Cancer Program
Statistical Report
I’m proud to present the fourth annual Cancer Program Report reflecting 2007 data and activities at Cleveland Clinic in Florida. The Program continues to grow: 709 patients were treated for cancer at our institution in 2007 compared to 449 in 2004, 497 in 2005, and 571 in 2006. We continue to add physicians and surgeons to our professional staff, who specialize in oncology and bring new and current expertise to the care of our patients. In 2008, we were surveyed by the Commission on Cancer and are proud to have received three year accreditation with commendation as a Community Hospital Comprehensive Cancer Center.

Our Cancer Program continues its commitment to provide comprehensive, quality, multidisciplinary, safe, and patient oriented care to patients diagnosed with cancer. The Program provides clinical services adept in the prevention, education, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, and surveillance for recurrent disease, support services, and end-of-life care for our patients. Patients referred to Cleveland Clinic for diagnosis, staging, and treatment of their cancers receive the advantages of inpatient areas dedicated only for the care of cancer patients, an outpatient chemotherapy infusion unit, the invitation to participate in clinical research trials, and a Cancer Prevention Clinic that offers genetic testing, family phenotyping, and counseling.

This report will update you on the activity of our cancer services, weekly cancer conferences, quality improvement program, cancer registry and database, community outreach programs, patient education and support groups, and ongoing clinical trials.

The Cancer committee has chosen to review lung cancer in this year’s report. In 2007, lung cancer was the third most common cancer treated at our institution. It was the third most common cancer among men and second among women. It is a devastating illness, accounting for the most cancer-related deaths in men and women for the past several decades. Unlike breast, prostate, and colorectal cancer, reported in our previous annual cancer statistic reports, lung cancer is not a screen-worthy disease. Unfortunately, most patients with lung cancer present with symptoms due to advanced local or metastatic disease that is not amenable to cure. Patients are often very ill from co-morbidities. A comprehensive and multi-specialty approach for treatment and palliation is essential to maximize patient care, comfort and function. With this goal, it is not surprising that 85 % of our patients who received surgery had it performed with minimally invasive techniques. Prevention, rather than screening, is the most effective strategy for reducing the burden of lung cancer. Risk education is paramount, namely the cessation of smoking. In this light, the Cleveland Clinic Florida, along with the entire Cleveland Health Care System has been smoke-free since June of 2005. People seeking employment at our institution are not hired if they smoke, but are offered smoking-cessation therapy prior to re-applying. Employees who were hired prior to June 2005 were offered the same.

It is my pleasure to present this report for your review. The Cancer Committee is proud of the strides we continue to make for our patients ensuring that they continue to receive the best, safest, and most personalized care possible.

Mark E. Sesto, MD, FACS
Cancer Committee Chairman
Cancer Committee

Mark E. Sesto, MD, FACS, Chairman, General and Oncologic Surgery
Elizabeth Stone, MD, Cancer Liaison Physician, Medical Oncology
Christopher Chen, MD, Quality Control Coordinator, Radiation Oncology
Chieh-Lin Fu, MD, Quality Improvement Coordinator, Hematology
Maria Artze, MD, Radiology
Mariana Berho, MD, Pathology
Viviana Boronat, MD, Clinical Research
Margaret Gilot, MD, Breast Surgical Oncology
Nicolas Muruve, MD, FACS, Urology
Thomas Summers, DO, Medical Oncology
Carron Bramwell, Director of Telemetry
Lee Ghezzi, Director of Quality Assurance
Mohammed Ibrahim, Pharmacy
Cara Kondaki, LCSW, ACSW, Oncology Social Worker
Kelly Large, CTR, Cancer Registry Coordinator
Kerry Major, Chief Nursing Officer
Sonia Wisdom, MSN, CCRN Director Medical Surgical Department

Hospital Services

Diagnostic Imaging Services
  Digital Mammography
  MRI/Breast MRI
  CT/PET Scanning
Double balloon small bowel enteroscopy
Endoscopic Ultrasound, gastrointestinal and trachea-bronchial
Enterostomal Therapy
Hereditary Prevention Clinic/Genetic Testing
Home Health
Hospice
Invasive Radiology Services
  Stereotactic/Ultrasound Guided Core Needle Breast Biopsies
  CT Guided Radiofrequency Ablation
  Chemoembolization of Liver Tumors
Laboratory
Nutritional Services
Oncology Social Services
Outpatient Services
Pain Management
Pastoral Care
Pharmacy
Photodynamic Therapy
Rehabilitation
Special Transportation
Wound Care
Community Outreach

At Cleveland Clinic in Florida, our commitment to compassionate, quality care remains our primary goal. In the past year we have increased our community outreach through several innovative programs.

