

Mercy Health – Clermont Hospital
Annual Report on 2010 Activities
Non-Hodgkin Lymphoma
Outcomes Study



Cancer Program Summary

The Mercy Health - Clermont Hospital Cancer Program has maintained approval by the American College of Surgeons since 2002. In addition to a wide range of diagnostic and treatment services, our hospital offers many programs to provide assistance to both our patients and their families as they cope with a diagnosis of cancer. Our support services include nutritional support, spiritual support, rehabilitation, palliative care, educational programs for our patients and the community, information on access to clinical trials and cancer support groups and programs, many of which are provided through participation with the American Cancer Society.

To meet the growing and changing needs of the patients and the communities we serve, our Cancer Committee continually strives for Cancer Program excellence by annually reviewing our services, performing patient care studies, and by setting annual goals to improve and enhance our services.

Mercy Health - Clermont Hospital implemented many patient care improvements, sponsored a large number of patient, community, and staff educational offerings and increased our services last year. These included:

- Implementation of CarePath/EPIC electronic medical record
- Development and implementation of AJCC electronic staging form in SoftScript
- Pharmacy completed “Critical Point” educational program on compounding skills of IV medications, compounding practices USP797 requirements.
- Radiation oncologist is on site for daily radiation treatments.
- Skin Cancer Screening
- “Healthy Eating and Cancer Prevention” presented by Dr. Peter Sheng, MD at a local grocery

Cancer Conferences

Cancer conferences provide a format for multidisciplinary involvement in the planning of care for cancer patients and are an important part of our cancer program. They are integral to improving the care of cancer patients and provide education to physicians and hospital staff while maintaining patient confidentiality.

All specialties are invited to attend and physicians from Medical Oncology, Radiation Oncology, Diagnostic Radiology, Pathology, and General Surgery specialties are present to discuss treatment options for the types of cancers presented at the conferences. Treatment based on national guidelines and prognostic indicators, including AJCC stage, is the focus of discussions.

Cancer Registry

The National Cancer Registrars Association provides the following description of the work that Cancer Registrars perform:

“Cancer registrars capture a complete summary of the patient’s disease from diagnosis through their lifetime. The information is not limited to the episodic information contained in the health care facility record. The summary or abstract is an ongoing account of the cancer patient’s history, diagnosis, treatment, and current status.

The cancer programs at Mercy Health make accurate data collection a priority. Cancer Registrar certification (CTR) is required and is maintained by continuing education in cancer data collection standards, cancer program requirements and in the diagnosis and treatment of cancer.

Mercy Health – Clermont Hospital Cancer Committee

The Cancer Committee, a multi-disciplinary team of hospital employees, staff physicians and members from the American Cancer Society, meets quarterly to direct the activities of the Cancer Program by monitoring our performance, reviewing our available services and programs and determining what enhancements are needed to meet the needs of our cancer patients.

Our mission is to ensure that our patients, their families and our communities have access to a full-range of medical services, supportive programs and services and community outreach activities that impact quality of life and survival. Our focus is on prevention, screening and early detection programs and quality of life services.

Mercy Health - Clermont Hospital 2010-2011 Cancer Committee Membership

Physician Members

Foroogh Jazy, MD, Chair Radiation Oncology
Peter Sheng, MD - Medical Oncology
Ted Heffernan, MD -Radiology
Ila Mehta, MD -Pathology
Brian Shiff, MD - General Surgery
Apruva Mehata, MD -Medical Oncology

Cancer Program Coordinators

Deborah Vickers, RN,- Cancer Program Coordinator
Brian Shiff, MD - Quality of Registry Data
Peter Sheng, MD - Cancer Conference Coordinator
Rene Diaz, RT (T) - Community Outreach
Ila Mehta, MD - Cancer Liaison/ Quality Improvement

Allied Health Members

Deborah Vickers, RN- Nursing
Diane Morrison, RN - Nursing
Alice Miller, RT, RHIT, CTR- Cancer Registry
Roger Leinberger, RT (R)- Radiology
Jeanne Kinaid, RD LD CDE- Dietary
Kay O'Rourke, Med BCC- Spriitual Care
Andrea Anderson- American Cancer Society
Rene Diaz, RT (T) - Radiation Oncology
Tom Eichstadt, RPH- Pharmacy
Dani Hext, RN -Quality Director
Anne Ewers, RN- Palliative Care
LeAnne Stewart, RN- Nursing

