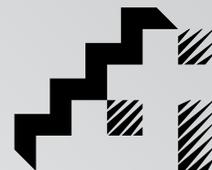


2010



Cancer Program Annual Report
and Outcome Study on
Colon Cancer

Mercy Hospital Anderson



MERCY
HEALTH PARTNERS

Annual Report on 2009 Activities

Cancer Program Summary

Mercy Hospital Anderson offers the highest quality of cancer care as evidenced by the tri-annual approval of our cancer program by the Commission on Cancer, American College of Surgeons. The Approvals Program, a voluntary component of the CoC, sets quality-of-care standards for cancer care and reviews cancer programs to ensure they conform to those standards. Approval by the CoC is given only to those facilities that have voluntarily committed to providing the highest level of quality cancer care and that undergo a rigorous evaluation process and review of their performance.

In 2009, under the leadership of the Cancer Committee, our Cancer Program was awarded for the second time the Outstanding Achievement Award (OAA). This award was established in 2004, and is designed to recognize cancer programs that strive for excellence in providing quality care to cancer patients. A facility receives the OAA following the on-site evaluation by a physician surveyor during which the facility demonstrates a Commendation level of compliance with six standards that represent the full scope of the cancer program and also receives a compliance rating for the remaining 30 standards. Achieving and exceeding compliance with the required standards of care set by the CoC, assures our patients that they will receive the best of care from diagnosis, throughout the treatment period and continuing through end of life care.

In addition to a wide range of diagnostic and treatment services, our hospital offers many programs to provide assistance to both our patients and their families as they cope with a diagnosis of cancer. Our support services include nutritional support, spiritual support, rehabilitation, palliative care, educational programs for our patients and the community, information on access to clinical trials and cancer support groups and programs, many of which are provided through participation with the American Cancer Society.

To meet the growing and changing needs of the patients and the communities we serve, our Cancer Committee continually strives for Cancer Program excellence by annually reviewing our services, performing patient care studies, and setting annual goals to improve and enhance our services.

Mercy Hospital Anderson implemented many patient care improvements, sponsored a large number of patient, community and staff educational offerings and improved many of our services last year.

2009 Cancer Program Achievements include:

- Improved Blood management based on findings of the Strategic Healthcare Report, which focuses on the appropriate utilization of blood products and improves the quality, safety, and efficiency of blood component therapy, with implementation of a new order sheet to the outpatient cancer center.
- Spiritual Care Services developed a Resource Packet to support the spiritual and emotional needs of persons newly diagnosed with cancer and persons living with cancer.
- Implemented Genetic testing and consultation in the Women's Center.
- Implemented Powerscribe for Mercy Imaging Services, a new voice recognition program for dictating imaging procedures with a significant reduction in turn around time for reports.
- Invited a cancer survivor from the community to participate in the Cancer Committee to provide patient feedback and viewpoint.

Mercy Anderson Cancer Committee

The Cancer Committee, a multi-disciplinary team of hospital employees, staff physicians and members from the American Cancer Society, meets quarterly to monitor our performance, review our available services and programs and determine what enhancements are needed to meet the needs of our cancer patients.

Our mission is to ensure that our patients, their families and our communities have access to a full-range of medical services, supportive programs and services and community outreach activities that the impact quality of life and survival. Our focus is on prevention, screening and early detection programs and quality of life services.

Mercy Hospital Anderson 2009-2010 Cancer Committee Membership

Cynthia Westermann, MD - Chair (2009)	Pathology
Jeffrey Grass, MD - Chair (2010)	Radiation Oncology
K. Ann Weichert, MD, Cancer Liaison	Medical and Radiation Oncology
Alfonso Barnes, M.D.	GYN Oncology
Karen Dyehouse, MD	Medical Oncology
Wm, Edward Richards, M.D. (2010)	GYN Oncology
Peter Ruehlman, M.D.	Medical Oncology
Joel Sorger, MD	Orthopedic Oncology
W. Victor VanGilse, MD (2009)	General Surgery
Mark Thomas, M.D. (2010)	General Surgery
Kevin Weber, M.D.	Radiology
Leslie Altmeier, RN, MSN	Women's Services
Bill Carroll, RPh	Pharmacy
Colleen DeHaan, BS, RT (R) (CT) (MR)	Radiology
Neil Fedders, OTR/L (2010)	Physical Therapy
Kelly Franer, RN, MSN, CNP	Cancer Center
Scott Gardner, BSPT, MPT (2009)	Physical Therapy
Debbie Kern	Cancer Survivor
Laura Metzler	American Cancer Society
Kay O'Rourke, BCC, M.Ed	Spiritual Care
Carol Owens, RN, BBA (2009)	Clinical Director Acute Care
Mary Parr, RN	Cancer Center
Karen Smith, RHIA, CTR	Cancer Registry
Lisa Thomas, BSN, RN	Quality and Case Management
Cristina Walter, MS, RN, CCM (2009)	Cancer Center and B3
Mardee White, RN	Palliative Care

