2013 Cancer Program

ANNUAL REPORT AND COMPARATIVE STUDY ON MELANOMA





2012 Cancer Program Summary

The Jewish Hospital – Mercy Health offers the highest quality of cancer care as evidenced by the approval of our cancer program by the Commission on Cancer, American College of Surgeons and Foundation for the Accreditation of Cellular Therapy for our Bone and Marrow Transplant Center. Under the leadership of the Surgical Oncology Specialty Quality Committee, our Cancer Program has also received commendations for excellence in key areas of patient care. Achieving and exceeding compliance with the required standards of care set by the American College of Surgeons, Commission on Cancer, assures our patients that they will receive the best of care from diagnosis, throughout the treatment period and continuing to end of life care.

In addition to a wide range of diagnostic and treatment services, our hospital offers many programs that 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 our collaboration with the American Cancer Society.

To meet the growing and changing needs of the patients and the communities we serve, our Surgical Oncology Specialty Quality 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. The Blood and Marrow Transplant Program's affiliation with the National Marrow Donor Program (NMDP) and the Center for International Blood and Marrow Transplant Research (CIBMTR) allows patients access to national and international research protocols and increases their opportunity for participation in cutting edge oncology clinical trials.

The Jewish Hospital — Mercy Health implemented many patient care improvements, sponsored a large number of patient, communities and staff educational offerings and improved many of our services in 2012. Cancer Program Achievements include:

- Purchased and implemented tomosynthesis technology in mobile mammography department.
- Co-management agreement signed with OHC (Oncology Hematology Care) to provide oversight for the oncology service line.

The Jewish Hospital — Mercy Health Surgical Oncology Specialty Quality Committee

The Surgical Oncology Specialty Quality Committee is a multi-disciplinary team comprised of hospital employees, staff physicians and members from the American Cancer Society. The committee meets quarterly to monitor the hospital's cancer program's performance and to review the available services and programs. Our mission is to provide a patient-focused, integrated and comprehensive cancer program. We will serve in a compassionate and efficient manner, providing state-of-the-art technology and research, through caring for people one individual at a time.

2012 Cancer Committee Membership

Physician Members:	Discipline:
Elizabeth Weaver, MD	Chair, Radiology
James Essell, MD	Medical Oncolog
Kevin Monroe, MD	Pathology
Scott Hobler, MD	General Surgeon
Peter Fried, MD	Radiation Oncol
Allied Health Members:	Department:
Becky Allen, MS, CRA, RT (R)	Cancer Program Administrator
Elena Stein, MAHL, BCC	Pastoral Care
Kathy Smith, RN, MSN	Patient Services
Jenny Martin, RN, MBA	Quality Manager
Carolyn Green, RT, (R)(M)	ARDS Radiology
Chris Warders, RD, LD	Nutrition
Robin Hite, RT (R)(T)	Radiation Oncold
Cathy Beumer,	Pain Managemer
Michael DeVoe, PharmD	Pharmacy
Casey Faber	American Cance Society

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	Discipline:	Lyn Sontag, Psy.d, ABPP	Clinical Psychologist		
	Chair, Radiology	Annette Shepherd, RT (R)(T)	Community Member		
	Medical Oncology	Jenny Martin, RN, MSN	Performance		
	Pathology		Improvement		
	General Surgeon	Beverly Weinstein, RTRM	Mammography		
	Radiation Oncology	Vickie Estridge, BSN, RN, OCN	Clinical Manager, BMTU		
	Department:	Chris Hensley	Research RN		
	Cancer Program Administrator	Debra Steinbauch, MA, CCC-SLP	Rehabilitation Services		
	Pastoral Care	Yvonne Duhart, RHIT	Cancer Registry		
Patient Services					
Quality Management		Cancer Program Coordinators:			
	ARDS Radiology	Kevin Monroe, MD	Quality of Registry Data		
	Nutrition	Yvonne Duhart, RHIT	Cancer Conference		
	Radiation Oncology	Elizabeth Weaver, MD	Community Outreach,		
	Pain Management		Cancer Liaison		
	Pharmacy		Physician		
	American Cancer	Jenny Martin, RN, MBA	Quality Improvement		

Cancer Conferences

Cancer Conferences provide a multidisciplinary format for the development of a plan of care for the cancer patient. The conferences are integral to improving care and providing education to physicians and hospital staff. Consultative services and education are optimal when physicians representing all oncology related disciplines participate in the discussion. Patient identities are kept confidential.