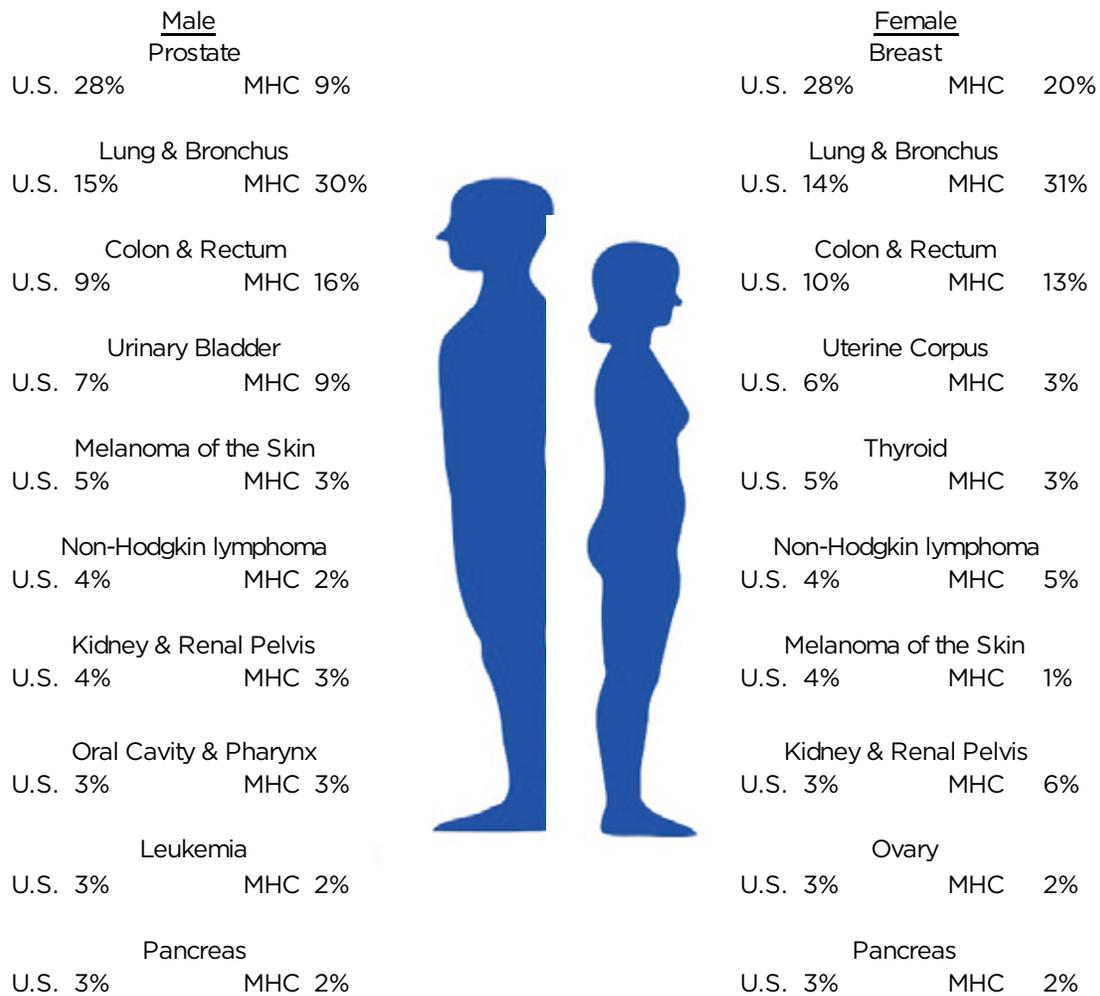
2010 Cancer Data Summary and Comparisons

Top Cancer Sites in 2010 by Sex

Distribution of our sites by gender revealed a higher incidence of lung cancer in both sexes. MHC has less prostate and breast incidence than the national average. MHC has a higher incidence of colorectal cancer in males than the national average. These differences are not felt to be reflective of the true incidence of these cancers in our community, but rather a reflection of services offered at MHC.

