

Cancer Program Annual Report

2006



1328 Twenty-Second Street
Santa Monica, CA 90404-2091

2006 Cancer Committee Members

Robert Wollman, M.D., Radiation Oncology, Chairman

Trista Aarnes-Leong, CTR, Cancer Registry

Warren Allen, M.D, Pathology

Richard Andersen, Pharm.D., Pharmacy

Robert Andrews, M.D., Otolaryngology

Stanley Brosman, M.D., Urology

Mary Jo Byrne, MSW, Social Work

Rebecca Crane-Okada, PhD, RN, AOCN, CNS, Clinical Nurse Researcher

Ramona Crear, CTR, Cancer Registry

Maggie DiNome, M.D., General Surgery

Shirley Edwards, MSN, AOCN, RN, CNS, Director of Education

Mark Faries, M.D., Surgical Oncology

Rebecca Fleming, RD, Nutrition Services

Kathryn A. Henick, M.D., Hematology/Oncology

Heidi Hoffman, M.D., Diagnostic Radiology

Maribelle Kim, RHIA, Health Information Management

Wendy Lade-Merritt, Community and Senior Education

Jan Inouye Malek, RN, MN, AOCNS, Radiation Oncology

Gerald Markovitz, M.D., Pulmonary Medicine

Silvana Martino, D.O., Hematology/Oncology

Sister Marlene Panko, SSND, Chaplain Services

Vicki Schiller, M.D., Diagnostic Radiology

May Lin Tao, M.D., Radiation Oncology

Phillip Williams, RN, Nursing Oncology

Marc Wishingrad, M.D., Gastroenterology

Letter from the Chairman

As chairman of the Saint John's Health Center Cancer Committee, it is my privilege to present our 2006 Oncology Annual Report. The Cancer Program at Saint John's Health Center continues to grow and expand.

Our Annual Report details the activities of the Cancer Program at Saint John's Health Center; some of the highlights include:

- ◆ Implementation of the Palliative Care Program for Oncology, ICU and Medical patients.
- ◆ Implementation of a Chemotherapy Consent for patients receiving chemotherapy in the hospital.
- ◆ Continued efforts towards improvement in service excellence in the areas of inpatient oncology and radiation oncology.
- ◆ Continued monitoring of quality assurance in the areas of pathology, diagnostic radiology, radiation oncology and inpatient oncology.

The Cancer Committee sets goals each year. The following goals were set and achieved in 2006:

- ◆ Present community education programs on non melanoma skin cancer and breast cancer awareness.
- ◆ Continue the Teen anti-smoking outreach programs.
- ◆ Expand the Palliative Care Program to include oncology patients on CSS-1.
- ◆ Implement an inpatient pilot hospice program to include acute care units.
- ◆ Expand the availability of molecular diagnostic testing in the Pathology Department.
- ◆ Improve timeliness of surgical starts and improve turn around time of surgeries.
- ◆ Implement a system dictation feature requiring citation review of every patient's medication on the H&P, discharge summary and operative report by the dictating physician.
- ◆ Promote and begin accessioning patients into the "Multi-Center Selective Lymphadenectomy" Trial II (MSLT-II) Sentinel Lymph Node Clinical Trials.

Malignant melanoma is the focus of this Oncology Annual Report. Mark Faries, M.D., a surgical oncologist with the John Wayne Cancer Institute, evaluated the survival of our melanoma patients as well as the treatment options for patients with recurrences. I am pleased to report that our data exceeds national benchmarks substantially.

Our Cancer Program would not be the success it is without the support and enthusiasm of our team members. I would like to thank all of the physicians, nurses, technologists, and administrative staff who have graciously offered their time and talent to making our Cancer Program a success.

Sincerely,

Robert Wollman, M.D.
Department of Radiation Oncology
Chairman, Cancer Committee



Cancer Liaison Physician Report

As a Comprehensive Community Cancer Center, Saint John's Health Center provides patients with the most advanced treatment in surgical, radiation and medical oncologic care. In 2006, over 1,700 cancer patients were treated at Saint John's Health Center reflecting the outstanding reputation of Saint John's Health Center as a cancer treatment facility. Saint John's Health Center has also been on the forefront of providing patients with minimally invasive laparoscopic and now robotic options for their surgical care, which has greatly enhanced patients' recovery.

In addition to providing state of the art care, Saint John's Health Center also focuses on the importance of community education and awareness in the early detection and prevention of cancer. Several community forums and lectures were sponsored by the hospital throughout the year highlighting common cancer types and providing patients with the information necessary to be active participants in their care. In addition, Saint John's Health Center is embarking on a grand project to become a leader in translational medicine offering patients the benefits of groundbreaking basic science research for their cancer are without undue delay.

This year, melanoma has been highlighted. With the pioneering work of Donald Morton, M.D. and the John Wayne Cancer Institute, over 490 melanoma patients are treated at Saint John's Health Center each year, and we continue to be involved in a collaborative effort to reduce cancer-associated morbidity, mortality and suffering for our patients.

Maggie DiNome, M.D., F.A.C.S., F.S.S.O.

Cancer Liaison Physician

American College of Surgeons Commission on Cancer

Community Education

The Community Education Program offered a variety of programs, classes, health fairs and screenings for our community. In 2006, the following Community Education Forums were held:

- ◆ *Freedom from Smoking*
Smoking Cessation Course developed by The American Lung Association
- ◆ *It's Your Skin—Wear It Well*
Skin Cancer Prevention and Treatment featuring:
Plastic Surgeons Harvey A. Zarem, M.D. and Vivanti Jain, M.D.
Dermatologist Gerald G. Bennett, M.D. speaking on Mohs Micrographic Surgery
Medical Director of Radiation Oncology, Robert C. Wollman, M.D., Topical X-Ray Treatments
- ◆ *Santa Monica Chamber Health Fair*
Advance Practice Nurses presented a *No Smoking* information table targeting teens
- ◆ *Breast Health Update*
Breast Cancer Prevention and Treatment featuring:
Associate Director of the John Wayne Cancer Institute Breast Center, Helen Mabry, M.D.
CEO of Santa Monica Hematology-Oncology Consultants, Marilou Terpenning, M.D., F.A.C.P.
Medical Oncologist, Premiere Oncology, Agustin Garcia, M.D.

Cancer Registry

The Cancer Registry maintains a computerized database of over 27,000 cancer cases diagnosed and/or treated at Saint John's Health Center since 1990. In 2006, 1,748 cases were added to the database, of which 1,564 were diagnosed and/or received their first course of treatment at Saint John's Health Center. The Cancer Registry reports all cases to the Los Angeles County Cancer Surveillance Program, as part of the California Cancer Registry.

The data maintained by the Cancer Registry is available for use by the medical staff, hospital administration, other health care professionals for special studies, end-results reporting, medical education, patient care evaluations, and research. In 2006, the Cancer Registry responded to 250 requests for data from physicians, administrators, hospital staff, and outside sources. The data is used for treatment planning and evaluation, outcome measures, clinical research, and cancer program strategic planning.

The Cancer Registry performs lifetime follow-up on all analytic cancer patients, collecting ongoing diagnostic and treatment results. In 2006, the Cancer Registry followed over 13,500 cancer cases.

For information regarding the Cancer Registry or for data requests, please contact the Cancer Registry at (310) 829-8859.

Cancer Conferences

Cancer Conferences at Saint John's Health Center are multidisciplinary, and include Breast Conference, Pre-Op Surgical Conference, Gastroenterology Conference, and General Tumor Board. The conferences are attended by physicians from all specialties. Physicians representing the fields of General Surgery, Surgical Oncology, Hematology/Oncology, Radiation Oncology, Diagnostic Radiology, Pathology, Internal Medicine, Family Practice, Pulmonary, Gastroenterology, and Plastic Surgery all attended Cancer Conferences in 2006. Cancer Conferences focus on pretreatment evaluation, staging, treatment strategies, referrals to research protocols and rehabilitation.

In 2006, there were a total of 109 meetings, with 392 cases presented, of which 391 cases were prospective. The primary sites presented reflect our caseload as well, with 25% of the caseload representing the analytic cases. The most frequently presented site was breast and melanoma. The other primary sites presented include but are not limited to: bladder, colon, esophagus, gallbladder, head and neck, leukemia, liver, lung, lymphoma, pancreas, prostate, rectum, small bowel, stomach, testis, and thyroid.

Institutional Review Board

The Joint Institutional Review Board (IRB) between Saint John's Health Center and the John Wayne Cancer Institute is charged with protecting the rights and welfare of human research subjects and assessing the risks and benefits of proposed research. Among its most important activities is to ensure compliance with state and federal guidelines governing research involving patients.

The IRB is currently assisting with nearly 110 active research protocols involving Saint John's investigators. For questions about the IRB or research submission requirements contact the IRB Office at (310) 582-7427.

John Wayne Cancer Institute

The John Wayne Cancer Institute (JWCI) at Saint John's Health Center is a cancer research institute dedicated to the understanding and curing of cancer in order to eliminate patient suffering worldwide. It's mission is accomplished through innovative clinical and laboratory research and the education of the next generation of surgical oncologists and scientists.

