



FLORIDA HOSPITAL
TAMPA



2015 Cancer Program Annual Report

**With Statistical Data
From 2014**



Our Mission:

*Extending the healing
ministry of Christ*

Florida Hospital Tampa is a member of Adventist Health System which is a faith-based health care organization headquartered in Altamont Springs, Florida.

Our Vision:

To elevate the health of our community through quality, innovation, and compassionate care.

Our Values:

Integrity, Compassion, Balance, Excellence, Stewardship and Teamwork



CANCER COMMITTEE CHAIRMAN'S

The Cancer Program is led by the Florida Hospital Tampa Cancer Committee and is fully accredited by the American College of Surgeon's Commission on Cancer. This multidisciplinary team of physicians and other medical professionals specialize in the diagnosis and/or treatment of cancer. In addition, the Committee oversees administrative and support services involved in the care of all cancer patients. It is the responsibility of the Cancer Committee to monitor, assess, and identify changes needed to maintain an exceptional cancer program. In 2015, the Cancer Committee met eight times to discuss yearly goals and initiatives set established along with monitoring compliance to the standards set forth by the Commission on Cancer.

In 2015, the Cancer Committee's Clinical Goal was to work on improving the support group program available to our patients. This goal was set as a result of the Cancer Patient Needs Assessment that took place in 2014 as part of our patient navigation process. A subcommittee was formed to research the support groups already established in the community and then to identify where there was still a need. After thorough review, it was felt that through the community, the majority of the patients needs would be met. A spreadsheet was compiled and distributed to the different cancer care areas as a resource for patients.

The Cancer Committee also established its 2015 Programmatic Goal; which was to pledge to join the American Cancer Society and the National Colorectal Cancer Roundtable's *80% by 2018 Colorectal Cancer Campaign*. By doing so, the Cancer Committee agreed to develop a plan to increase colorectal cancer screening rates at Florida Hospital Tampa. A subcommittee was established to move the initiative forward. The subcommittee decided to start with an employee campaign, reaching out to all employees who met the criteria for screening colonoscopies by sending mailer out to remind them to have their colonoscopies performed. The Digestive Health Physicians with Florida Hospital Physician's Group participated by offering open access colonoscopies to patient who qualified, saving patients the need for a consultation office visit and co-pay. In December of 2015, Florida Hospital Tampa was awarded an American Cancer Society Colorectal Cancer Partnership Award of \$5,000.00 to continue community outreach for their efforts in the *80% by 2018 Colorectal Cancer Campaign*.

Interdisciplinary Cancer Conferences continued to be well-attended by pathologists, radiologists, surgeons, radiation oncologists, medical oncologists and other members of the medical staff. In 2015, four site-specific cancer conferences were held each month for breast, gastrointestinal cancers, brain/central nervous system cancers and spine conference with a total of 493 patients being presented.

The Cancer Committee at Florida Hospital Tampa remains committed to excellence in patient care and continued quality improvement. As Committee Chair, I would like to thank the medical staff, administration, nursing, research, support staff and the Cancer Data Office for their dedication to our patients and the Cancer Program.

Sincerely,

Ronald Prati, Jr., M.D.

Ronald Prati, Jr. M.D.

Florida Hospital Tampa

Cancer Committee Chairman



2015 CANCER COMMITTEE MEMBERS

Physicians:

Ronald Prati, Jr, MD, Medical Director , Chair & Radiology

Harvey Greenberg, MD, CoC Liaison & Radiation Oncology

Geza Acs, MD, Pathology

Brad Bjornstad, MD, Administration

Charles Cox, MD, Surgeon

Jonathon Heath, MD, Pathology

John Koval, MD, Radiation Oncology

Cecilia Parada, MD, Pathology

David Rippe, MD, Radiology

Alexander Rosemurgy, MD, Surgeon

Sharona Ross, MD, Surgeon

Egberto Zayas, MD, Medical Oncology

Administrative and Support Staff Members

Rachel Shelton, Director of Oncology Services

Jimmie Lee Cummins, CTR, Manager, Cancer Registry

Wanda Alverio-Sarcina, Dietician

Sheri Borgia, RN, Oncology Nursing

Margie Boyer, RN, Women's Health Nurse Navigator

Brittan Collett, Marketing

Jennifer Cooper, Director of SE Center for
Digestive Diseases

Suzanne Coviello, Cancer Conference Coordinator

Samantha Dillon, Marketing

Mary Esele, ARNP, Radiation Oncology

Julia Francoeur, Women's Health & Digestive Health
Physician Business Development

Jim Gatton, Administrative Director, Outpatient Services

Deadra Griffeth, RN, MA, M.Div, Spiritual Care

Amy Janes, Manager, Radiation Oncology

Aimee Keller, Director, Imaging Services & Breast Care
Center

Paula Leonard, MSW, Case Management

Tina Levandoski, RN, Lung Patient Nurse
Navigator

Stephanie McLean, American Cancer Society

Kelly Mulkowsky, RN, Oncology Nursing

Mary Ostien, Cancer Research Coordinator &
Patient Educator

Susan Paniello, Outpatient Rehabilitation Services

Brandi Rhody, RN, Lung Patient Nurse Navigator

Michelle Robey, Marketing

Rachelle Scarfone, MSW, Case Management

Randy Slavens, CTR, Cancer Registry

Denise Smith, Manager, Breast Care Center

Kimberly Spade, RN, Oncology Nursing

Wayne Taylor, Manager, Pharmacy

Brenda Tindle, Cancer Conference Coordinator

Theresa Winsey, Breast Patient Navigator

Colorectal Cancer Screening

The American Cancer Society states that “colorectal cancer is the second leading cause of cancer death in the United States among men and women combined, yet it is one of the most preventable”. In the American Cancer Society’s Facts and Figures 2014, it was estimated that in 2014 there would be 136,830 new colon and rectal cancer diagnosed within the United States with approximately 114,560 of them being diagnosed in Florida.