Cancer Program Coordinators

Kathryn Weichert, MD	Quality of Registry Data
Jeff Grass, MD (2009)	Cancer Conference
Cynthia Westerman, MD (2010)	Cancer Conference
Carol Owens, RN, BBA (2009)	Community Outreach
Mary Parr, RN (2010)	Community Outreach
Kelly Franer, RN, MSN, CNP (2010)	Community Outreach
Cynthia Westerman, MD (2009)	Quality Improvement
Jeff Grass, MD (2010)	Quality Improvement

Cancer Conferences

Cancer conferences provide a format for multidisciplinary involvement in the planning of care for cancer patients. They are integral to improving the care of cancer patients and provide education to physicians and hospital staff. Consultative services and education are optimal when physician representatives from the disciplines involved in the diagnosis and treatment of cancer participate in the discussions. Patient identities are kept confidential.

Mercy Hospital Anderson offers prospective, patient-oriented and multidisciplinary Cancer Conferences, which provide free consultative services to our patients and education to the medical and hospital staff. All specialties are invited to attend and physicians from Medical Oncology, Radiation Oncology, Diagnostic Radiology, Pathology, Thoracic Surgery and General Surgery specialties are present to discuss possible treatment options for the types of cancers presented at the conferences. Treatment based on national guidelines and AJCC staging is the focus of discussions. National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology, information on open clinical trials, and cancer registry data are provided for the cancer sites presented.

Cancer Conferences are held at Mercy Hospital Anderson four times a month. The conferences are on the following days: the first Wednesday at 11:30 am, General Conference, the second Friday at 07:00 am, Breast Conference, the third Thursday at 7:00 am, Thoracic Conference, and the fourth Wednesday at 11:30 am, General Conference. These are approved by the Ohio State Medical Association for one Category 1 CME credit hour.

Cancer Registry

The Cancer Registry is a vital component of the cancer program, providing data for programmatic and administrative planning, research, and for monitoring patient outcomes. Data are collected according to the current standards of the Commission on Cancer to create a detailed cancer-focused record for all reportable tumors diagnosed and/or treated at our hospital. Each record entered into the database contains information on the diagnosis, extent of disease, treatment received, recurrence of disease and lifetime follow-up for each patient. Aggregate data are analyzed and published without patient identifiers to protect the confidentiality of each patient entered into the cancer database according to Ohio state laws and HIPAA regulations.

A Cancer Registrar performs the collection, interpretation, analysis and reporting of cancer data. The National Cancer Registrars Association defines Cancer Registrars as data management experts who collect and report cancer statistics for various healthcare agencies. Registrars work closely with physicians, administrators, researchers, and health care planners to provide support for cancer program development, ensure compliance with reporting standards, and serve as a valuable resource for cancer information with the ultimate goal of preventing and controlling cancer. The cancer registrar is involved in managing and analyzing clinical cancer information for the purpose of education, research, and outcome measurement.

