

2010 Annual Report

Alvin & Lois Lapidus Cancer Institute

LifeBridge Health

Dear Colleagues,

This year's report reflects the ongoing growth and development of The Alvin and Lois Lapidus Cancer Center. The past year has been especially successful in the growth and development of two particular departments. The Alvin and Lois Lapidus Cancer Center opened The Herman and Walter Samuelson Breast Care Center under the direction of fellowship trained surgeon, Dr. Dawn Leonard. The year also saw the appointment of a new chief of Radiation Oncology, Dr. Jeanette Linder.

The Herman and Walter Samuelson Breast Care Center opened in June of 2009. The center offers a comprehensive service including screening and diagnostic tests and treatment for breast cancer. Some of the most advanced technologies for the evaluation of breast disease in the Baltimore area are now found at our center. The center's highly trained team includes a dedicated breast surgeon, a dedicated radiologist, registered nurses, a nurse navigator and mammographers. The Breast Care Center is equipped with the most current diagnostic imaging modalities including breast MRI exams and digital mammography, one of the most advanced technologies available to detect breast cancer. Full-field digital mammography has revolutionized the practice of mammography by providing a crisper, sharper image that increases the diagnostic information the radiologist needs in detecting cancers and breast abnormalities. Of course, ultrasound remains a vital imaging modality, especially for woman under the age of 40. When an ultrasonically guided biopsy is indicated, it is performed by a trained interventional radiologist.

As part of The Breast Care Center's comprehensive program we offer patients bone density screening and genetic counseling. Although, opened only six months ago, the program has seen steady growth in the number of patients served. The program has been especially successful in community outreach with an interest in high risk screening, young women with breast cancer and reaching out to the underserved community. New patients diagnosed with breast cancer are presented in a multi-disciplinary conference that includes physicians from multiple specialties. Each new case is discussed with a team of surgeons, radiation oncologist, pathologists and medical oncologists. During these conferences, staging, national comprehensive cancer network guidelines are discussed and the optimal treatment for the patient is recommended. This process allows the patient to benefit from an entire team of physicians at the start of their care.

During the past year, the department of radiation oncology has seen tremendous growth and development. With a huge commitment to patient safety and state of the art services, Dr. Jeanette Linder has begun a project of epic proportions. Not satisfied with the overwhelming success in bringing Cyberknife stereotactic radiosurgery to Maryland, the Alvin and Lois Lapidus cancer center has acquired The Varian TrueBeam system. This technology does not replace the Cyberknife but complements it. This technology combines conventional radiation with intensity modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT), respiratory gating and stereotactic radiotherapy to deliver radiation that is safer, more precise and faster than prior technologies. Using the Eclipse system we are now able to offer patients state of the art treatment planning. Combined with an upgrade to the linear accelerator for IMRT and IGRT the program offers a comprehensive choice of therapy that optimizes patient safety and patient outcomes.

Breast Cancer Treatment

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Breast cancer remains the most common form of cancer in women of all races in the United States. It is the second leading cause of cancer death in all races except in women of Hispanic descent, in whom it remains the leading cause of cancer death. The American Cancer Society estimates that greater than 260,000 new cases of breast cancer were diagnosed in 2010. Of these 80 % were invasive cancers – capable of spreading to distant sites and, if untreated, ultimately contribute to cancer mortality. Although breast cancer incidence and death rates continue to decline, the Society also estimates that during this same period 38,000 women died of breast cancer.

For the average woman the chance of being diagnosed with an invasive breast cancer in her lifetime is a little less than 1 in 8 (12.15%) and the chance of dying from breast cancer is 1 in 35 (2.85%). Despite media and anecdotal reports, the median age at breast cancer diagnosis remains 61. The good news is that the incidence rate of breast cancer has declined in this age population. Between 1999 and 2006 the incidence rates declined by 2.5 % per year in women 50 years of age or older. In women under the age of 50, the incidence rates have remained stable since 1996. Although Caucasian women over the age of 45 have the highest incidence, they continue to have the best survival. In contrast, Black women over the age of 45 have a lower incidence and those under the age of 45 have a higher incidence rates than their counterparts. Black women also have the poorest survival rates among all age groups and populations.

