ST ALEXIUS MEDICAL CENTER
2010 CANCER ANNUAL REPORT

2010

St. Alexius PrimeCare

Published December 2010
2009 Data

Table of Contents

The St. Alexius Medical Center Cancer Program is accredited by the American College of Surgeons Commission on Cancer (CoC).

Mission

Based on the Gospel values and our own heritage of healing, the mission of St. Alexius Medical Center is to use our presence as a means of touching and caring for people in a Christ-like manner, and to always exhibit the hospitality as reflected in the Rule of St. Benedict: ***"Let all be received as Christ"***

Vision

The vision of St. Alexius Medical Center is to use our presence to extend Christ's healing ministry through excellence of service, collaborative relationships and a commitment to quality to those we serve.

Values

Community

A coming together of people who commit themselves to a mission, caring for and challenging each other to use their personal gifts and skills to serve.

Respect

Giving and showing reverence, esteem and consideration for self and others.

Stewardship

Working together to care for all resources for the good of all people.

Healing Presence

An atmosphere that affirms the whole person: body, mind and spirit.

Personal and Professional Growth

An ongoing commitment to expand knowledge and develop skills in order to enhance service, improve quality and reach one's fullest potential.

St. Alexius Cancer Program

St. Alexius Medical Center is proud to be recognized as an accredited cancer program, approved by the American College of Surgeons Commission on Cancer with commendation. This award means that, in addition to meeting all 36 standards of care, St. Alexius Medical Center was commended for exceeding the standards in multiple areas. The dedicated team of physicians, nurses and staff at St. Alexius is not resting on its laurels and has set a series of goals to designed to continue to improve this high level of cancer care.

Commission on Cancer

THE COMMISSION ON CANCER AWARDS THIS

Certificate of Accreditation

WITH COMMENDATION

to the Community Hospital Cancer Program of

St. Alexius Medical Center

Bismarck, ND

Program approved through 2011

STEPHEN B. EDGE, MD, FACS
CHAIR, COMMISSION ON CANCER
AMERICAN COLLEGE OF SURGEONS

DIANA DICKSON-WITMER, MD, FACS
CHAIR, ACCREDITATION COMMITTEE
AMERICAN COLLEGE OF SURGEONS

The American College of Surgeons does not warrant or make any guarantees or assurances related to outcomes of treatment provided by institutions which have cancer programs accredited by the Commission on Cancer.

St. Alexius Medical Center
2010 Cancer Committee

Physician Members

Tarek Dufan, MD (Chair 04/2010)	Radiation Oncologist
Ferdinand Addo, MD	Medical Oncologist
William Altringer, MD	General and Vascular Surgeon
Ward Fredrickson, MD	St. Alexius Chief of Pathologist Services
Shiraz Hyder, MD	Vice President Medical Affairs/Neurologist
Doug Peterson, MD	Radiologist
Vijay Rao, MD	Medical Oncologist
John Watkins, MD (Co-chair 04/2010)	Radiation Oncologist

Non-Physician Members

Ken Dykes, MPA	Bismarck Cancer Center (BCC) Director
Janel Eckroth, RN	Cancer Program Coordinator
Donna Gage, MSN	Cancer Program Administrator
Julie Jeske, MBA	Director of Marketing
Joan Johnson, RPh	Pharmacist
Shrikant Kubsad, PhD	Medical Physicist (BCC)
Elaine Kucera, MT(ASCP)	Clinical Research Director
Liz Meidinger, LSW	Social Worker
Linda Rambough, RN	Oncology Nursing
Tara Schilke, RN	BCC Oncology Program Coordinator
Rosanne Schmidt, RN	Administration
Sandy Tschosik, RN	Community Health Services Coordinator
Karen Waliser, RN	Quality Improvement
Tracy Wildeman, CTR	Cancer Registry Director
Judy Wittmier, CTR	Cancer Registry Consultant

Breast Cancer Research

Dr. Vijay Rao, Oncologist at Mid Dakota Clinic and
Dr. John Watkins, Radiation Oncologist from Bismarck Cancer Center,
Mindy Sturn, BDRS and Elaine Kucera, Director
From St. Alexius Medical Center Clinical Research Services

Treatment for breast cancer depends on the stage of the disease, but often includes surgery, radiation therapy, and chemotherapy. There is a continual search for better methods of treating and diagnosing breast cancer. St. Alexius Medical Center's Clinical Research Services has collaborated on a number of clinical trials with Mid Dakota Clinic, PC, Bismarck Cancer Center, and FEK Addo PC Clinic over the years. We recently spoke with some of the physicians from these facilities and asked them questions about new and upcoming treatment options available for breast cancer patients and the importance of continued research.

