Jefferson University Hospitals

Cancer Program Site Specific Outcomes Analysis 2010

(with Statistical Data from 2009)

Ovarian Cancer Report

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Ovarian cancer is a rare but deadly cancer affecting 1 of 72 American women. In 2009, there were 21,500 cases in the US, with 14,600 deaths. In comparison, breast cancer, with 192,370 cases, had 40,170 deaths. Ovarian cancer is the 9th most common cancer in American women, but it is the 5th most common cause of cancer deaths.

Overall, the incidence of ovarian cancer has been declining by 1% per year since 1992. However, Pennsylvania has a higher than average age-adjusted rate of ovarian cancer, at 13.8 per 100,000. Pennsylvania had 1,106 reported ovarian cancers in 2007.

Risk factors for ovarian cancer include increasing age (up to age 80), white race, the cancer susceptibility genes BRCA1, BRCA2 and HNPCC, nulliparity, early menarche or late menopause, endometriosis, infertility, and polycystic ovary syndrome. Oral contraceptive use, multiparity, and tubal ligation decrease the risk. A major unmet need in ovarian cancer is the lack of effective screening for this disease.

Epithelial ovarian cancer is the most common histology. This includes the subtypes of serous (which sometimes presents as primary peritoneal carcinomatosis), mucinous, endometrioid, clear cell, and transitional. More rare types, including the Sex Cord Stromal tumors (granulosa cell, thecoma, fibroma, Sertoli cell, and Sertoli-Leydig cell) and Germ cell tumors (dysgerminoma, yolk sac, embryonal, choriocarcinoma, and teratoma) are rare and are treated differently.

Most ovarian cancers spread locally, to the opposite ovary and to the lymph nodes. More advanced cancers spread within the peritoneum, including the omentum, the pelvic sidewall, and the underside of the liver. Disease outside the peritoneal cavity is relatively rare at diagnosis.

Screening for ovarian cancer is unfortunately, neither lifesaving nor cost effective. Most studied have been tumor markers such as CA125 and transvaginal ultrasound. Unfortunately neither of these methods are sensitive or specific. A major study showed that 100 biopsies were needed to detect one cancer using these methods. Research is ongoing to find a reliable screening method for ovarian cancer.

Signs and symptoms of ovarian cancer are subtle. Women with early ovarian cancer report symptoms of abdominal pain, bloating, and urinary urgency greater than 50% of the time. Unfortunately, these symptoms are nonspecific, and ovarian cancer may not enter the differential diagnosis for many months. More advanced ovarian cancer presents with symptoms of abdominal distention due to ascites, nausea, anorexia/early satiety, or dyspnea.

Staging of Ovarian cancer is based on the International Federation of Obstetrics and Gynecology (FIGO) staging system. Stage I is disease limited to the ovary. Stage II is disease in both ovaries, or in one ovary with local lymph nodes or positive washings. The majority of patients present in stage III, which includes disease that has spread to organs inside the peritoneum, including the omentum, lymph nodes outside the pelvis, the capsule of the liver, or to the surfaces of intraperitoneal organs. Stage IV disease includes patients with disease that has spread outside the peritoneum, usually to the lungs. Staging is usually done surgically, along with radical hysterectomy.

The standard of care for surgery is maximal debulking, which leaves no disease greater than one centimeter behind. The surgeon will also remove the uterus, adnexa and regional lymph nodes unless contraindications exist. Available data show that women who have their surgery done by a trained Gynecologic Oncologist have the best survival.

Most women with stage III or higher disease are offered neoadjuvant or adjuvant chemothrapy. The NCI has issued a clinical bulletin stating that women with maximally debulked ovarian cancer should be offered intraperitoneal therapy, although controversy exists among oncologists worldwide regarding the feasibility and acceptability of this therapy. Another controversial area of this disease is the role of maintenance chemotherapy in the setting of minimal residual disease.

Radiation therapy is not commonly used in the treatment of ovarian cancer.

Jefferson's Experience

Jefferson's Oncology Data Services lists 402 ovarian, fallopian tube, and primary peritoneal cancer cases in the period 2000-2010. 81 of these patients were seen for relapsed or recurrent disease, and the remainder was diagnosed at this institution. The racial distribution was 77% white, 10% Black, 4% Asian, and 9% unknown. This contrasts with the national data showing 88% White patients nationally.

