

2013 CANCER COMMITTEE

Annual Report



CANCER COMMITTEE CHAIRMAN'S REPORT

PATRICIA W. GOLDBLATT, MD, FCAP



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Over the past four years during which I have served as Chairperson of the hospital Cancer Committee, I have begun my portion of the annual report by sharing the number of new cases added to our database over the past year as a means of demonstrating the magnitude of our program and the continued confidence

that we have gained from our community and outlying areas. Annually, our cancer registry accessions around 1,600 cases. Of greater significance, however, is the number of cases in our entire database, which is up to 30,500 at the present time. This large number is due to the fact that our program has continued to follow patients included in our program since its inception, maintaining our original registry reference date, strengthening the long-term follow up data made available by the National Cancer Registry.

In addition to this enormous undertaking, our Cancer Program has begun to participate in the Rapid Quality Reporting System (RQRS) recently established by the Commission on Cancer, whereby data on select quality measures is reported to the National Cancer Data Base (NCDB) as it is made available (rather than by a certain deadline) so that feedback on the data and notifications about treatment expectations are provided on time to help the actual patients entered into the database and not merely used as statistics for retrospective review. Compliance with this new standard awards participating accredited facilities with commendation, as it requires a tremendous level of commitment by the registry to uphold and provides a much greater opportunity for the registered patients to personally benefit from the program.

The ongoing activities of our program remain robust. At our weekly multidisciplinary cancer conferences, selected patients benefit from a roundtable discussion among several physicians and allied health professionals who specialize

in several different cancer diagnosis and treatment specialties about complicated or unique issues, enabling input from experts in multiple fields. As our site-specific study for 2013, we chose to undertake a 25-year review of our breast cases, focusing on recurrence and the circumstances common among breast cancer recurrences to ensure our breast cancer treatment performance measures are consistent with or better than national data. In addition, we implemented several quality improvement studies, including a National Cancer Data Base Completeness Study performed by our registry, ensuring that all of the abstracted fields were filled out with the most correct answers. The committee assessed the need to increase options and capabilities for breast lesion biopsies, and as a result, the hospital purchased the Hologic Breast Biopsy System. Using this technique, patients may either be upright or prone to allow more flexibility in biopsy positioning and comfort for the patients. In addition, time taken by the actual biopsy portion of the procedure is diminished.

Other patient care improvements added to our program in 2013 included the addition of Genetics Counselor Diana Tulley, M.S., who takes an active role in the research of family history and recommendation of potentially useful genetic markers in newly diagnosed cancer patients and their families. Before, these services were available only by referral.

Through our community needs assessment, we discovered that cancer was the number one cause of death in Florida. Therefore, we planned several community outreach projects in prevention and screening. Our smoking cessation programs were offered at the hospital and in collaboration at other community events.

