



2011 | Oncology Annual Report



UNITED
HOSPITAL

Allina Hospitals & Clinics

Our Annual Report Features the Work of the Gastroenterology Program

For the betterment of our oncology patients and cancer care programs, we study the past, assess the present and direct our focus to the future. United Hospital, with the support of the Oncology Service Line of Allina Hospitals & Clinics, is dedicated to creating a future in which we are charged with, and excited by, a renewed emphasis on providing an exceptional experience and the highest quality care for our patients.

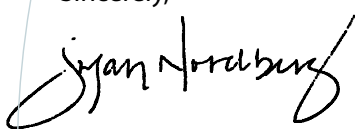
Embracing patients with cancer, whether newly diagnosed, in active treatment, remission or advanced stages of disease, is the priority of United Hospital's Gastroenterology Program and Oncology Service Line. This year's spotlight article features information on pancreatic and biliary cancers. The Gastroenterology Program is just one example of United's level of commitment to our patients, utilizing advanced imaging and treatment techniques with the overall goal of accurate, collaborative and integrative care across the patient's health care continuum. To this end, all of our cancer programs incorporate nurse coordinators prepared to draw patients into a care model that ensures ease of access, care navigation and a multidisciplinary care team.

Our oncology care team utilizes many resources to design individualized care plans that incorporate the best practice standards of care and the informed choices of the patient. Coordination of care and communication between and within the care team are seamless. Care plans are specifically tailored to address the needs of the patient prospectively, with the ability for dynamic alterations to the course of care when transitions are warranted.

United is fortunate to have great partners in cancer care. Within Allina, our associates include cancer care services through the Virginia Piper Cancer Institute; integrative health therapies and services through the Penny George Institute for Health and Healing; and cancer rehabilitation through the Sister Kenny Rehabilitation Institute. Beyond Allina, our team of specialists includes Minnesota Oncology; St. Paul Radiology; St. Paul Lung Clinic, Hospital Pathology Associates and others. Surgeon groups include: Allina Medical Clinics; Aspen Medical Group; River Falls Medical Clinic; Colon and Rectal Surgery Associates; Minnesota Gastroenterology, P.A.; Minnesota Surgical Associates, P.A.; Metro Urology; St. Paul Surgeons, Ltd.; and United Neurosurgery Associates.

The exemplary work being done in United's Gastroenterology Program and Oncology Services demonstrates our high level of commitment to our community, our oncology patients and the future of cancer care.

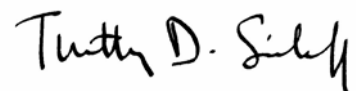
Sincerely,



Susan Nordberg, BS, RT(R)(T), CMD
Director, Oncology Services, United
and River Falls Area hospitals



Clay Ahrens, MHA
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United Hospital Cancer Care Services 2011 Oncology Annual Report

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Spotlight on Pancreatic-Biliary Cancer

By James B. Nelson, MD
Minnesota Gastroenterology, P.A.



James B. Nelson, MD
Photo courtesy of Minnesota Gastroenterology, P.A.

Cancers of the pancreas and biliary system are some of the lesser common cancers but are some of the deadliest. Pancreatic cancer ranks tenth in overall cancer frequency, with more than 43,000 new cases in the United States each year.

But it remains the fourth leading cause of cancer deaths,

accounting for 6% of all cancer-related deaths. One of the primary reasons is that early detection of pancreatic cancers occurs infrequently, with 52% of patients having distant metastases and 30% having regional spread or locally advanced, unresectable disease at time of diagnosis, leaving at most 20% with potentially resectable disease.

Biliary cancers or cholangiocarcinomas are even rarer with 2,500 new cases reported each year in the U.S., with an overall incidence of one new case per 100,000. However, higher incidences are reported in other populations including Japan, with an incidence of 5.5 cases per 100,000. It, too, is no less deadly, with only 10% felt to be surgically resectable at time of diagnosis and a mean survival of six months. Despite the dismal prognoses, advances in detection, staging, and surgical as well as other adjuvant treatments are extending and improving the quality of life in these patients.

