2009
Cancer Annual Report

FAMC
Fremont Area Medical Center

Cancer Care at Fremont Area Medical Center

By Stephen J. Dreyer, MD, Cancer Liaison Physician and General Surgeon

Fremont Area Medical Center (FAMC) has a Community Hospital Cancer Program that is fully accredited by the American College of Surgeons through the Commission on Cancer (CoC). In the United States, approximately 80% of the 1.3 million people diagnosed with cancer each year are treated at these designated facilities. As a member of this organization, FAMC has made a voluntary commitment to continuously improve cancer screening, and diagnostic and treatment services for patients that seek care at this facility.

Belonging to this organization also requires a period of external assessment of cancer program activities to assure that they adhere to the cancer program standards. Following a program survey in May of 2009, FAMC received a 3-year Approval Award with Commendation in three areas of program activity — Prevention and Early Detection Programs, Cancer Registry Staff Education, and Quality Improvements.

Cancer care faces a very significant challenge in the near future. A value-based competitive medical marketplace will be created that emphasizes a greater accountability for the cost and outcome of care provided to cancer patients. To prepare for this transformational change in the practice of medicine, the Commission on Cancer has radically revised the program standards and data management tools.

These revisions focus on providing care to the individual patient in a manner that can be documented in order to analyze and improve the process and achieve the best possible outcome. Healthcare facilities with a CoC Accredited Program have a distinct advantage in this new, competitive environment. Data quality will play an important role in adapting to a value based medical marketplace. A CoC Accredited healthcare facility will have access to tools that improve data accuracy, as well as access to comparative data bases, so that it can effectively plan, evaluate, and improve cancer care and generate outcomes that exceed national standards.

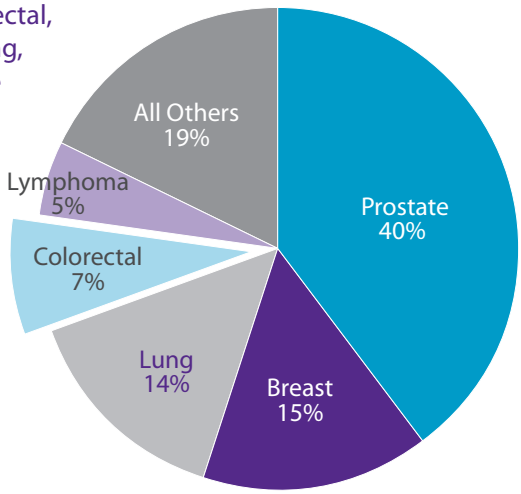
To prepare for the new challenges of greater accountability and competitiveness, the cancer program at Fremont Area Medical Center has fully implemented the revisions to the program standards in the past year. Processes have been implemented that evaluate and support the important working relationship between clinical stage, treatment planning, and outcome, as well as standards to assure the continuous monitoring of data quality and the patient care process.

Processes are in place to monitor use of the clinical stage by the initial treating physician to develop an appropriate treatment plan. The quality indicators that measure the rate of adherence to treatment guidelines are regularly reviewed to assure that they accurately reflect the level of care provided at this facility. A review of these data reports clearly indicates that patient care at FAMC consistently exceeds the national results for five of the six quality measures for colon, rectal, and breast cancer. A new step has been added to the annual audit of tumor registry data to assure that the Collaborative Stage of disease is accurate, timely, and complete, so that outcomes of a treatment process can be fully evaluated.

In conclusion, maintaining accreditation of the cancer program at Fremont Area Medical Center is very important. The standards provide a framework of structure and process to deliver comprehensive, multidisciplinary cancer care. The data standards enable healthcare providers to continuously evaluate and improve diagnostic and treatment services to achieve the best possible outcomes for the patients seeking care at this facility. A well-organized cancer program is also very important for adapting to the changing nature of cancer care and assuring patients that they will continue to receive quality care close to home.

2009 Primary Site Analysis

In 2009, there were 234 new analytic cases added to the tumor registry at Fremont Area Medical Center. The five most common sites were prostate, breast, lung, colorectal, and lymphoma. In Nebraska, the five most common sites are prostate, breast, lung, colorectal, and bladder, with lymphoma being the sixth most common site. There are fewer bladder cancers listed in the FAMC tumor registry because the majority are diagnosed and treated in a private facility.



Prostate cancer continues to have the highest percentage of new cases each year. This is due to the aggressive screening program employed through physician offices and the wide referral area that has developed for the specialized surgical services related to this disease site.