Most women will survive their diagnosis. The American Cancer Society estimates that there are more than 2.5 million women with a history of breast cancer living in the United States, and most are living cancer free. According to National Cancer Institute's Surveillance Epidemiology and End Results (SEER) data, the overall 5 year relative survival rate from 1990-2006 was 89%. When found early and confined to the breast, the 5-year survival rate is 98%. Fortunately the majority of breast cancers (60%) continue to be diagnosed while the cancer is still confined to the breast and has the highest chance of being cured. Among the proportion of women diagnosed with spread to regional lymph nodes (30%), the 5-year survival rate drops to 83.6%. In the 5% who have distant spread of the disease, defined as metastasis to other organs such as the brain, bone liver or lungs, the overall 5-year survival drops to 23.4%. When broken down by race, Caucasian women have the most favorable relative 5-year survival rates of 90.2%. Their Black counterparts have a relative survival rate of

Breast Cancer Treatment, continued

77.5%. LifeBridge Health Cancer Registry reports comparable survival rates to national averages and national trends. There were 1557 female breast cancer patients diagnosed or who received initial treatment for breast cancer at a LifeBridge Health facility during the 1996-2002 period. The overall 5-year survival rate during that period was 86.2% with a similar disparity noted when Caucasian and African-American survival rates are analyzed: 91.8% and 78.6% respectively. In the subsequent 5 year span (2003-2007) the number of patients initially diagnosed or treated at a LifeBridge Health facility decreased to 1075.

The overall 5-year survival rate was 84%. The respective survival rate among Caucasian women was 84% and 83% in their Black counterparts. During this same period, relative survival rates for women who presented with localized disease was 86%, 78% for women with regional spread and 39% for women with distant spread. This represents a slight decline in overall survival, local and regional subsets but an improvement in those with distant disease at diagnosis when compared to national statistics and institutional statistics from 1996-2002: 90% for local, 83.1% for regional and 26.1% for distant spread. One notable distinction between the LifeBridge Health patient population and population used to generate national statistics is the relatively high number of Black women treated for breast cancer at LifeBridge Health - 50% of all breast cancer patients treated at LifeBridge Health during that time were Black and the survival rates in this population exceed those noted nationally

Prevalence and Risk Factors

The factors that have the greatest impact on relative risk of developing breast cancer are not modifiable – sex and age. Although breast cancer can occur in both men and women, it is far more common in women. The relative risk of developing breast cancer increases with increasing age up to age 80 but is most significant after the age of 65 than before age 65. This is felt to be due to numerous factors including longer life expectancy, changes in reproductive patterns, long term post-menopausal hormone use, the rising prevalence of obesity and increased detection through screening.

Closely following these factors is a personal history or a family history of breast cancer. A history of breast cancer in a first-degree relative doubles one's risk of developing breast cancer. If the relative developed cancer prior to menopause, the risk is tripled and if the relative had bilateral breast cancer the risk increased 5 times. It is estimated that up to 5% of breast cancers are due to inherited cancer syndromes – specifically inherited mutations in two breast cancer associated genes, BRCA 1 and BRCA2. These mutations are present in less than 1% of the US population but, female mutation carriers for these genes have a 50-75% chance of developing a breast cancer by age 70 and a 50% chance of developing an ovarian cancer by age 70. Although breast cancers caused by mutations in these genes make up the minority of breast cancer cases, genetic counseling is important for individuals with strong family histories of breast and ovarian cancers. Surveillance for these patients is more aggressive and

Breast Cancer Treatment, continued

modalities such as prophylactic mastectomy or oophorectomy can significantly reduce the incidence of breast cancer in this population.

Hormonal influences are also very important in affecting breast cancer risk. Factors that increase the total number of ovulatory cycles and duration of estrogen exposure, such as early menarche, late menopause, nulliparity or late parity also increase the risk of breast cancer. Women with menarche at or before age 12 have a fourfold increase in the risk of breast cancer compared to women whose menarche is after age 13. Women who enter menopause after age 55 have double the risk of women who enter menopause before age 45. Long term use of exogenous estrogen and obesity is also associated with an increased risk of breast cancer.

Exposure to ionizing radiation over the chest in moderate to high doses before the age of 40 also increases the risk of breast cancer. Such an increased risk is seen in women treated with radiation for Hodgkin lymphoma, women who underwent repeated fluoroscopic chest radiography for scoliosis or tuberculosis and atomic bomb survivors in Japan who were adolescents at the time of exposure. Additional factors such as smoking, diet, environmental exposure, lack of exercise and a previous biopsy demonstrating atypical proliferative changes also play a role.