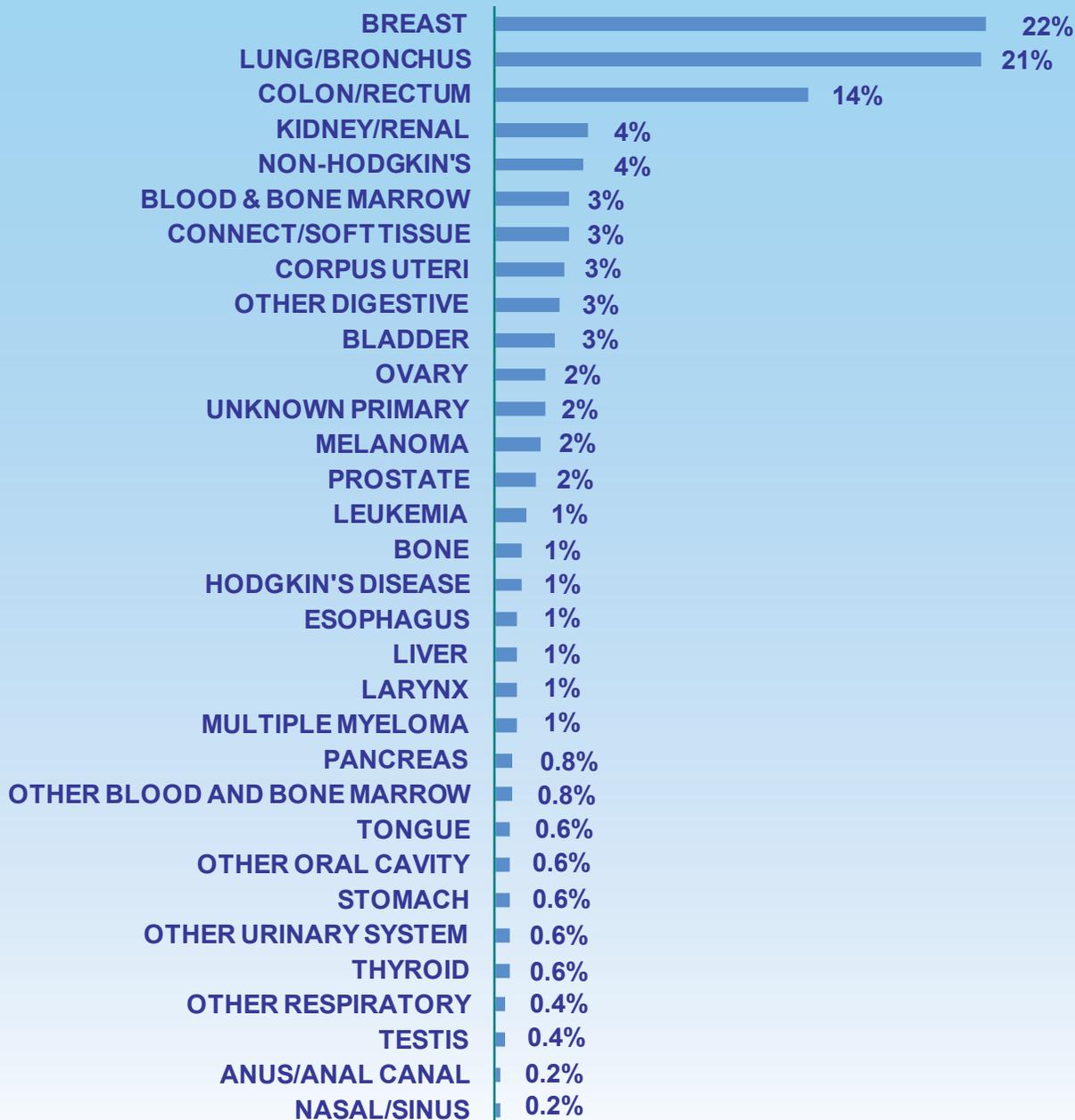
Registry data is submitted 100% error free to the National Cancer Data Base (NCDB) annually as a requirement of the Commission on Cancer for all approved cancer programs. Submission of data to the National Cancer Database provides feedback to assess the quality of patient care. This feedback enables cancer programs to compare treatment and outcomes with the regional, state and national patterns. Major differences between the facility data and the national data are reviewed in an effort to identify the reasons for these differences.

Cancer data is also submitted to the Ohio Cancer Incidence Surveillance System (OCISS). All reported data are used to support research, track trends, initiate epidemiologic studies, generate journal articles and provide data for allocation of services. The data are analyzed to identify opportunities for community cancer awareness and screening where higher stages (III-IV) of cancers are seen. This data also provides a means of identifying possible cancer clusters within the state.

2009 Cancer Data Summary and Comparisons

The total number of cases in the Mercy Hospital Anderson Cancer Registry database since the 2003 reference date is 4,409 cases. 4,015 of these cases are available for analytic studies. During 2009, a total of 521 cases were accessioned into the registry database, 488 analytic (newly diagnosed) cases and 33 non-analytic (recurrent cancer) cases. The statistics contained in this report represent only analytic cancer cases.

Mercy Hospital Anderson Percent of Newly Diagnosed 2009 Cases- 488 Analytic Cases



Top Cancer Sites in 2009

The top sites at Mercy Anderson in 2009 were breast, lung/bronchus, colorectal, kidney/renal and non-hodgkin's lymphoma.