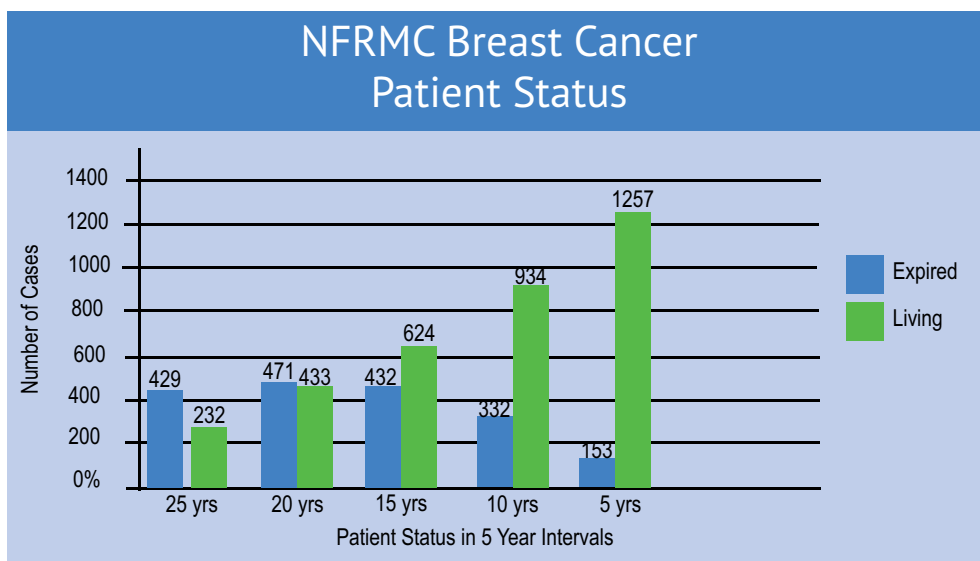
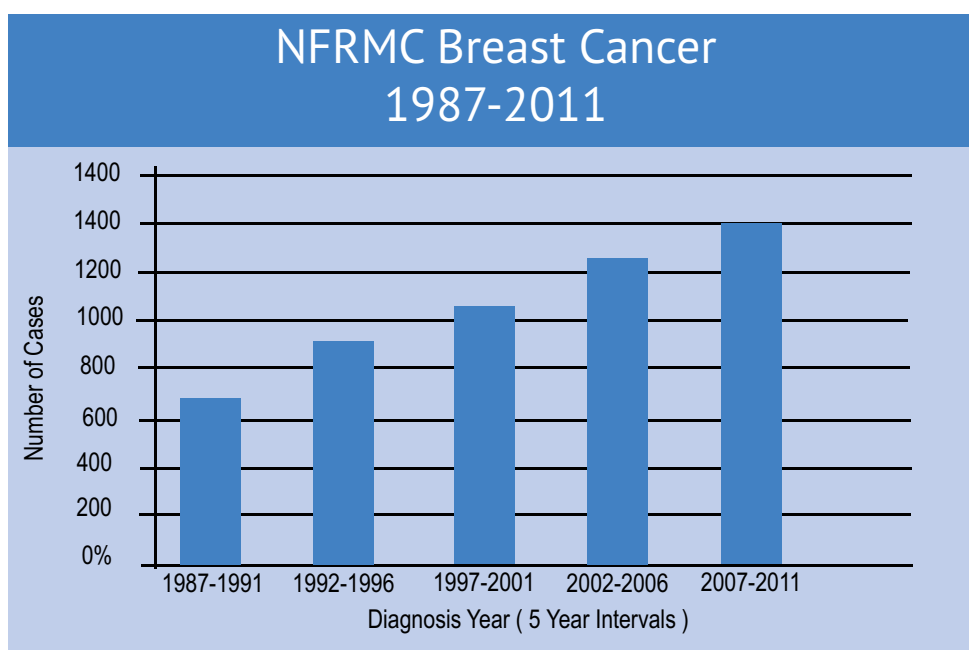
The goal of the Cancer Committee at North Florida Regional Medical Center is to continue to provide our patients with an improving system of care continuously. Our program, therefore, remains active in researching ways to improve the resources that we already have and developing services that will enable patients to benefit from as many services in the same location as possible.

FOCUS STUDY: 25-YEAR BREAST CANCER TREATMENT QUALITY IMPROVEMENT STUDY

The Cancer Committee requested a study to review breast cancer cases diagnosed at NFRMC over the last 25 years,

CRITERIA FOR EVALUATION:

Criteria: Cancer Registry to collect data and present breast cancer cases over the last 25 years, noting recurrence and second primaries. Data is to be collected in five-year intervals for a 25-year period, include the number of patients diagnosed, survival, average age at diagnosis, range of age at diagnosis, number of patients presenting with multiple primaries and summary stage at diagnosis.



Summary:

The committee reviewed the data, and they noted a decline in multiple primaries over the last 25 years – specifically lowering 3 percent per year. They did note that our average age of patient has increased above the national average of 61. They noticed a definite increase in case load more than doubling in the last 25 years.