Early Detection

Screening for breast cancer is supported by more scientific evidence than for any other type of cancer as an effective tool for early detection of cancer. At least eight randomized clinical trials have evaluated the role of breast cancer screening using mammography with or without clinical examination. All have shown a beneficial effect of mammography among women ages 50 and older. There is a 34% reduction in breast cancer mortality with screening by seven years of follow-up. The Cancer Intervention and Surveillance Modeling Network (CISNET) developed by the National Institutes of Health to measure the effect of cancer-control interventions to the general population, analyzed the reasons behind the 24% drop in breast cancer mortality between 1989 and 2000, the first recorded decline in death rate since 1975. Screening, as practiced in the United States, reduced the death rate from breast cancer in the range of 7-23%, with a median of 15%. The CISNET group determined that all of the models agreed on several points: both screening and adjuvant treatment contribute to reducing breast cancer mortality, each is thought to contribute equally and the observed reduction cannot be attributed to either acting alone.

Despite developments with mammographic technology, improving accuracy and detection rates, screening mammography is not a panacea. The standard two-view mammogram does not detect all cancers in all patients. Studies indicate that between 7-30% of breast cancers that become clinically evident over the course of a year will not be visible on a screening mammogram performed within that period. This limitation is more pronounced in women with dense breasts, as seen in younger women, premenopausal women and women with fibrocystic

Breast Cancer Treatment, continued

change. False positive studies are also an issue. Of 1000 women screened in the United States 7 % (70) will be called back for additional imaging and only 1% (10) will be referred for biopsy. In the remainder, the abnormality is demonstrated to be a benign finding or superimposition of normal breast tissue. The impact of false positive studies on a woman's well being can last for years – preventing them from continuing annual screening. Although the term “false-positive” implies an error has occurred one must remember that screening tools for a large population should have a high enough level of sensitivity to capture the majority of abnormal or potentially abnormal findings. In fact, it is essential to call back many healthy individuals for further diagnostic imaging to capture as many cancers as possible but also to avoid unnecessary biopsy procedure as well.

Some women are still reluctant to undergo mammograms due to fear, modesty or pain and discomfort from mammographic compression. The rate of women who undergo screening mammography, which has been demonstrated to save lives through early detection and treatment, has yet to exceed 70% of eligible women over the age of 40 in any ethnic population in the United States. One study found that greater than 70% of women reported discomfort during screening mammogram ranking their pain as 4 or less on a scale of 0 to 10. Of these 96% reported that the pain was “less than” or “as expected” and 94% indicated that they were “very likely or somewhat likely to get a mammogram next year”. According to this study, 39% reported that the most stressful aspect of the procedure was waiting for results and suggests that adherence to screening recommendations may be more likely to occur when patients and practitioners are able to anticipate and address the most painful and stressful elements of mammography. The Herman & Walter Samuelson Breast Care Center at Northwest Hospital routinely employs the use of radiolucent cushioned pads during mammography. Studies demonstrate that the use of a cushioned pad has been shown to reduce discomfort during mammography for up to 75% of patients. On a visual analog scale the decrease in discomfort by use of the pad was 47%. The pad does not impair image quality and makes is easier for patients to be relaxed, warm and comfortable during examination – factors that increase compliance with screening recommendations and dispel I fear and anxiety surrounding mammography screening.

Breast MRI is now a well-established screening tool in women with high risk for developing breast cancer, such as women with a strong family history or evidence of a genetic mutation. MRI has high sensitivity (94-100%) but lower specificity (37-97%) in breast cancer detection and may lead to false positive rates and additional unwarranted biopsy. MRI is not a substitute for screening or diagnostic mammography or ultrasound. It supplements the use of these standard imaging tools in appropriately selected clinical situations and in these populations is can help detect breast lesions missed on mammogram or sonogram. The American Cancer Society has outlined guidelines for use of MRI

Breast Cancer Treatment, continued

for use as an adjunctive screening and diagnostic tool and in the properly selected patient populations, sensitivity and specificity is in the higher ranges.

Recently the FDA approved digital breast tomosynthesis, a three-dimensional mammography technique that allows exploration of the interior structures of the breast without the superimposition of other tissues. By allowing the X-ray tube to move through an arc, it acquires a series of projection images of the breast from multiple angles. These images can then be processed to create clear, highly focused 3-D images throughout the breast instead of only in a two dimensional plane. This technology is hoped to expand diagnostic capability and accuracy, finding and characterizing lesions more accurately while at the same time reducing false positive rates.