The majority (85%) of pancreatic cancers are adenocarcinomas that arise from the ductal epithelium, with 75% developing in the head of the pancreas, 15-20% in the body, and 5-10%

in the tail. They typically spread first to regional lymph nodes followed by distant spread to the liver. The overall incidence of pancreatic cancer has remained stable in males. However, the incidence in females has increased by 0.6% per year since the mid-1990s, which correlates with increasing smoking rates in women. The median age of diagnosis is 69 in whites and 65 in African-Americans. The incidence of pancreatic cancer is also affected by race, with African-American males having an incidence of 16.2 cases per 100,000 versus white males with an incidence of 12.1 cases per 100,000. The reasons for these differences remain unclear, although dietary factors, obesity, and smoking, as well as genetic factors, may all contribute.

Smoking is the most common risk factor associated with pancreatic cancer, with an estimated two to five times greater risk of developing the disease in smokers than nonsmokers. Smokeless tobacco also increases the risk. In a number of studies, obesity, especially central obesity, is associated with a higher incidence of pancreatic cancer with a lower incidence among people with diets rich in fresh fruits and vegetables. Long-standing diabetes mellitus has also been cited as a risk factor for pancreatic cancer by the National Comprehensive Cancer Network (NCCN), along with the sudden development of adult onset diabetes mellitus in patients over 50. Chronic pancreatitis, typically due to excessive alcohol consumption in conjunction with smoking, is another significant risk factor for pancreatic cancer resulting in a 26-fold increase.

Genetic factors associated with pancreatic cancer have been extensively studied and are attributed to causing 5-10% of cases of pancreatic cancer. The molecular genetics of pancreatic cancer have been elucidated, with 80-95% having mutations in the KRAS-2 gene. Other frequently found mutations include the CDKN2, p53, and Smad4 genes. In fact, up to 10% of patients with chronic pancreatitis, a group with a higher risk for developing pancreatic cancer, have KRAS mutations. Families with BRCA-2 mutations not only have a high risk of developing breast cancer,

but also may have an increased risk of developing pancreatic cancer, with some studies showing a 7% risk by age 80. This risk may be significantly higher in BRCA-2 carriers when there is family history of pancreatic cancer. The PALB-2 gene produces a protein that interacts with BRCA-2 and can also confer an increased risk of pancreatic cancer if mutations occur. Both of these tumor suppressor genes are inherited in an autosomal dominant fashion and an FDA-approved assay (Panexia) is available to screen for these genetic alterations in high-risk patients.

Patients who might benefit from genetic screening include individuals with two or more first or second degree relatives with pancreatic cancer or those with known BRCA-2 or PALB-2 mutations in their family. Genetic testing may also be considered for: patients with pancreatic cancer and at least one first or second degree relative also with pancreatic cancer; individuals of Ashkenazi Jewish ancestry who either have pancreatic cancer or have a first degree relative with pancreatic cancer.

Cholangiocarcinomas are cancers that arise from the biliary epithelium, over 90% of which are adenocarcinomas. The most common location is at the union of the right and left hepatic ducts, the so-called Klatskin tumor. Intrahepatic and distal cholangiocarcinomas, which arise in the intrapancreatic portion of the bile duct, occur less frequently. The etiology remains unclear, although long-standing inflammation, including patients with primary sclerosing cholangitis or certain parasitic infections, may predispose the biliary epithelium to malignant transformation. As indicated earlier, the frequency varies from 2 to 6 cases per 100,000 in Western countries and up to 7.3 cases per 100,000 in Israel. Native Americans have the highest annual incidence in North America, with 6.5 cases per 100,000. The higher prevalence in Asian populations is felt to be due to endemic, chronic parasitic infections. The peak prevalence occurs in sixth through the seventh decade, with a male-to-female ratio of 1:2.5.