Over the last year, the Institute's scientists and surgeons have made progress toward that bold mission. By investigating multiple approaches to the treatment and elimination of this disease, the Institute is at the forefront of cancer research. Early detection, genetics, proteomics, quality of life, surgical techniques, and surgical oncology training through their fellowship program are just a few of the areas on which the Institute is focused.

Today, the Institute is extending its expertise to new areas of cancer research, clinical practice and education, including programs focusing on melanoma, breast, gastrointestinal, and prostate cancer. The Institute's facilities include specialized research laboratories in Cancer Immunology and Immunotherapy, Molecular Oncology, Experimental Therapeutics, Protein Biochemistry, and Skeletal Biology. These specialty units expand upon the Institute's historic expertise in cancer surgery, immunotherapy, medical technologies, and translational research—which rapidly transforms laboratory findings into clinical applications.

Positive Appearance Center

The Positive Appearance Center (PAC), a non-profit facility, was the first of its kind on the Westside to address the cosmetic side effects and comfort needs to cancer treatment. The Center has a warm boutique-like setting which provides a nurturing environment where cancer patients may receive individualized and specialized care. The Center offers an array of products and services to meet the needs of men and women undergoing cancer treatment.

The PAC carries breast prostheses, mastectomy bras, camisoles, and bathing suits, as well as wigs and other alternatives including hats, caps, turbans, and scarves. The Positive Appearance Center also carries support garments for lymphedema and a certified fitter on staff for both compression garments and mastectomy prosthesis and bras. There is no charge for fittings or consultations.

In addition the PAC carries skin care products, sun blocks and sun protective hats, especially important for melanoma patients.

The Positive Appearance Centers also hosts the Look Good, Feel Better program sponsored by the American Cancer Society on a quarterly basis. The 2006, the Look Good, Feel Better program met in March, June, and October.

The Positive Appearance Center is open for walk-in visits Monday through Friday from 10 am to 4 pm. Appointments are encouraged, though not required, for fittings of prostheses and wigs. Home visits are available when needed.

The Positive Appearance Center is located in the John Wayne Cancer Institute Breast Center at Saint John's Health Center.



John Wayne Cancer Institute Breast Center

The John Wayne Cancer Institute Breast Center was founded in 1993 by its current director, Armando E. Giuliano, M.D. The Breast Center, located within Saint John's Health Center (SJHC), provides multidisciplinary care to patients with breast problems. Cutting-edge research is performed under the umbrella of JWCI, which supports and maintains the laboratories and administrative structure of the breast program. Thus, the Breast Center functions in a unique environment that blends a rigorous academic program with the beauty and efficiency of an extraordinary community hospital, Saint John's Health Center, listed as one of the top 50 hospitals in the United States by *AARP Modern Maturity* in May/June 2002. The state-of-the-art Breast Center was recognized by *Self* magazine in 1999 as one of the ten best breast centers in the United States. This recognition is based on outstanding patient care and new and innovative clinical, translational, and basic science research that is carried out in a warm and inviting setting.

The Breast Center has two surgical oncologists, three dedicated breast imaging specialists, two endocrinologists, (dedicated to the management of hormone deficiency syndrome in breast cancer), an oncology nutritionist, two full-time oncology nurses, one Ph.D. oncology nurse researcher on site, the Banchik Family Breast Cancer Library, and a Positive Appearance Center (to address body image issues). The Library offers a comfortable setting in which to review the latest information about breast cancer and its treatment. Both popular and professional books, literature, and videotapes are available for patients and their families to use at the Center or to check out and take with them for further review. Internet access is also available for patient and family use. The Breast Center offers treatment for benign breast disease as well as a comprehensive approach to the detection and management of cancer in its earliest forms. The program provides patients with breast cancer screening, breast health education, supportive care, and prevention strategies. Additionally the Center provides interdisciplinary care for patients with complex problems in breast cancer. Patients are evaluated for multimodality treatment (surgery, radiation therapy, chemotherapy, and/or hormonal therapy) by a team of physicians and nurses. The program approaches the patient as a whole person and includes dedicated breast imaging, breast pathology, breast radiation oncology, surgical oncology, medical oncology, nutritional counseling, psychosocial support, plastic and reconstructive surgery, community service and outreach, and research. The Breast Center collaborates closely in programs and in referral of patients to the American Cancer Society, Wellness Community, and WeSpark.

The Breast Center offers its patients a level of medical expertise and an increasing repertoire of innovative diagnostic and therapeutic procedures not available at most community hospitals and often not offered at other tertiary cancer centers. For instance, the Breast Center is one of the very few centers that also treat patients with breast disease-related endocrine disorders such as osteoporosis and hormone deficiency syndrome in cancer patients. With the addition of our satellite digital imaging unit, more than 18,000 breast imaging studies were performed in 2006. There were nearly 700 new breast cancer, thyroid cancer, and parathyroid tumor cases evaluated in 2006. Annually there were nearly 7000 patient visits.

In 1999 the John Wayne Cancer Institute expanded its spectrum of academic training programs to include a separate Breast Center Breast Fellowship for surgeons interested in advanced training in the field of breast disease. Commencing in 20002, the Society of Surgical Oncology (SSO) has recognized the need for a discrete breast fellow, and the JWCI Breast Center is a participating program. The JWCI Breast Center Interdisciplinary Breast Fellowship Program trains one fellow funded by the Susan G. Komen Breast Cancer Foundation.

The unique clinical resources of the Breast Center and the basic science resources of the JWCI have a proven track record in obtaining National Institutes of Health and philanthropic support and have made major contributions to the treatment and understanding of breast cancer. The sentinel node biopsy, which has altered breast cancer management throughout the world, was developed at this institution from a philanthropic grant. Commencing in 1991, a grant enabled us to perform the research that has resulted in a new way to treat breast cancer. This minimally invasive operation has had a major impact on the treatment of node-negative women, especially those who are postmenopausal.



Inpatient and Outpatient Services

Patients requiring inpatient care are treated at Saint John's Health Center 52 bed oncology unit on the first floor of the Chan Soon-Shiong Life Sciences Building. Nursing staff receive special training and certification in oncology. An oncology clinical nurse specialist works closely with nursing administration in quality assurance monitoring, education and training activities. The oncology unit fully utilizes the team approach to patient care management with discharge rounds patient care conferences, bioethics consultations and multi-professional training seminars which include clinical social workers, pastoral care, rehabilitation services, nursing staff, pharmacists, and physicians. Case Managers provide discharge planning, emotional support and utilization review.

Saint John's Health Center offers a full range of outpatient services including referral services and at the John Wayne Ambulatory Cancer Center and the John Wayne Cancer Institute Breast Center.

Numerous support groups for patients and families focus on cancer information, nutrition, stress management and coping strategies. A library and audio-visual resource center are open to all patients and family members as well as the public. Genetic screening is also available for patients and their families. The Positive Appearance Center is a unique, one-stop service, adjacent to the John Wayne Cancer Institute Breast Center that helps patients deal with the cosmetic side effects and comfort needs related to their disease and cancer treatment.

Pharmacy

The pain management pharmacist (PMP) made pain assessments and provided management to 1,555 patients who were on PCA and/or epidural infusion Monday through Friday in 2006 (figure 1). In addition, 36 comfort care and 76 palliative care patients were followed by the PMP. The PMP presented a semi-annual quality assurance report on pain management to the Pharmacy and Therapeutic Committee. The report included data such as the number of PCA, comfort care and palliative care patients seen by the PMP, numbers of and types of interventions, drug utilization reviews, adverse events, and medication errors. The Committee reviews all protocol exceptions, therapeutic updates, formulary issues and other problems encountered.

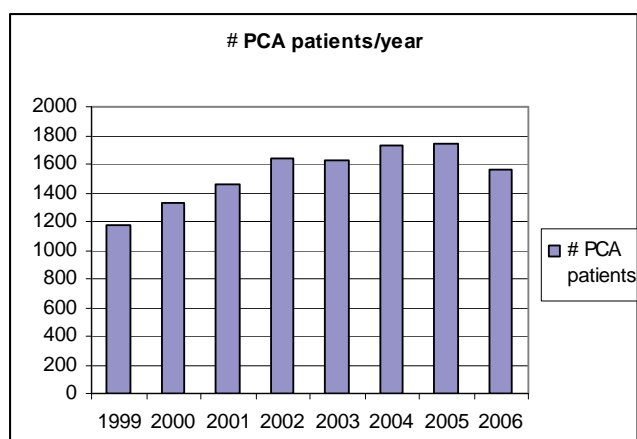


Figure 1.