Our median age at diagnosis was 60 years, younger than the national mean of 63. Our most common histology was serous, with 47% of cases. Following were other at (26%), endometrioid (12.7%), clear cell (6%), and mucinous (5.5%). Patients with serous histology had the shortest 5 year survival (44%), followed by endometrioid (61%) and mucinous (72%). Patients over 65 had a 34% 5 year survival, compared to patients under 65, with a 61% 5 year survival.

Jefferson's five year projected survival is not significantly different by stage than the NCI SEER data.

Jefferson's clinical care revolves around a multidisciplinary service. All cases are reviewed in conference by a team of gynecologic oncologists, medical oncologists, radiologists, pathologists and nurses. Teaching is emphasized, with residents, students and fellows involved at every level of care.

All patients are screened for clinical trials, and new trials are being evaluated and added constantly. Jefferson participates in the Gynecologic Oncology Group and has opened

and accrued patients to many of its clinical trials. We also manage the Jefferson Oncology Group, which makes clinical trials available to community hospitals throughout eastern Pennsylvania.

Jefferson has a variety of advanced treatment modalities available. We offer outpatient intraperitoneal chemotherapy. Our surgeons are part of a highly regarded gynecology training program which prepares residents for specialized cancer surgery. As a high-volume center, we are committed to providing our patients with the latest treatments as soon as they are available, and to offering patients participation in clinical trials which provide them access to new agents. Our overall goal is to extend survival as much as possible, with the best quality of life, as we work toward an eventual cure of this disease.

Ovarian Cancer – Jefferson Hospital 2000–2010

Trends in Ovarian Cancer Incidence

The incidence of ovarian cancer has decreased 1.0% per year since 1992. It remains quite higher, however, in some parts of the United States. As can be seen in Figure 1, Pennsylvania ranks very high in ovarian cancer (46th) with an age-adjusted rate of 13.8 per 100,000. The neighboring states all have high incidence rates also: DE (13.8), NY (13.6) and NJ (14.1).

The number of new ovarian cases in Pennsylvania in the most recent reported year (2007) was 1,106.

Wisconsin has the highest rate (15.3) and Mississippi the lowest (10.4).

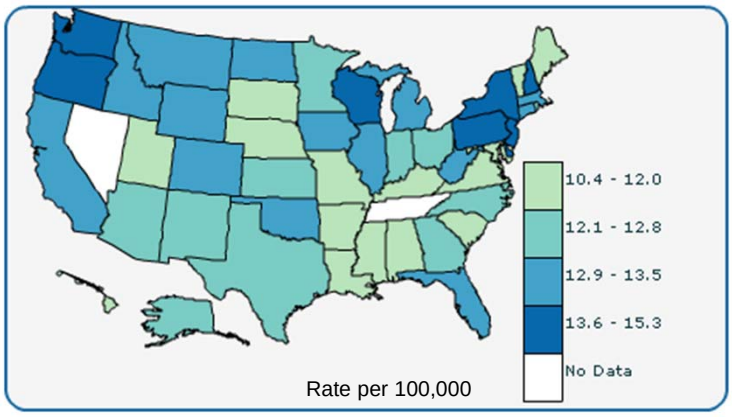


Fig 1. Comparative Ovarian Cancer Incidence by State for 2003-2007. Pennsylvania's rate was 13.8 per 100,000 - which is one of the highest rates in the country. Only 3 states reported higher rates.

Jefferson Hospital Caseload Trends – 2000 to 2010

The Oncology Data Services database contains a total of 402 new ovarian, fallopian tube, or peritoneal cancer cases covering the period of 2000 to 2010. A very small percentage (3.2%) of these cases were managed at the Methodist campus. A sizeable portion of the patient population during this period (81 patients in fact) were seen at Jefferson for management of recurrent/relapsed disease only.