Diagnostic approaches in suspected biliary and pancreatic cancers have evolved over time. The current generation of CT scanners

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Table 1: 2010 Pancreatic Cases by Gender at United Hospital

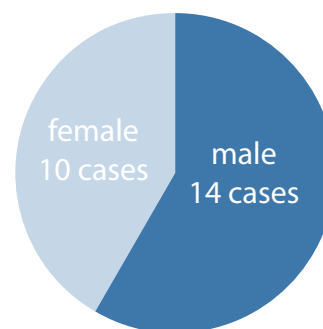


Table 2: 2010 Pancreatic Cases by Age at Diagnosis at United Hospital

Age	Male	Female
50-59	3	2
60-69	3	3
70-79	6	4
80-89	2	1
Total	14	10

Table 3: 2010 Pancreatic Cases by Stage of Diagnosis at United Hospital

Stage	Number	%
0	0	0%
1	0	0%
2	4	17%
3	3	12%
4	17	71%
Total	24	100%

*Source: United Hospital Tumor Registry Database for tables 1-5.

Table 4: 2010 Pancreatic Cases: Initial Treatment at United Hospital

Treatment	# of cases	%
Surgery	0	0%
Chemo	10	42%
Surgery/chemo	2	8%
Chemo/radiation	1	4%
Surgery/radiation/chemo	1	4%
None	10	42%

Table 5: 2010 Pancreatic Cases: Treatment by Stage at United Hospital

Treatment	Stage				
	0	1	2	3	4
Surgery	0	0	0	0	0
Chemo	0	0	0	1	9
Surgery/chemo	0	0	2	0	0
Surgery/radiation/chemo	0	0	1	0	0
Chemo/radiation	0	0	1	0	0
None	0	0	0	2	8

Table 6: Stage of Pancreas Cancers: 2008 NCDB Benchmark Comparisons—United Hospital versus Comprehensive Hospitals

Stage	United 2008	Minnesota 2008	National
0	0%	0.63%	0.49%
I	9.38%	5%	8.49%
II	18.75%	24.38%	19.74%
III	28.12%	11.87%	9.44%
IV	37.5%	51.87%	46.41%
UNK	6.25%	6.25%	15.43%
Col. Cases	32	160	12,056

©2011 National Cancer Data Bases (NCDB)/Commission on Cancer

with thin section imaging in conjunction with MRI/MRCP (magnetic resonance cholangiopancreatography) provide detailed imaging of the pancreatic parenchyma and ductal structures. ERCP (endoscopic retrograde cholangiopancreatography) can also provide imaging of pancreatic and bile duct abnormalities, including evaluation of strictures along with the ability to obtain tissue and place stents to palliate jaundice. Intraductal cholangioscopy and pancreatoscopy, using small catheters that are passed through an endoscope into the pancreatic or bile duct, permit direct visualization of the intraductal anatomy and directed biopsies. Endoscopic ultrasound (EUS) is another important diagnostic modality in the diagnostic toolbox, providing even more sensitive imaging of the pancreas and biliary tree and directed fine needle aspiration of masses.

Accurate staging of both biliary and pancreatic cancer is critical not only in determining prognosis but also determining optimum treatment. Multiple modalities are used for staging including thin slice CT, MRI/MRCP, and EUS, which together help to determine resectability. Criteria that suggest a resectable lesion includes absence of distant and regional nodal metastases and lack of vascular invasion. However, borderline resectable lesions with partial vascular effacement may still be surgical candidates or candidates for neo-adjuvant chemotherapy followed by resection. The utility of PET scans in the diagnosis and staging of pancreatic and biliary cancers remains uncertain, although current data does not suggest that it adds any additional useful information.

Surgical resection of pancreatic and biliary cancers offers the only hope for cure, but only 15-20% of patients with pancreatic cancers and only 10% of patients with cholangiocarcinomas have potentially resectable disease at time of diagnosis. Unfortunately, the prognosis for patients with pancreatic cancer remains poor even with an R0 (at least 1 mm of tumor-free tissue at the resected margin) or R1 (tumor within 1 mm of the resected margin) resections with a five-year survival of 10-25%. Nodal status significantly influences outcome with only 10% of node positive patients surviving

for five years after surgery, compared to a 25-30% five-year survival in node negative disease. Surgical morbidity and mortality from Whipple procedures (pancreaticoduodenectomy) have declined significantly over the last three to four decades, in large part due to a smaller number of highly trained surgeons performing the procedure. In a meta-analysis of 14 studies, a significant correlation was found between postoperative mortality and overall survival and high surgical volumes. In patients with focal involvement of the portal vein or superior mesenteric vein, resection and reconstruction of the vein is being performed at specialized centers, since the data suggests that these patients are no more likely to have nodal involvement or advanced histology. Greater use of adjuvant chemoradiotherapy, which typically includes gemcitabine and 5-FU based chemoradiotherapy, also has improved outcomes over time, with three-year survival rates of 45% in patients receiving adjuvant therapy versus 30% in those who do not.