The initial focus is on the early diagnosis of breast cancer. The recommendation is for women 40 years of age and older to have a mammogram annually. There are women who have a genetic predisposition to breast cancer; women who have a family history of breast or ovarian cancer or women who get breast cancer at a young age. These women benefit from BRCA genetic testing. Dr. John Watkins, radiation oncologist from Bismarck Cancer Center provided the following example highlighting what type of options are now available through analyzing genetic mutations. "A woman with BRCA genetic mutation (which represents 2-5 percent of all women diagnosed with breast cancer), may be recommended to undergo bilateral mastectomy and even ovary removal in order to minimize her risk of future cancer development."

Young women with dense breast tissue or patients with dense breast tissue and a negative mammogram may benefit from a breast MRI.

Breast cancer is treated with the focus of decreasing the recurrence of cancer and to treat cancer if it has returned. Several target agents are used in both of these situations. Targeted therapies are transforming the way people treat cancer. Dr. Watkins commented, "The most exciting new agents for breast cancer involve targeted agents. The essential premise is that not all breast cancers are the same at the biological level, and newer medications can target pathways specific to the individual patient's cancer cells. This results in improved effectiveness, often with fewer side effects."

Tamoxifen is the first targeted agent used. It targets the estrogen receptor. Newer agents that indirectly target the estrogen receptor by inhibiting extra-ovarian production include Arimidex (anastrazole), Femara (letrozole) and Aromasin (exemestane).

Herceptin, a newer chemotherapy agent with a different target, has been identified. Herceptin targets Her-2 neu (also called erb2 or EGFR2). Several agents using this target are available and others are still being investigated. The prototype Herceptin, which is a monoclonal antibody, is used in both adjuvant and metastatic settings.

Lapatinib is a protein kinase inhibitor that also targets the Her-2 neu gene receptor. It is presently used in the metastatic setting; however it is also under investigation in the adjuvant setting.

A new novel agent is TDM-1, a Her-2 neu targeting agent. This drug may be the next generation to Herceptin. It is a very potent agent that is designed to deliver a cancer-killing dose of chemotherapy directly inside tumors, sparing healthy cells from toxic side effects. Data from clinical trials of TDM-1 compared to Herceptin-Taxotere is showing sharply lower toxicities.

A drug currently under controversy, Bevacizumab (trade name Avastin), is a monoclonal antibody, that targets the angiogenesis pathway. Avastin was the first clinically available angiogenesis inhibitor. It was FDA approved in 2008 for the treatment of metastatic breast cancer. It showed improvement in progression free survival; however, there was no overall long term survival benefit observed.

PARP, Poly (Adenosine-disposphate-Ribose) Polymerase, is an enzyme that repairs damaged DNA, thereby preventing programmed cell death (apoptosis). All cells have PARP enzymes including cancer cells. Cancer cells use the PARP enzymes to repair the cells from chemotherapy. New investigational therapies being tested are "PARP inhibitors." The PARP inhibitors make the cancer cells receptive to chemotherapy so the cancer cells die.

At this time, there are eight PARP inhibitors in clinical trial development worldwide. According to current research on breast cancer, the inhibitors reflect a strategy of drug development known as "synthetic lethality," show antitumor activity without the toxicity associated with conventional chemotherapy. Dr. Vijay Rao, oncologist at Mid Dakota Clinic, indicates that PARP inhibitors are showing good results in patients with triple negative cancers.

Laboratory testing plays an important role in assisting in the treatment of breast cancer. There are a number of different laboratory testing approaches being evaluated at this time such as: tumor markers, biomarker testing, and genetic testing. More research needs to be done; however, these testing options have proven to be helpful in diagnosing and individualizing treatments.

Circulating tumor cells are used in clinical practice and clinical trials to monitor patients with metastatic breast cancer. Some patients with metastatic breast cancer have elevated tumor markers which can be monitored sequentially to determine if chemotherapy is working. These are CA27.29, CA15-3, CEA.

Genetic testing is specific to the individual tumor and helps to characterize how it is likely to behave. While generally all women with involved lymph nodes and/or Her-2 neu -amplified/ over-expressed tumors are recommended to receive chemotherapy, not all node-negative women with hormone receptor-sensitive, Her-2 neu -negative tumors have a known benefit to chemotherapy. Genetic signatures evaluate specific genes (e.g., 21 in Oncotype DX) and categorize women into low, intermediate, and high risk groups in terms of likelihood of distant metastatic disease following hormone therapy (after completion of locoregional therapy). Women at high risk (and some within the intermediate risk) groups do benefit from chemotherapy. Several other gene signatures are available including mammoprint.