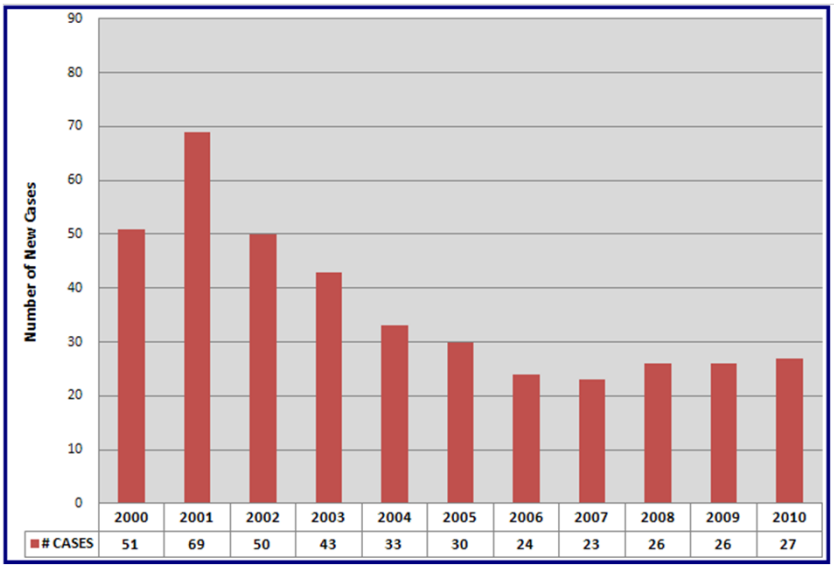


Fig 2. Ovarian / Fallopian and Peritoneal Cancer caseload trends at Jefferson, 2000 – 2010 (newly diagnosed only). Includes those treated at Methodist campus.

RACIAL DISTRIBUTION

Race	Ovary	Fallopian tube	Peritoneal	TOTAL	*NPCR (2003-2007)**
White	269	15	27	311 (77.4%)	87.7%
Black	36	4	0	40 (9.9%)	7.9%
Asian	14	0	0	14 (3.5%)	2.9%
Other/Unknown	36	0	1	37 (9.2%)	1.5%
TOTAL	355	19	28	n = 402	n = 103,338

*National Program of Cancer Registries (Ovary only)

AGE AT DIAGNOSIS

JEFFERSON (2000-2010) Age at Diagnosis				
Age Range	11 to 91			
Ovarian Age at Dx	Mean	59.7	Median	60.0

NCI SEER Median age = 63 (for 2004 - 2008)

MORPHOLOGY GROUPINGS

GROUP	Ovary	Fallopian tube	Peritoneal	TOTAL
Serous	154	14	21	189 (47.0%)
Mucinous	22	0	0	22 (5.5%)
Endometrioid	49	2	0	51 (12.7%)
Clear Cell	23	0	1	24 (6.0%)
Brenner	3	0	0	3 (0.7%)
Squamous	9	0	0	9 (2,2%)
Other	95	3	6	104 (25,9%)
TOTAL	355	19	28	402