Of the 40% of patients with locally advanced or borderline resectable pancreatic cancers, the optimum management remains controversial. In patients with locally advanced, unresectable disease, attempts to downstage with neo-adjuvant chemotherapy or chemoradiotherapy to improve the chances for resection have largely not shown any benefit, with median survival remaining poor at 10-12 months. On the other hand, neo-adjuvant chemotherapy or chemoradiotherapy in patients with borderline resectable disease has shown some promise. In one study of 160 patients classified as borderline resectable who completed systemic chemotherapy or chemoradiotherapy, 38% had R0/R1 resections with a five-year survival of 36%. In patients with metastatic disease, gemcitabine is more frequently given as a first-line agent. Gemcitabine has shown modest improvement in one-year survival (18% versus 2%), frequently improves symptoms including pain and weight loss, and is generally well-tolerated. Combination therapy with 5-FU, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX) has shown improved response rates and survival rates compared to gemcitabine,

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but at the expense of greater toxicity.

In general, cholangiocarcinomas have a poor prognosis with an overall five-year survival of 5-10%. As in pancreatic cancer, surgery provides the only means for a cure. Distal cholangiocarcinomas have the highest resectability rates compared to intrahepatic or perihilar lesions of 91% versus 60% and 56%, respectively. But even in potentially resectable distal lesions, tumor-free margins can only be achieved in 50% of cases. Preoperative biliary decompression via endoscopic stenting or percutaneous biliary drain placement has potential benefits including a reduction in postoperative complications such as bile leaks, but this is not universally followed.

The main prognostic factors that determine surgical outcomes are histologic margins, nodal status, and depth of invasion. Five-year survival rates for RO/R1 resections have been reported as high as 47% and up to 38% with node negative disease. Distal cholangiocarcinomas are treated with a Whipple procedure with five-year survival rates of 23-50%. Intrahepatic cholangiocarcinomas are treated by hepatic resection often with preoperative portal vein embolization used to increase the limits of a safe resection and improve the likelihood of a complete resection. Three-year survival rates from one institution of patients with mass-forming intrahepatic cholangiocarcinoma were as follows: Stage I (T1)—74%; Stage II (T2a)—48%; Stage II (T2b)—18%; Node positive—7%. Depending on the location, perihilar cancers are best treated with en bloc resection of the extrahepatic bile duct and gallbladder with up to a 10 mm margin, regional lymphadenectomy, and at times, partial hepatectomy. This aggressive approach has resulted in five-year survival rates of 50% or better in some series. Postoperative adjuvant chemoradiotherapy has been advocated by some, particularly in patients with positive margins or nodal disease. Neo-adjuvant chemoradiotherapy cannot be recommended at this time as supportive clinical trials have not yet been done.

For patients with microscopic or macroscopic residual disease following resection or locally

Table 7: Institute of Clinical Medicine, Tsukuba-Shi, Japan; Three-year Survival Rates of Patients with Mass-forming Intrahepatic Cholangiocarcinoma

Stage	%
Stage I (T1)	74%
Stage II (T2a)	48%
Stage II (T2b)	18%
Node positive	7%

Benefits of adjuvant radiotherapy after radical resection of locally advanced main hepatic duct carcinoma. Todoroki T, Ohara K, Kawamoto T, Koike N, Yoshida S, Kashiwagi H, Otsuka M, Fukao K. *Int J Radiat Oncol Biol Phys.* 2000;46(3):581.