At LifeBridge Health, we strive to raise breast health awareness and increase the compliance with mammography screening recommendations. There is a specific goal to increase the use of mammography among high risk and African-American women who make up a significant proportion of our breast cancer patient population. Programs such as Freedom to Screen target high risk and underserved populations and strive to raise education and awareness and access to breast health and breast cancer screening.

Progress in Surgery

Over the past twenty years, breast cancer surgery has become less and less invasive. Classical surgical therapy consisted of a Halstead radical mastectomy, which included the removal the breast as well as chest wall muscle and an extensive lymph node dissection and resulted in significant deformity and morbidity. Radical resection has given way to approaches that allow breast conservation (lumpectomy) with limited lymph node removal. Appropriately selected patients now have the option of selecting a total mastectomy with preservation of the underlying chest wall muscle or a lumpectomy. Sentinel lymph node biopsy, whereby only the first one or two lymph nodes that cancer cells are likely to involve in early metastasis are removed and analyzed, has replaced full axillary dissection. The presence of cancer metastasis to regional lymph nodes has important prognostic and therapeutic implications, as these cancers tend to have worse prognosis and are treated more aggressively.

In those patients who elect to have their breast removed, there are also new techniques for breast reconstruction. In addition to implant prosthesis reconstruction, there are options that use the patient's own tissues called autologous tissue transfer. Experienced plastic surgeons can now use muscle, subcutaneous fat and skin from the back, the abdomen and derriere to create an aesthetically pleasing breast reconstruction. There is also a focus on techniques that incorporate oncoplasty – local tissue rearrangement – into breast conservation approaches in an attempt to provide the patient with a more pleasing cosmetic result.

Breast Cancer Treatment, continued

Adjuvant Therapy

Adjuvant chemotherapy has repeatedly been shown to decrease the risk of recurrence and improve survival in all stages of breast cancer. The Early Breast Cancer Trialists's Collaborative Group (EBCTCG), which monitors all clinical trials studying the effects of chemotherapy and hormonal therapy, has shown that combination chemotherapy reduces the risk of annual recurrence of breast cancer by approximately 23% and even more so in younger women less than 40 years of age in which the reduction is by 41%. In addition, women with hormone-receptor positive breast cancer who receive adjuvant hormonal therapy with aromatase inhibitors or tamoxifen or tamoxifen followed by an aromatase inhibitor have substantially improved long-term survival. This improvement is largely irrespective of other characteristics such as age and nodal status, whether they also have other treatments such as chemotherapy. To date, the largest benefit has been shown with five years of tamoxifen, with an average reduction in breast cancer deaths by year 15 of 9% - across all ages. For an individual patient, the magnitude of benefit from chemotherapy or hormonal therapy depends largely on their baseline risk of recurrence in the absence of such systemic therapy. A patient who faces a high risk of recurrence, such as a patient who has 4 or more lymph nodes involved with cancer will benefit substantially more from taking chemotherapy than a patient who has no lymph nodes involved.

The challenge today is not in "treating" breast cancer but in defining those small groups of patients that may forgo treatment. For example, for patients with a hormone receptor positive tumor less than 1 cm, the survival rate is as high as 96% at eight years of follow-up. Some histologic subtypes, such as tubular, mucinous, papillary and adenoid cystic carcinomas, also have more favorable prognoses. There is increasing evidence that gene expression profiling of tumors may provide useful information regarding prognosis and the relative benefit from chemotherapy versus hormonal therapy. One such test, which is commercially available and widely used, is a 21 gene assay to determine a recurrence score (RS) which groups patients into three categories. Patients with a low RS have a good prognosis and respond to hormonal therapy with no added benefit from systemic chemotherapy. Patients with a high RS have a poorer prognosis and systemic chemotherapy has been shown to improve their overall disease free survival. Studies are still ongoing to determine the best treatment option for those patients with intermediate scores to determine which of patients in this category will benefit from systemic chemotherapy and which will benefit from hormonal therapy alone. There is also a 70 gene assay available that creates a distinct gene expression signature and stratifies patients into low and high risk subtypes that can also help select patients for systemic chemotherapy.