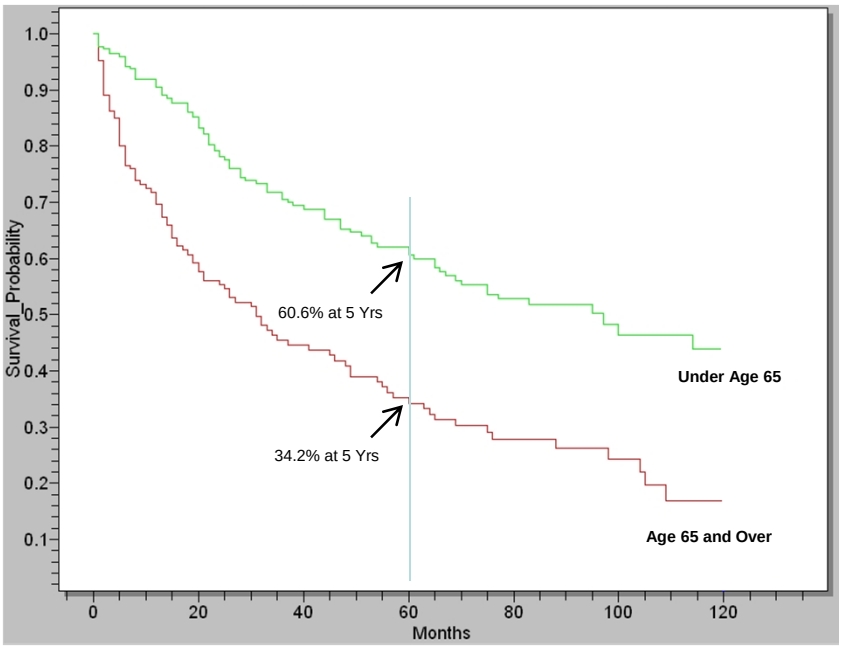
AJCC STAGE AT DIAGNOSIS

Ovarian/Fallopian Tube Cases			NCI SEER (2004-8)
AJCC	*N*	*Percent*	*Percent*
1A	43	11.5%	12.2%
1B	6	1.6%	0.9%
1C	25	6.7%	6.7%
2A	13	3.5%	1.8%
2B	7	1.9%	2.6%
2C	24	6.4%	2.6%
3A	11	2.9%	1.5%
3B	10	2.7%	2.2%
3C	126	33.7%	21.8%
4	69	18.4%	25.4%
Unstaged/NOS	40	10.7%	22.3%
Total	374	100.0%	100.0%

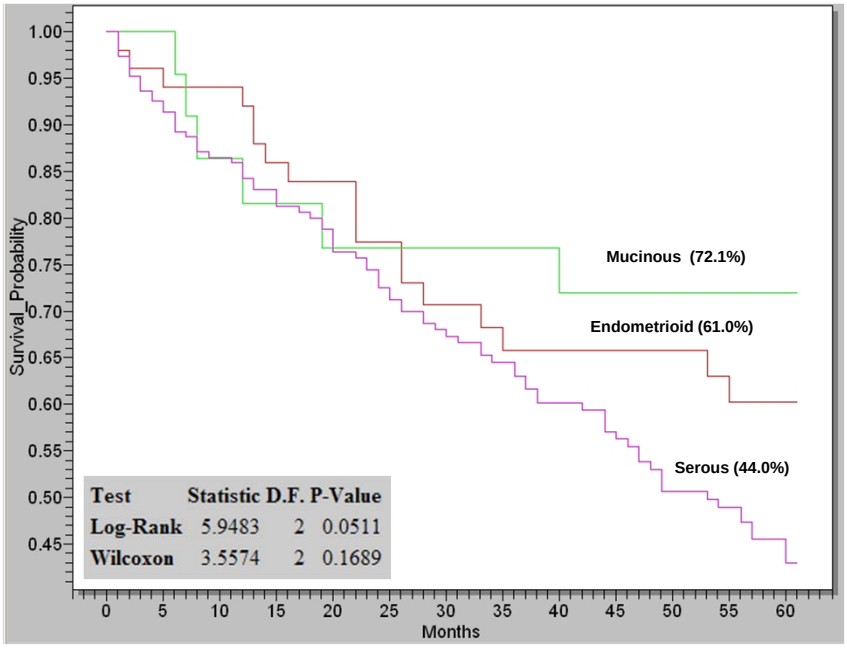
Note: No significant difference was found between racial groups. Likewise in the NCI SEER data, African American and White women had similar rates of advanced disease. In the national data, a slightly greater proportion of white women had 'localized' disease at diagnosis (19.8%) versus blacks (17.8%).