Research trials help to provide another option for the fight against cancer. Dr. Rao feels that through research trials, patients are able to get treatments that are not available through current standard treatment and the monitoring during clinical trials plays a vital role. Dr. Watkins stated, "Nearly every aspect of modern oncology care has been guided by the results of clinical trials and related research. As an example, only 25-30 years ago, women

had not been offered breast-conserving surgeries; however, thanks in large part to a group of surgeons who questioned whether all women with breast cancer required a mastectomy (as well as the courageous women who agreed to participate in the studies comparing these approaches), we now know that survival from early-stage breast cancer is similar and patients can elect a treatment that best suits their personal, cosmetic, and psychological preferences. Thus, for the past 25-30 years, women have had an opportunity to preserve their breast(s) if they elected to so. Now, thanks in large part to genetic sequencing and identification of patients at high risk for breast cancer recurrence after breast conservation (as well as development of ovarian and other cancers), we're able to further individualize treatment recommendations based upon each woman's specific risk, so she can have the best possible long-term survival."

As principal investigator with Clinical Research Services, Dr. Rao is conducting a study for patients who have completed treatment with trastuzumab as part of their therapy. After trastuzumab therapy, patients in the trial start on an oral investigational drug which may help to prevent their erb2 (Her-2 neu) positive breast cancer from returning, or delay the time until the cancer returns. There are currently 13 patients enrolled in this trial. We continue to search for clinical trials involving cutting-edge and promising investigative treatments for breast cancer.

Outreach Activities

St. Alexius has a long-standing tradition of meeting the healthcare needs of the communities we serve. It is through this interactive connection we live our mission of letting all be received as Christ. We continue to focus our outreach programs on improving the health and wellness of the people in our region.

In 2009, St. Alexius hired a community health services coordinator. The coordinator's role is to educate the general public on the benefits of early detection and intervention as well as promote health and disease prevention. This is accomplished through a series of St. Alexius sponsored health screens and by planning and participation in numerous health-related events. St. Alexius' marketing department works with the community health services coordinator to promote the screens and to create awareness regarding the importance of preventative exams.

St. Alexius Medical Center provides low cost or free health counseling, blood pressure, cholesterol, blood sugar and bone density heel scans, as well as weight, height, and body mass index (BMI) checks. Other screens offered include sleep apnea and peripheral vascular.

Screenings (July – December 2009)

Wellness
We measured 148 individuals' height, weight, BMI, BP, bone density and cholesterol/sugar screenings. A physician reviewed results with patients. Participants received printed education on osteoporosis, hypertension, cholesterol, diabetes and obesity.

Vascular
A vascular screening consisting of a carotid artery, abdominal aortic aneurysm, and peripheral vascular screen was held; 190 people participated.

Cholesterol
71 individuals had their cholesterol screened at this one day event.

Sleep Apnea
Over a six month period, 29 people were tested for sleep apnea.

Support Groups

Support groups help maintain interpersonal contact among its members and provide participants with various types of help. The help may take the form of evaluating relevant information, relating personal experiences, listening to and accepting others' experiences, providing sympathetic understanding and establishing social networks.

Breast Cancer Support Groups
Second Thursday of each month beginning at 5:30 p.m. Call 222-6100 for more information.

Look Good, Feel Better
Held at 2 p.m., on the second Monday of each month at Bismarck Cancer Center. For more information call 222-6100.

Look Out for Lymphedema
Take place at 3 p.m. on the first Thursday of each month at Bismarck Cancer Center. Call 222-6100 to learn more.

Mastectomy Education and Discussion Support Group
Held at 7 p.m. on the third Thursday of each month at Great Plains Rehabilitation Services. For more information call 530-4000.

Healthy Steps
Meets at 4 p.m. the second Monday of every month.