In 2009, lung cancer was the third most commonly reported site in the FAMC tumor registry. The stage distribution for these cases continues to reflect the state and national figures with the associated dismal survival rates.

In this annual report, colon cancer has been selected as a site specific study because of a quality measure regarding the management of this disease process.

2009 Goals and Objectives

CLINICAL:

1. Breast stereotactic biopsy service was initiated in the new Imaging Center at FAMC.
2. Book display was established in the medical oncology lobby to supply patients with specific information about their disease.
3. American Cancer Society (ACS) Road to Recovery program started to provide patients with transportation to their treatment sessions.
4. ACS provides new gas cards to patients who must travel greater than 50 miles for their treatment.

PROGRAMMATIC:

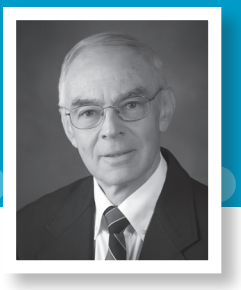
1. A process to be compliant with the newly-revised standard 4.3 (Physician Staging) was initiated.
2. The quality measures in the Cancer Program Practice Profile Reports were reviewed and edited to accurately reflect the clinical activity in this facility.
3. Pathology reports for resected specimens of colorectal and prostate cases, along with bone marrow examinations for hematologic malignancies, are reported in a synoptic format.
4. The new standard 7.2 was implemented with one educational activity focusing on clinical stage and the use of guidelines in the treatment planning process.
5. New process developed to assure accuracy of the Collaborative Stage.

COMMUNITY OUTREACH:

1. March Colon Cancer Awareness Month program to encourage colorectal screening employed new kits that were more specific.
2. Partnered with ACS and Susan G. Komen to promote breast cancer awareness in October 2009.
3. May 2009 Health Tracks theme "Combat Cancer" promoted importance of healthy lifestyles, screening, and prevention activities.
4. Partnered with Nebraska CARES and Husker Sports Network to support a multimedia statewide campaign to encourage colorectal screening.
5. I Can Cope program has been started with monthly meetings to provide patients and their families with information about their disease site.

PERFORMANCE IMPROVEMENT:

1. Stereotactic breast biopsy scheduling done on an as-needed basis, which has shortened waiting time.
2. A support group for patients enrolled in a cancer clinical trial was initiated.
3. Study of 5-year survival for non-Hodgkin's lymphoma patients treated at FAMC are similar to national results for local, regional, and distance stages of disease.
4. New processing solutions are being employed to increase lymph node harvesting in colorectal cancer resected specimens and improve the accuracy of pathologic staging.



FAMC Colorectal Cancer Report for 2009

By Stephen J. Dreyer, MD, Cancer Liaison Physician and General Surgeon

Approximately 146,970 new cases of colorectal cancer are anticipated for 2009, with 49,920 deaths expected. These figures indicate that this disease is the third most commonly diagnosed malignancy in the United States and is the second most common cause of cancer death.

A review of cancer cases entered into the tumor registry at Fremont Area Medical Center from 2004 to 2009 reveals that colon cancer is the third most commonly diagnosed malignancy in this patient population as well.

Site	Number	Percent
Prostate	545	41.2
Breast	245	18.7
Colon	129	9.8
Lung	121	9.2

Fortunately, the incidence rate for colorectal cancer has been declining for the past 20 years — from 66.3/100,000 in 1985 to 46.4/100,000 in 2005. In fact, the rate of decline has accelerated from 1998 to 2005, dropping 2.8% per year in men and 2.2% per year in women.

In conjunction with these changes, the mortality rate has also declined over this period, with a steeper rate of decline — 4.2% per year from 2002 to 2005, compared to 2% per year from 1990 to 2002 for men, and 1.8% per year for women from 1984 to 2002. The reductions in incidence and mortality rates are the result of many prevention and early detection activities, and improved treatment of the disease.

Research over the past two decades has resulted in the development of three concepts that are having an impact on the incidence and cure for colon cancer. Each of these concepts has influenced colon cancer care at this facility in a positive way.

First was the discovery of the adenoma-carcinoma sequence involving the transformation of normal colonic mucosa into proliferative and adenomatous changes followed by dysplasia and carcinoma. As a result of those studies, the colonic adenoma became recognized as a premalignant lesion.

As a corollary, the idea was developed that controlling polyp disease may influence the natural history of colon cancer. A pervasive screening and surveillance program could reduce the incidence of colon cancer and improve the survival probability for those patients who develop it by shifting the majority of cases to an early stage of disease at diagnosis.