OVARIAN / FALLOPIAN TUBE
FIVE YEAR OBSERVED SURVIVAL

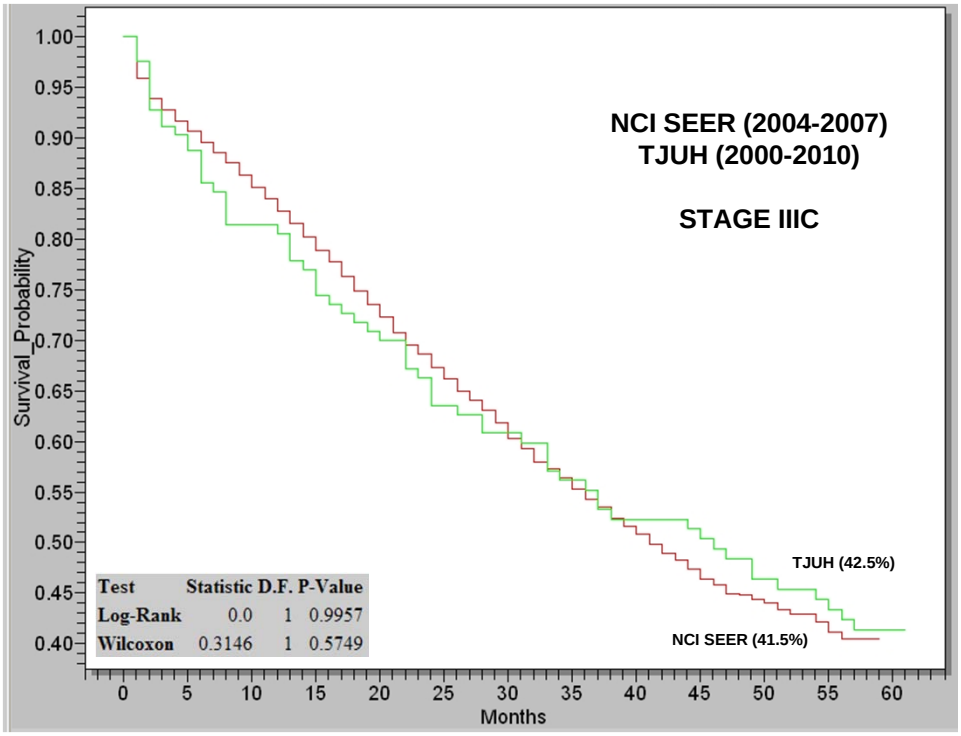
Observed Survival by Age-Group

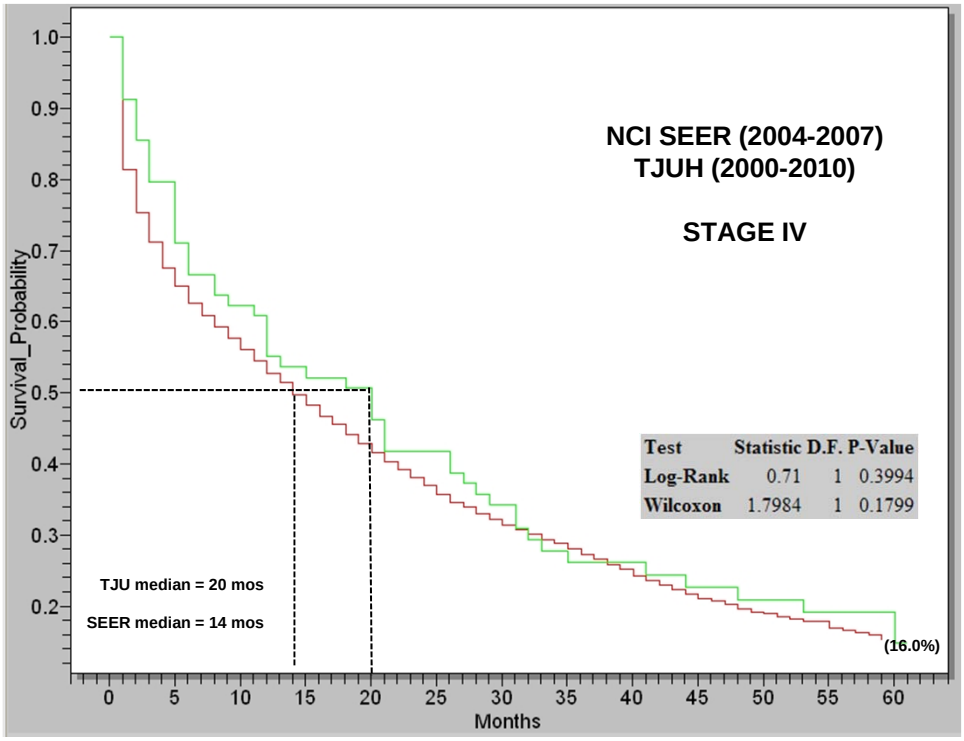


Observed Survival by Morphology

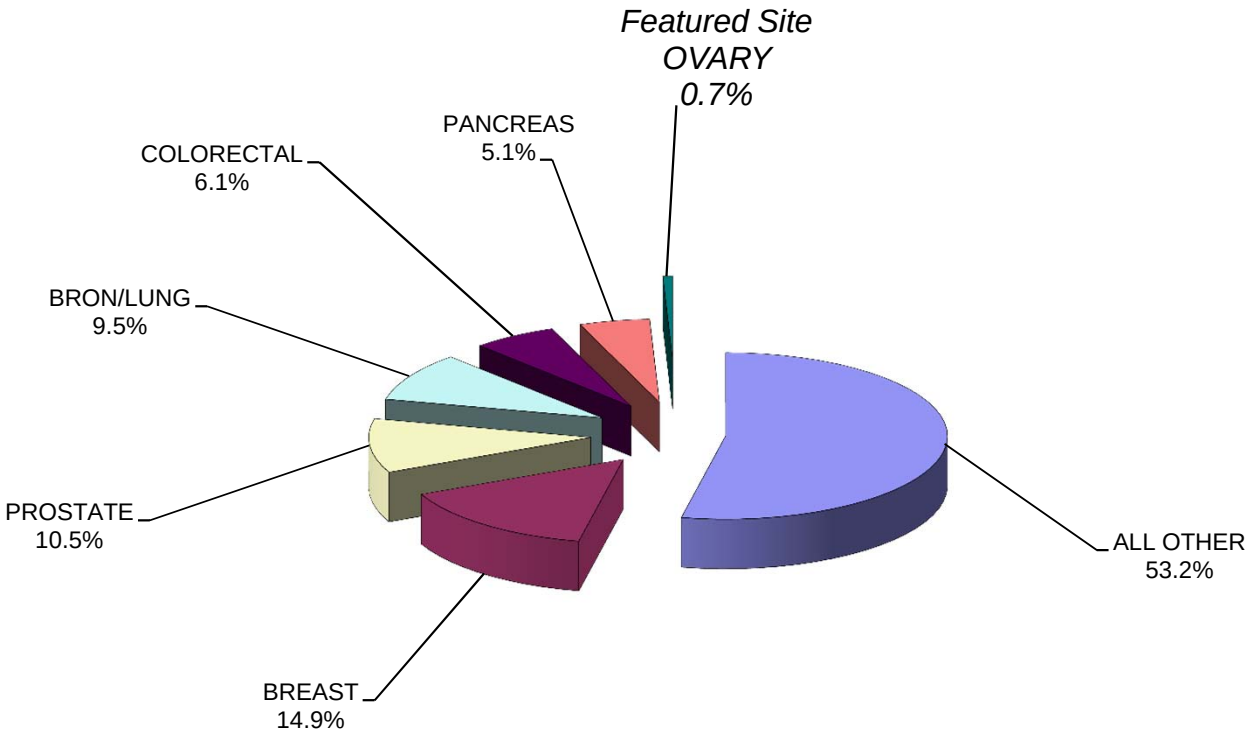


PROJECTED FIVE YEAR OBSERVED SURVIVAL
TJUH compared to NCI SEER
(Ovary & Fallopian Tube)





Thomas Jefferson University Hospital
Frequency of Cancer 2009



TJUH Site Distribution Report – AJCC Staging

Reference 2009 Analytic Cases (Newly Diagnosed – 3,244)

Primary Site	Total Cases	AJCC Stage										
		0	I	II	III	IV	Unk N/A	B/B	Male	Female	% TJUH Database *Invasive	ACS Est Fig *Invasive
Oral	140	2	14	14	21	79	9	1	101	39		
Esophagus	56	2	19	14	12	7	2	0	42	14		
Stomach	55	2	12	12	3	15	11	0	39	16		
Small Intestine	20	0	4	3	5	5	3	0	13	7		
Colorectal	**200**	**7**	**44**	**49**	**45**	**45**	**10**	**0**	**101**	**99**	***5.9%***	***9.9%***
Liver	89	0	34	7	21	10	17	0	69	20		