Featured Cancer Site
Breast Cancer

Derek Kane, MD, Surgeon at Mid Dakota Clinic
Julie Jeske, Director of Marketing, St. Alexius Medical Center

Breast cancer is the number one cancer among women in the United States and, at 17 percent of all reported cases among both men and women, the most common of all cancers, except for non-melanoma skin cancer[1]. Breast cancer accounts for approximately one-third of all cancer diagnoses in women. According to the American Cancer Society, about 207,090 new cases of invasive breast cancer are expected to be diagnosed in women in 2010 and 39,840 deaths are anticipated from the disease this year[2]. Although breast cancer is rare in men, it is not limited to only women. Less than one percent of all breast cancer detected, there will be approximately 1,970 new cases of breast cancer diagnosed in men in 2010 and 390 men will die from breast cancer this year in the US.[2]

Risk Factors
A risk factor is anything that makes it more likely you'll get a particular disease. Having one or even several risk factors does not mean you will develop cancer; most women with breast cancer have no known risk factors other than simply being female. Factors which can increase your risk of breast cancer include increasing age, a personal or family history of breast cancer, and obesity, just to name a few.

New Women's Imaging Center
St. Alexius Medical Center's new Women's Imaging Center opened in 2010. Conveniently located just off the east patient entrance, the center's spa-like atmosphere features healthcare professionals who have extensive experience in imaging, and women's health issues. Diagnostic services provided at the Women's Imaging Center include breast MRI, ultrasound, stereotactic breast biopsy and DEXA scan.

Breast Cancer Clinic
For patients, the initial diagnosis of breast cancer is a traumatic experience. The next steps can be equally overwhelming as the time in between consults with a variety of medical specialists can seem lengthy. In order to better serve the needs of patients newly diagnosed breast cancer, Mid Dakota Clinic, St. Alexius and Bismarck Cancer Center established a multidisciplinary Breast Cancer Clinic.

The purpose of the clinic is to reduce the anxiety experienced by patients and their families by streamlining consultations with general surgeons, medical oncologists, radiation oncologists and plastic surgeons. The multi-specialty team of experts tailors a comprehensive treatment plan for each individual patient. By working collaboratively in one location, a breast cancer patient is assured of a timely and multidisciplinary treatment plan.

Surgical Treatment Options

When it comes to breast cancer surgery, the prevention of cancer recurrence is the top priority. The goal is to remove the tumor so it won't reappear in the breast or spread to other parts of the body. A specific surgical procedure may be recommended based on the size, location, or type of breast cancer. Surgical treatment options include:

- Lumpectomy
- Partial or Segmental Mastectomy or Quadrantectomy
- Total Mastectomy
- Modified Radical Mastectomy
- Radical Mastectomy

Statistical Analysis
Breast Cancer Diagnosis And Treatment
St. Alexius Medical Center

Based on 2009 Cancer Registry Data

Tracy Wildeman, CTR, Central ND Cancer Registry

Most Commonly Occurring Cancer Diagnosis and Treatment at St. Alexius

One out of eight women in the US will be diagnosed with breast cancer during her lifetime. At St. Alexius Medical Center, 93 Breast Cancer cases were diagnosed and/or treated in 2009, the second most common cancer diagnosis. It has been the most frequently diagnosed tumor over the past ten years. As the chart below shows, this is consistent with national statistics.

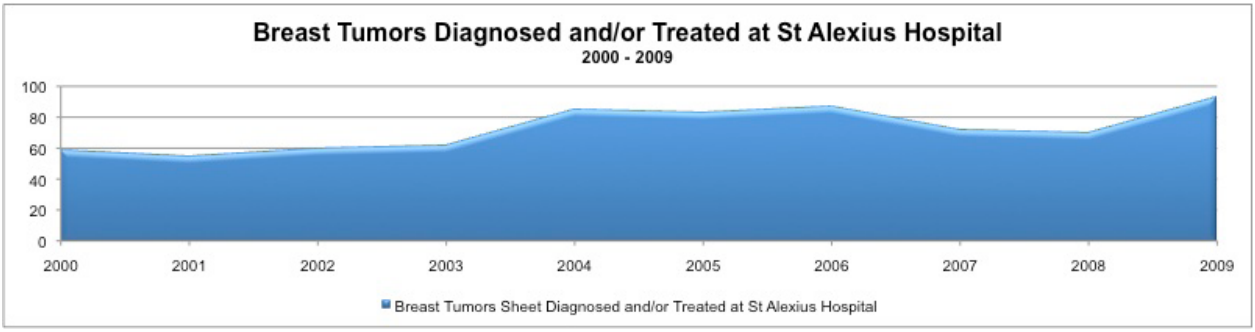
Top Cancer Sites at St. Alexius Medical Center	# 2009	% 2009	2000 - 2009	% 00-09	% US 2006
Prostate	111	19%	595	13%	12%
Breast	93	16%	724	16%	17%
Lung	82	14%	714	16%	14%
Colorectal	47	8%	508	11%	10%
Hematopoietic	33	6%	308	7%	7%
Bladder	30	5%	209	5%	4%
Gynecologic	27	5%	243	5%	6%
Thyroid	24	4%	198	4%	2%
Kidney	23	4%	154	3%	3%
All others	102	18%	852	19%	24%