The PMP provides pharmaceutical care at patients' bedsides, and the provision of such services, adjusting and titrating pain medication and symptoms improvement can require a significant amount of time. But it is important to individualize treatment plan for each patient and provide education to patients, families and other members of the health care team. Besides documenting the pain pharmacist effectiveness and proficiency in pain management, a new intervention type, "Facilitation Discharge" was added in 2007. Clinical interventions are not only organized around patient needs and directed at outcomes. Ideally discharge planning should start on the day of patient's admission. If pain management is an issue, a "Pain Pharmacist Referral" can be initiated anytime during the patient's stay. A retrospective review of all "Pain Pharmacist Referral" was done for a 12 month period to evaluate the impact of pain pharmacist on the facilitation of discharge. A total of 249 referrals were received from August 2006 to July 2007. The PMP evaluated all patients and

provided consultation and education. Six of the 249 patients were discharged on the same day after their pain and symptoms regimen were changed, ten patients were discharged within 24 hours, and twenty patients were discharged within 48 hours. An assumption was made that if a patient left one day earlier, \$2,700 would be saved per patient. The oncology unit requested the most pain pharmacist referrals. Subsequently the highest numbers of pain pharmacist intervention were made in the same unit (Figure 2).

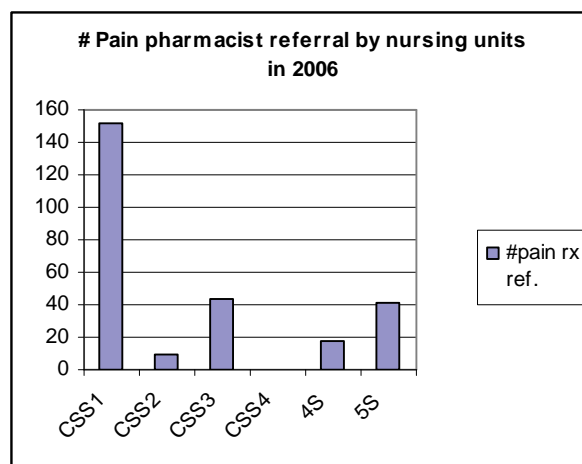


Figure 2

In 2006, the Medical Staff developed a pain management consultation procedure to encourage compassionate, high-quality, effective and efficient management of certain patient's symptoms of pain. When patients are admitted for inpatient service with a diagnosis of pain or for the primary purpose "pain management" they are subject to a mandatory evaluation by a PMP. The PMP will provide recommendations to the attending physician(s) and document them in the patient's medical record. A pain MD consultation will be required after 48 hours of hospitalization for "pain management" if the pain control is inadequate, or the attending physician declines or refused to follow pain management regimen suggested by the PMP or complicating and confounding factors, e.g. drug seeking behavior, are identified.

Some of the clinical activities provided by the pain management pharmacist include:

- ◆ Manage PCA and epidural patients.
- ◆ Provide consultation on patients through pain pharmacist referral program.
- ◆ Evaluate and provide pain and symptoms management on comfort care and palliative care patients.
- ◆ Provide "mandatory" pain consultation by admission diagnosis of pain.
- ◆ Provide education to medical, nursing staffs and patients and families.
- ◆ Review Omnicell dispensing and overrides reports.
- ◆ Provide lectures to medical and nursing staffs.
- ◆ Participate and report to different Committees in the Health Center
- ◆ Attend multidisciplinary discharge rounds and patient care case conference.

The PMP continues to review Omnicell (automated system) dispensing and overrides reports as part of the medication monitoring and utilizing reviews. At Saint John's Health Center, medication profiling interfaces with the Omnicell. The nursing staff requests to have certain medications that can be overridden for emergency or urgent uses.

Currently the PMP is working on a new clinical practice to improve MAR documentation while a patient is on medication patch. More involvement will be provided and discussed at the upcoming Pharmacy and Therapeutics Committee and education can be found in the Quarterly Dose Newsletter.

Pathology

The Department of Pathology is involved in many aspects of the cancer management care of patients. The eight board-certified pathologists are responsible for the accurate diagnosis, grading and staging of all cancers at Saint John's Health Center and the John Wayne Cancer Center. The pathologists work closely with oncologists, radiation oncologists and oncologic surgeons to provide the information necessary for cancer patients to receive the correct therapy for their particular cancer. They utilize state of the art laboratory technology and molecular diagnostics to assist them in determining the type and prognosis of cancer cells. Each pathologist has areas of expertise, such as cancers of the skin, of the breast, or of the bone marrow, all of which are frequently shared so that most cancers are diagnosed only after extensive interdepartmental review and consensus. Other integral services provided by the department include intraoperative consultation with frozen section diagnosis, performance of bone marrow biopsies, fine needle aspiration biopsies of both palpable and deep-seated tumors and leukopheresis for therapy of hematologic malignancies. Out of this wealth of experience, the department has provided critical research for the many collaborative publications that have been published by the John Wayne Cancer Institute faculty.

Diagnostic Radiology

The Department of Imaging performs a full range of routine diagnostic procedures including CT, MRI and ultrasound. Interventional specialists perform therapeutic procedures such as chemoembolization and radiofrequency ablation of the liver under CT guidance. A specialized staff in the Breast Cancer perform stereotactic core biopsies and pre-operative localization of breast lesions.

Spiritual Care

Serious illness often prompts one to reflect on human experience and the meaning of life. No matter what religious heritage they claim, an interfaith chaplain can help patients and their families deal with emotional and spiritual issues related to disease, suffering, and the human condition. A degreed and certified chaplain with background in spirituality, psychology of the human person, and Clinical Pastoral Education (CPE) is available to help patients draw on their own spiritual resources. At Saint John's Health Center, the chaplain sees oncology patients on the inpatient unit and in the Breast and Cancer Centers. Patients may also choose to receive visits from out faith-specific chaplains, including visiting rabbi and visiting Protestant clergy, or they may request our assistance in contacting a representative from their out faith community. The interfaith chaplain participates in rounds and is an integral part of the interdisciplinary care team.

Social Services

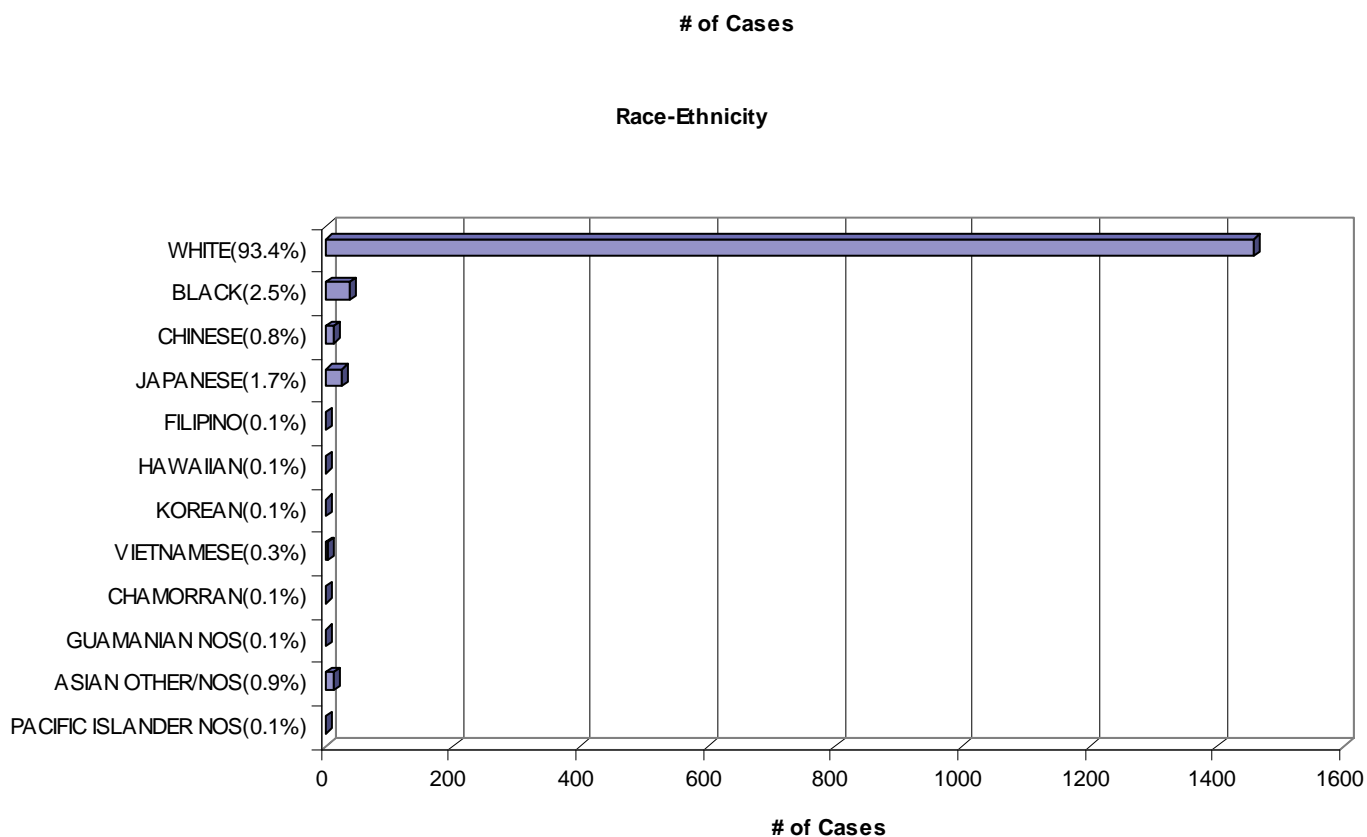
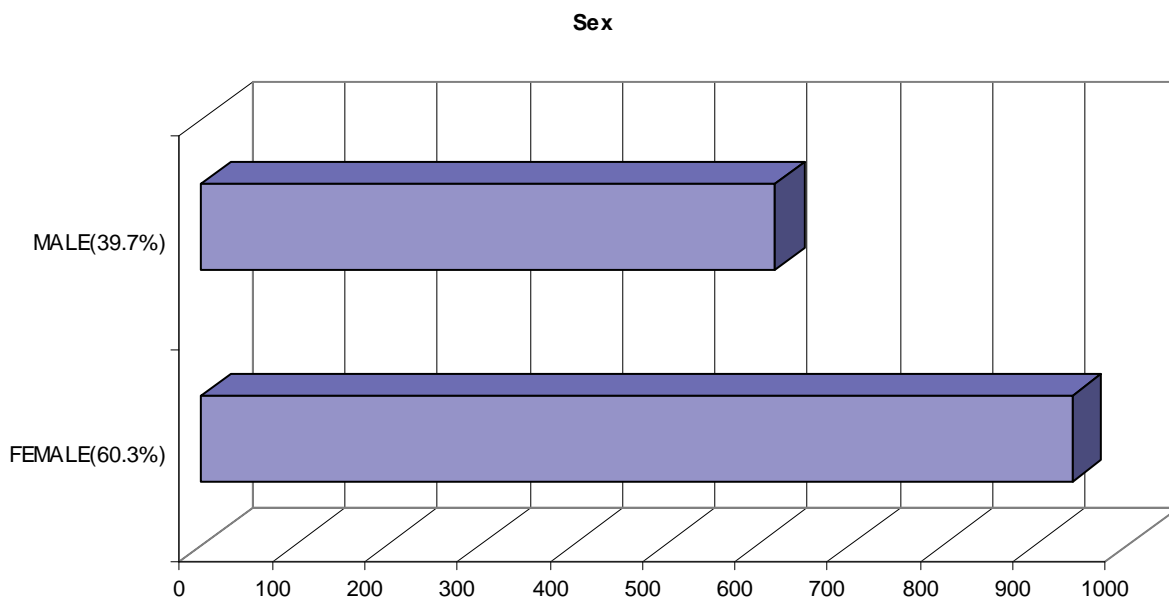
Total patient care extends beyond that provided by physicians and nurses. A diagnosis of cancer brings with it profound psychological trauma. Clinical social workers assist patients and family members in navigating their way through the disease process beginning with initial diagnosis and corresponding treatment. They provide crisis intervention, brief insight oriented psychotherapy, guided meditation for stress reduction, conflict resolution, assistance with health care directives, discussion of end of life issues, maintenance of resource library and support for staff members. They refer to agencies within the community such as American Cancer Society, Wellness Community, Our House and We Spark in an effort to support both the patients and their families. In addition, clinical social workers facilitate programs to increase cancer awareness and promote preventive intervention both medical and non-medical.