Recommendations:

The committee made the recommendation to pick a site each year and review the data for the last 25 years to see if there is an increase or decrease in patient load and to establish areas where improvements might need to be made.

Breast Cases Presenting with Multiple Primaries

Year	Number of Cases w/ MP	Percent
1987-1991	219/661	33
1992-1996	285/904	32
1997-2001	270/1056	26
2002-2006	293/1266	23
2007-2011	287/1410	20

Summary Stage at Diagnosis

Year	IS	Local	Direct Ext	LN	RE & LN	DIST	UNK
1987-1991	90	309	11	123	32	54	42
1992-1996	96	441	11	152	19	54	77
1997-2001	143	488	7	232	33	47	106
2002-2006	237	627	18	255	28	40	60
2007-2011	260	742	26	268	36	41	34





GENETICS COUNSELOR DIANA TULLEY, M.S., TAKES AN ACTIVE ROLE IN THE RESEARCH OF FAMILY HISTORY AND RECOMMENDATION OF POTENTIALLY USEFUL GENETIC MARKERS IN NEWLY DIAGNOSED CANCER PATIENTS AND THEIR FAMILIES. BEFORE 2013, THESE SERVICES WERE AVAILABLE ONLY BY REFERRAL.

Why is Genetic Counseling a Good Option?

Growing consumer awareness is likely increasing the number of questions patients are asking about their risk of cancer and the availability of genetic testing. How does the busy clinician address these questions? Genetic counselors are here to help.

Genetic counselors are specially-trained healthcare professionals with skills in medical genetics and counseling who work in a variety of settings including cancer genetic risk assessment. Genetic counseling for patients concerned about their cancer risk includes the following:

- Collecting a detailed cancer-focused personal and family medical history
- Assessing a person's risk of developing cancer based on this information
- Determining whether the history is suggestive of an inherited cancer syndrome
- Providing patient education and answering questions about cancer risks, the option of genetic testing and the risks and benefits of genetic testing
- Reviewing medical management options with or without genetic testing
- Providing psychosocial support and facilitating communication between patients and families
- Communicating back to primary care/referring physicians so that the information from the risk assessment can be used to appropriately manage cancer risk

Who Benefits from Genetic Counseling?

- Individuals with a personal and/or family history suspicious of hereditary cancer susceptibility
- Members of a family with a known cancer susceptibility syndrome
- Individuals with extreme cancer anxiety, even in the absence of heightened risk
- Individuals considering cancer genetic testing
- Individuals with questions about cancer risk in offspring or extended family members
- High risk individuals, including those with a known cancer susceptibility syndrome, with questions about cancer treatment, prevention and/or screening options
- Individuals who have undergone genetic testing through their physician and would like a more detailed discussion about their test results

Genetic counselors are health professionals with specialized graduate degrees and experience in the areas of medical genetics and counseling. More about cancer genetics, cancer genetic counseling or referral resources is available online at www.nsgc.org.

HER2/NEU METHODOLOGY IN BREAST CANCER PROFILE ACIS VS FISH

BY PATRICIA GOLDBLATT, MD AND BRITTANY WILKINS

Breast Profile 2010

Progesterone Receptor by ACIS
 HER2/NEU by ACIS
 HER2/NEU by FISH
 DNA ploidy analysis with S-phase
 Ki67 by IHCC

Breast Profile 2011

Progesterone Receptor by ACIS
 Estrogen Receptor Analysis by ACIS
 Ki67 by IHCC
 HER2/NEU by ACIS>Reflex to FISH 2+

Methodology

HER2/NEU by ACIS

HER2/ NEU immunoperoxidase marker applied to a breast tumor slide. Computer-assisted image analysis used to score antigen expression in a three tiered system (Herpetest®). Scores are interpreted according to ASCO/CAP guidelines Equivocal results may be reported.