Breast cancer is the second leading cause of cancer death in women, following lung cancer. The chance of dying from breast tumors has been going down, possibly the result of early detection and better treatment. Compared to the number of cases expected to be diagnosed in 2010 cited above, in 2006, there were 191,410 breast cancer diagnoses and 40,820 deaths from the disease[4]. In other words, over five years, despite an increase of 15,680 cases (+ 8.2 percent), the number of deaths dropped by almost 1,000 (- 2.4 percent).

Breast cancer awareness campaigns among young and old, men and women have raised the profile of breast cancer. These include programs such as Breast Cancer Awareness Month, observed in October of every year, organizations such as the Susan G. Komen for the Cure and local programs such as the multidisciplinary Breast Cancer Clinic at Bismarck Cancer Center, to list just a few.

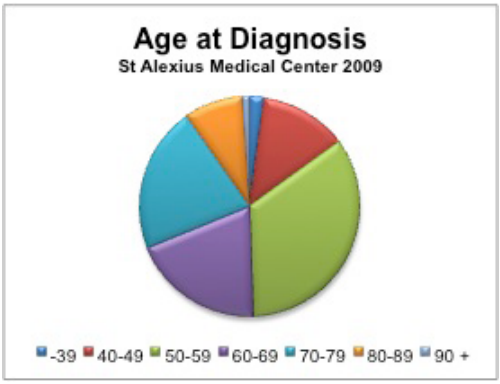
According to the Centers for Disease Control (CDC), the incidence of breast cancer in North Dakota is 119.7 to 125.5 per 100,000 people. The female breast cancer death rate in our state is 18.9 to 21.3 per 100,000 people (both statistics are age-adjusted to the 2000 US standard population)[4].

Breast tumors diagnosed and/or treated at St. Alexius have edged upward in the past ten years. From a decade low 55 cases diagnosed or treated at St Alexius in 2001, 93 patients were diagnosed or treated for breast cancer in 2009. While mostly occurring in women, two of the 93 breast cancer patients in 2009 were men.