Early stages of colon and rectal cancers usually do not have any symptoms, which is why the need for screening is necessary to detect these cancers in the early stages. Symptoms of colon and rectal cancer may include rectal bleeding, blood in the stool, a change in bowel habits or stool shape, decreased appetite or weight loss. National guidelines recommend that beginning at the age of 50, men and women who are at an average risk for developing colon and rectal cancers should begin screening to detect and allow for the removal of colorectal polyps that might become cancerous as well as detect cancer at an earlier stage. By diagnosing colon and rectal cancers at an earlier stage, patients experience less extensive treatments and tend to have a more successful outcome.

In 2014, colorectal cancers were the third largest population of cancer patients diagnosed and treated at Florida Hospital Tampa. A total of 91 new colon and 21 rectal cancers were diagnosed and treated with an additional 32 patients being seen with recurrence or progression of their colorectal cancer. The majority of the newly diagnosed patients had an early diagnosis thanks to the colonoscopy screening process.



Colorectal Cancer Screening

In 2015, the National Colorectal Cancer Roundtable established a national effort to get 80% of adults ages 50 and older regularly tested for colon cancer by 2018. The American Cancer Society joined this effort and invited Commission on Cancer accredited facilities to pledge to join the effort and to develop a plan to increase colorectal cancer screening rates at each facility. In January 2015, the Cancer Committee at Florida Hospital Tampa pledged to become part of this campaign. As part of the initiatives in 2015, postcards were sent out to all employees ages 50 and older reminding them to have their colonoscopies performed. In addition, postcards were sent into the community explaining the importance of early detection for colon and rectal cancers and offering a phone number to call with questions and to schedule a colonoscopy.



Shared Goal: Reaching 80% Screening for Colorectal Cancer by 2018

Dr. Yasser Saloum joined Dr. Michael Harris and Dr. Arthi Sanjeevi in the Digestive Health Center at Florida Hospital Tampa in 2015. These three physicians are board certified gastroenterologists who specialize in the management of diseases of digestive disorders including disorders and diseases of the esophagus, stomach, small bowel, pancreas, liver, gallbladder, colon and rectum. These advanced gastroenterologist have received special training in both General Gastroenterology and advanced endoscopy. The endoscopic procedures they do include colonoscopies and sigmoidoscopies used in the early detection of colon and rectal cancers. The Florida Hospital Digestive Care Center can be reached at (813)615-7028.



Dr. Yasser Saloum



Dr. Michael Harris



Dr. Arthi Sanjeevi

RADIATION ONCOLOGY

Don Lau Family Center for Cancer Care

The Florida Hospital Tampa Don Lau Family Center for Cancer Care is an established Center of Excellence that has been nationally recognized for its medical staff, cutting-edge technology, and innovation in treatment. Led by Medical Director, Dr. Harvey Greenberg, the center offers a comprehensive array of radiation therapy treatments for cancer patients. With collaboration with All Children's Hospital and the Florida Hospital Tampa Pediatric Care Center, the Don Lau Family Center for Cancer Care is one of the only programs in the Tampa Bay area to specialize in radiation oncology for pediatric patients. The center is also distinguished as a SAVI Center of Excellence for accelerated partial breast irradiation by Cianna Medical.



The Cancer Center offers:

- ◆ **Three-Dimensional Simulation and Treatment Planning:** This imaging technology uses three-dimensional information to visualize and target the cancer, as well as surrounding tissue and organs, so that an optimal treatment plan can be designed.
- ◆ **Multi-Modality Image Fusion:** Electronically incorporating data from different imaging methods such as CT, MRI, or PET, this technology provides more clinical information for treatment planning than any method alone.
- ◆ **External Beam Radiation Therapy:** External beam radiation delivers high doses of radiation to specifically target the affected cancer site and minimize the dose to surrounding normal tissue.
- ◆ **Intensity Modulated Radiation Therapy (IMRT):** With fewer side effects than standard radiation therapy, IMRT is a highly accurate radiation technology that spares normal tissue, allows for better radiation doses, and is able to treat tumors near critical organs.
- ◆ **Image-Guided Radiation Therapy (IGRT):** The most advanced form of radiation therapy available, IGRT enables doctors to precisely locate and visualize the tumor before each dose is administered. The state-of-the-art Varian Trilogy delivery system enables doctors to choose the most appropriate treatment for treating cancer in the body, head, or neck, and deliver treatments all on one machine in a single room.
- ◆ **Pediatric Radiation Oncology:** Collaborating with Johns Hopkins All Children's Hospital and the Florida Hospital Tampa Pediatric Care Center, this multidisciplinary program specializes in radiation oncology for children.
- ◆ **High Dose Rate (HDR):** HDR, or Brachytherapy, delivers higher dose radiation precisely at the site of the cancer; reducing the probability of unnecessary damage to surrounding healthy tissue. Multi-Lumen Mammosite and SAVI Brachytherapy devices provide this targeted therapy in the treatment of breast cancers; taking a patient's treatment down from six weeks to one week. Cylinder and Tandem and Ring Brachytherapy provides targeted therapy for the treatment of GYN cancers.
- ◆ **RapidArc:** This technology improves radiation dose distributions in the body while significantly shortening treatment time.
- ◆ **Stereotactic Radiosurgery and Radiotherapy:** This type of radiation therapy delivers high doses of radiation to precisely defined volumes in one to five treatments, instead of the many smaller doses given in standard radiation treatment.

