to validate these findings, but this could be an alternative for those women who are at high risk. The use of MRI still needs further research. The future should hold the answer on where this powerful imaging tool fits into breast cancer treatment and prevention.

Results from new research have provided continued validation for Oncotype DX. This test takes cancer tissue and can predict a recurrence score. This recurrence score can aid in determining a treatment plan depending on a high or low chance of recurrence. The score that Oncotype DX provides was based on data from Tamoxifen trials, as more data proves that aromatase inhibitors are superior there was concern whether Oncotype Dx would still be applicable. Researchers used tissue and data from the ATAC (an Aromatase Inhibitor) trial to prove that Oncotype DX can still accurately predict recurrence. The test will continually need calibration of its scoring scale as new trial data becomes available, but will continue to be a useful tool for developing a plan to treat breast cancer.

OncoVue® is a new breast cancer risk assessment tool that expands the traditional Gail Model of risk assessment. It combines 22 SNPs (Single nucleotide polymor-

phisms) associated with breast cancer risk with the Gail Model risk factors. (For more about SNPs, read Dr. Schneider's article in the Fall 2007 IUSCC Pink at www.cancer.iu.edu/programs/breast/iuccpink/.) This new assessment tool is a significant improvement and will help more women better understand their risk factors for breast cancer.

Scientists and researchers continue to expand their knowledge about biology, treatment, and prevention of breast cancer, but it is a slow process. Research is like the Tortoise and the Hare fable, although everyone would like a quick "win," the slow but steady route will cure this disease. Most importantly we need to encourage, thank, and remember the women who participated and continue to participate in clinical research trials.

-Contributed by Casey Allen, CCRP Coordinator for Breast Cancer Clinical Research Services IU Simon Cancer Center



Featured Web Site

BreastCancerTrials.org is a non-profit service that is dedicated to providing accurate information about breast cancer clinical trials. This patient-centered Web site includes trials funded by the National Cancer Institute, public research foundations, and the pharmaceutical/biotechnology industry. The goal is to help patients gain insight into the clinical trials process and make it easier and faster for them to find the clinical trials that are right for them.

This site has a section dedicated to answering questions and concerns about clinical trials. It includes information about terminology used in clinical trials and questions you should ask your doctor about participating in a trial. The site takes extra care to explain the design (i.e. randomization, crossover and placebo use) of breast cancer clinical trials, which can be confusing to many potential patients.

The greatest part about this site is its Match to Trial feature. By answering questions in four areas (below) a customized list of potential trials can be created.

- General information: Age, gender, menopausal status, and other medical conditions
- Cancer diagnosis: Details about your specific type of cancer (stage, biomarkers)
- Treatment history: Any prior surgery, radiation or systemic therapy
- Family history of cancer: For patients who are at high risk for breast cancer

This service offers the ability to find trials that are at institutions close to your home or across the country. If you are not interested in a customized trial match, you can browse trials listed on the site. These trials are organized by prevention, psychosocial, supportive, biological therapy, bisphosphonate therapy, chemotherapy, hormone therapy, radiation oncology, and other treatment. The trials available offer a variety of options for any woman wanting to participate in a clinical trial whether they are newly diagnosed or a 10-year survivor.

ARE YOU INTERESTED IN LEARNING MORE ABOUT BREAST CANCER?

Sign up to receive the *IUSCC Pink* Newsletter

Name: _____ *E-mail: _____

Street: _____ City/Zip: _____

*Newsletters will be sent by e-mail when applicable.

Return to Casey Allen at:

IU Simon Cancer Center
535 Barnhill Drive, RT 473
Indianapolis, IN 46202

INDIANA UNIVERSITY
MELVIN AND BREN SIMON
CANCER CENTER



Or send an e-mail to calallen@iupui.edu with the above information.

Do you have a story idea or just something to say about a story you've read in *IUSCC Pink*? Tell us about it! Would you like to share a personal experience? Contact us via e-mail calallen@iupui.edu, call 317-274-0594 or send mail to the address above.

Past editions of *IUSCC Pink* can be viewed at the IU Simon Cancer Center Web site, cancer.iu.edu, by selecting breast cancer in the cancer type section (<http://cancer.iu.edu/programs/breast/iuccpink/>).

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