HER2/NEU by FISH

- Amplification of the HER2/NEU gene by FISH is measured (Pathovision®)
- Equivocal results are rare

HISTORICAL RATIONALE FOR METHOD CHOICES:

- Both were used in prospective randomized adjuvant trials of Trastuzumab
- Positivity by ICH or amplification by FISH qualify individuals for treatment with Trastuzumab

IHC vs FISH

IHC Less expensive

Tumor cells can be visualized

Reflex testing for equivocal category (2+) – reflex testing expected in =30 percent case

FISH Gene amplification method

NFR HER2/NEU Method Comparison 2010-12

IHC score	No (% total)	FISH AMP (% AMP)	FISH EQUIV (% AMP+ EQ)	% AMP REPORTED IN LIT.
0	6 (6)	0	0	0
1+	41 (43)	5 (12)	1 (14)	1-3
2+	39 (41)	8 (20)	2 (26)	29
3+	9 (9)	8 (99)	0 (89)	96-98
Total	95 (100)	21 (22)	3 (25)	

% FISH positive 2+ IHC cases were 17% for Surgical Pathologists using manual read, 26% for cytotechnologists manual read and 29% cytotechnologists using ACIS-assisted method.



Consequences of Herceptest Reflex Cut-Offs

- 2+ 39/45 cases would be reflexed (41 percent of total)
- 5 percent of amplified HER2/NEU by FISH would be missed
- 1+ 80/95 cases would be reflexed (84 percent of total)
- No amplified HER2/NEU FISH would be missed

Consequences of HER2/NEU by FISH without IHC

- 1/74 (1.3 percent) cases in our experience and one to three percent of cases in the literature cases positive by IHC and potentially eligible for Trastuzumab would be missed

IN CONCLUSION:

Weighing the Pros and the Cons of Reflex Testing

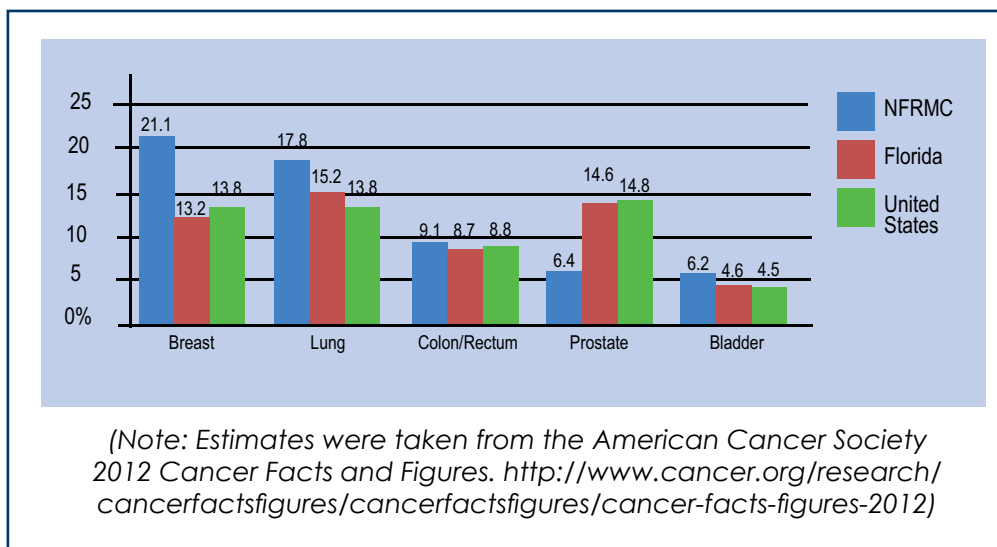
- Reflex testing for 2+IHC misses potentially FISH positive cases and still is required on 41 percent of cases, subjecting that proportion of patients to increased cost.
- Reflex testing for 1+ IHC does not pose a significant risk of missing FISH positive cases, but still is required on 84 percent of cases, eliminating the benefit of the reflex test philosophy.
- Reflexing to FISH delays results, so that the likelihood of a patient being scheduled for surgery before results are back is more likely.
- There is no significant risk of offering HER2/NEU by FISH up front.
- The benefit of testing for overexpression of HER2/NEU by IHC is debatable.