Primary Site Table

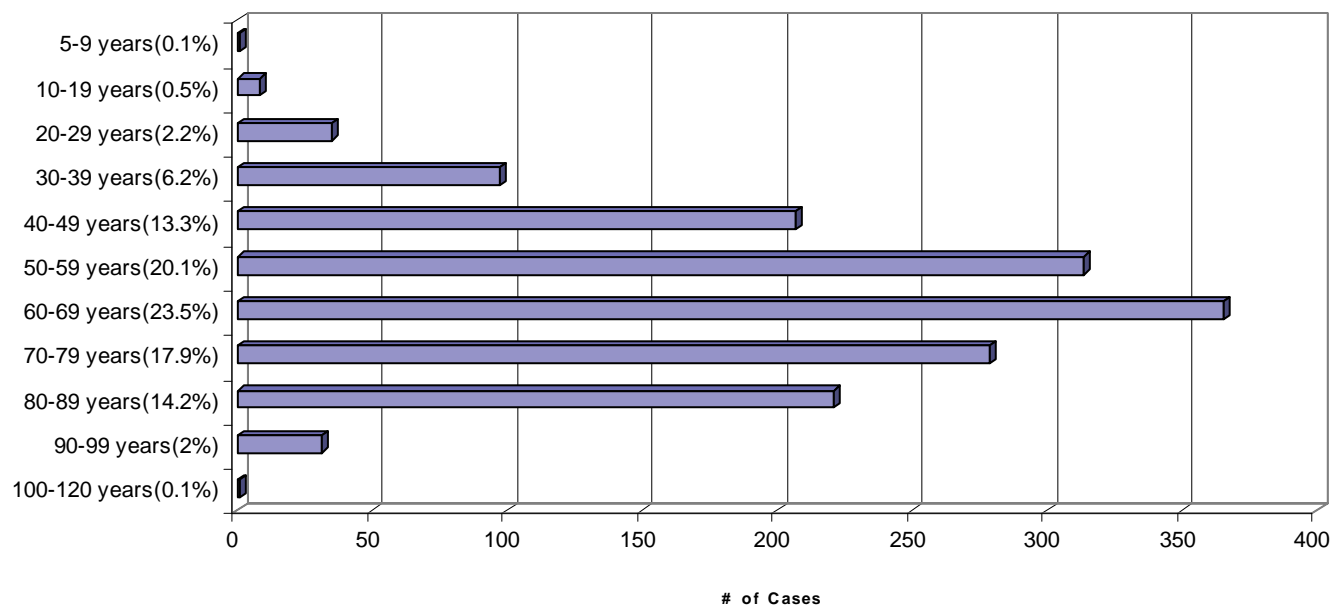
Site Group	Total Cases	Class		Sex		Stage						N/A	Unk.
		Analytic	NonAn	M	F	Stage 0	Stage I	Stage II	Stage III	Stage IV			
ALL SITES	1748	1564	184	706	1042	217	586	330	167	130	102	32	
TONGUE	4	4	0	4	0	0	1	0	1	1	0	1	
SALIVARY GLANDS, MAJOR	4	2	2	4	0	0	1	0	1	0	0	0	
GUM	1	1	0	0	1	0	0	0	0	1	0	0	
FLOOR OF MOUTH	2	2	0	1	1	0	1	0	1	0	0	0	
MOUTH, OTHER & NOS	2	2	0	1	1	0	1	0	0	1	0	0	
NASOPHARYNX	1	1	0	0	1	0	0	1	0	0	0	0	
HYPOPHARYNX	1	1	0	0	1	0	0	1	0	0	0	0	
ESOPHAGUS	9	6	3	6	3	1	0	2	0	0	0	3	
STOMACH	18	15	3	10	8	1	5	0	3	2	2	2	
SMALL INTESTINE	3	3	0	2	1	0	0	0	0	1	2	0	
COLON	91	73	18	41	50	5	18	17	19	14	0	0	
RECTUM & RECTOSIGMOID	36	31	5	22	14	3	8	8	6	3	2	1	
ANUS & ANAL CANAL	10	8	2	6	4	0	2	1	0	2	3	0	
LIVER	10	8	2	5	5	0	1	0	2	2	1	2	
GALLBLADDER	2	2	0	1	1	0	0	2	0	0	0	0	
BILE DUCTS	4	3	1	1	3	0	1	1	0	0	0	1	
PANCREAS	23	22	1	8	15	0	0	13	2	6	1	0	
PERITONEUM & OMENTUM	2	1	1	2	0	0	0	0	0	1	0	0	
NASAL CAVITY,SINUS,EAR	3	3	0	3	0	0	1	0	1	0	1	0	
LARYNX	10	9	1	10	0	0	2	4	1	1	0	1	
LUNG - SM CELL CA	11	11	0	5	6	0	0	0	1	6	0	4	
LUNG - NON SM CELL CA	91	80	11	37	54	0	26	7	15	30	2	0	
PLEURA	2	2	0	0	2	0	1	0	0	0	1	0	
LEUKEMIA	28	22	6	20	8	0	0	0	0	0	22	0	
MYELOMA	13	12	1	6	7	0	0	0	0	0	12	0	
OTHER HEMATOPOIETIC	14	13	1	7	7	0	0	0	0	0	13	0	
BONE	3	1	2	3	0	0	1	0	0	0	0	0	
SOFT TISSUE	16	8	8	8	8	0	2	4	1	0	1	0	
MELANOMA OF SKIN	490	450	40	296	194	103	241	57	41	2	1	5	
KAPOSIS SARCOMA	1	1	0	0	1	0	0	0	0	0	1	0	
OTHER SKIN CA	4	4	0	3	1	0	1	0	0	0	3	0	
BREAST	472	442	30	3	469	88	179	121	33	13	1	7	
CERVIX UTERI	7	6	1	0	7	0	4	0	0	2	0	0	
CORPUS UTERI	29	27	2	0	29	1	19	3	1	0	1	2	
UTERUS NOS	1	0	1	0	1	0	0	0	0	0	0	0	
OVARY	22	17	5	0	22	0	4	5	2	1	5	0	
VAGINA	3	2	1	0	3	0	0	0	0	0	1	1	
VULVA	2	2	0	0	2	1	0	1	0	0	0	0	
OTHER FEMALE GENITAL	2	2	0	0	2	0	0	0	1	0	1	0	
PROSTATE	86	77	9	86	0	0	4	63	5	4	0	1	
TESTIS	9	9	0	9	0	0	7	0	2	0	0	0	
PENIS	2	2	0	2	0	1	0	0	1	0	0	0	
BLADDER	32	27	5	25	7	13	3	8	1	2	0	0	
KIDNEY AND RENAL PELVIS	14	12	2	9	5	0	4	3	1	4	0	0	
BRAIN	7	6	1	2	5	0	0	0	0	0	6	0	
OTHER NERVOUS SYSTEM	3	2	1	0	3	0	0	0	0	0	2	0	
THYROID	58	54	4	18	40	0	32	2	11	8	0	1	
OTHER ENDOCRINE	2	2	0	1	1	0	0	0	0	0	2	0	
HODGKIN'S DISEASE	7	6	1	2	5	0	4	1	1	0	0	0	
NON-HODGKIN'S LYMPHOMA	62	53	9	27	35	0	12	5	13	23	0	0	
UNKNOWN OR ILL-DEFINED	19	15	4	10	9	0	0	0	0	0	15	0	