All other sites of incidence are comparable to the national average. MHC has a group of pulmonologist that are actively aiding other small county hospitals in the diagnosis of lung cancer. This may be contributing to our higher incidence of lung cancer.

2010 Top Cancer Sites by Sex Mercy Health - Clermont Hospital

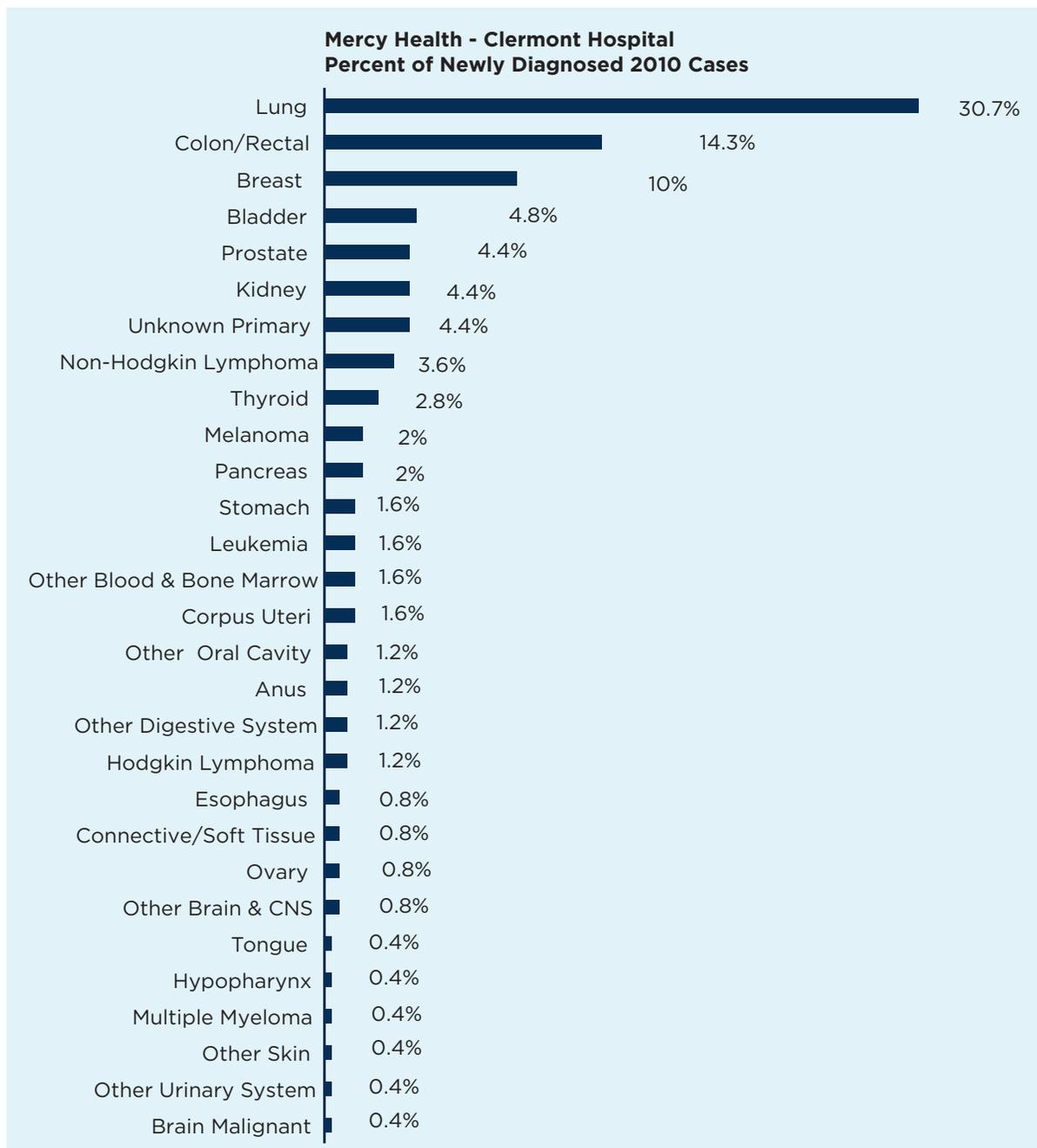


U. S. figures are estimated for 2010

Distribution of 2010 Cancer Sites

The total number of cases in the Mercy Health - Clermont Hospital Cancer Registry database since the 2003 reference date is 2,053 and 1,913 of these cases are available for analytic studies. During 2010 a total of 271 cases were accessioned into the registry database, 251 analytic (newly diagnosed) cases and 20 non-analytic (recurrent cancer) cases. The statistics contained in this report represent only analytic cancer cases.

The top 5 sites diagnosed or treated at Mercy Health - Clermont Hospital in 2010 were lung and bronchus, colorectal, breast, bladder, and kidney.



Outcome Study - Non-Hodgkin lymphoma

Non-Hodgkin lymphoma (NHL) is a group of more than 20 types of cancers that originate in the lymphocytes (a type of white blood cell) or lymph system. The lymphatic system is part of the immune system. The lymphatic system includes lymph vessels, lymph fluid, lymph nodes, tonsils, thymus and spleen. Usually lymphoma is first found in a lymph node. Non-Hodgkin lymphoma can occur at any age, although it is most commonly diagnosed in the elderly. The different types of non-Hodgkin lymphoma are grouped based on the type of lymphocyte affected. The two types of lymphocytes that can cause lymphoma are B-cells and T-cells. The most common types of lymphoma are diffuse large B-cell and follicular. For treatment and prognostic purposes, non-Hodgkin lymphomas are divided into two groups, aggressive (fast growing) and indolent (slow growing).

NHL Incidence and Mortality in the United States

Incidence – Non-Hodgkin lymphoma is the 6th most common cancer in the United States. The American Cancer Society (ACS) estimates 65,540 new cases of non-Hodgkin lymphoma will be diagnosed in 2010. Studies show that 1 in 44 men and 1 in 52 women will be diagnosed with non-Hodgkin lymphoma during their lifetime. Overall incidence has been stable since 1991 in men but has been increasing by a little over 1% per year in women since 1990. 56% of our NHL cases were male and 44% female.