Secondly, numerous population-based studies began to identify risk factors that could be modified to reduce the incidence of colorectal cancer. Among these are obesity, physical inactivity, diets high in red meat and fats, smoking, and inadequate consumption of fruits and vegetables.

The third concept regarding colon cancer evolved from clinical trials that demonstrated a survival advantage for patients with stage 3 disease who received chemotherapy. Since adjuvant treatment and survival have become interdependent factors, then accurate staging is a very important aspect in the treatment planning process to determine which patients would benefit from it.

In 1997, the Cancer Program at FAMC began an integrated effort to improve colon cancer care that emphasized education, screening, surveillance, and adjuvant treatment plans. The first step was to offer colon cancer screening kits at the annual health fair and other public education forums, with the help of the American Cancer Society. At that time, the availability of colonoscopy also increased as new physicians joined the Medical Staff, and health insurance plans began to offer it as a covered benefit. The result — over 900 screening colonoscopies are performed each year.

These efforts have led to significant progress in diagnosing colon cancer at an earlier stage, as well as removing numerous polyps which may ultimately reduce the incidence of this disease process in the FAMC service area. The stage at which colon cancer was diagnosed at Fremont Area Medical Center from 2000 to 2007 compares well with the national data.

The number of stage 3 and 4 cases of colon cancer indicates that a significant number of people still need to be educated and encouraged to begin the habit of regular colon cancer screening. For the past 3 years, FAMC has partnered with the American Cancer Society, Three Rivers District Health Department, and local pharmacies to promote screening during the month of March.

This program encourages people who have never been screened to begin annual fecal occult blood testing and to discuss this issue with their physician. Each year, the process for distributing, collecting, and processing the test kits has been further improved, and now produces some remarkable participation results by the public.

Treatment of Stage 3 Colon Cancer

Treatment planning that consistently adheres to nationally recognized scientifically valid guidelines is essential to achieving the best possible outcome. By 1997, numerous clinical trials conclusively demonstrated a 16% improvement in the 5-year survival rate for patients with stage 3 colon cancer who were treated with adjuvant chemotherapy. To promote increased utilization of this treatment modality, the Commission on Cancer developed the Cancer Program Profile Report. This is a web based electronic document that allows each cancer program to evaluate their rate of compliance with the treatment guideline for stage 3 colon cancer.

A review of the cases submitted by FAMC to the National Cancer Data Base reveals that 100% of stage 3 colon cancer cases seen at this facility were treated in accordance with this standard of care. For the past 5 years, the weekly Tumor Board has been prospectively discussing each colon cancer case diagnosed at FAMC. These staging and treatment planning sessions have benefited 110 patients. Unless contraindicated by other serious health matters, colon cancer patients have received care that is consistent with national treatment standards.

Data for colon cancer patients diagnosed and treated at FAMC closely reflects the national experience for stage at diagnosis. It differs significantly, however, regarding the age profile of colon cancer patients seen at this facility and survival. Compared to national aggregate data, the colon cancer patients treated at FAMC are older. This fact may contribute to the fact that the observed 5-year survival rate for colon cancer patients is slightly lower than the national figure.

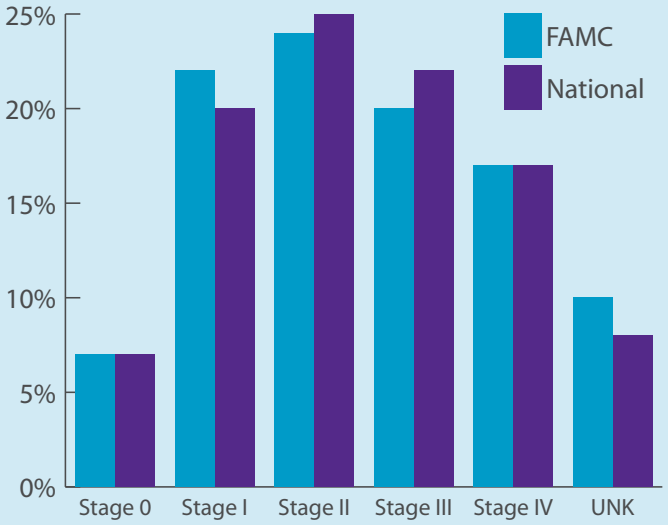
First Course of Treatment

National guidelines recommend resection as the primary form of treatment for stage 2 colon cancer unless there are some high risk features for the particular case. These factors include: less than 12 lymph nodes resected, poorly differentiated tumor, peritumoral lymphovascular invasion, perforation, or invasion of a surrounding structure.