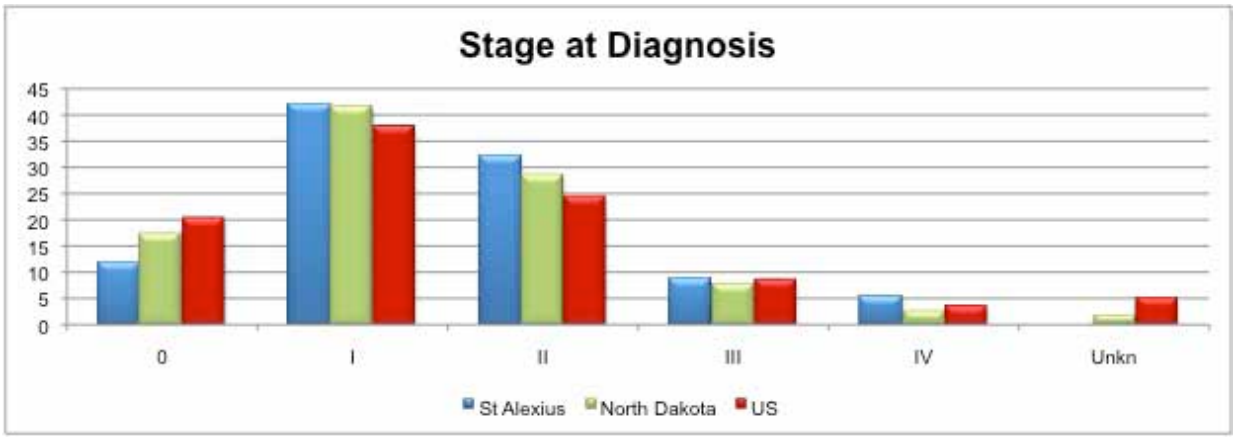
Age

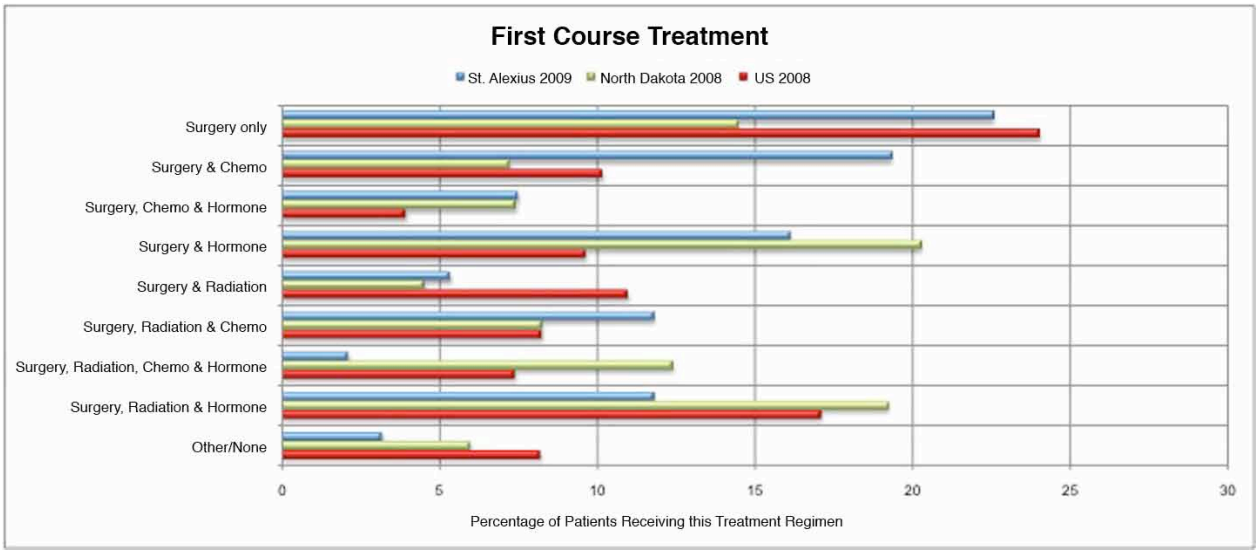
Half of the breast cancer patients treated or diagnosed at St. Alexius in 2009 were 59 years of age or younger (both of the males were over the age of 60). This is considerably higher than St. Alexius has experienced over the past ten years in this age group. Patients between 50 and 59 account for one quarter of the cases in the last decade. The ten year averages for St. Alexius are very similar to North Dakota and national statistics.



Stage at Diagnosis

Over one-half of the patients diagnosed at St. Alexius were in the early stages of the disease, with 42 percent being Stage I. However, only 12 percent of the patients are discovered in Stage 0, almost half the national average of 21 percent. Across the state of North Dakota, the percentage of cases diagnosed in Stage 0 approaches the national average, but still comes in at only 17 percent. This suggests that the current campaign of awareness and screening should continue to be a focus, whether self screening at home or through outreach programs in the community or community education. Coupled with the data in the previous section on the age at diagnosis, these programs may be targeted to individuals beginning in their twenties.

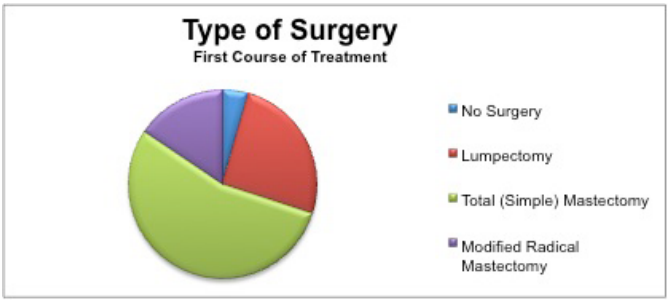




First Course of Treatment

St Alexius uses a multidisciplinary approach to treating breast cancer. Surgery is the foundation of the treatment, in combination with radiation therapy, chemotherapy and/or hormone therapy in most cases.

St Alexius' surgeons, in concert with Mid Dakota Clinic's medical oncologists, Bismarck Cancer Center's radiation oncologists and other diagnostic and treatment specialists, have instituted a Breast Cancer Clinic where breast cancer patients have the opportunity to meet with several cancer physicians in a single day. This multidisciplinary approach gives patients and doctors a picture of the whole treatment plan for the patient from the beginning.

