

***Happy New Year from
Research Advocacy
Network.....***

As we celebrate the close of 2005 we send best wishes to each of you for a healthy and happy new year. Thank you for your support!

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First-Ever Multi-Disciplinary Conference Addresses Non-Compliance Issues Related to Hormonal Therapy for Breast Cancer Patients

Stakeholders from the breast cancer community recently gathered in Washington, D.C. for the Compliance Strategic Initiative (CSI), a day-long symposium focused on helping ensure that breast cancer patients reap the full benefits of hormonal therapy. Held on November 2, 2005, the CSI brought together patient advocacy organizations including the Research Advocacy Network, oncology researchers, healthcare providers, and breast cancer survivors to discuss why patients do not always adhere with their hormonal therapy regimens, and how the community can work together to educate patients and help increase compliance rates. The CSI's member organizations included the American Cancer Society, CancerCare, the National Surgical Adjuvant Breast and Bowel Project (NSABP), and Y-ME National Breast Cancer Organization; the event was made possible through funding by AstraZeneca

Pharmaceuticals.

Although adherence to hormonal therapy may not be a widely-discussed issue within the advocacy community, the CSI reported that non-compliance rates have reached as high as 40% of breast cancer patients in some clinical studies. Each year approximately 100,000 women who are newly-diagnosed happen to have the types of breast cancer which respond to a five-year course of hormonal therapy. And there is a need to help these women adhere to their prescribed hormonal therapy, because according to Dr. Lawrence Wickerham, Associate Chair of the NSABP, research indicates "that five years of adjuvant hormonal therapy in postmenopausal women with estrogen-receptor-positive breast cancer prolongs survival and reduces recurrence."

To help lower the recurrence rates among these patients, the CSI symposium focused on raising awareness around the need for adherence, as well as exploring the reasons why women may not be complying with their treatment regimens. Four working groups addressed aspects of these issues, including the psychology behind non-compliance, the identification of barriers to compliance, communication between patients and providers, and the role of patient education. The multi-disciplinary working groups delved into these topics in an effort to identify resources and tools to help increase treatment compliance among breast cancer patients.

To this end, the working groups developed recommendations and action steps but it is still unclear to some participants how those suggestions will translate into actual follow-up and tangible outcomes driven by the members of the CSI. In the meantime, however, some of the symposium's participants are planning to bring the issue to their constituencies in order to draw wider attention to the correlation between non-compliance and increased risk of breast cancer recurrence. One such event is planned by Living Beyond Breast Cancer, which will be hosting a patient teleconference on aromatase inhibitors on January 31, 2006.* Dr. Wickerham is the featured speaker for that event, and the discussion will touch on the therapeutic benefit of compliance.

Because this issue has such broad implications for the thousands of women who opt for hormonal therapy every year, it is important to continue to bring the message of adherence to the breast cancer community. The CSI was a good first step in this direction, but it will be crucial to see how this discussion evolves and moves into actionable outreach that has the potential to truly impact patients.

**For more information on the teleconference planned by Living Beyond Breast Cancer on January 31, 2006 from 12:00 – 1:30 p.m. ET, call 610-645-4567 or visit www.lbbc.org.*

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Institute of Medicine Releases Report on Needs Facing Cancer Survivors

The Institute of Medicine (IOM), under the direction of the National Academy of Sciences, released a comprehensive report on November 7, 2005 detailing the needs and issues facing cancer patients as they complete their primary treatments and transition into survivorship. The IOM simultaneously hosted a meeting with the cancer community – including the Research Advocacy Network – to discuss the report in detail and answer any questions pertaining to the findings.

According to the report, entitled *From Cancer Patient to Cancer Survivor: Lost in Transition*, there are currently ten million American adults who have a personal history with cancer, and that number could grow as the U.S. population ages and as new treatments increase survival outcomes. With such a large number of post-treatment cancer patients, this is an important and growing population that should not be overlooked by the healthcare system.

Unfortunately, the IOM report reveals gaps in the follow-up care for cancer survivors once their primary treatment ends. To address these gaps in the system, the report focuses on increasing awareness of the medical and psycho-social needs of cancer survivors; defining what quality healthcare means for survivors as well as specific strategies to achieve it; and aiming to improve the quality of life for survivors by advocating for policies which promote equal access to insurance and ensure fair employment practices.