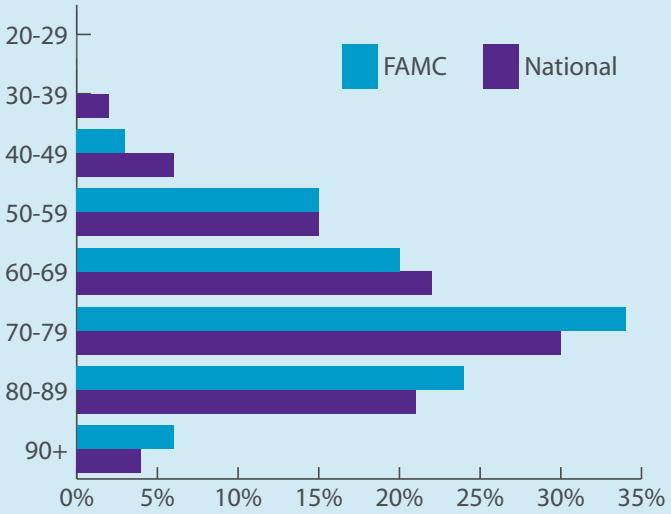
Regarding stage 2 colon cancer treated from 2000 to 2007, a significantly higher percentage of these patients received adjuvant chemotherapy at this facility than in other cancer centers. The main indication for administering adjuvant chemotherapy has been due to the limited number of lymph nodes in the resected specimens. The National Comprehensive Cancer Network guidelines require that a minimum of 12 lymph nodes be removed to insure reliable staging for treatment planning purposes. Beginning in 2008, a new technique was developed to increase the lymph node yield in each resected specimen. This improved technique will better assure that patients who could benefit from chemotherapy are identified.

Ultimately, all of the collaborative efforts to continuously improve screening, staging, and treatment planning will reduce the incidence of colon cancer in the FAMC service area and improve the lives and survival of patients that develop this disease process.

Stage at Diagnosis, 2000-2007



Age at Diagnosis, 2000-2007



Systemic Treatment for Stage IV Metastatic Colorectal Cancer

By M. Salman Haroon, MD, Chair of Cancer Committee, Director of Medical Oncology at Fremont Area Medical Center

Metastatic colorectal cancer is a stage 4 disease when the disease has metastasized to distant sites. The majority of patients with metastatic colorectal cancer are unlikely to be cured, although a small subset with visceral mets to the liver and/or lung are potentially curable with surgery. For most of the patients, treatment consists of systemic chemotherapy and is palliative in nature.

For decades, 5-Flurourocil (5-FU) was the mainstay of treatment. In the last ten years, there has been dramatic change in the systemic chemotherapy for metastatic colorectal cancer with the introduction of Irinotecan, Oxaliplatin, and targeted therapies. The targeted therapies include vascular endothelial growth factor receptor inhibitor Bevacizumab and the epidermal growth factor receptor inhibitor Cetuximab and Panitumumab.

These newer agents have been used in various combinations and with good success in not only improving disease-free survival, but also overall survival. The median survival with introduction of the newer agents in different combinations and sequencing is now approaching two years, which is a substantial improvement from the days when 5-FU was the sole agent available.

It is clear that the median overall survival with systemic chemotherapy shows meaningful improvement as compared to best supportive care. It seems from some available data that the long-term survival is also improving from the days of 5-FU plus Leucovorin.

The best way to combine and sequence these agents is not clearly established, but benefit from these therapies is clearly present when they are used at some point in time in a particular treatment sequence of specific regimens. Most patients initiate their systemic treatment earlier in the course, after the diagnosis when they are asymptomatic.

Until the development of the newer chemotherapeutic agents and targeted therapies, 5-FU and Leucovorin was the standard first-line therapy for metastatic colorectal cancer and is still available for patients who cannot tolerate more intense regimens. The available regimens include Mayo Clinic regimen for 5 consecutive days, once per month or weekly 5-FU and Leucovorin for 6 of every 8 weeks. Another option could be a short duration infusion of 5-FU/Leucovorin (DeGramont regimen). The other option is oral Capcitabin, which is given twice daily for 14 of every 21 days.

Another option is Irinotecan, which can be combined with 5-FU and Leucovorin and is a more effective regimen than 5-FU and Leucovorin alone. The triplet combination (Folfiri) is one of the standard options for first-line therapies for metastatic colorectal cancer. In the US, mostly Folfiri is used as a second-line option after failure of Oxaliplatin-based regimen Folfox. The other newer agent that was introduced successfully in the last decade and has moved into the first-line setting in combination with 5-FU and Leucovorin is Oxaliplatin (Folfox). Folfox is a standard treatment option for the first-line treatment of metastatic colorectal cancer.