advanced, unresectable disease, radiation therapy (RT) with or without 5-FU based chemotherapy is usually offered. Radiation therapy can take the form of external beam RT, stereotactic RT (often referred to as Cyberknife), and brachytherapy, which is done via endoscopic or percutaneous intraductal placement of thin wires of Ir-192. While the main benefit is reducing the rate of local recurrence, one small observational study along with a retrospective study suggested a survival benefit of 30-34% at five years in the RT group, versus 0-14% in the surgery-alone group in patients with microscopically positive margins. Photodynamic therapy (PDT), which involves intravenous injection of a porphyrin photosensitizer followed by endoscopic application of a specific wavelength of light to the tumor bed, has shown some promise not only in facilitating decompression of the bile duct but, in uncontrolled series, a possible survival advantage. The role of systemic chemotherapy is evolving in patients with advanced cholangiocarcinoma, with the combination of gemcitabine plus cisplatin being the most active, demonstrating both a reduction in tumor size and extending survival by 8 to 15 months. Second-line therapies include: GEMOX (gemcitabine plus oxaliplatin) and the monoclonal antibody, bevacizumab; gemcitabine plus capecitabine; and the tyrosine kinase inhibitor erlotinib plus bevacizumab. For

selected patients with unresectable intrahepatic cholangiocarcinoma, radiofrequency ablation, chemoembolization, and radioembolization using Yttrium-90 tagged glass or resin microspheres delivered via the hepatic artery, can provide local palliation.

Since the majority of patients with cholangiocarcinoma are unresectable, palliation of biliary obstruction by both percutaneous and endoscopic approaches plays a significant role in the care of these patients. For hilar obstruction, percutaneous drainage is often the approach taken as endoscopic stent placement in these patients may be less successful at achieving adequate drainage. Nonetheless, an initial endoscopic attempt at placing a stent is a reasonable first approach since there is, in general, less morbidity and unilateral drainage is usually sufficient to palliate jaundice. While there is no clear survival advantage in placing a plastic or self-expanding metal stent (SEMS), the patency rates of both uncoated and coated SEMS are significantly better than plastic stents (8 to 12 months versus 2 to 5 months), although they are more costly and at times more difficult to place endoscopically above hilar lesions. Therefore, the expected length of survival should be taken into account before deciding on stent type. There is some controversy whether coated SEMS have a higher patency rate than uncoated SEMS, but they do have a higher migration rate, a feature that permits endoscopic removal when used in patients with benign biliary strictures. Uncoated rather than coated SEMS are preferable in hilar lesions to also reduce the potential for occlusion of the cystic duct in patients with an intact gallbladder, as well as reducing possible occlusion of the contralateral main duct.

In summary, while the overall prognosis of patients with pancreatic and biliary cancers remains poor, advances in surgical approaches in conjunction with chemoradiotherapy and palliation of biliary obstruction all combine to improve patients' quality of life and, in many cases, significantly extend survival. At United Hospital, a comprehensive team of expert pancreatic-biliary surgeons, oncologists, radiologists, pathologists, and gastroenterologists work together to improve the care of this difficult group of patients.

References available on request.



2010 United Hospital Tumor Registry

Oncology Data Services is a major component of United Hospital's comprehensive Cancer Program and an important factor in the program's continued approval by the American College of Surgeons Commission on Cancer.

The primary responsibility of the Tumor Registry is to ensure that complete and accurate data is collected and maintained for all patients diagnosed and/or initially treated for cancer and certain benign tumors at United Hospital. The Tumor Registry utilizes computer software designed for the collection, management, analysis and reporting of data on these patients, who were initially diagnosed and/or treated at United Hospital. The Tumor Registry provides information to many agencies, including the Minnesota Cancer Surveillance System and the National Cancer Database.

The Tumor Registry has been in existence since 1993 and has more than 24,126 cases entered in the database. Maintaining lifelong follow-up of analytic cases is an essential role of the Registry. We currently follow 11,168 cases, with a five-year follow-up rate of 98%.

In the past year, there were 121 tumor conferences held (including weekly breast and lung tumor conferences and biweekly pancreatic/biliary and neuro-oncology case reviews) with 504 cases presented. A total of 1,915 persons attended these conferences, with an average of 16 physicians and staff in attendance and an average of four cases presented per conference.

Currently, two certified tumor registrars and a follow-up secretary maintain the data in the Tumor Registry. This information is available for use by the medical staff and other health care professionals for special studies, reports and research. The Registry staff responds to numerous requests for data from clinicians and administrative staff. This data is used for treatment planning and evaluation, outcome measurement, clinical research and cancer program strategic planning.