This year the Oncology Department initiated a mentoring program with the Girl Scouts of Broward County in partnership with our Breast Cancer Book Club, to provide education and mentoring to a Junior Girl Scout troop in our community. The girls were matched up with breast cancer survivors. Together with their mentors and the Oncology Department, they walked in the Making Strides Against Breast Cancer Walk, had several one on one meetings and received education on Breast Cancer by our Breast Cancer oncologist, Dr. Elizabeth Stone and oncologic breast surgeon Dr. Margaret Gilot. Troop 95 and the members of the Breast Cancer Book Club completed a quilt which we are proud to have displayed at the entrance to our cancer center, as well as displayed on the American Cancer Society website for the 2008 walk. For their hard work, Troop 95 received their Bronze award and an outstanding community service award from their State House Representative.

In the past year, Dr. Chieh-Lin Fu and Cara Kondaki, Oncology Social Worker, were approved as family support group facilitators through the Leukemia and Lymphoma Society. The Hematology/Oncology Department recently established an interactive support group, using movies, called Reel to Real for our blood cancer patients. Cleveland Clinic Florida continues to offer disease specific education including Multiple Myeloma Jeopardy and Lymphoma support.

With the American Cancer Society, Cleveland Clinic in Florida also participated in the annual Relay for Life and sponsored their kick-off and wrap-up events for the second year in a row. This year the Department of Oncology is proud to have initiated the American Cancer Society Look Good Feel Better classes. These classes are offered monthly to our chemotherapy patients. In addition, we established a monthly Man-to-Man prostate cancer support group with two dedicated facilitators.

Cleveland Clinic Florida also recently received certification as an American Cancer Society I Can Cope facility and has planned several community education programs in conjunction with that program.

During National Breast Cancer Awareness month, the Oncology Department sponsored our third annual community outreach table to provide education on the importance of monthly self-breast exams and yearly mammograms. In conjunction with Thoracic Oncology, the department also initiated a community outreach table during November's National Lung Cancer awareness month, to encourage smoking cessation and provide education and community referrals.

Our dedicated multidisciplinary team continues to strive for excellence in meeting the needs of our patients, and supporting the patient and family throughout their cancer diagnosis and treatment journey.

Elizabeth Stone, MD
Medical Oncologist

Cara S. Kondaki, LCSW, ACSW
Oncology Social Worker
### BREAST

<table>
<thead>
<tr>
<th>Protocol</th>
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<tbody>
<tr>
<td>Adjuvant Hormonal</td>
<td>NSABP B42</td>
<td>8863</td>
<td>Stage I-IIIA ER/PR+ completed 5yrs of hormonal therapy: Letrozole/placebo x 5yrs</td>
</tr>
<tr>
<td>ALTTO</td>
<td>N063D</td>
<td>8992</td>
<td>Adjuvant lapatinib/trastuzumab in HER2/ErbB2(+) primary breast cancer</td>
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<tr>
<td>Oncotype Dx Assay</td>
<td>PACCT-1</td>
<td>8881</td>
<td>Trial assessing individual options for breast cancer treatment</td>
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<tr>
<td>Adjuvant Chemo</td>
<td>E 5103</td>
<td>8974</td>
<td>Node (+)/High Risk Node (-) Chemo +/- bevacizumab</td>
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### GI

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<tr>
<td>Gastric/GE Junction</td>
<td>CALGB 80101</td>
<td>8676</td>
<td>Resected, adjuvant chemoRT: 5-FU/LV with RT vs. E/C/5-FU with RT</td>
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<tr>
<td>Colorectal. Metastatic</td>
<td>CALGB 80405</td>
<td>8902</td>
<td>First line, FOLFOX or FOLFIRI plus Cetuximab or Bevacizumab or both every 2 weeks. (suspended)</td>
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<tr>
<td>Colon. Adjuvant</td>
<td>E 5202</td>
<td>8944</td>
<td>High risk (5-FU, Leucovorin and Oxaliplatin +/- bevacizumab) Low risk (observation)</td>
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### GU