In recent years, the treatment of breast cancer has been enriched with new chemotherapy drugs and hormonal agents. In addition to tamoxifen, hormonal therapy now encompasses two new classes of drugs: aromatase inhibitors and estrogen receptor down regulators. Another exciting addition came in the form of

Breast Cancer Treatment, continued

an antibody targeting a specific receptor present on breast cancer cells in a third of all breast cancers – the Her2/neu antigen. These cancers have a worse prognosis compared with cancers that do not express the Her2 receptor. Studies have shown that the antibody, when added to multi-agent systemic chemotherapy, is very well tolerated and significantly enhances the efficacy of chemotherapy and the overall survival of those patients. Unfortunately, those patients with the worse prognosis and poorest survival have the most limited treatment options – the patients whose tumors are hormone receptor negative and who do not over express the Her2 antigen. For many of these patients their only systemic option is multi-agent chemotherapy. We encourage these patients to participate in clinical trials that aim to improve the outcome for this patient population.

Currently there are over 1000 clinical trials nationwide available for patients with breast cancer of various stages and presentation. Clinical trials are necessary to test new treatments and determine if treatments are effective. Only about 5% of breast cancer patients are currently enrolled in clinical trials in the United States. The National Accreditation Program for Breast Centers (NAPBC) recommends that certified centers enroll at least 2% of their breast cancer patients in clinical trials each year. At LifeBridge Health more than 4% of eligible patients enroll in clinical trials each year and benefit from cutting-edge research through clinical trials carried out under the auspices of the Southwest Oncology Group and the Clinical Trials Support Unit.

Radiation Therapy

Radiation therapy is recommended for many, though not all breast cancer patients. In patients who qualify for breast conservation, it has been shown in many prospective, randomized national and international trials to significantly reduce the risk of local recurrence compared to lumpectomy alone. Recurrence following lumpectomy is only a few percent higher than following mastectomy with equally good survival. In patients who have multiple positive lymph nodes, regardless of whether they choose to preserve their breasts or not, radiation has improved survival. The indications for radiation therapy involve a complex assessment of all the risk factors, including tumor size, margin status, presence and degree of lymphatic or vascular invasion, chest wall invasion, ratio of positive to negative nodes, age, menopausal status, receptor status, Her-2 status, proliferation index and sometimes additional circumstances. These factors are always considered in the context of the patient's general condition, physical ability to lay in the treatment position, whether there has been previous radiation and certain other, rare conditions that may increase the risk of side effects. Most patients who choose or require radiation are able to successfully and comfortably complete treatment.

Radiation therapy techniques are evolving. Most commonly, the whole breast is treated, with or without treating the lymph nodes. There are subsets of patients

Breast Cancer Treatment, continued

who qualify for less commonly prescribed treatments limited to the region of the lumpectomy alone, though many still consider this experimental. There are also some patients who may qualify for larger daily treatments in an attempt to reduce the overall number and duration of treatments. When evaluating the cosmetic results following treatment, preliminary data shows overall similar outcomes when grouping good and very good cosmetic results together. There is some skepticism about how many patients will maintain good cosmesis after ten or more years follow-up. Which course is appropriate for each patient requires a detailed conversation with the Radiation Oncologist.

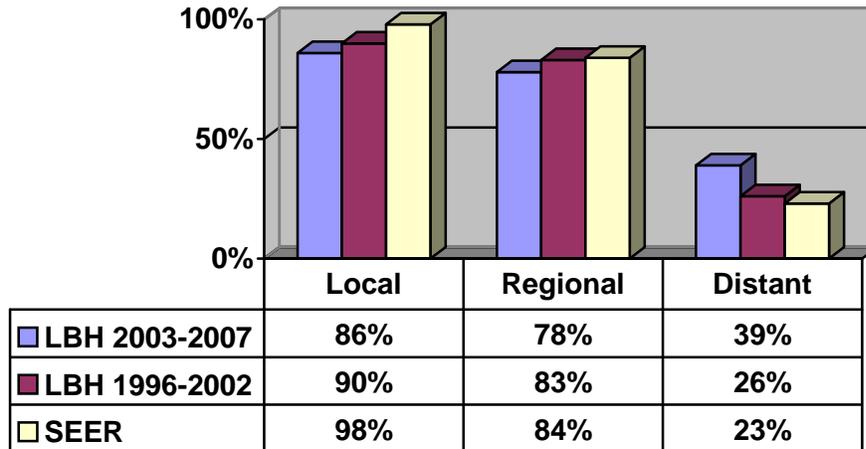
Multidisciplinary Center

A successful fight against breast cancer requires a team approach. Our patients at the Herman & Walter Samuelson Breast Care Center benefit from a multidisciplinary team dedicated to helping women navigate their breast cancer diagnosis and treatment. The multidisciplinary team has a core group of four dedicated health professionals: a breast surgeon, a medical oncologist, a radiation oncologist and a nurse navigator with extensive experience in oncology. The team expands when needed to include a genetic counselor and accesses other specialists to provide comprehensive care. Patients have access to specialized plastic surgeons, dieticians, rehabilitation and lymphedema specialists, neuropsychologists, support groups and image recovery specialists.