Analytic Case Distribution

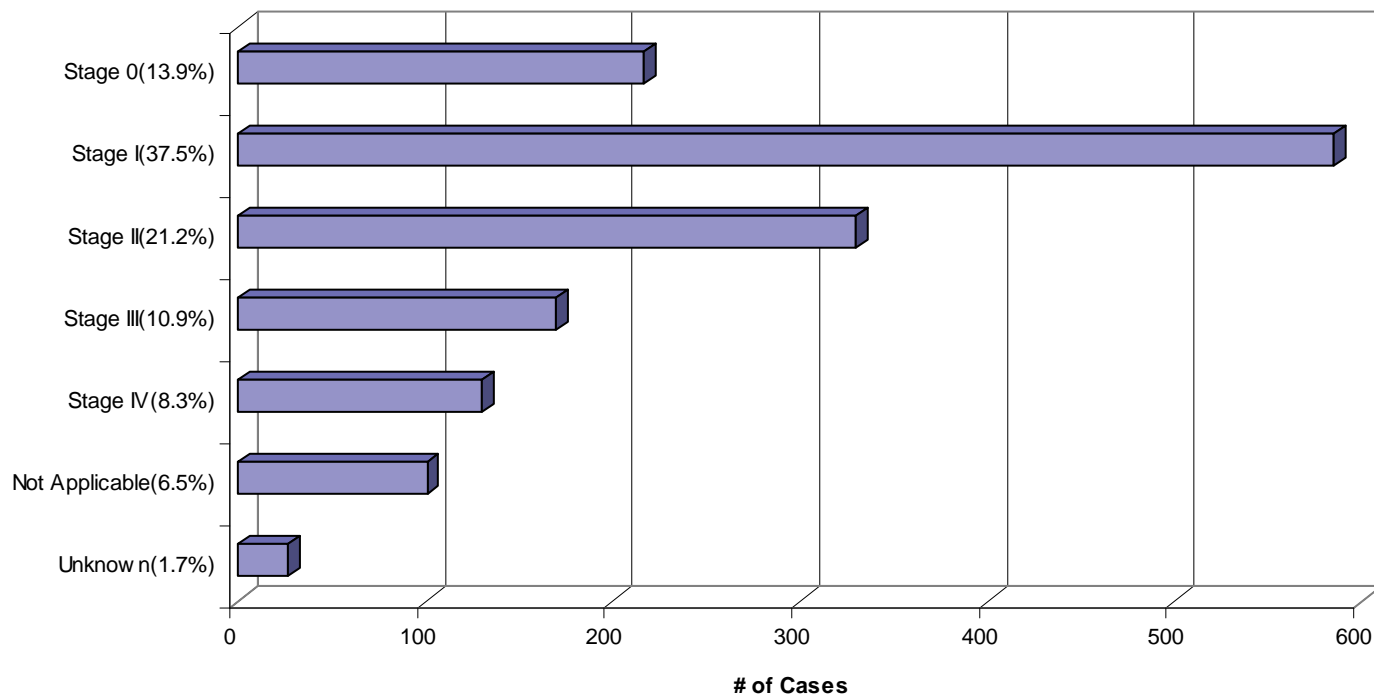


Analytic Case Distribution

Age at Diagnosis

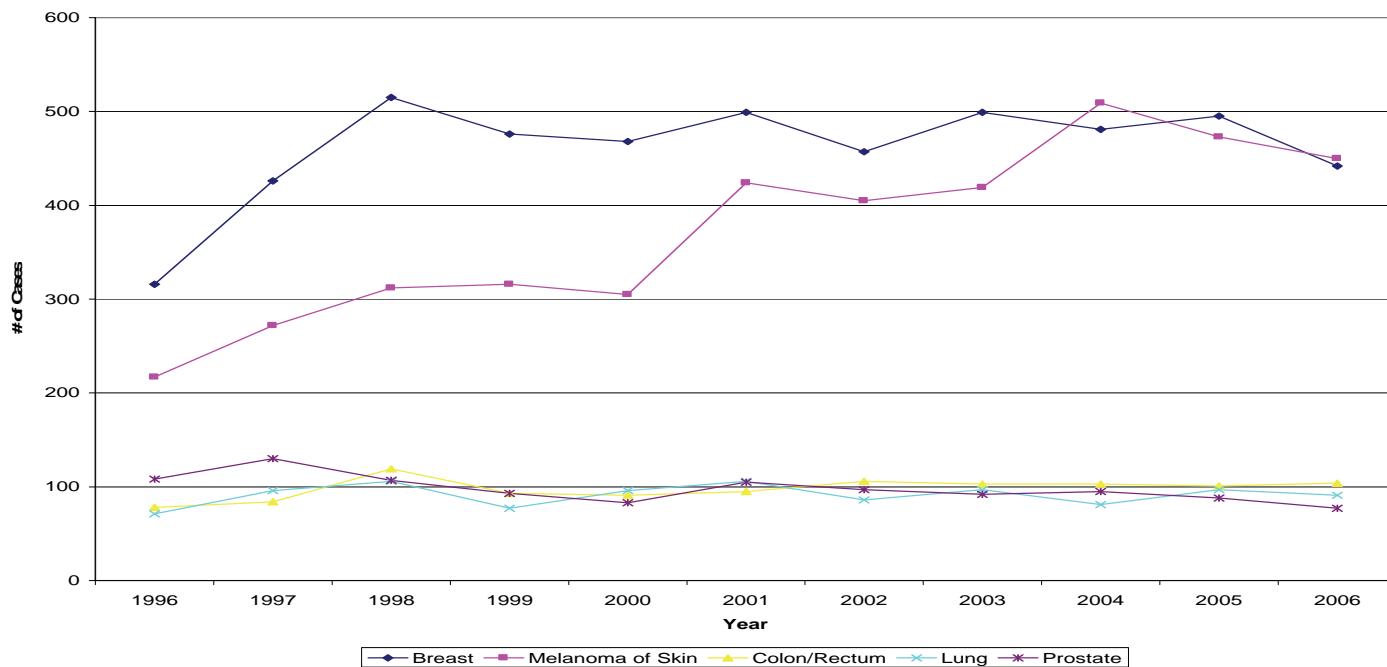


TNM Stage at Diagnosis

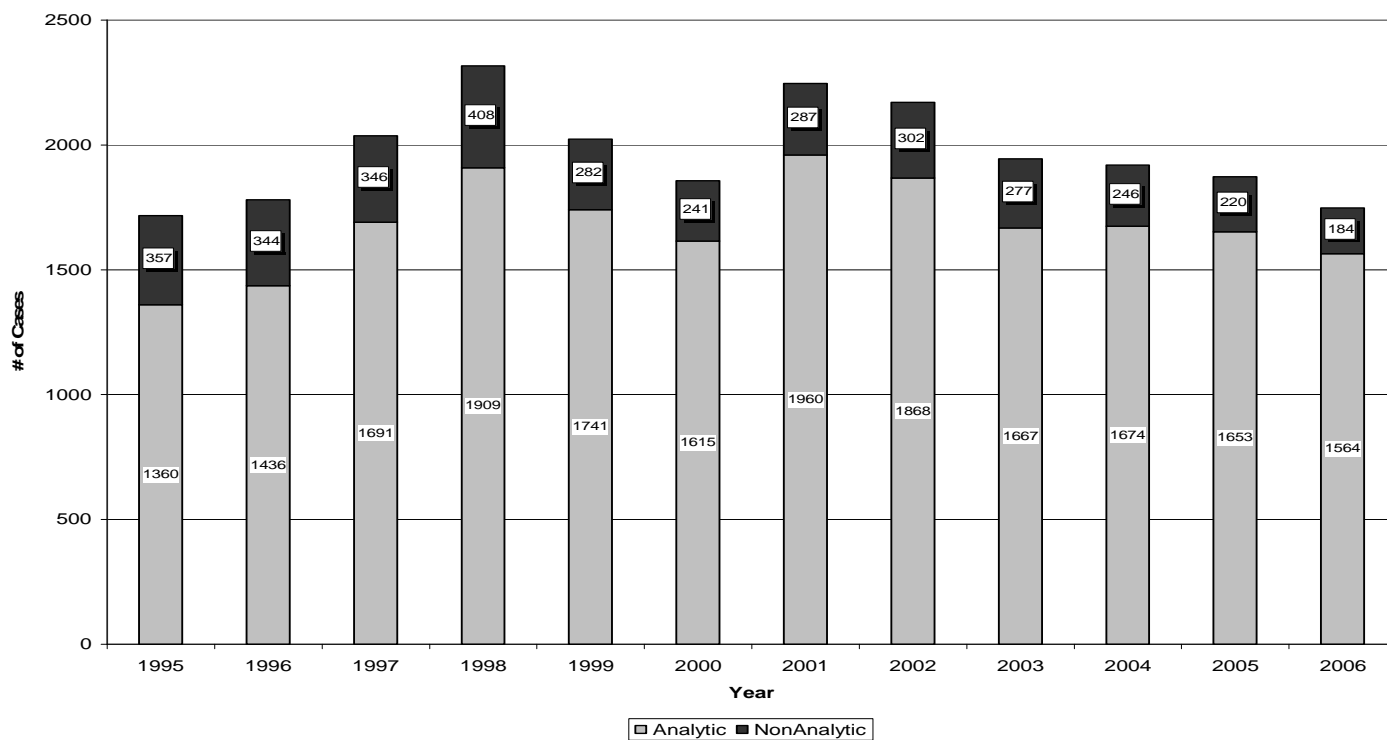


Analytic Case Distribution

Comparison of Selected Sites at Saint John's Health Center 1996-2006



Caseload Trend 1996-2006



Melanoma at Saint John's Health Center

Melanoma is one of the most rapidly increasing malignancies in the United States. The American Cancer Society estimates that there will be nearly 60,000 cases of melanoma here this year and over 8,000 deaths. Over the last several decades the incidence of melanoma has doubled in women and tripled in men. Since melanoma strikes many people at a relatively young age, it is responsible for more lost years of life than any other malignancies other than leukemia/lymphoma. Melanoma now represents the sixth most common cancer in both men and women. The explanation for this dramatic increase is not clear, but it demonstrates the need for expertise in the care of patients with melanoma.

As the home of the John Wayne Cancer Institute, a tertiary referral center for melanoma, Saint John's Health Center is the site of treatment for many patients with this disease. Saint John's provides services for the prevention and treatment of melanoma at all stages of the disease. These services include provision of counseling for sun protection, skin cancer screening, diagnostic biopsy, surgical excision and staging, and therapy for metastatic disease.

Prevention of melanoma includes protection from ultraviolet radiation and early removal of precursor lesions. At Saint John's, the Positive Appearance Center provides recommendations for protection from UV radiation including clothing and hats, which may provide the optimal means of protection. In addition, information regarding the best sunscreen protection is available there. The Positive Appearance Center has sunscreens which provide excellent protection against both ultraviolet A and ultraviolet B radiation.

Education and melanoma screening is also provided by Saint John's physicians. This takes place both at the John Wayne Cancer Institute and at the offices of numerous Saint John's affiliated dermatologists. The Saint John's pathologists are extremely experienced in diagnosing melanocytic lesions and serve as a referral center for difficult cases. The expertise of the department allows for accurate diagnosis and appropriate treatment of patients with melanoma and melanoma-related conditions. Patients with risk factors for melanoma such as fair skin, a prior personal or family history of melanoma, a history of atypical nevi previous sunburns are seen and counseled regarding sun protection and dermatologic surveillance.

Melanoma is generally treatable through surgery once it is diagnosed. This treatment includes wide local excisions with surgical margin width dictated by the thickness of the primary lesion. Frequently, the large cutaneous defects created by such excisions require surgeons who are experts in reconstructive procedures. Both the melanoma surgeons at John Wayne Cancer Institute and the Saint John's-affiliated plastic surgeons have extensive experience with reconstructive flaps, facial reconstruction and skin grafting. This expertise allows patients to enjoy the fastest recovery with the most acceptable cosmetic and functional results.

In many patients with melanoma, there is a substantial risk of metastasis. This is what makes melanoma potentially life threatening. If melanoma is to metastasize, the most likely first site of metastasis is in regional lymph nodes. In the past, the determination of lymph node status was made by removing all of the potentially affected lymph nodes in a prophylactic or elective lymph node dissection. Physicians at John Wayne Cancer Institute, under the leadership of Donald L. Morton, M.D. developed the Sentinel Lymph Node (SLN) technique as a significant improvement in the care of patients with melanoma. This technique has since become the world standard in melanoma and more recently in breast cancer. Research led by John Wayne Cancer Institute has demonstrated that a considerable experience with lymphatic mapping and SLN biopsy is necessary to maintain optimal accuracy of the technique. In a large international, multicenter study led by John Wayne Cancer Institute, the false negative rate (missed SLN) was found to be over 10% during the first 45 procedures performed at a given center. The rate fell to approximately 5% thereafter. With the enormous experience of this institution, the false negative rate here is 2% or less. Experience is vital not only among the surgeons performing the operation, but also the Nuclear Medicine Department performing the pre-operative lymphoscintigrams which identify the sentinel node sites, and in the Pathology Department that examines the resected nodes for evidence of metastases. Without the combined efforts of all of these areas, the accuracy of the test and care of the patients would suffer.