BREAST CARE CENTER

At Florida Hospital Tampa

The Florida Hospital Tampa Breast Care Center is dedicated exclusively to breast care, offering a comprehensive program focusing on breast cancer prevention, early detection, treatment and recovery. The Breast Care Center is an Accredited Center of Excellence by the American College of Radiology (ACR), fully accredited in mammography, stereotactic breast biopsy, breast ultrasound, ultrasound-guided breast biopsy, breast MRI and MRI guided breast biopsy.

Services provided at the Breast Care Center include:

- ◆ 2D and 3D Digital Mammography
- ◆ Breast Ultrasound
- ◆ Breast MRI
- ◆ Genetic Testing, BRCA Analysis
- ◆ Stereotactic, Ultrasound-guided and MRI-guided biopsy
- ◆ Bone Densitometry (DEXA)
- ◆ Patient Navigation
- ◆ Multimodality Breast Cancer Conference
- ◆ Breast Cancer Support Group



In 2015, the Breast Care Center worked with Dr. Charles Cox, a local breast cancer surgeon on a pilot study of a new non-radioactive surgical guidance technology for locating non-palpable breast lesions. Instead of using the current technique of wire localization, this new surgical guidance technology uses an FDA approved electromagnetic wave reflective device which can be safely placed within the designated area of the breast. Using image guidance, the reflector can be placed up to 7 days before the planned surgery. At the time of surgery, the surgeon can then use a detection device to locate the area to be surgically removed. The outcomes of the study showed that this new surgical guidance technology is safe and effective for guiding the excision of non-palpable breast lesions.



CANCER REGISTRY

The Cancer Registry at Florida Hospital Tampa is responsible for the collection, management, analysis, and reporting of information on any patient diagnosed and/or treated for cancer (and certain benign central nervous system tumors) for four of seven Florida Hospital Tampa Division Hospitals. The Cancer Registry plays an active role in maintaining cancer program accreditation through the American College of Surgeons' Commission on Cancer for Florida Hospital Tampa.

Since 1998, using specialized software, the Cancer Registry has collected demographic, diagnostic, and treatment data on 24,528 cancer cases. The Registry provides lifelong, annual follow-up on each patient originally diagnosed and/or treated at Florida Hospital Tampa. This enables the hospital to remain in contact with its patient-base, and ensures continual monitoring of treatment outcomes and follow-up.

In 2014, a total of 1,807 new cases were added to the Cancer Registry for Florida Hospital Tampa. Of these, 1,325 were newly diagnosed cancer who underwent diagnostic work-up and/or some form of treatment at Florida Hospital Tampa. Data is routinely reported to the Florida Cancer Data Systems (Cancer Registry for the State of Florida); and is submitted annually to the National Cancer Data Base.

The Cancer Registry follows the guidelines as set forth by the American College of Surgeons' Commission on Cancer and by the Florida Cancer Data Systems. In keeping with the standards of the Commission on Cancer, The Florida Hospital Tampa Cancer Registry facilitates several multi-disciplinary Cancer Conferences monthly. The design of the Cancer Conferences is to ensure that all patient cancer treatment plans are discussed amongst the team of physicians and other healthcare providers. The Cancer Registry is currently staffed with five fulltime employees, four of whom are Certified Tumor Registrars (CTR's), For more information, please contact the Cancer Registry at (813)615-7108.

On behalf of the Cancer Data Office, I wish to thank the Administration, Physicians and support staff for all their invaluable help and support this past year.

Sincerely,

Jimmie Lee Cummins B.S. CTR



Cancer Registry Staff

Manager: Jimmie Lee Cummins, BS, CTR

Cancer Conference Coordinator: Brenda Tindle & Suzanne Coviello

Abstractors: Randy Slavens, CTR, Dolly Smith, CTR & Angela Swilley, CTR

CANCER REGISTRY QA STUDY

Monitoring Compliance to Evidence-Based Guidelines

An in-depth analysis was performed on all of the newly diagnosed colon cancers in 2014 to verify that these cases were evaluated and treated according to national evidence-based guidelines. At Florida Hospital Tampa, it had been established that the guidelines set forth by the National Comprehensive Cancer Network (NCCN) would be the treatment guidelines that would be followed. At the time of the study, 89 new colon cancer cases had been added to the Cancer Registry database for 2014. All 89 cases were reviewed by a physician from the Cancer Committee and his findings were reported back to the Cancer Committee. His findings showed that patients were being treated according to the national treatment guidelines set forth by NCCN.