Pancreas	**167**	**1**	**14**	**83**	**14**	**53**	**2**	**0**	**83**	**84**	***5.1%***	***2.9%***
Larynx	61	5	21	7	5	22	1	0	44	17		
Bronchus/Lung	**309**	**0**	**65**	**19**	**69**	**141**	**14**	**1**	**134**	**175**	***9.5%***	***14.8%***
Melanoma	106	12	42	19	16	10	7	0	71	35		
Breast	**488**	**107**	**203**	**116**	**32**	**12**	**17**	**1**	**2**	**486**	***11.7%***	***13.1%***
Uterus	54	0	33	6	7	1	7	0	0	54		
Ovary	23	0	6	2	5	9	1	0	0	23		
Prostate	**342**	**0**	**0**	**278**	**37**	**14**	**13**	**0**	**342**	**0**	***10.5%***	***13.0%***
Bladder	81	34	23	11	5	6	2	0	61	20		
Kidney/Renal Pelvis	129	2	82	10	9	12	14	0	85	44		
Eye & Orbit	34	0	5	2	1	2	24	0	19	15		
Brain/CNS	259	0	0	0	0	0	259	0	121	138		
Thyroid	157	0	104	11	22	20	0	0	41	116		
Lymphoma	105	0	21	33	17	30	4	0	58	47		
Myeloma	32	0	0	0	0	0	32	0	20	12		
Leukemia	51	0	0	0	0	0	51	0	30	21		
Others	286	7	38	35	18	8	179	1	145	141		
TOTALS	**3244**	**181**	**784**	**731**	**364**	**501**	**679**	**4**	**1621**	**1623**	***42.7%***	***53.7%***