Mortality – Non-Hodgkin lymphoma is the sixth highest cause of cancer deaths in American women and the eighth most common cause of cancer deaths in American men. The ACS estimates 20,210 non-Hodgkin lymphoma deaths in 2010. Death rates for NHL increased during most of the past 2 decades but have been decreasing by about 3% - 4% since 1997.

Signs and Symptoms

Symptoms include: swollen painless lymph nodes, unexplained weight loss, fever, night sweats, itchy skin, coughing or trouble breathing, along with overall weakness and tiredness.

Risk Factors

Risk factors for non-Hodgkin lymphoma include:

- Weakened immune system
- Infections including:
 - Human immunodeficiency virus (HIV)
 - Epstein-Barr virus (EBV)
 - Helicobacter pylori, H. pylori
 - Human T-cell leukemia/lymphoma virus (HTLV-1)
 - Hepatitis C virus
- Age
 - Most cases of non-Hodgkin lymphoma occur in people over the age of 60

Researchers are now studying the effects of obesity and work with herbicides to see if these factors increase the risk of non-Hodgkin lymphoma.

Diagnostic Methods

Swollen lymph nodes are the most common symptom. A physical exam is completed along with a complete blood count. Biopsy of an enlarged node is completed for tissue diagnosis.

Factors that Determine Treatment and Prognosis

Histology - Histology refers to the microscopic structure of the tissue in the tumor. There are more than 20 different types of lymphomas and although all are cancers of the lymphocytes, they each behave differently and have different treatment options and outcomes.

According to data in the National Cancer Data Base, 33% of the non-Hodgkin lymphomas in CoC-approved cancer programs were large B-cell diffuse lymphomas with 27% follicular types.

Findings: Our histology types were different than the national average. 10% of our cases were large B-cell lymphoma and 39% were of follicular origin. This maybe due to the low number of cases compared. Thirty one cases were diagnosed at MHC from 2003-2008.