The Cancer Conferences are prospective, patientoriented and multidisciplinary by design. Medical Oncology, Radiation Oncology, Diagnostic Radiology, Pathology, and General Surgery specialties are present to discuss diagnostic evaluations and possible treatment options for the types of cancers presented at the conferences. Physicians from all specialties, including Medical and Surgical residents are invited to attend.

Treatment options that are based on national guidelines and AJCC staging are the foundations of the discussions. National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology, information on open clinical trials, NCDB and cancer registry data are provided for the cancer sites presented.

The Jewish Hospital — Mercy Health Cancer Conferences

The **Surgical Cancer Conferences** are held at The Jewish Hospital — Mercy Health on the fourth Wednesday of each month at 7:30 a.m. in the Conference Room D.

The **Breast Cancer Conferences** are conducted 1st and 3rd Wednesdays of each month at 8:00 a.m. in Conference Room D.

The **Thoracic Cancer Conference** is held on the 2nd and 4th Friday of each month at 7:00 a.m. in room 303 at the Annex (bank) building. All of these programs are approved by the Ohio State Medical Association for one Category 1 CME credit hour.

The **Medical Cancer Conference** is held on the second Tuesday of each month at 12 Noon in the Conference Room A & B.

The Bone Marrow Transplant Multidisciplinary Team Meeting is held each Wednesday in Conference Room A & B at 8:30 a.m.

Cancer Registry

The Cancer Registry is a vital component of the Cancer Program, providing data for programmatic and administrative planning, research, and for monitoring patient outcomes. Data are collected according to the current standards of the Commission on Cancer to create a detailed cancer-focused record for all reportable tumors diagnosed and/or treated at our hospital. Each record entered into the database contains information on the diagnosis, extent of disease, treatment received, recurrence of disease and lifetime follow-up for each patient. Aggregate data is analyzed and published without patient identifiers to protect the confidentiality of each patient entered into the cancer database according to Ohio state laws and HIPAA regulations.

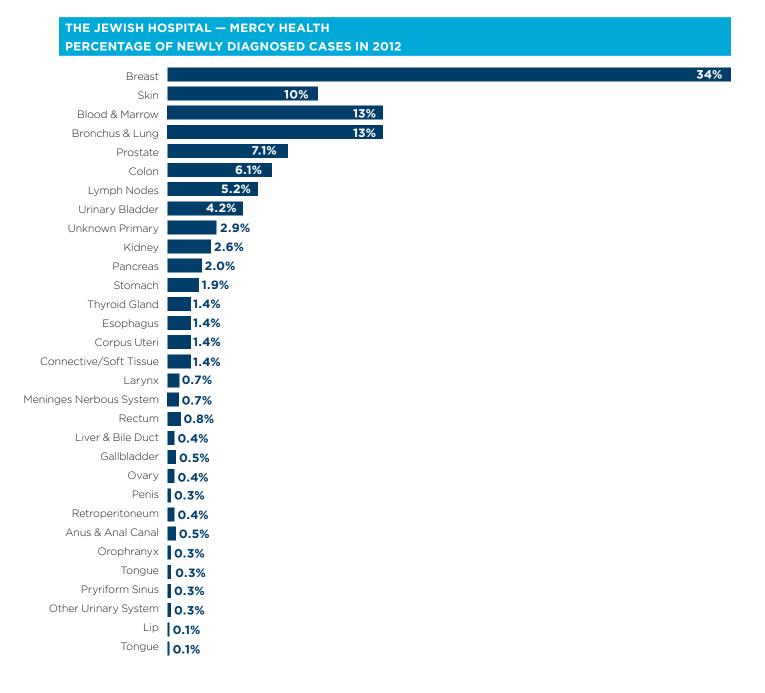
A Cancer Registrar performs the collection, interpretation, analysis and reporting of cancer data. The National Cancer Registrars Association defines Cancer Registrars as "data management experts who collect and report cancer statistics for various healthcare agencies." Registrars work closely with physicians, administrators, researchers, and health care planners to provide support for cancer program development, ensure compliance with reporting standards, and serve as a valuable resource for cancer information with the ultimate goal of preventing and controlling cancer. The Cancer Registrar is involved in managing and analyzing clinical cancer information for the purpose of education, research, and outcome measurement.