The available data supports the view that efficacy of Folfox is comparable to Folfiri in first-line setting, and the choice of regimen is determined by expected toxicities of each regimen for a particular patient in context of his/her co-morbidities.

The targeted therapies include Bevacizumab, which is a vascular endothelial growth factor (VEGF) inhibitor. Inhibition of the VEGF produces a marked anti-tumor response as it blocks the blood supply, which is a necessary prerequisite for tumor growth. Bevacizumab has been successfully combined with combination chemotherapy regimens like Folfox and Folfiri and has improved outcomes. Bevacizumab is associated with potentially serious side effects, including bowel perforation, bleeding, systemic hypertension, and thromboembolic events.

The other two available and approved agents, which target the epidermal growth factor receptor (EGFR), are Cetuximab and Panitumumab. These agents are approved only for patients with wild-type K-RAS tumors. Activating mutations in K-RAS are detected in approximately 40% of metastatic colorectal cancer. K-RAS mutations are associated with poorer prognosis and are resistant to EGFR targeted therapies.

Cetuximab can be used in combination with Irinotecan for patients with

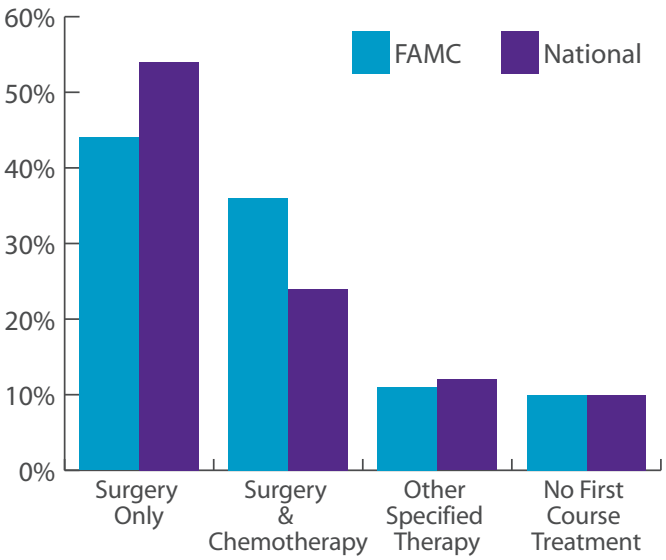
wild-type K-RAS tumors who have failed Irinotecan previously and may also be used as a single agent for patients who cannot tolerate Irinotecan. Cetuximab is given every week. The adverse effects associated with EGFR inhibitors are skin toxicity with acne-form rash, diarrhea, fatigue, nausea, and hypomagnesemia. Interestingly, there are some reports that indicate that the severity of the skin reactions correlates with increased efficacy.

The other serious side effect is infusion reaction associated with EGFR inhibitors. A benefit of Panitumumab over Cetuximab may be a lower risk of infusion reaction, particularly in high-risk geographic regions, such as the middle and southeastern US.

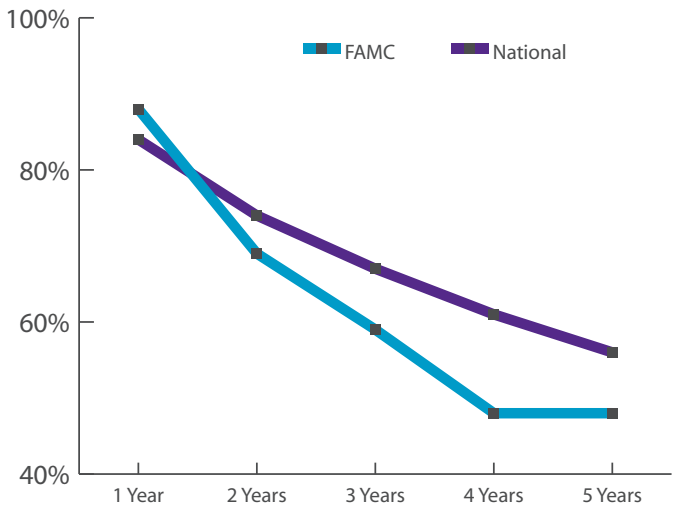
Cetuximab and Panitumumab have, more or less, similar efficacy and the two drugs may be interchangeable as a single agent in metastatic colorectal cancer.