Melanoma at Saint John's Health Center

Saint John's physicians are also involved in considerable research to improve the current use of SLN biopsy. This research involves one recently completed pivotal clinical trial, and two ongoing additional trials. The first trial, the Multicenter Selective Lymphadenectomy Trial (MSLT) I was headquartered at John Wayne Cancer Institute and conducted at centers throughout the United States, Europe and Australia. The trial was recently reported in the *New England Journal of Medicine* and demonstrated the prognostic importance of the SLN, the improved disease-free survival of patients who underwent the procedure and the improved overall survival of patients with micrometastatic melanoma who were able to have this disease removed early after detection by the SLN technique. A smaller phase II trial evaluating a novel radiopharmaceutical, Lymphoseek, was recently completed. This new agent has been shown to target lymphatic tissue through specific receptors found on immune cells in the lymph node. The results of this trial should be available and reported in the next year. Finally, there is a second international study being led by the physicians here. This is the MSLT II trial which seeks to answer a critically important remaining question in the management of patients with melanoma.

Among patients with evidence of melanoma in the SLN, only a minority of approximately 20-25% will have additional involved lymph nodes discovered after undergoing the current standard therapy of a completion lymph node dissection (CLND). It is not clear that patients are provided a survival advantage by undergoing this larger and more potentially morbid procedure. Although research here has revealed characteristics that suggest higher or lower rates of non-sentinel node metastasis, no method has been determined to reliably select patients to have or avoid the second operation. The MSLT II trial assigns those patients with positive sentinel nodes who enroll to standard treatment of CLND or to clinical observation utilizing ultrasound to follow the at-risk lymph nodes. On completion, the trial will determine whether one treatment is associated with better outcomes and establish a new standard of care.

The risk of further dissemination of cancer in patients with melanoma metastases in lymph nodes is considerable, and an effective adjuvant therapy to decrease that risk is desirable. However currently available options of adjuvant therapy are not satisfactory. The only FDA-approved medication in the setting of resected melanoma nodal metastases is interferon- α . This medication has been clearly shown to decrease the risk of recurrence of melanoma, but it has failed to consistently show an improvement in overall survival. This modest activity is balanced against considerable toxicity related to the treatment including fever, muscle ache, nausea, depression, and fatigue. The physicians at JWCI and Saint John's have therefore continued to conduct research toward development of improved treatment options. This includes numerous trials of immunotherapy in the adjuvant setting. Several of these trials utilized the melanoma vaccine Canvaxin in conjunction with the immune adjuvant bacille Calmette-Guerin (BCG). These international, multicenter studies included patients with resected Stage III and Stage IV melanoma. The trials did not demonstrate improvements in outcome related to the vaccine, but did reveal extremely high rates of survival overall. The etiology of these good results are currently under evaluation and may stem from the selection of appropriate patients, the performance of good surgical resection or the impact of non-specific immune stimulation by BCG.

Another immunotherapy trial that is currently ongoing at John Wayne Cancer Institute/Saint John's Health Center is open to patients who have undergone resection of melanoma metastatic to lymph nodes (Stage IIIB and Stage IIIC). A large number of the patients' B lymphocytes are removed through leukopheresis and are treated to make a vaccine against a tumor-specific protein. These vaccine cells are then re-infused in an effort to stimulate an anti-tumor immune response.