All approved Cancer Programs are required by the Commission on Cancer to submit registry data that is error free to the National Cancer Data Base (NCDB) annually. As a result of the data submission to the NCDB programs are able to benchmark their performances and outcomes to that of regional, state and national patterns. Major differences between the facility data and the national data are reviewed in an effort to identify the areas of improvement.

In addition, cancer data is submitted to the Ohio Cancer Incidence Surveillance System (OCISS). All reported data is used to support research, track trends, initiate epidemiologic studies, generate journal articles and provide data for allocation of services. The data is analyzed to identify opportunities for community cancer awareness and screening where higher stages (III-IV) of cancers are seen. This data also provides a means of identifying possible cancer clusters within the state.

2012 Cancer Data Summary and Comparisons

The total number of cases in The Jewish Hospital — Mercy Health Cancer Registry database since the 2003 reference date is 12,456 cases, 11,140 of which are available for analytic studies. During 2012, a total of 983 cases were accessioned into the registry database; 888 analytic (newly diagnosed) cases and 95 non-analytic (recurrent cancer) cases.



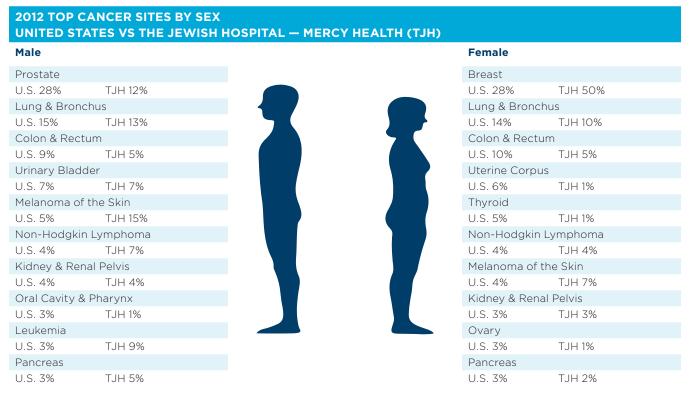
Top Cancer Sites in 2012

The top sites in 2012 were Breast (34 percent), Skin (10 percent), Blood and Marrow (13 percent), Lung (13 percent) and Prostate (7.1 percent).

2012 *NATIONAL VS HOSP INCIDENCE BY GENDER					
OP US/OH SITES MALE	#US	%US	#TJH	%TJH	
All Sites	789,620	100%	357	100%	
Prostate	217,730	28%	44	12%	
Lung and Bronchus	116,750	15%	48	13%	
Colorectal	72,090	9%	18	5%	
Bladder	52,760	7%	24	7%	
Melanoma of skin	38,870	5%	54	15%	
NHL	35,380	4%	25	7%	
Kidney & Renal pelvis	35,370	4%	14	4%	
Oral cavity & pharynx	25,420	3%	5	1%	
Leukemia	24,690	3%	31	9%	
Pancreas	21,370	3%	18	5%	

Compared with the estimated 2012 state and national data, our incidences of breast cancers are higher than the state and national averages. Potential explanations for the higher incidence include the availability at The Jewish Hospital — Mercy Health of ultrasound guided needle biopsies and stereotactic biopsies for breast cancer. Additional diagnostic studies provided by the hospital are digital and mobile mammography and breast MRI. The Jewish Hospital — Mercy Health provides sentinel lymph node biopsy for melanoma. Of special note is the FACT accreditation held by the Blood and Marrow Transplant Center.

Distribution of cases by gender reveals that breast cancer is the top site for females (50%) while melanoma of the skin was the top site in males (15%). The table demonstrates the percentage of cases seen at The Jewish Hospital — Mercy Health compared to the national average incidence for each cancer site.



American Cancer Society Inc., Surveillance and Health Policy Research, Facts and Figures, 2012 U.S. figures are estimated for 2010. Hospital figures are actual

Review of Quality Study

Compliance with NCCN guidelines for Sentinel lymph node biopsy in Cutaneous Melanoma

Incidence and Mortality in the United States:

According to the American Cancer Society, it is estimated that in 2013 there will be 76,690 new cases of melanoma in the United States. An estimated 9,480 deaths from melanoma are expected in 2013, of which 6,280 will be males. The increasing rate of melanoma diagnosis is the highest in the United States of any cancer. It is the fifth most common cancer in males in the United States and the seventh in females.