Study Results

- Stage 0—colon cancers that have not grown beyond the inner lining of the colon.
 - ⇒ 31 patients
 - ⇒ No NCCN guidelines
 - ⇒ 31 Colonoscopies performed, 28 went on to surgery
- Stage I—colon cancers that have grown into the layers of the colon wall, but have not spread outside the colon wall itself.
 - ⇒ 14 patients
 - ⇒ NCCN guidelines— surgery with/without lymph node surgery
 - ⇒ 14 colonoscopies performed, 13 went on to surgery, 7 had a lymph node surgery
- Stage II—colon cancers that have grown through the wall of the colon and possibly into nearby tissue, but have not yet spread to the lymph nodes.
 - ⇒ 14 patients
 - ⇒ NCCN guidelines— surgery including lymph nodes followed by observation, chemotherapy or clinical trial
 - ⇒ 13 colonoscopies performed, 14 went on to surgery
- Stage III—colon cancers that have spread to nearby lymph nodes, but have not spread to other parts of the body.
 - ⇒ 10 patients
 - ⇒ NCCN guidelines— surgery including lymph nodes followed by observation, chemotherapy or clinical trial
 - ⇒ 8 colonoscopies performed, 10 went on to surgery, 3 received chemotherapy
- Stage IV—colon cancers that have spread from the colon to other organs or tissues.
 - ⇒ 16 patients
 - ⇒ NCCN guidelines— surgery with/without removal of metastatic site &/or, chemotherapy +/- immunotherapy
 - ⇒ 6 colonoscopies performed, 9 went on to surgery, 9 received chemotherapy, 3 received immunotherapy

Florida Hospital Tampa
2014 Site Distribution Table

PRIMARY SITE	TOTAL	CLASS		SEX		CS STAGE GROUP						
		Analytic	Non-Analytic	M	F	0	I	II	III	IV	UNK	N/A
ORAL CAVITY	42	30	12	33	9	0	1	2	5	18	10	6
LIP	0	0	0	0	0	0	0	0	0	0	0	0
TONGUE	9	6	3	6	3	0	1	0	2	5	1	0
OROPHARYNX	8	7	1	8	0	0	0	1	0	4	3	0
HYPOPHARYNX	1	1	0	1	0	0	0	0	0	0	1	0
OTHER	24	16	8	18	6	0	0	1	3	9	5	6
DIGESTIVE SYSTEM	432	326	106	255	177	47	47	107	68	94	61	8
ESOPHAGUS	26	15	11	23	3	1	5	4	2	6	8	0
STOMACH	40	31	9	22	18	1	4	9	11	11	4	0
COLON	110	91	19	58	52	32	13	14	11	23	17	0
RECTUM	33	20	13	18	15	6	4	7	6	6	4	0
ANUS/ANAL CANAL	5	4	1	1	4	0	0	1	2	0	2	0
LIVER	31	19	12	20	11	0	4	2	4	8	8	5
PANCREAS	134	105	29	74	60	4	10	52	20	31	16	1
OTHER	53	41	12	39	14	3	7	18	12	9	2	2
RESPIRATORY SYSTEM	251	181	70	116	135	1	65	21	43	85	34	2
NASAL/SINUS	2	2	0	2	0	0	0	0	0	0	0	2
LARYNX	12	9	3	10	2	0	4	2	1	2	3	0
LUNG/BRONCHUS	233	166	67	101	132	1	60	18	42	83	29	0
OTHER	4	4	0	3	1	0	1	1	0	0	2	0
BLOOD & BONE MARROW	146	52	94	77	69	0	0	0	0	0	0	146
LEUKEMIA	67	23	44	40	27	0	0	0	0	0	0	67
MULTIPLE MYELOMA	36	11	25	15	21	0	0	0	0	0	0	36
OTHER	43	18	25	22	21	0	0	0	0	0	0	43
BONE	5	4	1	4	1	0	0	0	0	3	2	0
CONNECT/SOFT TISSUE	11	6	5	7	4	0	5	0	2	0	4	0
SKIN	35	17	18	23	12	2	5	5	1	4	15	3
MELANOMA	30	16	14	19	11	2	5	5	1	4	13	0
OTHER	5	1	4	4	1	0	0	0	0	0	2	3
BREAST	470	426	44	3	467	85	201	111	41	15	15	2
FEMALE GENITAL	48	34	14	0	48	2	12	3	8	5	16	2
CERVIX UTERI	10	6	4	0	10	0	3	2	0	0	5	0
CORPUS UTERI	25	19	6	0	25	0	8	1	4	3	9	0
OVARY	9	6	3	0	9	0	1	0	4	2	2	0
VULVA	2	2	0	0	2	1	0	0	0	0	0	1
OTHER	2	1	1	0	2	1	0	0	0	0	0	1

Florida Hospital Tampa
2014 Site Distribution Table

PRIMARY SITE	TOTAL	CLASS		SEX		CS STAGE GROUP						
		Analytic	Non-Analytic	M	F	0	I	II	III	IV	UNK	N/A
MALE GENITAL	44	18	26	44	0	0	7	11	0	9	17	0
PROSTATE	41	16	25	41	0	0	5	10	0	9	17	0
TESTIS	3	2	1	3	0	0	2	1	0	0	0	0
OTHER	0	0	0	0	0	0	0	0	0	0	0	0
URINARY SYSTEM	75	52	23	51	24	9	20	4	5	17	17	3
BLADDER	32	22	10	23	9	9	7	3	1	4	8	0
KIDNEY/RENAL	42	29	13	27	15	0	13	1	4	13	8	3
OTHER	1	1	0	1	0	0	0	0	0	0	1	0
BRAIN & CNS	88	69	19	37	51	0	0	0	0	0	1	87
BRAIN (BENIGN)	5	3	2	4	1	0	0	0	0	0	0	5
BRAIN (MALIGNANT)	36	28	8	19	17	0	0	0	0	0	0	36
OTHER	47	38	9	14	33	0	0	0	0	0	0	47
ENDOCRINE	53	47	6	18	35	0	23	4	5	2	4	15
THYROID	38	35	3	10	28	0	23	4	5	2	4	0
OTHER	15	12	3	8	7	0	0	0	0	0	0	15
LYMPHATIC SYSTEM	73	36	37	43	30	0	18	5	4	19	27	0
HODGKIN'S DISEASE	12	5	7	6	6	0	2	4	1	2	3	0
NON-HODGKIN'S	61	31	30	37	24	0	16	1	3	17	24	0
UNKNOWN PRIMARY	29	23	6	13	16	0	0	0	0	0	0	29
OTHER/ILL-DEFINED	5	4	1	1	4	0	0	0	0	1	1	3
ALL SITES	1807	1325	482	725	1082	146	406	273	182	274	230	296

Class:

Analytic—a patient who was either initially diagnosed and/or received all or part of their initial course of therapy at Florida Hospital Tampa.