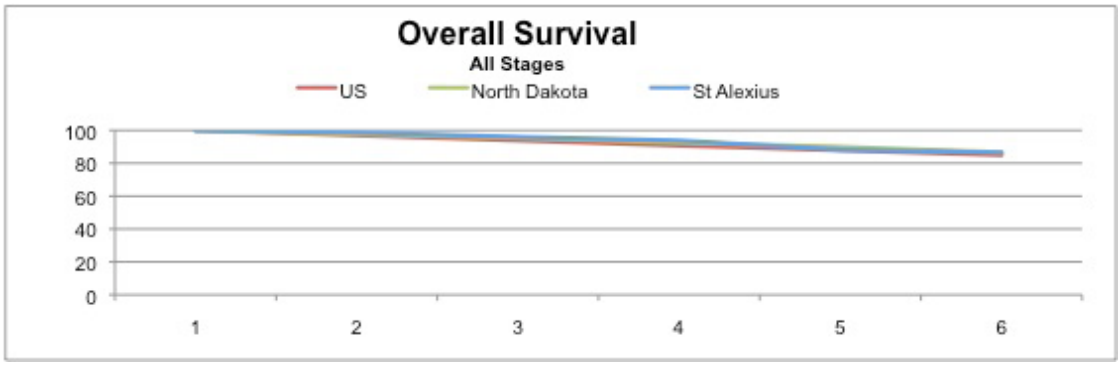


Survival

Survival rate is the benchmark of success for cancer treatment programs, and the watershed mark is survival for the first five years after diagnosis and treatment. The following charts are taken from the St. Alexius Medical Center's database in the Central ND Cancer Registry and the National Cancer Database comparing survival in two ways.

The first chart shows the observed survival of St. Alexius, North Dakota, and the country as a whole over a five year period. The data does not discriminate based on whether the patient died from cancer or other causes. St. Alexius data is based on 577 of 605 patients: only those who were treated at St. Alexius and successfully followed during the period. Patients who were diagnosed at St. Alexius and treated at another facility, as well as those who have been "lost to follow up" have been excluded from the data.

The prognosis of survival from breast cancer is very good. On the average, 85 percent of all people diagnosed with breast cancer pass their five year anniversary. The survival rate is virtually identical, whether we are looking at St. Alexius, North Dakota, or the US.



Cancer cases accessioned (that is recorded and tracked) by the Commission on Cancer registries are subdivided into a "Class of Case" according to where the patients were diagnosed and treated. The most frequently used classifications are:

Class of Case 0: Diagnosis is at the accessioning facility (St. Alexius) and all of the first course of treatment is performed or the decision not to treat was made at another facility.

Class of Case 1: Diagnosis and all or part of the first course treatment or the decision not to treat occurred at the accessioning facility (St. Alexius).

Class of Case 2: Diagnosis was made at another facility, and all or part of the treatment or the decision not to treat occurred at the accessioning facility
(St. Alexius).

Class of Case 3: Diagnosis and all of the first course treatment was performed elsewhere. The case was revealed in History & Physical during a doctor visit for another reason.

For the purposes of this study, we are using only those cases which have been treated at St. Alexius – Class of Case 1 or Class of Case 2 and excluding those who have not been treated at St. Alexius.

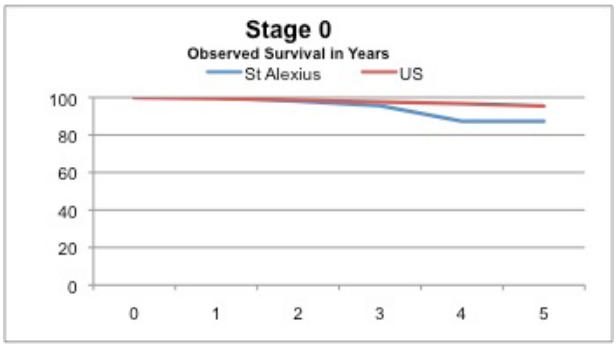
Breast Cancer Stages

The stage describes the extent of the cancer in the body. It is based on whether the cancer is invasive or non-invasive, the size of the tumor, how many lymph nodes are involved, and if it has spread to other parts of the body. The stage of a cancer is one of the most important factors in determining prognosis and treatment options.