Key recommendations from the report include the following:

- Defining "cancer survivorship" as a distinct phase of the cancer journey, in order to increase awareness of survivorship issues
- Developing a comprehensive care plan for all cancer patients after primary treatment ends, including a summary of care received and specific recommendations for medical follow-up
- Bringing together the National Cancer Institute (NCI), Centers for Medicare and Medicaid Services (CMS), Department of Veterans' Affairs (VA), and other relevant organizations to coordinate multi-disciplinary efforts and develop new models to ensure the delivery of appropriate follow-up care for all cancer survivors
- Increasing education and resources for healthcare providers on the needs of cancer survivors so they can address and support those quality-of-life issues
- Reducing and ultimately eliminating discrimination against cancer survivors in the work place, while supporting survivors' short-term and long-term limitations in their ability to work
- Ensuring that survivors have access to adequate healthcare through changes to federal and state policies
- Conducting long-term research on cancer survivors to better understand and address their unique needs

Although the IOM report provides a disconcerting look at the lack of consistency in care for cancer survivors in the United States, it does go on to create a comprehensive overview of the resources and services that are needed to support this population and increase their chances at staying cancer-free. Hopefully the ideas and recommendations contained within the report will be taken seriously by policy makers, healthcare providers, government organizations, and patient advocacy groups so that these concepts can be translated into actions that will positively impact the lives of cancer survivors.

An executive summary and more information on the IOM report is available at www.iom.edu.

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San Antonio Breast Cancer Symposium 2005

The 28th Annual San Antonio Breast Cancer Symposium (SABCS) was held December 8-11. The SABCS is unique in that basic, translational and clinical research are all presented to the same audience. Participants interested in one area can get more information by attending poster sessions, which included over 1000 abstracts. This recap will focus on clinical research that has implications for changing treatment. For more information on these and other SABCS presentations go to <http://www.abstracts2view.com/sabcs05/>

To assist you with the drug names these terms are keyed for reference the first time they are used in the articles:

Brand name	Generic Name
¹ Herceptin	¹ trastuzumab
² Adriamycin, Rubex	² doxorubicin
³ Cytosan, Neosar	³ cyclophosphamide
⁴ Taxotere	⁴ docetaxel
⁵ Paraplatin	⁵ carboplatin
⁶ Nolvadex	⁶ tamoxifen
⁷ Arimidex	⁷ anastrozole
⁸ Taxol	⁸ paclitaxel

⁹**Anthracycline:** A member of a family of chemotherapy drugs that are also antibiotics. The anthracyclines act to prevent cell division by disrupting the structure of the DNA. The anthracyclines include daunorubicin (Cerubidine), doxorubicin (Adriamycin, Rubex), epirubicin (Ellence, Pharmorubicin), and idarubicin (Idamycin). Source:

<http://www.medterms.com/script/main/art.asp?articlekey=20134>

Herceptin¹ Studies

Dr. Slamon, Director, Clinical and Translational Research, Jonsson Comprehensive Cancer Center, University of California, reported on the Breast Cancer International Research Group (BCIRG) trial 006 that compared doxorubicin² and cyclophosphamide³ followed by docetaxel⁴ (AC→T) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab¹ (AC→TH) with docetaxel, carboplatin⁵ and trastuzumab¹ (TCH) in HER2 positive early breast cancer

patients.

As expected from the Herceptin studies reported on in May at ASCO, participants receiving trastuzumab did better than those receiving only the standard AC→T. At 23 month median follow up the relapse-free rate was 73% for AC→T, 80% for TCH and 84% for AC→TH. The difference between the anthracycline⁹ arms was not statistically significant.

The issue of sorting out the cause of cardiac toxicity associated with Herceptin and an anthracycline was addressed in this study. At this early point in the trial it appears that Herceptin alone may not be the cause of the toxicity. The standard (AC→T) and the non-anthracycline (TCH) arms had fewer adverse cardiac events than the AC→TH arm. More research will be needed to fully understand the best way to use Herceptin in the treatment of women who are HER2 positive.