Age - Age at diagnosis is an important prognostic indicator. Most non-Hodgkin lymphomas are diagnosed after age 60 when significant and debilitating comorbidities may affect the patient's overall health and ability to withstand the rigors of treatment such as chemotherapy. If a patient cannot be optimally treated, survival and quality of life may be dramatically affected.

Findings: Age at diagnosis was significantly higher at MHC for the 50-69 year age range. We had 64% of patients diagnosed in this age range compared to 39% in the NCDB data base. Other age ranges were comparable.

Blood test results: The serum lactate dehydrogenase (LDH) is an indicator of how much disease there is in the body. The higher the level of LDH, the more disease is present. Those with a lower level of LDH at diagnosis will do better than those with a high level.

Performance status: This is a measurement of how fit and self-sufficient the patient is and whether or not symptoms are present. As with other cancers, patients who are otherwise healthy and fit will do better than those who are weakened or sick. The presence of one or more symptoms, called B-symptoms, (fever for 3 or more days, weight loss exceeding 10% of body weight within 6 months, and drenching night sweats) indicates that the disease may be in more parts of the body than can be identified by the usual tests.

Non-Hodgkin Lymphoma - nodal Mercy Health - Clermont Hospital Diagnosed 2003 - 2008

Lymphoma Histology	U.S.	MHC
	%	%
Large B-Cell Diffuse, NOS	33%	10%
Follicular, NOS	11%	6%
Non-Hodgkin, NOS	10%	3%
Other Specified Types	9%	10%
Small B Lymphocytic, NOS	8%	10%
Follicular Grade 1	7%	23%
Malignant Lymphoma, NOS	5%	19%
Follicular Grade 2	5%	10%
Mantle Cell	4%	0%
Follicular Grade 3	4%	6%
Marginal Zone B-Cell	4%	3%

Source: National Cancer Database

Stage – Stage at diagnosis is an important tool used to plan treatment and predict prognosis. Staging must be completed to determine the extent of the disease. Bone marrow biopsy is completed along with CT scans, MRI scans and PET CT scans to aid in staging.

The AJCC cancer staging schema for lymphoid neoplasms differs from the TNM schemas for other primary sites. Extent of disease is based on the number of lymph node regions involved and whether other sites, such as the spleen, are involved. Stages range from stage 1 (localized) through stage 4 (diffuse or disseminated, including bone marrow involvement). If the lymphoma involves organs outside the lymph system, such as liver, brain or spine, treatment is usually not as successful.

Stage at Diagnosis Comparison

Findings:

Stage I - National average was 18% and MHC was 23%.

Stage II - National average was 15% and MHC was 6%.

Stage III - National average was 20% and MHC was 39%.

Stage IV - National Average was 30% and MHC was 23%.

Stage Unknown - National Average was 17% and MHC was 10%.

The differences in stage at diagnosis may be attributed to the small number of patients included in the study years at MHC, which can skew the data.

Treatment Modalities

Treatment is based on many factors, including stage of disease, non-Hodgkin lymphoma histology, patient age and other comorbidities at the time of diagnosis.

Watchful Waiting

If lymphoma is a slow growing (indolent) watchful waiting or active surveillance may be recommended. Patients are closely monitored on a regular basis. No treatment will be given in these cases until symptoms arise.

Chemotherapy

Chemotherapy is the most common form of treatment for non-Hodgkin lymphoma. Two types of drug agents are typically used: alkylating agents (cytotoxic agents that inhibit the cell division by reacting with DNA), and nucleosides (agents that inhibit DNA and RNA replication and prevent cancer cells from growing).

Single drug treatments may be given for indolent NHL, while combination treatments are given for aggressive types or recurring NHL. Examples of chemotherapy agents given singly include Fludaribine, Cladribine, Chlorambucil, and Cyclophosphamide. The combination drugs used frequently include Cyclophosphamide, Hydroxdaunomycin, Vincristine and Prednisone known as CHOP, Cyclophosphamide, Vincristine and Prednisone known as CVP, and Bleomycin, Doxorubicin, Cyclophosphamide, and Vincristine known as BACOD. These regimens may also include the monoclonal antibody Rituximab.