Compared with the estimated 2009 state and national data, our incidence of breast cancer continues to be higher than Ohio and national incidence. This is likely due to having a Women's Center that offers a wide range of diagnostic tools in the detection of all stages of breast cancers. Our incidence of lung cancer continues to be higher than Ohio and national incidence. This is likely due to our having radiologists with specialized training and active thoracic surgery practices on staff. Our prostate cancer cases continue to be low. This is attributed to the fact that there has been a shift in referral patterns. Colorectal and Non-Hodgkin's lymphoma are comparable with the state and national trends.

Top Cancer Sites - 2009			
Primary Site	US	OH	MHA
Lung & Bronchus	15%	17%	21%
Prostate	13%	10%	2%
Breast	13%	12%	21%
Colorectal	10%	10%	14%
Bladder	5%	5%	3%
NHL	4%	4%	4%
Melanoma	5%	3%	2%

Estimated Figures for US/Ohio
American Cancer Society, Facts & Figures 2009

Distribution of our sites by gender revealed a similar comparison to Ohio and the U.S. as above. We have seen fewer prostate cancers and more lung cancer cases for both male and female patients. These differences are not felt to be reflective of the true incidence of these cancers in our community, but rather a reflection of the types of services available at our facility.

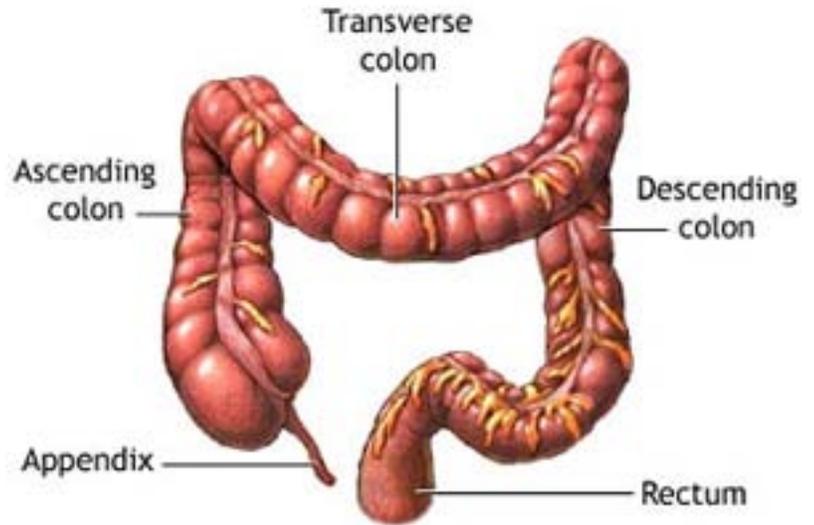
2009 Top Cancer Sites by Gender Mercy Anderson			
			
Male		Female	
Prostate		Breast	
U.S. 25%	MHA 5%	U.S. 27%	MHA 35%
Lung & Bronchus		Lung & Bronchus	
U.S. 15%	MHA 27%	U.S. 14%	MHA 18%
Colon & Rectum		Colon & Rectum	
U.S. 10%	MHA 15%	U.S. 10%	MHA 13%
Urinary Bladder		Uterine Corpus	
U.S. 7%	MHA 6%	U.S. 6%	MHA 5%
Melanoma of the Skin		Non-Hodgkin lymphoma	
U.S. 5%	MHA 3%	U.S. 4%	MHA 2%
Non-Hodgkin lymphoma		Thyroid	
U.S. 5%	MHA 6%	U.S. 4%	MHA 2%

American Cancer Society, Facts and Figures, 2009

Colon Cancer Outcome Study

Anatomy and Physiology of the Colon

The colon is a muscular tube about 5 feet long that absorbs water and salt from digested food and stores waste. It has 4 sections, the ascending colon on the right side of the lower abdomen, the transverse colon, the descending colon on the left side of the lower abdomen and the sigmoid colon, which is “S”-shaped and is located between the end of the descending colon and the rectum, the last 6 inches of the colon. Based on tumor location, part or all of one or more of these sections may be removed at surgery.



ADAM

Incidence and Mortality in the United States

Incidence –Excluding skin cancers, colon cancer is the 3rd most common cancer in the United States. The American Cancer Society (ACS) estimates 102,900 new cases of colon cancer will be diagnosed in 2010. Studies show that 1 in 19 men and 1 in 20 women will be diagnosed with colon cancer during their lifetime.