Non-Analytic—a patient who was diagnosed and received their entire initial course of therapy elsewhere, and presented to Florida Hospital Tampa with a recurrence or progression of their disease.

Top 5 Sites for 2014

Breast
Lung
Blood and Bone Marrow
Colorectal
Pancreas

Top Sites at Florida Hospital Tampa by Gender

Top 5 Sites for
Females in 2014

1. Breast
2. Lung
3. Colorectal
4. Pancreas
5. Thyroid

Females made up 60%
of the 2014 Patient Population.

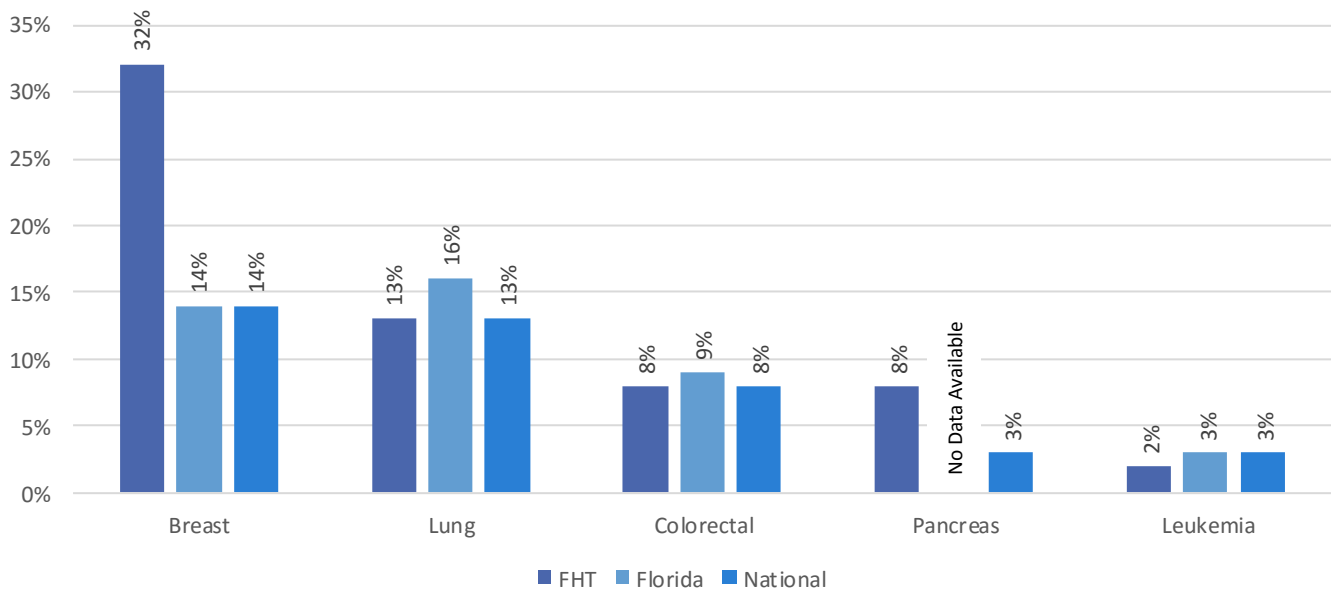
Top 5 Sites for
Males in 2014

1. Lung
2. Colorectal
3. Pancreas
4. Prostate
5. Leukemia

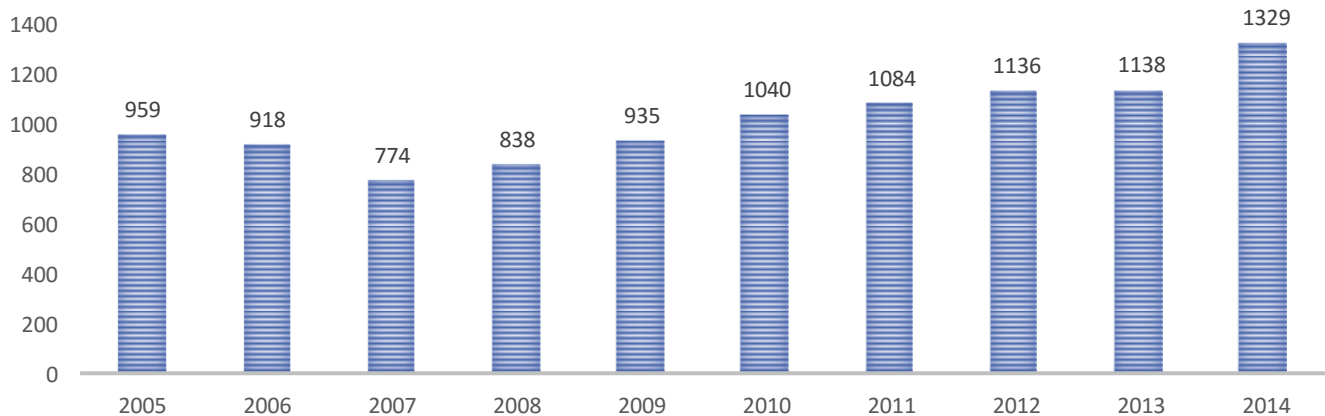
Males made up 40%
of the 2014 Patient Population.