****The percentages of cancer incidence for Jefferson's most frequent cancer sites for 2009 are highlighted. They are compared to the American Cancer Society's national estimates and exclude basal and squamous cell skin cancers and in situ carcinomas, except for urinary bladder.**

ONCOLOGY DATA SERVICES REPORT

The Oncology Data Services Department is a critical element to the cancer program at Thomas Jefferson University Hospital. It's designed to coordinate the collection, management, analysis and dissemination of cancer information.

All cancer patients diagnosed and/or treated at TJUH are entered into the cancer database. The data collected includes patient demographics, medical history, diagnostic findings, cancer treatment, and lifetime follow-up. These data are handled with the utmost care and patient confidentiality is required. Data are submitted to the National Cancer Data Base (NCDB) and the Pennsylvania Cancer Registry (PCR), allowing comparative analysis with other hospitals for studies and educational purposes. These data are utilized to conduct important studies and to improve the care and treatment of cancer patients. Selective data are sent from the NCDB to the American Cancer Society Web site for public viewing.

The reference date for the cancer database is January 1, 2000. We maintain a total database of 73,772 patients. Annual lifetime follow-up of patients is conducted according to the Commission on Cancer guidelines. Currently a total of 21,185 patients are being actively followed, with a follow-up rate of 91.29% for our living patients since our reference year of 2000. For the five year reference date, we are following 12,337 living patients, with a follow-up rate of 95.24%. Both percentages of follow-up are above the required rate for Commission on Cancer approved cancer program standards.

During 2009, a total of 3,761 cancer cases were accessioned into the Registry. Of these, 3,244 were analytic (diagnosed and/or treated at Thomas Jefferson University Hospital), and 517 were non-analytic (diagnosed and/or treated elsewhere and receiving subsequent care at Jefferson). As noted in our Frequency of Cancer pie chart, the top five leading sites of cancer within our hospital for the year 2009 were: Breast, Prostate, Lung, Colorectal and Pancreas. We have compared our data to the American Cancer Society Facts and Figures 2009, to NCI SEER (Surveillance, Epidemiology, and End Results), and to the NCDB (National Cancer Data Base).

The professional staff of the Oncology Data Services Department consists of one manager (CTR), one special projects coordinator (CTR), three oncology data specialists (CTRs), two oncology data assistants, and one follow-up coordinator.

As the statistics suggest, cancer care is an important and integral component of our hospital's activity. Interdisciplinary cooperation of many departments and individuals is required to carry out the huge number of duties necessary to provide first-rate cancer care. This high level of care is evidenced by our accreditation from the American College of Surgeons. Leadership is the key element in an effective cancer program and its success depends on an effective cancer committee. Our current Cancer Committee Chairperson is Andrew E. Chapman, MD, and our Co-Chairperson is Anne L. Rosenberg, MD.

The ODS Staff encourages the use of registry data and during 2009 many requests for data were submitted to the ODS Department. The data was used for: annual statistics, follow-up information, research activities, survival analysis, quality management studies, health care planning and outcome evaluation and improvement. The Oncology Data Services Department remains committed to providing quality data to health care professionals in a timely and efficient manner. Requests for registry data should be directed to the **ODS Department at (215-955-0042)**

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