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<tr>
<td>Prostate, Stage D2</td>
<td>CALGB 9594</td>
<td>8663</td>
<td>Intermittent vs continuous combined androgen deprivation</td>
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<tr>
<td>Renal Cell, adjuvant</td>
<td>CTSU E-2805</td>
<td>8869</td>
<td>May be registered pre or post-surgery. T1b -T4, N0-2: Sunitinib vs. sorafenib vs placebo</td>
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### LUNG

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<tr>
<td>NSCL Early Stages</td>
<td>E 1505</td>
<td>8937</td>
<td>Stage IB-IIIA NSCLC chemo +/- bevacizumab</td>
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<tr>
<td>NSCLC Surgical</td>
<td>CALGB 140503</td>
<td>8975</td>
<td>Lobectomy vs. sublobar resection NSCLC &lt; 2 cm</td>
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### HEMATOLOGY STUDIES

#### LEUKEMIA

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<tr>
<td>MDS</td>
<td>CALGB 10105</td>
<td>8677</td>
<td>Primary or secondary MDS: Oral VEGF TKI (PTK787/ZK222584) (suspended)</td>
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#### LYMPHOMA

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<td>NHL, untreated</td>
<td>CALGB 50303</td>
<td>8883</td>
<td>Stage II/III/IV diffuse large B-cell: R-CHOP vs. dose adjusted EPOCH-R</td>
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#### PHARM SPONSORED

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<td>MDS</td>
<td>Alexion</td>
<td>8810</td>
<td>Examination of PNH, by Level of CD59 on Red and white blood cells, in bone marrow failure syndromes (EXPLORE)</td>
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<tr>
<td>Paroxysmal Nocturnal Hemoglobinuria</td>
<td>Alexion</td>
<td>8726</td>
<td>PNH Registry</td>
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<tr>
<td>ITP</td>
<td>Grifols</td>
<td>9004</td>
<td>To assess the safety and the efficacy of a new intravenous immune globulin (IGIV31 Grifols 10%) in patients with idiopathic (immune) thrombocytopenic purpura.</td>
</tr>
<tr>
<td>NSCL</td>
<td>Eli Lilly</td>
<td>8893</td>
<td>Non-small Cell Lung Cancer: The impact of Ethnic Origin on Patients being Treated Second Line with Pemetrexed</td>
</tr>
<tr>
<td>Blood-based Assay</td>
<td>BioTheme</td>
<td>8895</td>
<td>A Blood-based Diagnostic Assay for Human Cancers</td>
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The Cancer Registry is an integral component of Cleveland Clinic Florida’s Cancer Program. The registry collects, analyzes and reports cancer-related data to the Florida Cancer Data System and the National Cancer Database. The Cancer Registry maintains data on all cancer patients seen since January 1, 2004 including, but not limited to demographic information, diagnostic findings, histology, stage of disease, type of treatment and survival information. The Registry also monitors follow-up of our patients through a lifetime tracking record.

In 2007, 709 patients were diagnosed and/or received initial treatment at Cleveland Clinic Florida. The top five primary sites include prostate, rectum, lung and bronchus, colon and breast. The following figure compares the percentage of cases at Cleveland Clinic Florida to the rest of Florida, as well as the United States.

Weekly Cancer Conferences are held to encourage multidisciplinary discussion of diagnostic and treatment recommendations, as well as provide education to physicians and other staff on the latest site-specific treatment guidelines. Cases are selected for presentation on the basis of complexity, unusual manifestation of the disease, or special interest. In 2007, a total of 70 cases were presented at Cancer Conference, representing 10% of our total cases.
Lung Cancer – Radiation options and new technology

Radiation therapy technology continues to evolve rapidly in the management of lung cancer.

Many of the patients at Cleveland Clinic Florida will receive treatment with the latest technological advances in linear accelerator development and treatment planning software, specifically with the Varian Trilogy system.

As the leading image-guided radiotherapy (IGRT) system, Trilogy marks the beginning of a new generation of cancer care. The versatile Trilogy system combines imaging and treatment technologies, and can be used to deliver the widest range of external beam radiotherapies with daily image guidance: 3D conformal radiotherapy, IMRT, stereotactic radiosurgery, fractionated stereotactic radiation therapy and intensity-modulated radiosurgery for cancer treatments.

Advanced imaging capabilities built into the system allow therapists to position patients for treatment with sub-millimeter accuracy. A respiratory gating system compensates for any tumor movement that occurs as a patient breathes. This is particularly useful for lung cancers which tend to “move up and down” with patient respiration. State-of-the-art motion management techniques allow doctors to coordinate treatment with a patient’s breathing patterns. During these treatments, patients can continue to breathe naturally, reducing stress and increasing comfort. An optical guidance system with infrared cameras continuously monitors the patient’s position to provide therapists with real-time feedback about any changes in a patient’s position. Through more precise targeting of the beam, radiotherapy can be more effective at treating disease while simultaneously reducing side effects of the treatment.