Per the American Cancer Society's Cancer Facts & Figures 2014, an estimated 1,665,540 new cancer cases would be diagnosed in 2014. Of those, 114,560 new cases would be diagnosed in the state of Florida. The graph below shows a comparison of the top sites newly diagnosed at Florida Hospital Tampa to the estimated percent of new cases estimated for the state and nationally.

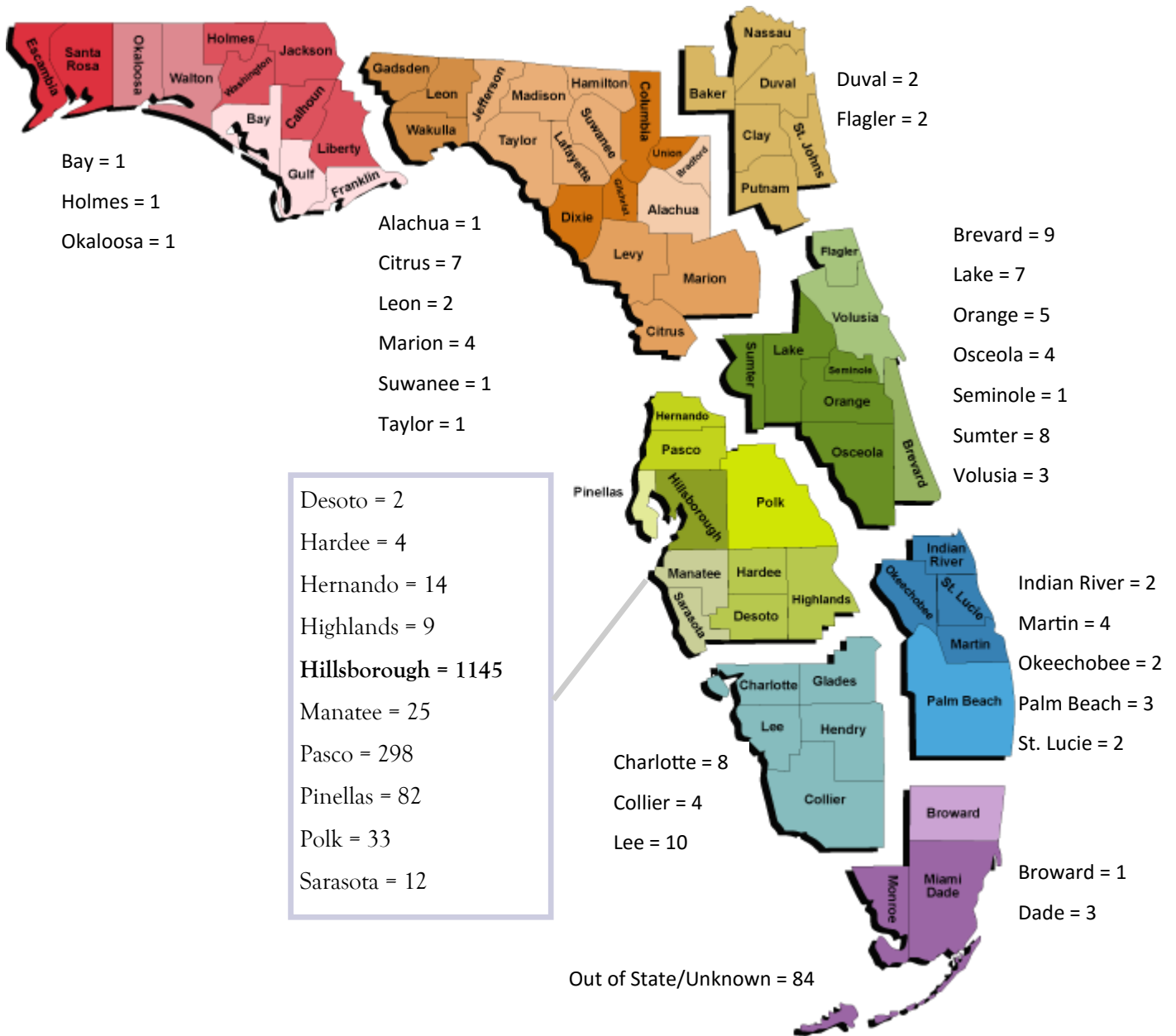
2014 Top Sites for FHT Compared to State and National Estimations



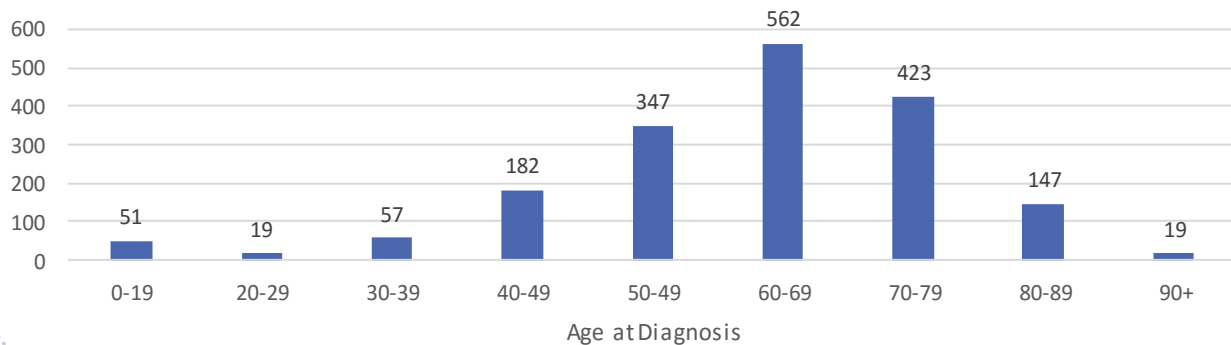
2005 - 2014 Comparison of New Cancer Cases at FHT