Anatomy and Physiology of the Skin: The skin is noted as the largest organ in the human body. Its primary role is to function as a barrier to the environment. It is comprised of three main layers: epidermis, basement membrane, and dermis. The epidermis has several layers starting with the stratum corneum, stratum lucidum, stratum granulosum, stratum spinosum, and stratum germinatum going from superficial to deep, respectively. Basal cells comprise these layers and differentiate as they migrate superficially. Melanocytes are another cell type present that produce melanin from tyrosine and cysteine. Melanin in turn deters the harmful absorption of UV radiation. The degree of skin pigmentation is determined by the rate of melanin production and melanosome degradation. The quantity of melanocytes is relatively equal in all races. The basement membrane is located between the epidermis and dermis and is comprised mainly of type 1 collagen. The dermis contains the blood supply, nerves, and adnexal structures of the skin, which include hair follicles and sebaceous glands.

Risk factors for Melanoma: UVB radiation is the main risk factor for sunburn injury and melanoma. It can cause considerable DNA damage to the skin. Studies also demonstrate an increase in the relative risk of melanoma in patients with higher numbers of dysplastic nevi. There is also a familial link to melanoma. The genetic component is present in about 14% of melanoma cases. Genes that have been implicated include: MC1R, ASIP, and

TYR. Xeroderma pigmentosum is a risk factor for melanoma.

Pathogenesis: Melanoma has a complex and poorly understood pathogenesis. It can arise from transformed melanocytes anywhere that these cells are located. 90% of melanoma is found on the skin. However, it may also occur in the oral and anogenital mucosal surfaces, esophagus, meninges, and the eye. Approximately 4% of melanoma is found at the metastatic stage with no notable primary. Once a melanocytes transforms into a malignant cell, it proliferates into a tumor with usually in a radial growth pattern along the epidermal plane. This is followed by a vertical growth phase. Mutations in retinoblastoma tumor suppressor proteins have been seen in both familial and sporadic cases of melanoma. Aberrant increases in RAS and PI-3K/AKT signaling are seen in sporadic melanoma.

Types of Melanoma: The main types of melanoma are superficial spreading, nodular, lentigo maligna, and acral lentiginious. The most common is superficial spreading and comprises 70% of melanoma cases. Superficial spreading are flat lesions located on the skin except for the palms of the hand and soles of the feet. They have a characteristic prolonged growth phase. Nodular melanoma is considerably more aggressive and has a characteristic vertical growth phase. They comprise 15% of melanoma cases. Lentigo maligna are usually located on the head and neck area and are rather large at time of diagnosis. They have the best prognosis as the vertical growth phase occurs late. Acral lentiginous is the least common subtype. It occurs mainly is people of darker skin and occurs most frequently on the palms of the hand, soles of feet, and in the subungal areas.

Signs and Symptoms: The main types of melanoma are superficial spreading, nodular, lentigo maligna, and acral lentiginious. The most common is superficial spreading and comprises 70% of melanoma cases. Superficial spreading are flat lesions located on the skin except for the palms of the hand and soles of the feet. They have a characteristic prolonged growth phase. Nodular melanoma is considerably more aggressive and has a characteristic vertical growth phase. They comprise 15% of melanoma cases. Lentigo maligna are usually located on the head and neck area and are rather large at time of diagnosis. They have the best prognosis as the vertical growth phase occurs late. Acral lentiginous is the least common subtype. It occurs mainly is people of darker skin and occurs most frequently on the palms of the hand, soles of feet, and in the subungal areas.

Diagnosis: Diagnosis of melanoma usually requires a biopsy, however, visual diagnosis is still employed. The hallmark "ugly duckling" sign is used to distinguish melanoma from other skin pathologies. If a biopsy shows melanoma, a larger biopsy is then taken based on the thickness of the lesion.