Certainly, there has been meaningful improvement in the therapeutic options and survival of this lethal disease. Nevertheless, much more work needs to be done in the future to further improve survival, decrease toxicity, and eventually accomplish a cure and, for that, participation in ongoing clinical trials is warranted.

First Course of Treatment of Colon Cancer, 2000-2007



Observed 5 Year Survival Rate for Colon Cancer



2009 Cancer Committee

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Milo Anderson, MD, Family Practice

Stephen Dreyer, MD, FACS, General Surgery, Cancer Liaison Physician

Mark Johannsen, MD, Radiology

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Julie Martin, RTT, CMD

Brett Richmond, VP, Professional Services

Diane Roucka, CTR

Julie Samuelson, RN, MSN, Director, Performance Services

Kathe Strand, MSW, CSW

2009 Primary Site Table - Fremont Area Medical Center

Primary Site	Cases	Sex		Class of Case		Stage Distribution - Analytic Cases Only						
		M	F	Analytic	Non-Analytic	Stg 0	Stg 1	Stg 2	Stg 3	Stg 4	N/A	Unk
ORAL CAVITY & PHARYNX	3	3	0	3	0	0	1	0	0	2	0	0
Tongue	1	1	0	1	0	0	1	0	0	0	0	0
Salivary Glands	1	1	0	1	0	0	0	0	0	1	0	0
Gum & Other Mouth	1	1	0	1	0	0	0	0	0	1	0	0
DIGESTIVE SYSTEM	27	9	18	27	0	0	4	5	8	5	3	2
Esophagus	1	0	1	1	0	0	0	0	0	0	0	1
Stomach	4	1	3	4	0	0	0	1	1	0	2	0
Small Intestine	1	0	1	1	0	0	0	0	0	0	1	0
Colon Excluding Rectum	12	4	8	12	0	0	3	3	3	3	0	0
Rectum & Rectosigmoid	6	3	3	6	0	0	1	1	3	1	0	0
Anus, Anal Canal & Anorectum	1	0	1	1	0	0	0	0	1	0	0	0
Liver & Intrahepatic Bile Duct	1	1	0	1	0	0	0	0	0	1	0	0
Other Biliary	1	0	1	1	0	0	0	0	0	0	0	1
RESPIRATORY SYSTEM	35	23	12	33	2	0	5	2	10	17	0	1
Larynx	1	1	0	1	0	0	1	0	0	0	0	0
Lung & Bronchus	34	22	12	32	2	0	4	2	10	17	0	1
BONES & JOINTS	1	1	0	1	0	0	1	0	0	0	0	0
SOFT TISSUE	1	1	0	1	0	0	0	0	0	0	0	1
SKIN - Melanoma	1	1	0	1	0	0	0	1	0	0	0	0
BREAST	36	0	36	35	1	5	12	10	5	2	0	2
FEMALE GENITAL SYSTEM	3	0	3	3	0	1	2	0	0	0	0	0
Corpus & Uterus, NOS	2	0	2	2	0	1	1	0	0	0	0	0
Vulva	1	0	1	1	0	0	1	0	0	0	0	0
PROSTATE	93	93	0	87	6	0	0	64	20	3	0	0
URINARY SYSTEM	19	15	4	18	1	1	7	1	3	6	0	1
Urinary Bladder	7	4	3	6	1	1	0	1	2	2	0	1
Kidney & Renal Pelvis	11	10	1	11	0	0	6	0	1	4	0	0
Ureter	1	1	0	1	0	0	1	0	0	0	0	0
BRAIN	1	1	0	1	0	0	0	0	0	0	1	0
LYMPHOMA	12	7	5	11	1	0	4	4	1	2	0	0
Hodgkin Lymphoma	2	0	2	2	0	0	0	2	0	0	0	0
Non-Hodgkin Lymphoma	10	7	3	9	1	0	4	2	1	2	0	0
MYELOMA	4	2	2	3	1	0	0	0	0	0	4	0
LEUKEMIA	6	5	1	6	0	0	0	0	0	0	6	0
Lymphocytic Leukemia	2	2	0	2	0	0	0	0	0	0	2	0
Myeloid & Monocytic Leukemia	4	3	1	4	0	0	0	0	0	0	4	0
MISCELLANEOUS	4	1	3	4	0	0	0	0	0	0	4	0
Total	246	162	84	234	12	7	36	87	47	37	18	7

Note: Exclusions: Skin - basal & squamous. This report excludes primary sites with a count of '0'.