2014 Patient Population by County



2014 Patient Population by Age

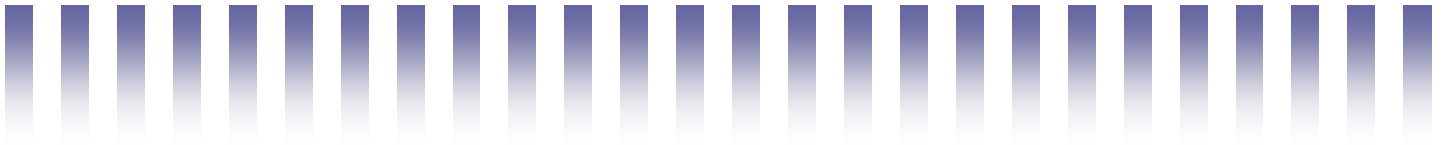


Clinical Research Studies

At Florida Hospital Tampa

Open to Enrollment in 2015

Clinical trials are research studies that explore current treatments, develop new treatments or ways to improved the quality of life for patients dealing with cancer. Patients have to meet the set criteria per the protocol and sign a consent to participate in the clinical trial. At Florida Hospital Tampa, many protocols are offered through the Digestive Health Program, the Breast Program and for pediatric patients seen in the Radiation Oncology Program. In 2014, 12% of the newly diagnosed patients seen at Florida Hospital Tampa were enrolled on a clinical trial. Forty-one (41) patients were enrolled on a treatment trial, eight (8) patients were enrolled on a diagnostic trial and 114 patients were enrolled into patient registry studies.



Pancreas and Hepatobiliary Protocols

- **Epidural vs General Anesthesia in LESS Cholecystectomies:** A prospective, comparative, controlled, safety-assessor blinded study to determine if epidural anesthesia results in less postoperative pain and faster recovery compared to patients that receive general anesthesia for LESS cholecystectomy.
- **MOM-M402-103/NINJA:** A Phase I (multiple ascending dose segment, Part A) and Phase II (randomized, repeat treatment cycle segment, Part B), two-part multicenter study to evaluate the safety and efficacy of M402 in combinations with Nab-Paclitaxel and Gemcitabine in patients with metastatic pancreatic cancer.
- **PCYC-1137-CA:** A randomized, multicenter, double-blind, placebo-controlled, Phase II/III study of the Bruton's Tyrosine Kinase inhibitor Ibrutinib in combination with Nab-Paclitaxel and Gemcitabine versus placebo in combination with Nab-Paclitaxel and Gemcitabine, in the first line treatment of patients with metastatic pancreatic adenocarcinoma.
- **Phase III TH-302 + Gemcitabine in Pancreatic Cancer:** A study to evaluate efficacy, safety & tolerability of gemcitabine in combination with TH-302 compared to gemcitabine in combination with placebo in patients with previously untreated locally advanced unresectable or metastatic pancreatic adenocarcinoma.
- **Pre-Operative Hyperbaric Oxygen Therapy in Patients Undergoing Pancreaticoduodenectomy:** A study to assess the safety, tolerability & toxicity of preoperative HBOT in patients undergoing a pancreaticoduodenal resection for premalignant and malignant tumors of the common bile duct, perampulla & duodenum.

Clinical Research Studies

At Florida Hospital Tampa

Open to Enrollment in 2015

Pancreas and Hepatobiliary Protocols (continued)

- **PV-10 in Hepatocellular Carcinoma:** A Phase I study to assess the safety, tolerability & pharmacokinetics of PV-10 chemoablation of cancer metastatic to the liver or hepatocellular carcinoma not amenable to resection or transplant.
- **Visualization in LESS Cholecystectomies:** An investigator-initiated prospective single group study to develop a grading system for laparoscopic visualization and predicting factors that affect visualization during laparoscopic cholecystectomies.
- **Neoadjuvant vs. Adjuvant Chemotherapy for Resectable Pancreatic Cancer:** An investigator-initiated comparative randomized, multicenter study for patient to either receive 3 cycles of neoadjuvant gemcitabine + nab-paclitaxel followed by pancreaticoduodenectomy followed by 3 cycles of adjuvant gemcitabine + nab-paclitaxel or pancreaticoduodenectomy followed by 6 cycles of adjuvant gemcitabine + nab-paclitaxel.
- **RenovoRx– Observational Patient Registry Study:** A multicenter, post-market, prospective, observational study following treatment with intra-arterial delivery of chemotherapeutic agents using the RenovoCath R120 Catheter and assessment of safety and performance of the RenovoCath R120 Catheter.
- **RenovoRx Phase 4 Trial:** A post-marketing dose escalation safety study of locally delivered intra-arterial Gemcitabine in unresectable adenocarcinoma of the pancreas.
- **PBI-05204 in Stage IV Metastatic Pancreatic Adenocarcinoma:** A Phase II, multi-center, single arm open label, Bayesian adaptive study designed to evaluate the safety and efficacy of PBI-05204 in patients with Stage IV metastatic pancreatic adenocarcinoma.