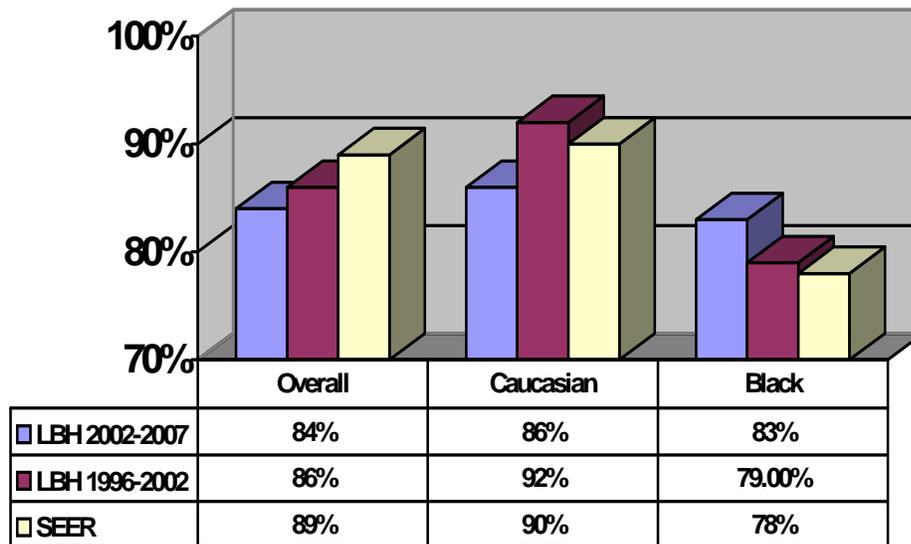
A phone call to the Breast Center connects the patient or their health care provider to the dedicated nurse navigator who can perform an initial assessment of their needs. The navigator then assists the patient through their journey – through multidisciplinary assessment, additional diagnostic testing, referral to support groups and services, surveillance planning and survivorship. Most cases are also discussed in the Multi-Disciplinary Breast Cancer Conference or Tumor Board where physicians review cases with the pathologists as well as other specialists from surgery, oncology, radiation oncology, nursing, pharmacy, genetics and nutrition to provide the best possible care using national standards of care and accepted guidelines. Each patient has a care plan designed to take into account not only their disease state, but also their psychosocial needs in a compassionate, individualized fashion.

In summary, the Alvin & Lois Lapidus Cancer Institute and Herman & Walter Samuelson Breast Care Center provide a multifaceted approach to breast cancer. Comprehensive services including screening and diagnostic imaging, genetic counseling, a broad spectrum of treatment options and clinical trials rounded out with support groups, image recovery and transportation services make this state of the art program and optimal place for care.