The Trilogy system includes technology for positioning the patient exactly, using images of the tumor and surrounding anatomy taken just prior to each treatment. The images are used to verify tumor position immediately before the radiation beam is switched on. This gives clinicians the ability to maximize the dose to the tumor, and minimize the dose to surrounding healthy tissue.

The Trilogy system is built around an advanced medical linear accelerator, a machine that rotates 360 degrees around the patient to deliver radiotherapy treatments from many angles. With Trilogy, we have the option to treat small lesions using stereotactic radiosurgery, which is delivered in a single treatment; or stereotactic radiotherapy, which is delivered over a few days; as well as more traditional forms of radiotherapy. Recent studies conducted by the Radiation Therapy Oncology Group (RTOG) division of the National Cancer Institute (NCI) have demonstrated the efficacy and safety of image-guided Stereotactic Radiosurgery in management of early stage lung cancers or patients with lung metastases. This is a particularly appealing technology for patients who may not be able to undergo surgery due to other medical conditions.

IMRT for lung cancer can be delivered by specially equipped linear accelerators guided by a revolutionary computer system. After a comprehensive series of tests and evaluations, each patient’s unique and complex data are programmed into the IMRT computer to create the ideal treatment plan. Computer-generated imaging of the exact location of the tumor within the patient allows the oncology team to calibrate the radiation beam therapy with an accuracy that has never before been available. The beam itself is shaped by the linear accelerators’ 120 computer-controlled “fingers” and can be directed on a 360-degree axis. The painless procedure is repeated in a series of outpatient visits, enabling patients to return to the privacy of their own homes after each treatment.

Chris Chen, MD
Radiation Oncologist
Lung Cancer 2007 Data

Lung cancer is the most common cause of cancer mortality worldwide for both men and women, causing approximately 1.2 million deaths per year. In the United States in 2007, there will be an estimated 215,000 new cases of lung cancer and 162,000 deaths. In contrast, colorectal, breast, and prostate cancers combined will be responsible for only 124,000 deaths. Around 1953, lung cancer became the most common cause of cancer deaths in men, and in 1985 it became the leading cause of cancer deaths in women. Although lung cancer deaths have begun to decline in men, the death rate in women continues to rise and almost one-half of all lung cancer deaths now occur in women. In 2007, 68 cases of lung cancer were treated at the Cleveland Clinic in Florida representing the 3rd most common cancer treated. It was the 3rd most common cancer treated in men and the second most common cancer treated in women.

Early diagnosis and treatment is essential for successful outcomes and improved survival. Unlike breast, prostate, and colorectal cancer, (reported in our previous annual cancer statistic reports), lung cancer is not a screen-worthy disease. The diagnosis of lung cancer is primarily based upon evaluation of individuals with symptoms. Unfortunately, 75 percent of patients with lung cancer present with symptoms due to advanced local or metastatic disease that is not amenable to cure. Screening for lung cancer is not widely used, since no screening test to date, (chest radiography, sputum cytology, or CT), has been shown to reduce mortality. Consequently, systematic screening with either CT or chest x-ray is not unequivocally recommended by any major professional organization. Therefore, prevention, rather than screening, is the most effective strategy for reducing the burden of lung cancer.
A number of environment and lifestyle factors have been associated with the subsequent development of lung cancer, of which cigarette smoking is the most important, responsible for approximately 90% of cases. Other factors include environmental toxins such as second-hand smoke, asbestos, ionizing radiation and polycyclic aromatic hydrocarbons, pulmonary fibrosis, HIV infection, genetic and dietary factors.