Phase III randomized trial comparing doxorubicin and cyclophosphamide followed by docetaxel (AC→T) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (AC→TH) with docetaxel, carboplatin and trastuzumab (TCH) in HER2 positive early breast cancer patients: BCIRG 006 study. Abstract 1.

An update on the HERceptin® Adjuvant Trial (HERA) that was originally presented in May at ASCO was reported. HERA compared standard chemotherapies to standard chemotherapies plus Herceptin for 1 or 2 years. After a median of 1.5 years of follow-up, two-year cancer-free survival was 86% for patients treated with Herceptin and 77% for patients who did not receive Herceptin. Additional follow-up will be necessary to determine whether Herceptin significantly improves overall survival. Significant adverse effects included severe heart problems, which developed in 0.5% of patients treated with Herceptin.

Trastuzumab (H: Herceptin) following adjuvant chemotherapy (CT) significantly improves disease-free survival (DFS) in early breast cancer (BC) with HER2 overexpression: the HERA Trial. Abstract 11.

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Surgical Biopsy for Diagnosis of Breast Cancer

Stephen B. Edge, MD, from Roswell Park Cancer Institute in Buffalo, New York reported for his colleagues affiliated with the National Comprehensive Cancer Network (NCCN) on the comparison of needle to surgical biopsies for the diagnosis of breast cancer.

The multicenter study recently conducted by the NCCN evaluated 6,282 women who underwent needle biopsy (55%), open surgical biopsy (42%), or other (3%) for the initial evaluation of possible breast cancer. Biopsies showed that 16% had stage 0 or ductal carcinoma in situ disease, 46% had stage I disease, and 38% had stage II disease. Most patients (61%) underwent breast-conserving surgery and the rest underwent mastectomy.

The conclusion of the study was that needle biopsy for the initial evaluation of breast cancer is preferable to surgical biopsy. Of the 3481 women who underwent needle biopsy, 23% had to have a breast re-excision compared with 92% of the 2650 women who underwent surgical biopsy. Patients who underwent a re-excision also required more days to complete surgery compared with those who did not undergo a re-excision (45 vs. 29 days, respectively).

Dr. Edge concluded that "the use of needle biopsy may be a useful quality benchmark for breast cancer care".

Surgical biopsy to diagnose breast cancer adversely affects outcomes of breast cancer care; finding from the National Comprehensive Cancer Network. Abstract #12.

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Improved overall survival for women taking anastrozole⁷

Walter Jonat, Director, Obstetrics and Gynecology Clinic, University of Kiel, Germany reported that a meta-analysis of three European trials: the Italian Tamoxifen Anastrozole trial, the ARNO 95 trial, and the Austrian Breast and Colorectal Cancer Study Group Trial 9. The results of the meta-analysis showed that women taking anastrozole rather than tamoxifen⁶ had a 29% (P = .038) improvement in overall survival.

The analysis also found a 39% improvement in distant recurrence-free survival and a 45% improvement in event-free survival in women on anastrozole. There was also benefit in outcomes with anastrozole when looking at local recurrences, distant recurrences, or appearance of cancer in the contralateral breast.

The results of this analysis are consistent with research comparing aromatase inhibitors to tamoxifen.

Switching from Adjuvant Tamoxifen to Anastrozole in Postmenopausal Women with Hormone-Responsive Early Breast Cancer: a Meta-Analysis of the ARNO 95 Trial, ABCSG Trial 8, and the ITA Trial. Abstract 18

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Treatment with Taxotere⁴

For more than a generation the combination of Adriamycin² and cyclophosphamide³ (AC) had been the standard treatment for women with early stage breast cancer. However, Adriamycin can cause cardiotoxicity, especially in the elderly or patients with underlying heart problems. Also studies of women with advanced breast cancer have suggested that Taxotere has greater anticancer activity than Adriamycin.

Based on the final analysis of the trial comparing TC (docetaxel/cyclophosphamide) to standard AC (doxorubicin/cyclophosphamide) in women with early stage breast cancer, physicians and patients may have another alternative. Stephen Jones, MD, Medical Director, US Oncology Research, Houston, Texas reported that at a median follow-up of 66 months, TC compared to AC was associated with 33% disease-free survival (P = .015). There was also a 24% reduction in the risk of death, which did not reach statistical significance [P = .13].