Mortality – Colon cancer is the third highest cause of cancer deaths in Americans, after lung and prostate/breast cancers but when found early, it is highly curable. The ACS estimates 49,920 colon cancer deaths in 2009, and 51,370 deaths in 2010. For more than 20 years, the death rate from colorectal cancer has been decreasing for both men and women. In the U.S. there are now more than 1 million colorectal cancer survivors. There are many possible reasons for this. Polyps are being removed at colorectal screenings before they can turn cancerous. Screening allows for earlier diagnosis when cancers are more likely curable. In addition, colorectal cancer treatment has improved over the past several years.

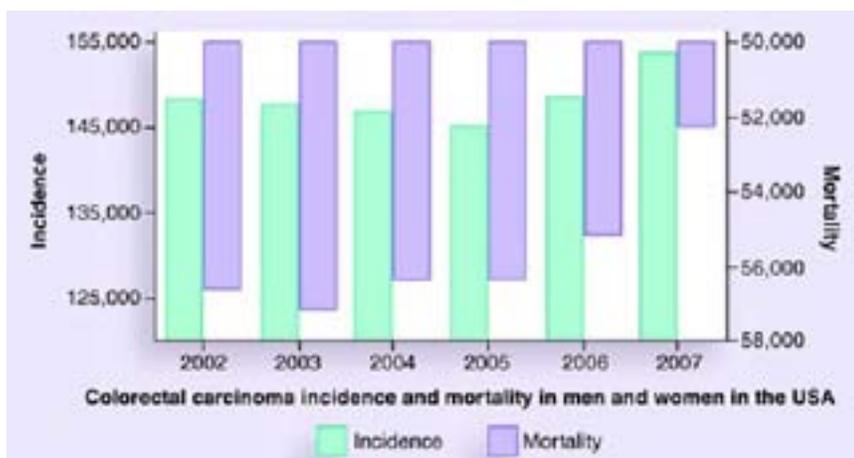


Figure 2. Incidence and mortality of colorectal carcinoma in men and women in the USA over the past 6 years. Over the last 3 years there has been an increase in the incidence of colorectal carcinoma. Fortunately, a decrease in mortality has been observed over the same period of time.

Risk Factors for Americans

Factors you can control:

- Sedentary lifestyle
- Type of diet (high in red meats and processed foods increase risk; high in fruits and vegetables decrease risk.)
- Being overweight (particularly around the waist)
- Smoking or alcohol use
- Type 2 diabetes

Factors you can't control:

- Age – most colon cancers are found in people over age 50
- Personal history of colorectal polyps or colorectal cancer
- Personal history of inflammatory bowel disease
- Family history of colorectal cancer – 1 in 5 people with colorectal cancer have a family history
- Inherited syndromes - about 5% -10% of colorectal cancers are caused by inherited gene changes
- Familial adenomatous polyposis (FAP) – about 1% of colorectal cancers are due to FAP
- Hereditary non-polyposis colon cancer (HNPCC) or Lynch syndrome, accounts for about 3%- 5% of all colorectal cancers
- Racial and ethnic backgrounds
- African-Americans have the highest colorectal risk of all racial groups in the U.S.
- Jews of Eastern European descent (Ashkenazi Jews) have one of the highest colorectal cancer risks of any ethnic group in the world.

Prevention

While the exact cause of colon cancer is unknown, invasive colorectal cancer is a preventable disease. In developed countries, the most important factor in the recent decline of colorectal cancer is early detection through screening programs. Following screening guidelines can decrease the mortality rate from colorectal cancer in the United States by an estimated additional 50%. New and more comprehensive screening strategies are also needed to improve survival.

Many colorectal cancers can be prevented by following the recommendations below:

- Genetic testing for high risk groups
- Healthy lifestyle practices including diet, exercise and weight
- Dietary supplements including vitamins, calcium and magnesium
- Use of non-steroidal anti-inflammatory drugs (NSAIDS) such as ibuprofen (Motrin, Advil) and naproxen (Aleve) may lower risk

Screening and Diagnostic Methods

Screening – Because colorectal cancer is often asymptomatic until it is advanced, screenings are essential to early detection. Colorectal tumors found after symptoms appear, tend to be larger and more difficult to treat and cancers that are diagnosed early are more likely to be curable. Experts such as the American Cancer Society recommend following a testing schedule beginning at age 50 or earlier if a family or personal history exist. The American Cancer Society guidelines are included below.