Specific information from Oncology Data Services is available upon request. Call 651-241-8110 or fax requests to 651-241-7878.

United Hospital Cancer Care Services

Cancer Incidence by Site – 2010*

SITE	2010
Brain/Central Nervous System (CNS)	24
Meningiomas	19
Other CNS	9
Head/Neck	17
Esophagus	5
Thyroid	48
Stomach	11
Other Digestive	11
Liver	8
Other Biliary	5
Pancreas	24
Bladder	59
Kidney	40
Testis	4
Other Urinary	3
Hematologic	52
Lymphomas	60
Melanomas	21
Other Sites	19
Unknown	4

*Includes benign borderline cases.

2010 Analytic Cases

New cases in 2010	1,334
Malignant cases	1,297
Benign/borderline	37
Male	578
Female	756

Historical Data

Total analytic cases in Registry	24,126
Total cases in follow-up	11,168
Follow-up rate	98%
Tumor Conferences	121
Cases presented at Tumor Conferences	504

Total New Cases for 2010

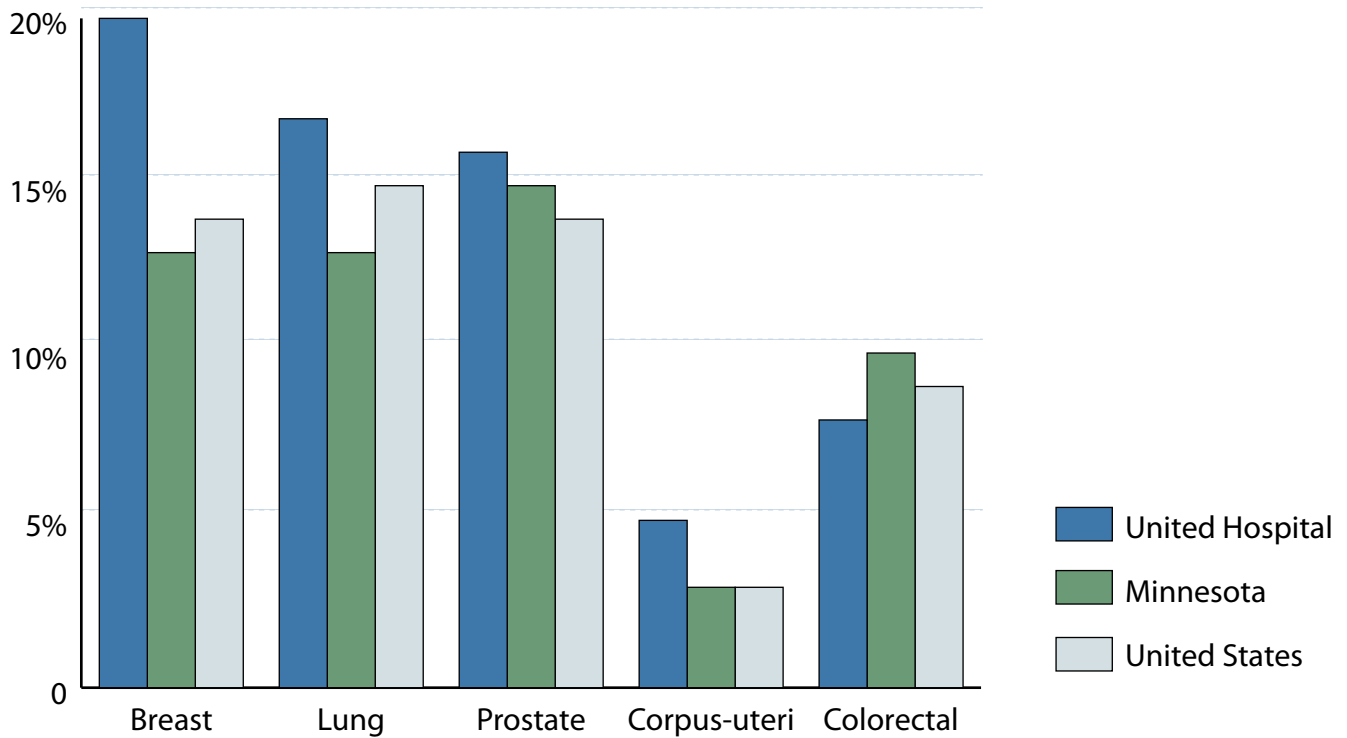
United Hospital	1,297*
Minnesota	25,080
United States	1,529,560