One serious drawback of this presentation was the lack of statistics about cardiotoxicity. The presenter indicated only that TC had no more cardiotoxicity than AC.

Final analysis: TC (docetaxel/cyclophosphamide, 4 cycles) has a superior disease-free survival compared to standard AC (doxorubicin/cyclophosphamide) in 1016 women with early stage breast cancer. Abstract 40.

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Dose-Dense Chemotherapy

Clifford Hudis, MD, Chief, Breast Cancer Medicine Service, Memorial Sloan-Kettering Cancer Center, New York reported the five year follow-up for CALGB 9741 (Phase III randomized study of sequential chemotherapy using doxorubicin², paclitaxel⁸, and cyclophosphamide³ or concurrent doxorubicin and cyclophosphamide followed by paclitaxel at 14 and 21 day intervals in women with node positive stage II or IIIA breast cancer).

Dose dense scheduling of chemotherapy once every 2 weeks was superior to every 3 week treatment. There was a decreased hazard ratio of 25% for women who received chemotherapy over a 22-week period rather than a standard 33-week schedule. However, the study determined that the sequence in which breast cancer chemotherapy drugs were administered to patients made little difference in outcomes.

Final analysis: TC (docetaxel/cyclophosphamide, 4 cycles) has a superior disease-free survival compared to standard AC (doxorubicin/cyclophosphamide) in 1016 women with early stage breast cancer. Abstract 41.

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New Fact Sheets

Two new fact sheets have been added to the "What it Means for Me" Fact Sheet Series. The new topics are on the results of the Avastin and Herceptin studies in breast cancer. These are available for download on the [Research Advocacy Network Publications](#) area of the website.

- [Avastin Studies: What It Means For Me](#)
- [Herceptin Studies: What It Means For Me](#)

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Advocate Institute adds playbacks from "Research Into Practice" Lecture Series

The Advocate Institute has added three session playbacks from the NCCN / RAN Advocate Lecture Series on "Research Into Practice." This series is an excellent way for advocates to better understand the influencers and barriers to advancing research results into clinical practice. The one hour sessions can be accessed at:

<http://www.researchadvocacy.org/advocateInstitute/>

Research Advocacy Network Welcomes New Members!!!

Thanks to all of you who have recently joined the Network. For those that have not yet please go to www.researchadvocacy.org and click on "Join". There is no dues for Network membership and this will assure that you receive all notices and have access to Network programs.

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Research Advocacy Network Activities:

- **Oct 31 to Nov 14**—NCCN/ RAN Advocate Lecture Series: Research Into Practice

(Playbacks of this series are now available in the Courses section of the Advocate Institute at <http://www.researchadvocacy.org/advocateInstitute/>)

- **Nov 18-21**—ECOG (Eastern Cooperative Oncology Group)
- **Dec 3**—PRIM&R / ARENA Pre-Conference Workshop for IRB Community Members
- **Dec 3-6**—PRIM&R / ARENA Annual Conference
- **Dec 8-11**—San Antonio Breast Cancer Symposium
- **Jan 13-14**—St. Louis Komen Affiliate Research Advocate Workshop
- **Jan 19**—Patient Advocate Committee Training at the Gynecology Oncology Group (GOG)
- **Jan 19-21**—Patient Advocate Committee at the Radiation Therapy Oncology Group (RTOG)

Do you know of conferences/meetings/ activities that you would like posted to the calendar? Let us know at info@researchadvocacy.org.

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Your Donation Makes a Difference!

We need your help! If you believe in the hope of research and the power of advocacy, you can help the Research Advocacy Network by sending a donation. RAN is an exempt 501 c 3 organization and dependent on your support to keep going. Our mailing address is: East Rand Rd, Suite 175, Arlington Heights, IL 60004. Thanks!

Another way to donate is just by shopping! Buy your office supplies, books, sporting gear, CDs and everyday items at the iGive Mall at www.iGive.com/ResearchAdvocacyNetwork. You can shop at 500+ stores and without even knowing it, you'll be helping Research Advocacy Network at the same time. A check was just received from this program and we want to say thank you for supporting Research Advocacy Network in this way!

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