CANCER REGISTRY REPORT

Cancer registry is an information system that collects, stores and analyzes data on persons with cancer. Since 1987, Certified Tumor Registrars (CTRs) have been collecting information on each cancer patient that has been diagnosed and/or received treatment at North Florida Regional Medical Center (NFRMC). This collection of data is reported to the Florida Cancer Database System and the National Cancer Data Base. The information generated from this data submission is evaluated by these agencies. The resulting statistics on cancer incidence and survival rates are essential for improving patient care.

Of the 1,312 new cancer cases added to the registry at NFRMC in 2012, female breast cancer accounted for 21.1 percent of cases, followed by lung cancer at 17.8 percent, colorectal cancer at 9.1 percent, prostate cancer at 6.4 percent and bladder cancer at 6.2 percent. The chart below compares the incidence of the same primary cancers at NFRMC, the State of Florida and across the United States.

SITE	NFRMC		FLORIDA		UNITED STATES	
	NUMBER	%	NUMBER	%	NUMBER	%
FEMALE BREAST	277	21.1	15540	13.2	226870	13.8
LUNG	233	17.8	17860	15.2	226160	13.8
COLORECTAL	120	9.1	10200	8.7	143460	8.8
PROSTATE	84	6.4	17160	14.6	241740	14.8
BLADDER	81	6.2	5460	4.6	73510	4.5
ALL SITES	1312		117,580		1,638,910	



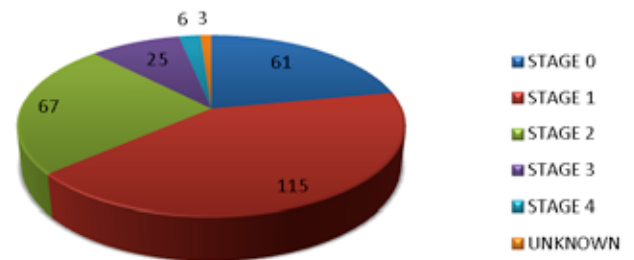
As a Commission on Cancer approved program, NFRMC is required to achieve a 90 percent patient follow-up rate. Follow-up is used to monitor a patient's health over time after treatment and provides an indispensable record of patient outcomes. This lifetime follow-up is unique to cancer registries since no other type of registry follows patients for the remainder of their lifetime. Our follow up rate at NFRMC is currently at 92 percent.

According to the National Cancer Institute, staging describes the severity of a person's cancer based on the size and extent (reach) of the original (primary) tumor and whether or not cancer has spread in the body (metastasized). Staging helps the doctor plan the appropriate treatment and is used in predicting prognosis (outlook) for a person with the disease. Stage 0 cancer is a cancer that has not spread to nearby tissue. The higher the number, the more advanced the cancer has become. Stage I cancer has generally been diagnosed early where stage IV cancer has advanced beyond the primary site to other areas.

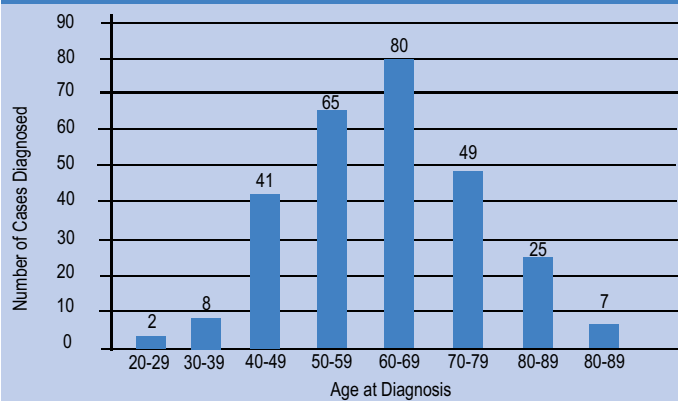
An important part of early breast cancer detection is a screening mammogram. The American Cancer Society recommends that women who are 40 years old and older should have a screening mammogram every year.