There was a bimodal distribution of the stage of our lung cancer patients at presentation. The stage IA patients by and large represented incidental findings in asymptomatic patients who received chest imaging studies for another reason. The others presenting at a late stage is more in standing with the known demographics of the presentation of lung cancer patients. The “unknown” represents patients diagnosed at our institution then subsequently staged and treated elsewhere. Adenocarcinoma was the most common histologic type of lung cancer followed by non-small cell carcinoma and squamous cell carcinoma.
Lung Cancer 2007 Data Continued

Treatment selection for patients with lung cancer is dependent on the clinical stage of the tumor and patient’s functional status. Traditionally, staging has been performed by radiographic imaging and invasive techniques, (mediastinoscopy and video-assisted thoracoscopy). The advent of newly developed endoscopic techniques has given pulmonologists access to deeper portions of the chest allowing for more complete and accurate staging. Endobronchial ultrasound, (EBUS), and endobronchial ultrasound guided biopsies are new techniques that permit pulmonologists to identify cancers and associated lymph nodes. The ultrasound probe is driven through the bronchial tree on the tip of the bronchoscope. Transbronchial biopsies can then be performed under direct real-time visualization. Cleveland Clinic in Florida was the first site in South Florida to perform this procedure. Subsequently, more than 100 EBUS and EBUS directed biopsies have been performed by members of the Department of Pulmonary Medicine over the past 2 years with 90% success. EBUS eliminates the need for invasive surgical staging 90% of the time. It can also be used in conjunction with endoscopic esophageal ultrasound, (EUS), to provide even more extensive access to thoracic and mediastinal structures and further expanding the breadth and reliability of the staging process.

Auto-fluorescence bronchoscopy is another new diagnostic technique utilized in the Department of Pulmonary Medicine at Cleveland Clinic Florida where a special light source is utilized to illuminate the airway making it possible to identify malignant and pre-malignant lesions not visible with traditional light bronchoscopy. It is one of the first modalities demonstrating efficacy in screening high-risk patients for possible pre-malignant lesions or early cancers.

Based on the assumption that a level of pulmonary impairment exists in these patients, most of whom smoked the better part of their lives, pre-operative pulmonary functional assessment is essential to predict peri-operative risk and post-operative pulmonary reserve. Surgery is recommended for patients with good pulmonary functional reserve and early stage, (I and II), lung cancers. Those with more advanced cancers are candidates for multimodal therapies. Thirty-two percent of our patients had surgery alone, 1% had radiation alone, 10% had chemotherapy alone, 27% had multimodality therapy, 6% had palliative therapy, and 24% had diagnosis alone, many of which were treated elsewhere.

Of our patients who had surgery, 50% had partial lobectomies, (wedge resections), 47% had lobectomies, and 3% had laser ablations.
Eighty-five percent of the surgical procedures for lung cancer were performed with a minimally invasive technique, (VATS or video assisted thoracoscopic surgery). Though cosmetically appealing, the real advantage to minimally invasive surgery over “open” thoracotomy lies in less post-operative pain, less adverse effect on pulmonary function, a quicker return to normal activity, shorter hospitalization, and better tolerance for adjunctive chemotherapy, which can be initiated sooner.

For patients who present with advanced lung cancer that are deemed not candidates for surgical resection, other minimally invasive techniques are available to afford palliation and improve cancer-related symptoms such as shortness of breath, wheezing, or pain. These techniques are optimally performed in conjunction with the Departments of Pulmonary Medicine and Interventional Radiology. Endo-bronchial stents can be placed to open airways and improve oxygenation. Tumor obstructing the airway can also be directly destroyed by laser and electrocautery bronchoscopy. Brachytherapy is a technique where a radiation catheter is placed into the patient’s airway affected by the cancer for direct delivery of radiation. It can be utilized in patients that have already been treated with external beam radiation. Cancers can be significantly reduced in size by destroying them with locally delivered photodynamic therapy or radiofrequency ablation. Our thoracic surgeons are also National Cancer Institute Clinical Investigators, which opens our patients to enrollment in national research protocols and experimental therapies when conventional therapies are less than effective.

As previously stated, prevention, rather than screening, is the most effective strategy for reducing the burden of lung cancer. Education regarding the risks associated with the development of lung cancer is the most effective means of prevention. In June of 2005, Cleveland Clinic in Florida went smoke-free along with the entire Cleveland Clinic Health System. In 2007, the Section of Thoracic Surgery began a unique educational program called Students Attending Thoracic Surgery, (StATS), to give local high school students a rare opportunity to see first-hand the effects of smoking on the lungs. Students are able to interact with our surgeons and then observe a lung operation. In addition to delivering a strong argument as to the consequences of smoking, students are also exposed first hand to a career in medicine.

References:
Cleveland Clinic, located in Weston and West Palm Beach, Florida, is a not-for-profit, multi-specialty, academic medical center that integrates clinical and hospital care with research and education. Cleveland Clinic has approximately 150 physicians with expertise in 35 medical centers that integrate clinical and hospital care.

About Cleveland Clinic, located in Weston and West Palm Beach, Florida.