Radiation Therapy

External beam radiation therapy, alone or in combination with chemotherapy, is used less often but can be used for early stage lymphoma to treat a single lymph node chain. Radiation treatments can be given for residual tumor after chemotherapy regimen is completed.

Immunotherapy

Immunotherapy is a process in which the immune system is enhanced, induced or suppressed to maximize the body's ability to remove disease on its own. Monoclonal antibodies work on cancer cells similar to the way natural antibodies work by identifying and binding to the target cells. The most common immunotherapies for NHL are Rituximab (Rituxan) and Alemtuzumab (Campath). These drugs are given for initial treatment and recurrence of some types of NHL.

Radioimmunotherapy combines radiotherapy with monoclonal antibody therapy. Zevalin® has been approved by the FDA as a first-line radioimmunotherapy treatment for certain types of follicular lymphomas.

Interferons are proteins that help strengthen the immune system and are given alone or along with chemotherapy.

Bone Marrow Transplants

In some cases, a bone marrow or stem cell transplant may offer the best chance for long term survival. There are two types of transplants, (autologous transplant), which uses blood-forming cells collected from the patient and (allogeneic transplant), which uses blood forming cells from a family member or unrelated donor. The goal of a transplant is to destroy cancer cells in marrow, blood and other parts of the body and then replace the blood stem cells to create healthy bone marrow. Patients receive high dose chemotherapy and or radiation therapy to destroy bone marrow and suppress the immune system before transplant.

Stem Cell Transplant

In this type of autologous transplant, the patient's blood is passed through a machine that removes the stem cells (immature cells from which all blood cells develop). This process is called apheresis and is completed over three to four days. The patient then receives treatment to kill any cancer cells and the stem cells are frozen until they are transplanted back into the patient.

Treatment Comparison to National Cancer Database

Findings:

Stage 1 – patients received several types of treatment 29% received surgery only, 14% received radiation and chemotherapy, 14% received chemotherapy and hormone, 14% received other specified treatment and 29% received no treatment. MHC stage 1 patients received treatment more often than other facilities in the NCDB database.

Stage 2 – 25% patients received chemotherapy only and 75% of the patients received chemotherapy and hormone. More patients received chemotherapy and hormone than the NCDB average.

Stage 3 – 20% of patients received chemotherapy only, 20% received surgery, chemotherapy and hormone, 50% received

chemotherapy and hormone and 10% of the patients received no treatment. More patients received treatment at MHC than the NCDB average.

Stage 4 – 29% of patients received chemotherapy only, 29% received surgery, chemotherapy and hormone, and 43% received chemotherapy and hormone. All stage IV patients received some form of treatment, 19% of NCDB stage IV patients did not receive any form of treatment.

Stage Unknown – 33% of patients received chemotherapy only, 33% received chemotherapy and hormone and 33% received no treatment. Treatment varies with the types of treatment in the NCDB average.

Course of treatment discrepancies in the comparison with the NCDB data may be due to the small number of cases diagnosed and evaluated at Mercy Hospital Clermont.

Non-Hodgkin Lymphoma- Diagnosed 2003 - 2008

Treatment by Stage Comparison - National Cancer Data Base vs Mercy Health - Clermont Hospital

Treatment Type	NCDB	MHC	NCDB	MHC	NCDB	MHC	NCDB	MHC	NCDB	MHC	NCDB	MHC
	Stage 1		Stage 2		Stage 3		Stage 4		Stage N/A		Stage Unknown	
Surgery Only	15%	29%	8%	0%	7%	0%	5%	0%	12%	0%	10%	0%
Surgery and Chemotherapy	6%	0%	8%	0%	10%	0%	7%	0%	7%	0%	7%	0%
Radiation and Chemotherapy	8%	14%	7%	0%	2%	0%	3%	0%	1%	0%	3%	0%
Chemotherapy only	17%	0%	26%	25%	32%	20%	33%	29%	19%	0%	25%	33%
Surgery, Chemotherapy and Hormone	2%	0%	3%	0%	6%	20%	4%	29%	1%	0%	2%	0%
Chemotherapy and Hormone	4%	14%	11%	75%	13%	50%	13%	43%	4%	0%	5%	33%
Other Specified Therapy	29%	14%	23%	0%	14%	0%	16%	0%	8%	0%	16%	0%
No 1st Course Rx	20%	29%	14%	0%	16%	10%	19%	0%	47%	0%	33%	33%
% of Cases for Stage Group	18%	23%	15%	13%	20%	32%	30%	23%	1%	0%	17%	10%