The strongest risk factor for breast cancer is age. The National Cancer Institute states a woman's risk of developing breast cancer increases as she gets older. They report that breast cancer is most frequently diagnosed among women ages 55 to 64 with the median age at diagnosis being 61 years. The following graph illustrates the age distribution of female breast cancer at NFRMC for the year 2012 which closely mirrors the national statistics. The median age at diagnosis for NFRMC is 63 years which is slightly higher than the national median age.

NFRMC Breast Cancer Stage at Diagnosis

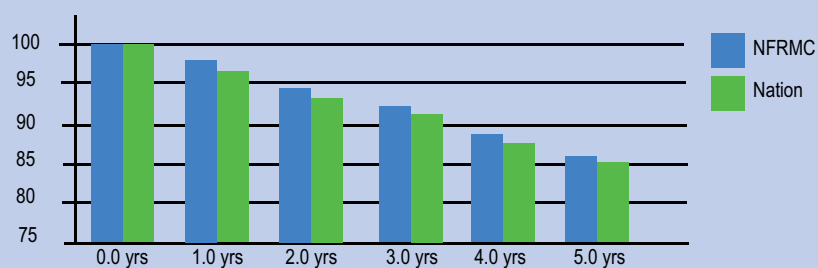


NFRMC Breast Cancer By Age Diagnosed 2012



The following chart shows the 5-year survival rate of breast cancer for NFRMC and the nation. The survival rate for NFRMC is similar to that of the nation in comparison.

Breast Cancer 5 Year Survival Diagnosed 2003-2006



PRIMARY SITES OF CANCER 2012

NORTH FLORIDA REGIONAL MEDICAL CENTER

PRIMARY SITE	TOTAL CASES	SEX		AJCC STATE GROUP						
		M	F	0	I	II	III	IV	UNK	N/A
ALL SITES	1312	533	779	129	409	210	216	193	71	84
ORAL CAVITY	38	31	7	0	3	3	8	20	4	0
LIP	0	0	0	0	0	0	0	0	0	0
TONGUE	13	12	1	0	1	1	1	7	3	0
OROPHARYNX	1	0	1	0	1	0	0	0	0	0
HYPOPHARYNX	0	0	0	0	0	0	0	0	0	0
OTHER	24	19	5	0	1	2	7	13	1	0
DIGESTIVE SYSTEM	199	99	100	6	32	40	60	48	11	2
ESOPHAGUS	6	3	3	0	1	2	1	1	1	0
STOMACH	11	6	5	0	2	3	2	3	1	0
COLON	85	40	45	3	16	18	32	14	2	0
RECTUM	35	24	11	1	8	6	10	7	3	0
ANUS/ANAL CANAL	7	2	5	1	0	3	2	0	1	0
LIVER	9	4	5	0	2	0	3	2	1	1
PANCREAS	34	15	19	0	2	5	6	19	2	0
OTHER	12	5	7	1	1	3	4	2	0	1
RESPIRATORY SYSTEM	247	136	111	2	69	22	54	80	19	1
NASAL/SINUS	0	0	0	0	0	0	0	0	0	0
LARYNX	11	7	4	2	5	1	1	1	1	0
LUNG/BRONCHUS	233	127	106	0	63	21	52	79	18	0
OTHER	3	2	1	0	1	0	1	0	0	1
BLOOD & BONE MARROW	24	10	14	0	0	0	0	0	0	24
LEUKEMIA	15	8	7	0	0	0	0	0	0	15
MULTIPLE MYELOMA	6	1	5	0	0	0	0	0	0	6
OTHER	3	1	2	0	0	0	0	0	0	3
BONE	0	0	0	0	0	0	0	0	0	0
CONNECT/SOFT TISSUE	6	2	4	0	4	0	1	0	0	1
SKIN	43	26	17	2	15	4	7	2	12	1
MELANOMA	42	25	17	2	15	4	6	2	12	1
OTHER	1	1	0	0	0	0	1	0	0	0
BREAST	280	3	277	61	116	69	25	6	3	0
FEMALE GENITAL	135	0	135	10	77	8	22	11	7	0
CERVIX UTERI	7	0	7	0	2	2	0	1	2	0
CORPUS UTERI	75	0	75	1	60	4	7	3	0	0
OVARY	25	0	25	0	5	2	10	5	3	0
VULVA	24	0	24	9	9	0	3	1	2	0
OTHER	4	0	4	0	1	0	2	1	0	0