*Excludes benign/borderline cases (37)

United Hospital Cancer Percentage by Gender for Major Sites

Site	Total Cases	Male		Female	
		Cases	%	Cases	%
Breast	260	3	1%	257	99%
Lung	214	83	39%	131	61%
Prostate	210	210	100%	n/a	0%
Gyn	109	n/a	0%	109	100%
Colorectal	98	44	45%	54	55%

United Hospital Cancer Incidence of Major Sites Compared to Minnesota and the United States



Care Navigation: Guiding, Educating and Supporting Oncology Patients

Care coordination for cancer patients is receiving new emphasis in hospital-based cancer centers. Within Allina Hospitals & Clinics, programs to guide oncology patients through the complexities of cancer care have been initiated by the Virginia Piper Cancer Institute and will be implemented at United Hospital in the next few months.

In Allina's program, experienced registered nurses function as coordinators who offer individualized assistance to oncology patients. The nurse coordinator's goal is to embrace the cancer patient by ensuring they receive the care and services they need in a timely manner.

Ideally, the nurse coordinator becomes a trusted guide, educator, and support person throughout the patient's cancer experience. The nurse coordinator works with a multi-disciplinary care team, allowing for streamlining of referrals to specialists and reducing wait times between physician visits and procedures.

The nurse coordinator keeps open the lines of communication so the patient, family, and care team are all fully informed. This includes serving as a liaison between the cancer specialists and primary care physicians.

Educating patients about the complexities of cancer and treatment choices is a crucial aspect of the nurse coordinator's role. By improving patient education, nurse coordinators enable informed decision-making by patients. In addition, the care navigator provides access to resources important to the patient's well-being, including chaplains, family counseling, support groups, cosmetic services, mental health services, complementary therapies, palliative care and survivorship programs.

The nurse coordinator can reduce a patient's anxiety by listening to concerns and helping



prioritize and sort through vast amounts of information. This education and psychosocial support is designed to improve a patient's preparedness for treatment and ongoing care.

Nurse coordinators help to realize cost savings and efficiency improvements in the complex world of oncology. By addressing problems patients have at home, nurse coordinators may reduce emergency department visits and inappropriate hospital admissions. They can ensure efficient and effective care is delivered with vigilant symptom management, prevention of test duplication, medication management and coordination of appointments.

Nationally, care navigation and patient-centric oncology care is an emphasis in the quality standards issued by the Commission on Cancer (CoC) of the American College of Surgeons.

"United Hospital is accredited by the CoC with commendation," said Susan Nordberg, director of oncology services at United. "We are extremely pleased to offer care coordination services to our patients."

Cancer Committee Members

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Oncology Services Directory

United Hospital provides support services for cancer patients through a wide variety of resources.

Allina Home Care & Community Services Palliative Care	651-635-9173
American Cancer Society Navigator Services Support Groups/Programs	651-241-6408
The Breast Center of United Hospital	651-241-8300
Cancer Rehabilitation Services, Sister Kenny Rehabilitation Institute	651-241-8290
Clinical Research Service	651-241-8455
Inpatient Oncology Unit 2500	651-241-8100
Neuro-Oncology Services	651-241-8575
Oncology Administration	651-241-8445
Oncology Tumor Registry/Data Services	651-241-8110
Outpatient Infusion Center Services	651-241-8466
St. Paul Cancer Center Medical Oncology Radiation Oncology GYN Oncology Thoracic Oncology/Surgery	651-241-5525
St. Paul Lung Clinic	651-224-5895
United Hospital Foundation Willbrandt Breast Cancer Memorial Fund	651-241-8022
United Hospital Operator	651-241-8000
United Pain Center	651-241-7246
United Hospital Pastoral Care	651-241-8889



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