For patients whose melanoma has spread to distant sites, prognosis is poor. Recent studies in this patient population have shown 5-year survival in fewer than 10% of patients and virtually no long-term survivors. The physicians here use surgical and novel systemic therapies to try to improve this record. Surgeons at John Wayne Cancer Institute are strong proponents of surgical resection in appropriately selected patients with this stage of disease. Our results demonstrate much higher survival among patients undergoing surgical resection of between 20-40% depending on the site and extent of disease. The recently conducted multicenter study headquartered here of vaccine therapy after resection of Stage IV disease demonstrated a 5-year survival of approximately 40%.



Melanoma at Saint John's Health Center

For patients in whom surgical resection is not feasible, John Wayne Cancer Institute and Saint John's physicians offer a large number of novel clinical treatment protocols of combinations of chemotherapy, immunotherapy, antibodies and other targeted molecules. These trials include both investigator-initiated and multicenter studies in partnership with the NCI and Industry. The institution serves as a referral center for much of the western United States, and we treat patients from around the country and around the world.

Finally, the John Wayne Cancer Institute at Saint John's Health Center conducts advanced translational research in melanoma. This research includes examination of methods of early detection of metastatic disease through RT-PCR analysis to measure circulating tumor cells in the blood, or pathologically occult metastases in sentinel lymph nodes. We have also evaluated proteomic analysis of patient serum to begin to elucidate differences between patients who suffer recurrent disease and patients who do not. We have a long history of examining immune responses in patients with melanoma. These include naturally developing immune responses and responses that are induced by immunotherapy. This research has led to the development and testing of immunotherapies such as vaccines and monoclonal antibodies. The research has been presented at many national and international scientific and medical meetings and has been published in many scientific journals. The dissemination of these data helps to advance the course of research toward a cure for this difficult and increasingly prevalent disease.

Below, please find the data regarding patients receiving their first course of treatment for melanoma Saint John's Health Center. Survival data has been examined for patients treated between 1999 and 2004 to allow for adequate follow up duration. These cases include those patients primarily treated here. There are also a large number of melanoma patients who come here for second opinions and later courses of treatment. In addition, a list of recent melanoma-related research publications is provided.


Respectfully submitted,

Mark B. Faries, M.D. , F.A.C.S.

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Assistant Member, John Wayne Cancer Institute

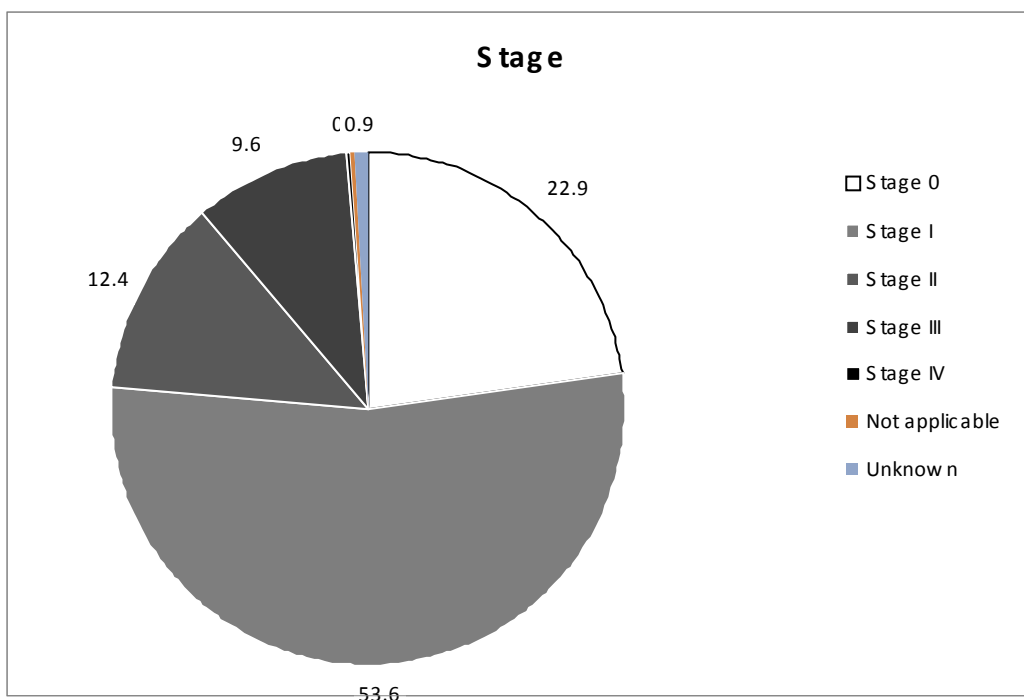
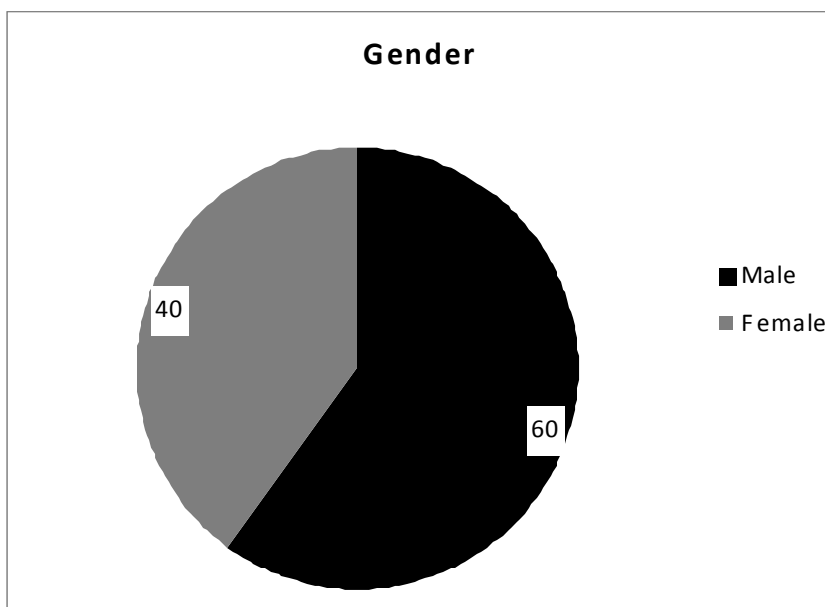
Director, Translational Tumor Immunology



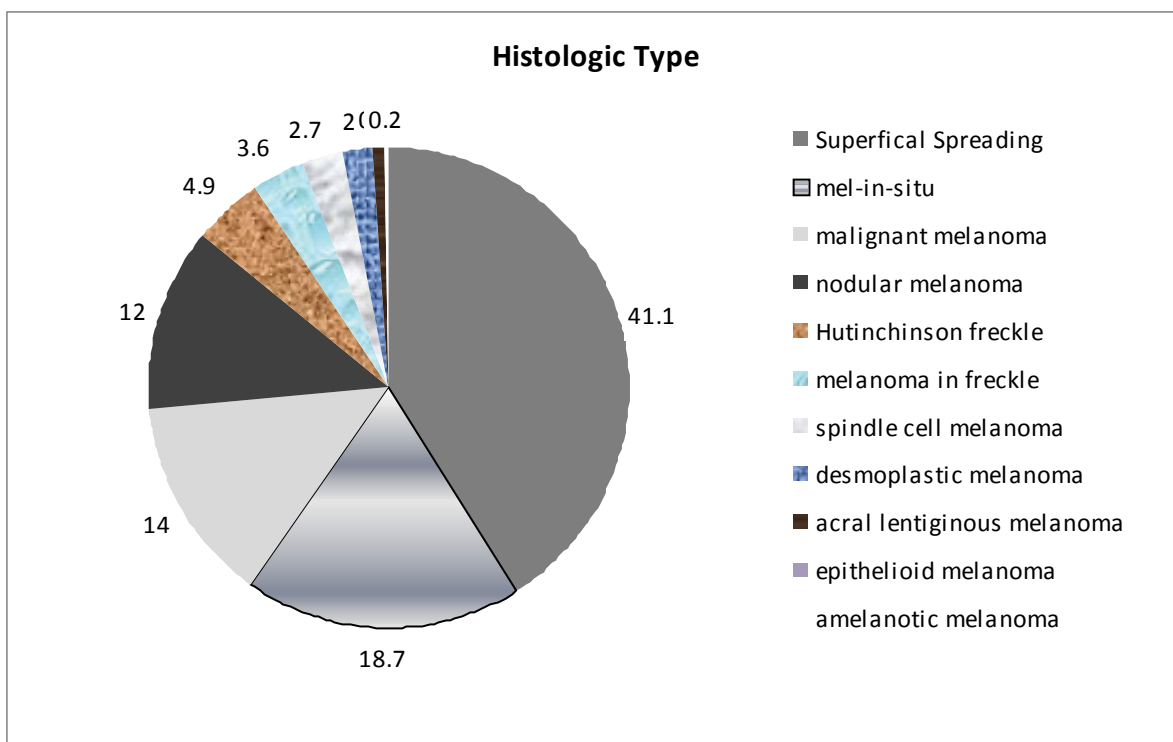
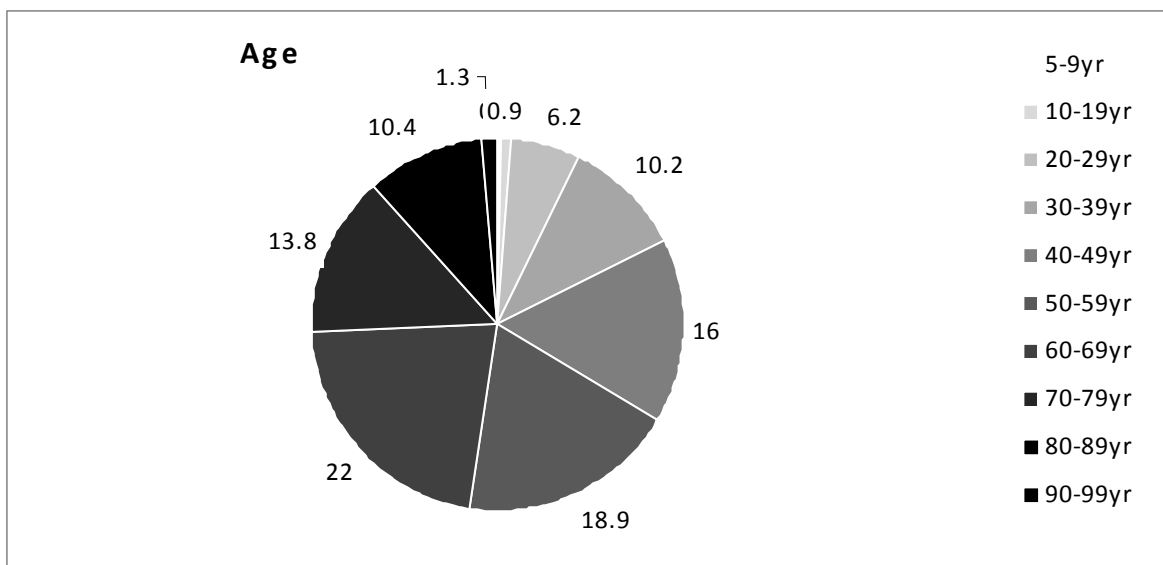
Melanoma at Saint John's Health Center