PRIMARY SITES OF CANCER 2012
NORTH FLORIDA REGIONAL MEDICAL CENTER (CONT.)

PRIMARY SITE	TOTAL CASES	SEX		AJCC STATE GROUP						
		M	F	0	I	II	III	IV	UNK	N/A
MALE GENITAL	93	93	0	0	26	44	17	4	2	0
PROSTATE	84	84	0	0	21	42	15	4	2	0
TESTIS	8	8	0	0	5	1	2	0	0	0
OTHER	1	1	0	0	0	1	0	0	0	0
URINARY SYSTEM	133	84	49	48	43	17	10	13	1	1
BLADDER	81	57	24	42	14	14	4	6	1	0
KIDNEY/RENAL	46	22	24	2	28	3	5	7	0	1
OTHER	6	5	1	4	1	0	1	0	0	0
BRAIN & CNS	25	8	17	0	0	0	0	0	0	25
BRAIN (BENIGN)	0	0	0	0	0	0	0	0	0	0
BRAIN (MALIGNANT)	5	4	1	0	0	0	0	0	0	5
OTHER	20	4	16	0	0	0	0	0	0	20
ENDOCRINE	29	7	22	0	15	2	5	1	4	2
THYROID	27	7	20	0	15	2	5	1	4	0
OTHER	2	0	2	0	0	0	0	0	0	2
LYMPHATIC SYSTEM	33	18	15	0	9	1	7	8	8	0
HODGKIN'S DISEASE	2	0	2	0	1	0	0	0	1	0
NON-HODGKIN'S	31	18	13	0	8	1	7	8	7	0
UNKNOWN PRIMARY	27	16	11	0	0	0	0	0	0	27
		0	0	0	0	0	0	0	0	0
OTHER ILL-DEFINED	0									



COMMUNITY OUTREACH COORDINATOR REPORT

REPORT BY MARY HILL, DNP, COMMUNITY OUTREACH COORDINATOR

In 2013, North Florida Regional Medical Center (NFRMC) offered many cancer prevention and early detection and survivor support programs to meet the needs of the community. Programs were provided based on a needs assessment and focused to promote smoking cessation; healthy eating, lifestyle and addressing obesity concerns; prevention and treatment of specific cancer types; early detection of specific cancer types; cancer survivorship support and education; building community resources for cancer patients.

We began offering monthly tobacco cessation classes at the Cancer Center of NFRMC in August 2013 to provide a face-to-face 'Tools to Quit' onsite program in partnership with the Suwannee River Valley Area Health Education Center (AHEC). Each participant is given a program workbook with a quit day supply bag with tools and educational materials. A four-week supply of nicotine replacement therapy (NRT) is also provided. Topics addressed during the program included selecting a quit date; how to cope with withdrawal from nicotine and identifying triggers; how to handle triggers, stress management and detailed description of available nicotine replacement therapies (NRTs).

Bedside visits and counseling were provided throughout the year to hospitalized patients diagnosed with lung cancer with referral to smoking cessation programs available through Tobacco Free Florida. Personalized programs offered over-the-phone quit coaches, online programs and face-to-face programs. Nicotine replacement products are provided through Tobacco Free Florida to help patients stay tobacco free.