Source: ©2011 National Cancer Data Base (NCDB) / Commission on Cancer (CoC)

Survival

Survival rates vary among the cell types of NHL and the stage at diagnosis. Overall, the one year survival for NHL is 80%, 5 year survival is 67%, and 10 year survival is only 56% according to American Cancer Society statistics.

Survival by Stage

Comparison of Mercy Health - Clermont Hospital to National Survival

Findings:

Mercy Health - Clermont Hospital survival for 2003 is less than the American Cancer Society statistics. One year survival is comparable. Five year survival is 25% less in patients diagnosed at MHC. This discrepancy may be due to patients pre-existing co-morbidities or age of patient at time of diagnosis.

National Cancer Database

Non-Hodgkin Lymphoma-nodal 5 Year Survival Diagnosed 2003

	Year				
	1	2	3	4	5
Stage 1	87.6%	82.4%	79.0%	75.4%	72.0%
Stage 2	82.4%	74.9%	71.3%	68.3%	64.9%
Stage 3	78.9%	70.3%	65.9%	61.7%	58.0%
Stage 4	68.9%	60.2%	55.3%	51.0%	47.9%
Overall	77.3%	69.6%	65.3%	61.4%	58.1%

Mercy Health - Clermont Hospital

Non-Hodgkin's Lymphoma-nodal 5 Year Survival Diagnosed 2003

	Year				
	1	2	3	4	5
Stage 1	100%	100%	100%	100%	100%
Stage 2	100%	100%	0%	0%	0%
Stage 3	100%	0%	0%	0%	0%
Stage 4	100%	0%	0%	0%	0%
Overall	100%	67%	33%	33%	33%

Summary of Findings and Recommendations:

Gender Comparison – Our male/female incidence is comparable to the national incidence. 31 cases were diagnosed at MHC from 2003-2008 17 were male and 14 were female

Histologies – the most prominent type of NHL lymphoma diagnosed at MHC was follicular lymphoma at 39%. Malignant lymphoma NOS was 19% and large B-cell lymphoma with 10%. This was opposite of the U.S. statistics.

Age – 85% of cases diagnosed with NHL lymphoma at MHC were in the 59-79 age range we had a higher incidence in those age ranges than in the US.

Stage – More stage 1 and stage 3 cases were diagnosed at MHC than in the US, with less stage 2 and stage 4 cases were diagnosed when compared to the NCDB for 2003-2008.

Survival – 5 year survival for 2003 was 25% less than the American Cancer Society. This maybe due to the small number of patients followed for survival.

Recommendations: Continue to capture all treatment information to reflect the accurate and complete cancer data that can be used for cancer control and epidemiological research, public health program planning, and patient care improvement.

Provide access to the Cancer Resource Center at Mercy Health – Clermont Hospital and provide access to the latest clinical trial information available for new promising therapies in the treatment of lymphoma.

Present cases at cancer conference for discussion of treatment options for lymphoma patients based on stage along with discussion of the NCCN treatment guidelines

Clinical Trials

For information on access to clinical trials in your area:

- Call the American Cancer Society, Clinical Trials Matching Service (a free, confidential program) at 1-800-303-5691 or visit www.cancer.org
- Visit the National Cancer Institute (NCI) website at: www.cancer.gov/clinicaltrials/search
- Visit the Coalition of Cancer Cooperative Groups at: www.cancertrialshelp.org

References

- American Cancer Society, Facts and Figures, 2010
- National Cancer Institute: <http://www.cancer.gov/cancertopics/types/non-hodgkin>
- LymphomaInfo.net: <http://www.lymphomainfo.net/therapy/immunotherapy/index.html>



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