**LifeBridge Health Breast Cancer Treatment
Relative 5-Year Survival Rate:
Female Patient by Stage at Diagnosis**



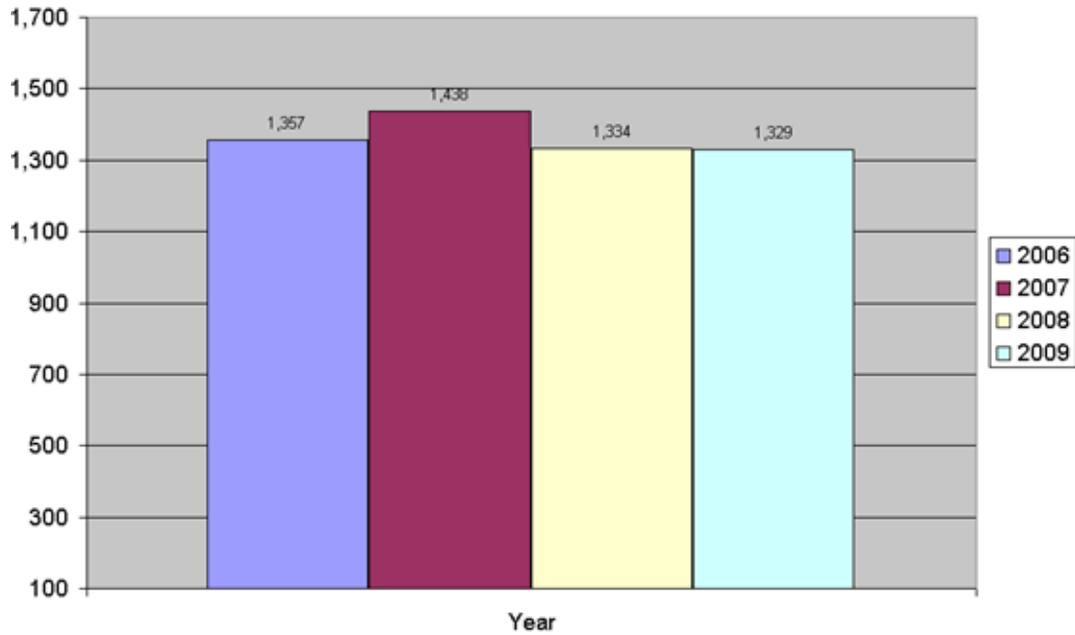
**LifeBridge Health Breast Cancer Treatment
Relative 5-year Survival
Female Patients By Race**



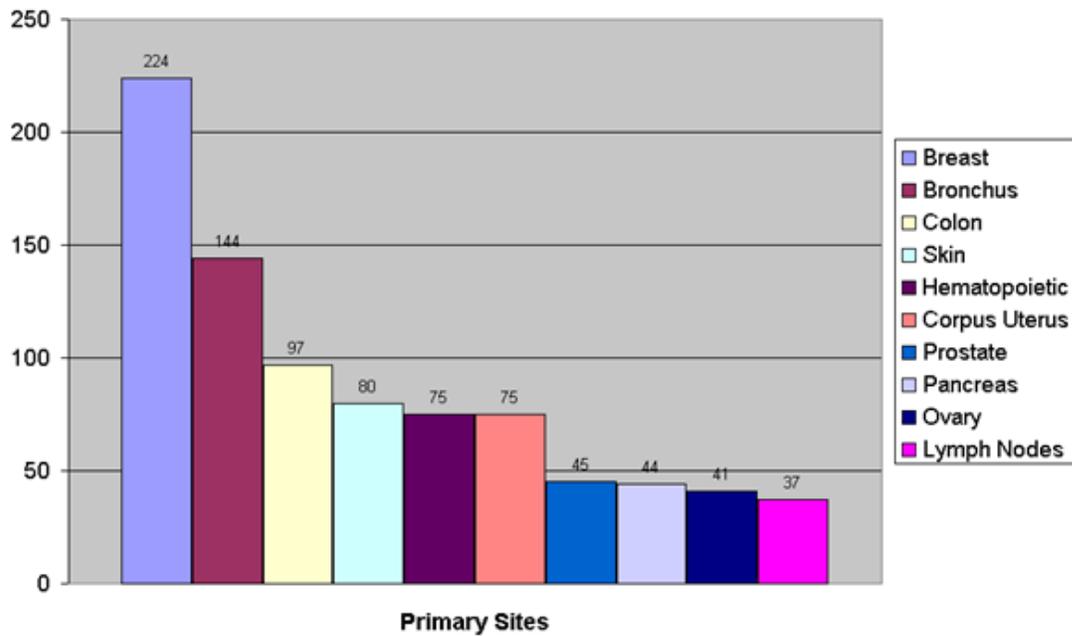
Oncology Registry Activities

2010 Annual Report

LifeBridge Health Analytic Cases



Top Ten Sites for 2009



Annual lifetime follow-up of patients with cancer is an important part of the Oncology Registry. Lifetime follow-up directly benefits patients by reminding them, through letter or phone call, that routine medical examinations are encouraged. This process potentially brings lost patients back under medical supervision, providing continued surveillance to ensure early detection of a possible recurrence or a new primary malignancy. Every patient with a diagnosis of cancer is followed on an annual basis. The Oncology Registry at LifeBridge Health consistently maintains contact with over 90 percent of all eligible patients in the database and over 94 percent of patients diagnosed within the last five years.