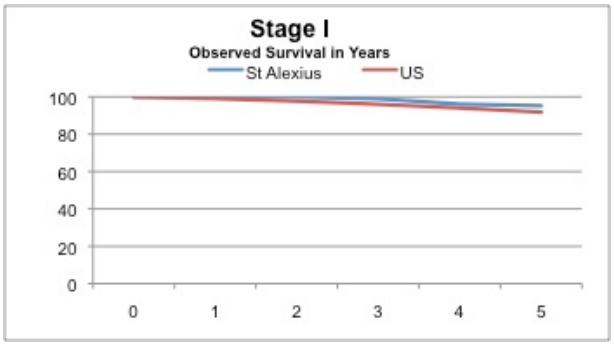
Most common tumor stages

- **Stage I** - Cancer cells have not spread beyond the breast, and the tumor is no more than 2 cm (about 3/4 of an inch) across.
- **Stage II** - One of the following conditions apply: the tumor is less than 2 cm across, and the cancer has spread to the lymph nodes under the arm; the tumor is between 2 and 5 cm (about 3/4 inch to 2 inches) with or without spreading to the lymph nodes under the arm; the tumor is larger than 5 cm but has not spread to the lymph nodes under the arm.
- **Stage III** (Locally Advanced) - In this stage, the tumor in the breast is more than 5 cm across, and has spread (sometimes extensively) to the underarm lymph nodes or tissue near the breast. A condition called inflammatory breast cancer is also treated as a Stage III cancer.
- **Stage IV** (Metastasized Cancer) - In Stage IV the cancer has spread from the breast to other parts of the body. In about 75 percent of cases, the cancer has spread to the bone. The cancer at this stage is considered to be chronic and incurable, and the usefulness of treatments is limited. The goals of treatment for Stage IV are a complete or partial response, stabilization of the disease, or slowing the disease progression.

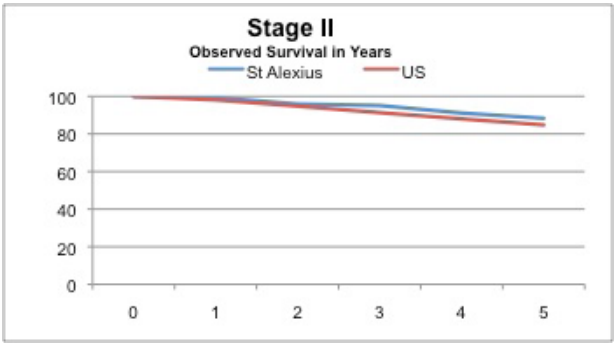
The following graphs show the value of early detection. Again, the comparison between St. Alexius and the US statistics is virtually identical.



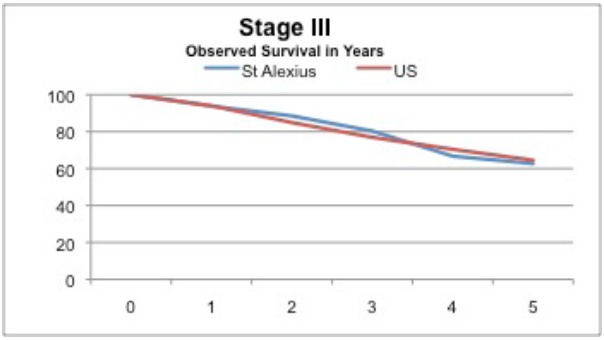
Ninety-five percent of breast cancer patients with Stage 0 disease celebrate the fifth anniversary of their survival.



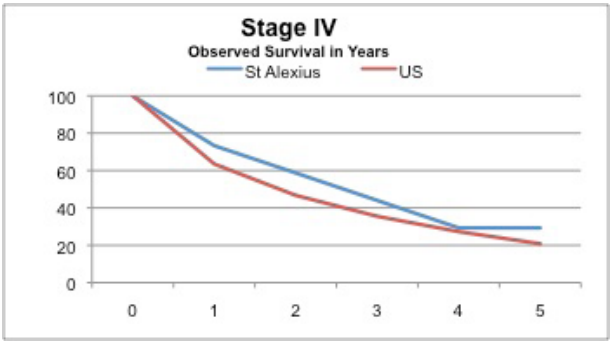
Nine out of ten Stage I patients reach their fifth year of survivorship.



Eighty-five percent of Stage II patients survive at least five years.



Six out of ten Stage III patients are five or more year survivors.



Two out of ten cancer patients diagnosed with Stage IV cancer reach their five year survivorship.

St. Alexius Medical Center, along with their affiliated physicians, Mid Dakota Clinic and Bismarck Cancer Center, has made notable advances in promoting early detection, screening and in the sponsorship of a multidisciplinary clinic targeting the treatment of breast cancer in the Bismarck area. Tumors are being detected at younger ages, in earlier stages and treated with more diversified treatments with increasing success. The effect of many of these new initiatives have not had enough time to be reflected in five year survival statistics, and will show in these statistics in the years to come.

[1] http://www.cdc.gov/CANCER/breast/statistics/
[2] http://www.cancer.gov/cancertopics/types/breast
[3] http://www.cdc.gov/features/breastcancerawareness/
[4] http://www.cdc.gov/cancer/bresat/statistics/state/htm