Educational programs promoting healthy lifestyle to prevent cancer were provided by the cancer program and hospital staff and were offered as community health education to the citizens of North Central Florida throughout the year including the following: Suwannee Valley Health Fair; Health Fair for Women Veterans; Women and Wellness Symposium; Community Health and Safety Fair for Levy County; Healthy Aging-Because You Have a Lot of Living Left to

Do; Community Health and Safety Fair for Dixie County; Community Health and Safety Fair for Alachua County Senior Center; Healthy Work Environment Health and Safety Fair NFRMC. Monthly obesity management informational forums were offered onsite by the hospital.

Educational programs aimed at reducing the incidence of specific cancer types provided to community residents, community physicians, nurses and allied health professionals included the following: A Matter of Life and Breath: Update on Lung Cancer Prevention and Treatment; Oncology Nursing Society Lung Cancer Symposium; Women and Wellness Symposium; Leukemia and Lymphoma: Treatment and Prevention; Knowledge Express-The Cancer Center and Cyberknife; Lung Cancer: Prevention and Treatment; Breast Intentions-Most Women Don't Know Their Risk for Breast Cancer. The use of staging, prognostic factors and evidenced-based treatment guidelines were reviewed.

NFRMC worked in collaboration with the American Cancer Society as the only local host site for Cancer Prevention Study 3 during the Fall of 2013. This large scale research study by the American Cancer Society was aimed at gaining a greater understanding of how lifestyle, genetics and the environment affect cancer and how we can better prevent the disease. Working together, we were able to surpass the goals set by the American Cancer Society for our North Central Florida enrollment sites with a total of 386 study participants (129 percent of our goal)!

Screening programs aimed at decreasing the number of patients with late stage disease included a Lung Cancer Screening Program provided to reduce cost of lung cancer screenings through low-dose computerized tomography (CT) scans to the eligible twelve individuals referred to the program during the year. Eligibility requirements included people ages 55 to 74 years old who are asymptomatic and free from current disease and current or former smokers with a 30-pack-year smoking history. NFRMC also offered 31 free screening colonoscopies through the Endoscopy Center

– one each day during March, Colon Cancer Awareness Month. The free screenings were made available to those in need who had recently lost jobs and health insurance and who were eligible for a screening colonoscopy. A plan is in place to refer and follow screened patients with positive findings.

The Cancer Center's Health and Healing Place hosted a variety of scheduled classes focused on cancer survivorship support and education. Weekly and monthly classes included the following: "Heart of Healing" meditation group provided activities aimed at enhancing self awareness and creating a sense of wellbeing; "Look Good Feel Better" classes offered by the American Cancer Society provided information and cosmetic advice to women battling cancer; Leukemia and Lymphoma Society and Waldenstrom's Lymphoma support groups provided an opportunity for survivors of blood cancers to connect, network and provide encouragement and support to one another. Art for Wellbeing Classes were offered in six week sessions (March through April and July through August in 2013) and allowed cancer survivors to support one another and to express themselves by creating artwork as a form of healing. A monthly Caregiver Connections Support Group (offered three times monthly at the NFRMC Senior Healthcare Centers) provided an opportunity for caregivers of cancer patients and others with long term illness to discuss concerns in a supportive group setting.

The Cancer Program at NFRMC works in collaboration with the American Cancer Society to assist in meeting the needs of people diagnosed with cancer in the geographic region served by the hospital (North Central Florida Counties: Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Sumter, Suwannee, Union). We collaborate to develop community outreach activities and work closely with our local American Cancer Society (ACS) representative on new strategies to accomplish this goal. We seek to provide education from ACS guidelines regarding the prevention and early detection of cancer. We aim to ensure that prevention and early detection activities follow nationally accepted evidence-based guidelines and interventions.