Colonoscopy - Many people choose to have a screening colonoscopy. Colonoscopy is a procedure that uses a tiny camera to examine the entire colon and rectum. They are useful in finding tumors at an early stage. Colorectal cancers often begin as polyps, benign “mushroom-like” growths on the surface of the colon. Although most polyps remain benign, some can turn cancerous. Colonoscopies can often prevent colorectal cancers from developing by removing polyps before they become cancerous.

American Cancer Society Screening Guidelines for Colorectal Cancer

Beginning at age 50, both men and women should follow one of these testing schedules:

Tests that find polyps and cancer

Flexible sigmoidoscopy every 5 years*, or

Colonoscopy every 10 years, or

Double-contrast barium enema every 5 years*, or

CT colonography (virtual colonoscopy) every 5 years*

* If the test is positive, a colonoscopy should be done.

Tests that primarily find cancer

Yearly fecal occult blood test (gFOBT)**, or

Yearly fecal immunochemical test (FIT) every year**, or

Stool DNA test (sDNA), interval uncertain**

** The multiple stool take-home test should be used. One test done by the doctor in the office is not adequate for testing. A colonoscopy should be done if the test is positive.

The tests that are designed to find both early cancer and polyps are preferred if these tests are available to you and you are willing to have one of these more invasive tests. Talk to your doctor about which test is best for you. The American Cancer Society recommends that some people be screened using a different schedule because of their personal history or family history. Talk with your doctor about your history and what colorectal cancer screening schedule is best for you.

Insurance coverage requirements for colonoscopies and other screenings varies depending on the state in which you live. Ohio is among the 18 states that currently do not require insurance companies to provide coverage for colonoscopies and other colorectal screening procedures that follow acceptable medical guidelines.

Genetic Testing for Colorectal Cancer – Role in Prevention and Early Detection

Genetic testing can be considered for families with a strong family history of colon cancer. Genetic test results may allow for a more accurate assessment of a person's cancer risk. Prior to genetic testing it is recommended to meet with a genetic counselor. Genetic testing can help determine if members of a family have inherited a high risk for developing colon cancer due to syndromes such as familial polyposis (FAP) or hereditary non-polyposis colorectal cancer (HNPCC).

FAP is a rare form of hereditary colon cancer. People with FAP develop hundreds of polyps in the colon that are not initially cancerous, but eventually may develop into cancer. The polyps usually develop by age 35 and in many cases polyps develop in the mid teen years. FAP is caused by a mutation on the APC gene which is known to be a tumor suppressor gene. Mutations can result in the loss of ability to restrict tumor growth. Research has shown that when the APC gene is defective, or mutated, it usually produces a protein that is shorter than those created by normal versions of the gene. Therefore, one way to test for a genetic mutation that causes FAP is to look for evidence that APC gene proteins are truncated, or shorter. The most widely available FAP genetic test is protein truncation testing, or PTT. If you have a family history of FAP, screening is recommended.

Lynch syndrome is a rare inherited condition that causes mutations in specific genes. It is also known as hereditary non-polyposis colorectal cancer (HNPCC). Families with Lynch syndrome have a higher incidence, approximately 80% lifetime risk, of colon cancer. Three out of 100 cases of colon cancer are thought to be caused by Lynch syndrome. Cancers caused by Lynch syndrome are characterized by early onset (average age under 45), the development of neoplastic lesions and microsatellite instability. Microsatellite instability is detected in 90% of colon cancers occurring in patients with Lynch Syndrome, and is also found in 10-15% of sporadic colorectal carcinomas.

Factors to consider with genetic testing include:

- Genetic testing can be emotionally difficult.
- If a mutation is found in one family member, relatives that are not tested may make false assumptions about their own status.
- Cost of testing may not be covered by health insurance provider.
- Risk of discrimination by employer or health insurance provider; however the Federal Genetic Information Nondiscrimination Act of 2008 was passed to prevent this from happening.
- When considering genetic testing, genetic counseling is highly recommended prior to testing.