Melanoma Clinical Parameters and Survival Data

Review of demographic features demonstrates a typical distribution with slight male predominance and the majority of patients over 50 years old. These data confirm the relatively high frequency of melanoma in younger age groups, however, relative to most other malignancies. In addition, the majority of patients were diagnosed at an early stage. There was a fairly broad distribution of histologic subtypes with a predominance (41.1%) superficial spreading.

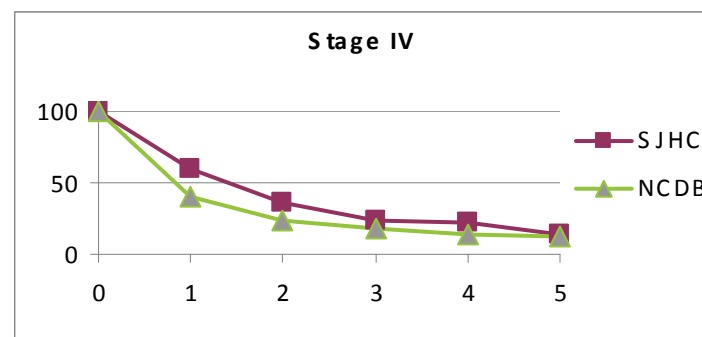
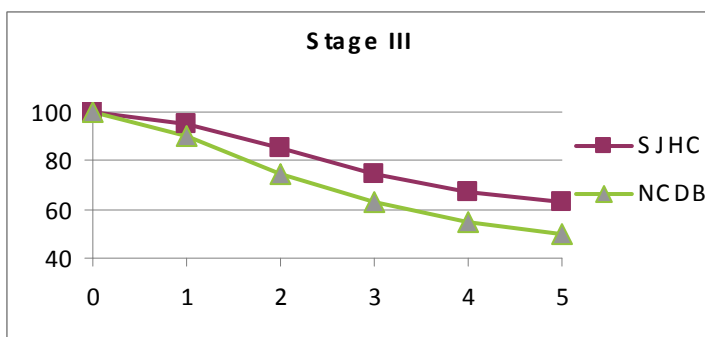
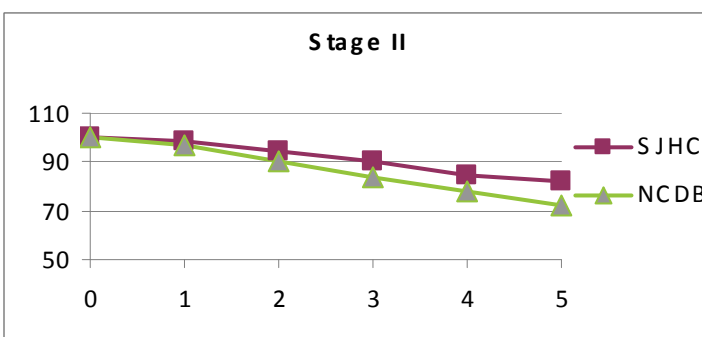
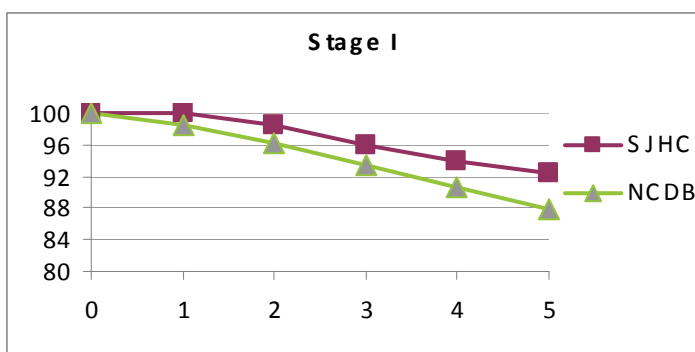
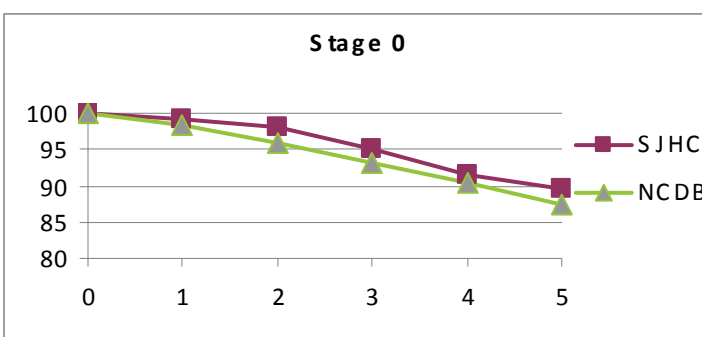
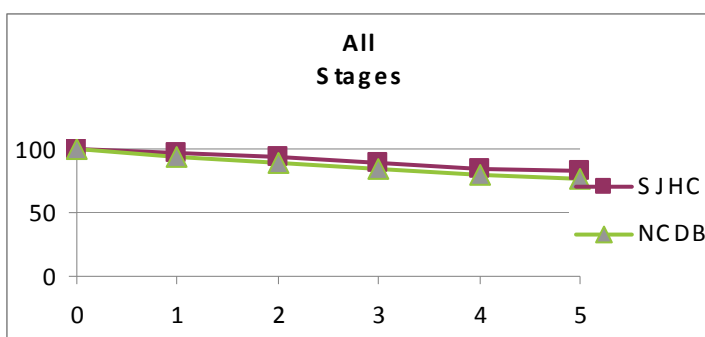


Melanoma at Saint John's Health Center



Melanoma at Saint John's Health Center

Survival analysis by stage was conducted using data from years for which there is reasonable follow up duration (1999-2004). These curves were compared to the survival for the same stage groupings from the National Cancer Database. Although such a direct comparison is not wholly reliable due to potential variations in prognostic factors other than stage, the comparison suggest patients are receiving good treatment for melanoma at Saint John's Health Center.



Melanoma at Saint John's Health Center

John Wayne Cancer Institute 2006 Melanoma-related publications/presentations

Manuscripts

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Melanoma at Saint John's Health Center

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Definition of Terms:

Analytic Cases: Patients initially diagnosed and/or received first course of treatment at Saint John's Health Center. Statistical analyses in this report are based on analytic cases only.

Non-Analytic: A case first diagnosed and treated at another facility, including cases first diagnosed at autopsy.

First Course of Treatment: The initial tumor-directed treatment or series of treatments.

NOS: Not otherwise specified

Stage of Disease: The stage of disease is determined at the time of diagnosis, based on the AJCC TNM Staging Manual, 6th edition.

Survival Analysis: Proportion of patients surviving an interval of time from the time of diagnosis, expressed in percentage. The actuarial method provides a means for use of all follow-up data accumulated until the close of the study and any additional information on the survival pattern of the group being studied. The relative survival rate is used when the actual cause of death is unavailable, and indirect adjustment for normal mortality is performed.

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