Staging: Melanoma was initially staged by histological depth of invasion. This is called Clark's method. Clark's I is melanoma in the epidermis and has not penetrated the basement membrane. Clark's II is into the papillary dermis. Clark's III is down to the junction of the papillary and reticular dermis. Clark's IV is into the reticular dermis. Clark's V is melanoma invasion into the subcutaneous fat. More recently, Breslow's classification is used. Stage I is tumor depth less than or equal to 0.75 mm. Stage II is 0.76 to 1.5 mm. Stage III is 1.51 to 2.25 mm. Stage IV is 2.25 to 3 mm. Stage V is greater the 3 mm depth of invasion of melanoma.

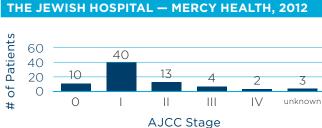
STAGING			
Stage	Survival (5 year)		
Melanoma in-situ	99%		
I - Invasive Melanoma	89-95%		
II – High Risk	45-79%		
III - Regional Metastasis	24-70%		
IV – Distant Metastasis	7-19%		

Prognosis: There are several factors that have been identified as influencing prognosis of melanoma. Melanoma on the extremities has a better prognosis than ones of the head, neck, or trunk. The 10 year survival rate is 82% vs 68%, respectively. Other factors that denote worse prognosis are ulceration of the lesion, increasing tumor depth >1.7 mm, increased number of mitoses, decreased number of tumor infiltrating lymphocytes, presence of tumor regression, and male gender.

Treatment of Melanoma: Treatment of melanoma ranges from simple excision to complex lymphadenectomy and immunotherapy. Lesions 1.0 mm or less can be excised with 1 cm margins. Lesions 1-4 mm thick require 2 cm margins. Lesions >4 mm are recommended to be excised with 2-3 cm margins. A sentinel lymph node biopsy (SLNB) is recommended in melanoma with tumor depth greater than or equal to 1.01 mm and T1b lesions (0.76 - 1.0 mm thick with ulceration, and/or mitotic rate >1 per mm 2). In general, a SLNB is not recommended in melanoma in situ or stage IA.

Palliative care for patients with advanced melanoma is best conducted by a multidisciplinary team. It focuses on an individualized plan for the patient that falls in line with the patient's wishes and allows for lifespan and quality of life to be optimized.

Melanoma at The Jewish Hospital - Mercy Health: At The Jewish Hospital - Mercy Health, there were 72 cases of melanoma in 2012. One-hundred percent of patients were Caucasian. Data analysis shows 23 patients had melanomas that had a tumor depth greater than or equal to 1.01 mm. Of this group, 20 patients had SLNB performed. In 3 patients SLNB was not done due to old age and comrbidities and it would not have had an effect on their further treatment and life expectancy. This is in 100% compliance with NCCN guidelines. There were 4 patients with melanoma with tumor depths ranging from 0.76 - 1.0 mm and with ulceration, and/or high mitotic rate. Two of them had SLNB and two other patients not done with documented reasons in the chart. So NCCN guidelines compliance is 100%.



MELANOMA AT

Graph 1. Stages of melanoma at TJH in 2012 according to AJCC staging guidelines.

Community Outreach

The Jewish Hospital — Mercy Health and Cancer Program, led by our Surgical Oncology Specialty Quality Committee, are committed to making a difference in our community. We do this through several means, including increasing cancer awareness through participation in local Health Fairs, conducting Awareness Month activities, increasing awareness of clinical trials and participation in or referral to American Cancer Society programs.

American Cancer Society Programs and Screening Guidelines

For information on American Cancer Society Programs and Screening Guidelines:

• Visit http://www.cancer.org or call 1-800-ACS-2345 (1-800-227-2345)

Informational websites

For information on breast and other cancers, call or visit:

- National Cancer Institute at 1-800-4-CANCER or www.cancer.gov
- People Living With Cancer: The official patient information website of the American Society of Clinical Oncology at www.cancer.net/portal/site/patient
- National Comprehensive Cancer Network at www.nccn.org/patients
- American Cancer Society 1-800-ACS-2345
 or www.cancer.org
- National Library of Medicine at www.nlm.nih.gov/medlineplus/healthtopics.html
- US TOO! International, Inc at www.ustoo.org

The Jewish Hospital



4777 E. Galbraith Road Cincinnati, Ohio 45236 513-686-3000

Clinical Trial Information

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/Sources:

American College of Surgeons

American Cancer Society

National Cancer Institute

Electronic Registry System