Signs and Symptoms

Warning Signs - Colorectal cancer usually has no symptoms in the early stages. You should see a physician for any of the following:

- blood in the stool
- a change in bowel habits (such as constipation or diarrhea)
- unexplained weight loss
- abdominal pain
- weakness and fatigue

Factors that Determine Treatment and Prognosis

Colon Histologies - Cancer histology refers to the microscopic structure of the tissue in the tumor. Several types can start in the colon. Adenocarcinomas account for about 90% - 95% of cancers starting in the colon. Other less common types include carcinoid tumors, gastrointestinal stromal tumors (GISTs) and lymphomas. Tumors with neuroendocrine differentiation typically have a poorer prognosis than pure adenocarcinoma variants.

According to data in the National Cancer Data Base, 90% of the colon cancers in CoC-approved cancer programs were adenocarcinomas with 10% other types. We have 92% adenocarcinomas and 8% other specified types, including carcinoid tumor, GIST tumor, neuroendocrine carcinomas, signet ring cell carcinomas and carcinoma not otherwise specified.

Findings: Our histology types compare favorably to the national data. We have a higher incidence of adenocarcinoma which can be explained by only 22% of our cases being stage 1.

Colon Cancers Diagnosed 2006 - 2007		
Histology	U.S.	MHA
	%	%
Adenocarcinoma, NOS	67%	76%
Adenocarcinoma in Adenomatous Polyp	7%	1%
Adenocarcinoma in Tubulovillous Polyp	8%	6%
Mucinous Adenocarcinoma	8%	11%
Other Specified Types	10%	6%
Total	100%	100%
Source: ©2010 National Cancer Data Base (NCDB) / Commission on Cancer (CoC)		

Age –Age at diagnosis may affect treatment options. Most colon cancers are diagnosed in the 7th and 8th decades of life when significant and debilitating comorbidities may affect the patient’s overall health and ability to withstand the rigors of treatment such as surgery and chemotherapy. If a patient cannot be optimally treated, survival and quality of life may be dramatically affected.

Findings: Most of our patients were diagnosed in their 70s and 80s. Our age distribution compares favorably to what was seen nationally.

National vs Mercy Hospital Anderson		
AGE AT DIAGNOSIS	U.S.	MHA
Pediatric	0.0%	0%
16-29	0.3%	0%
30-39	1%	1%
40-49	5%	5%
50-59	15%	22%
60-69	22%	22%
70-79	29%	23%
80-89	23%	20%
90+	4%	7%

Source: ©2010 National Cancer Data Base (NCDB) / Commission on Cancer (CoC)

Stage – Stage at diagnosis is the most important tool used to plan treatment and predict prognosis. AJCC cancer staging schemas define the T (tumor), N (nodes) and M (metastasis) status that summarize the extent of disease (how far the cancer has spread).

Findings: We had 1 stage 0 case. There were slightly more stage 1 and 2 cases, and significantly more stage 3. This was thought to possibly be related to patients having inadequate insurance coverage for screening colonoscopy or a lack of knowledge about screening guidelines. Our incidence of stage 4 was similar to that seen in the U.S. We also had significantly less stage unknown, probably related to our having more adenocarcinomas and less unstageable histologies (i.e. in a patient with carcinoids they are staged as “unknown”).

STAGE	2006 - 2007 Colon	
	U.S.	MHA
	%	%
0	7%	1%
1	20%	22%
2	24%	29%
3	23%	30%
4	15%	13%
N/A	0%	0%
UNK	11%	5%

Source: ©2010 National Cancer Data Base (NCDB) / Commission on Cancer (CoC)

Ohio continues to be one of the states that has not passed legislation requiring insurance companies to provide coverage for colonoscopies or other screening tests for cancer. However, the American Cancer Society is working to enact legislation to ensure insurance coverage of colorectal cancer screenings in Ohio. In March, the ACS partnered with the Ohio State medical Association in support of House Bill 451 and Senate Bill 64.

H.B. 451 requires certain health care plans to provide benefits for colorectal examinations and laboratory tests for cancer and already has 29 co-sponsors in the House. SB 64 is similar to another version that passed with broad bipartisan support in the last legislative session and requires certain health care policies, contracts, agreements, and plans, as well as the state’s Medicaid program, to provide benefits for colorectal examinations and laboratory tests for cancer.