Clinical Research Studies

At Florida Hospital Tampa

Open to Enrollment in 2015

Breast Cancer Protocols

- **Risk Comparison Study:** A retrospective study to examine the consistency among the results from three risk stratifying assays used in breast cancer treatment: Oncotype DX®, MammaPrint®, & Mammostrat® assays.
- **MINT Study:** A study to determine the predictive power of combinations of MammaPrint® & Blueprint® for sensitivity to neo-adjuvant chemotherapy as measured by pCR.
- **Cryoablation Study:** A study to determine the rate of complete tumor ablation in patients treated with cryoablation, with complete tumor ablation defined as no remaining invasive or in-situ carcinoma present upon pathological examination of the targeted lesion.
- **XOFT IORT Study I:** A non-randomized prospective multi-center study to assess local recurrence, serious adverse events, adverse events and their severity, & cosmesis following radiation therapy treatment using the XOFT Axxent System and balloon applicators.
- **XOFT IORT ExBRT (Phase II Trial):** A study to assess the rate of ipsilateral breast tumor recurrence in subjects treated with the Xoft Axxent Electronic Brachytherapy System when used for single-fraction, intra-operative radiation therapy treatment of early stage breast cancer when compared to a historical control of whole breast irradiation (WBI) at 5 and 10 years of follow-up.
- **Real-Time Surgical Guidance System for the Location of a Biopsy Cavity During Lumpectomy:** A multi-site study to determine whether the Surgical Guidance System (SGS) can be used to successfully locate percutaneously placed markers in breast tissue & to determine whether the success of the SGS system is affected by certain breast tissue specimens.
- **Real Time Surgical Guidance:** A multi-site, in vivo pilot study of a real-time Surgical Guidance System (SGS) for the location of a non-palpable breast lesion during excision.
- **SAVI SCOUT Registration Study:** A prospective, single-arm, multi-site, clinical evaluation of the SAVI SCOUT ® Surgical Guidance System for the location of non-palpable breast lesions during excision.
- **Reversal of Cell Polarity Study:** A retrospective chart review & tissue analysis designed to test the hypothesis that the extensive presence of retraction clefts is a morphologic reflection of molecular alterations involved in tumor-stroma interactions and thus in the lymphatic metastatic spread of breast cancers.



Clinical Research Studies

At Florida Hospital Tampa

Open to Enrollment in 2015

Pediatric COG Protocols

- **COG AALL-0433**—A randomized trial of Vincristine Strategies as an intensive treatment for intermediate risk relapse of childhood B-Precursor Acute Lymphoblastic Leukemia (ALL)
- **COG ACNS-0332**—A study of Carboplatin administered concomitantly with radiation and Isotretinoin as a pro-apoptotic agent in other than average risk Medulloblastoma/PNET patients.
- **COG ACNS-0831**— A Phase III randomized trial of post-radiation chemotherapy in patient with newly diagnosed ependymoma ages 1 to 21 years.
- **COG ACNS-0927**—A Phase I/II study of Suberoylanilide Hydroxamic Acid (SAHA, Vorinostat) & local irradiation followed by maintenance SAHA in children with newly diagnosed diffuse intrinsic gliomas (DIPG).
- **COG ACNS-1123**—A Phase II trial of response-based radiation therapy for patients with localized Central Nervous System Germ Cell Tumors (CNS GCT).
- **COG ANBL-12P1**—A pilot study using Myeloablative Busulfan & Melphalan (BuMel) consolidation following induction chemotherapy for patients with newly diagnosed high-risk neuroblastoma.
- **COG AREN-0532**—A treatment for very low standard risk favorable histology Wilms Tumors.
- **COG AREN-0533**—A treatment of newly diagnosed higher risk favorable Wilms Tumors.
- **COG AREN-0534**—A treatment for patient with bilateral, multicentric, or bilaterally-predisposed unilateral Wilms Tumor.
- **COG ARST-0332**—A risk-based treatment for non-rhabdomyosarcoma soft tissue sarcoma (NRSTS) in patients <30 years of age.
- **COG ARST-1321**—A Phase II/III randomized trial of preoperative chemoradiation or preoperative radiation plus or minus Pazopanib,
- **COG RCI-BME 11-TREO**—A Phase II study of Treosulfan, Fludarabine and low dose total body irradiation (TBI) as a preparative regimen for children with AML/MDS undergoing allogeneic hematopoietic cell transplantation.



Extending *the healing ministry of Christ* to our the Community

In 2015, Florida Hospital Tampa offered the following educational seminars to the community:

- Esophageal Disorders Summit
- Hepatic Tumor Summit
- Men's Health Fair
- Olympus LESS Training Course
- Pancreatic Cancer Community Seminary
- Pancreatic CME Dinner



In 2015, Florida Hospital Tampa participated in the following community events:

- Bucs Treasure Chest 5K
- Making Strides to End Breast Cancer
- Pancreatic Action Network's Purple Stride & Patient Celebration
- Pink Army Community Initiative for Early Detection of Breast Cancer
- Relay for Life for the American Cancer Society
- Tampa Bay Lightning Pink-Out Night



In 2015, Florida Hospital Tampa offered Community Support through:

- Breast Cancer Support Group offered twice a month in the FHT Breast Care Center
- FHT sponsored Reach to Recovery Program through the American Cancer Society