Tests and Tumor Markers for Colon Cancer Prognosis, Recurrence and Treatment

CEA and CA19-9 - In advanced colorectal cancers, the most commonly elevated markers are the CEA (carcinoembryonic antigen) and CA 19-9. While these tests are not useful in screening for colorectal cancer, they are useful marker to determine prognosis and tumor recurrence. An elevated CEA prior to surgery may be a predictor of a poorer outcome. An elevated CEA should be normal in about 4-6 weeks after surgery. Many physicians will re-check the CEA to determine whether all the cancer was removed. The CEA may then be followed about every 3-6 months to monitor the patient for recurrence. Sometimes the CA 19-9 can be used to monitor disease in patients with advanced or recurrent cancer when the CEA is not elevated.

Molecular markers can be used to define prognosis and guide treatment planning by predicting the benefit of adjuvant treatment in colorectal cancer. Identifying markers provides a more personalized approach in the treatment of colorectal cancer.

Microsatellite Instability (MSI) – Microsatellite instability, although useful for identifying Lynch Syndrome, is also an important prognostic and predictive marker for patients with stage II colon cancer. While adjuvant chemotherapy with 5-fluorouracil, leucovorin and oxaliplatin has been shown to be beneficial to patients with stage 3 disease, the benefit of adjuvant chemotherapy for stage 2 colon cancer has been less clear. In the QUASAR clinical trial it was demonstrated that only 3% of stage 2 colon cancers had improved outcomes with adjuvant 5FU-based chemotherapy. To assume that all stage 2 colon cancer should receive adjuvant 5FU would result in 97% of stage 2 cancers being grossly over-treated. The study showed that the way to approach the decision was to determine risk factors and help define which patients with stage II disease are likely to benefit from adjuvant therapy as well. Recent studies presented at ASCO, by Daniel Sargent, showed that patients with stage II colon cancer who have microsatellite instability did not benefit from 5-FU chemotherapy.

KRAS Status - KRAS (Kirsten rat sarcoma viral) refers to a gene that can be altered (mutated) in colon cancer cells. Studies show that if this alteration (mutation) is present, a patient may not respond to the anti EGFR drugs, [cetuximab (Erbix) and panitimumab (Vectibix)] and these should not be used. There are two type of KRAS genes; normal and mutated. The normal gene is also called the wild type allele; the mutated gene is described as abnormal or having an abnormal codon (abnormal DNA sequence). Knowing KRAS status of a patient's tumor allows treatment to be tailored to the individual.

Two leading cancer organizations, the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) now recommend KRAS testing as “best practice therapy”, the standard of care for people with metastatic colon cancer who are being considered for treatment with anti-EGFR medications.

Oncotype DX – Oncotype DX is a genetic test validated by American Society of Clinical Oncology to determine whether patients surgically treated for early-stage colon cancer may be likely to suffer a recurrence. The information provided by Oncotype DX has been shown to have independent value beyond currently used measures for determining colon cancer recurrence risk. Based on the analysis of seven different genes found in colon cancer tumors, after surgical resection has removed the tumor, a score is derived that assess the level of risk for recurrence as low, intermediate or high risk. The results of this test will help physicians and their patients decide if they should have a round of chemotherapy or if they should avoid the harsh side-effects and costliness of the drugs.

Treatment of Colon Cancer

Surgery – Often, tumors are identified during colonoscopy and surgery is recommended. For most tumors in the colon, a segmental resection called a hemicolectomy is required. The goal of surgery is to remove the tumor with wide margins to ensure that all the malignancy is removed. Open colectomy is the most common method of surgery. An incision is made in the abdomen and part of the colon is excised along with surrounding lymph nodes. Usually one third to one fourth of the patient's colon is removed depending on size and location of the tumor. The remaining sections are reattached. Current standards recommend that at least twelve lymph nodes from the area of the tumor be removed and examined microscopically.

Less invasive surgical resections are also available. Laparoscopic-assisted colectomy is a safe and effective alternative to standard open surgery for most patients with cancer that is confined to the colon. During this procedure, several small incisions are made and a laparoscope is inserted to aid in the removal of the colon and lymph nodes. DaVinci robotic surgery is also being used to surgically treat colon cancer.

Since the incisions are smaller with these less invasive procedures, recovery time and hospital stays are shorter, and patients experience less post-operative pain and quicker overall recovery.

Chemotherapy - Chemotherapy for colon cancer is most often given after surgical removal of the tumor and surrounding lymph nodes and is recommended for Stage 3 and some Stage 2 colon cancers. Chemotherapy drugs act by destroying cells, both cancer cells and healthy cells, so it can have many unwanted side-effects. Most are short-term and go away after treatment is completed. Chemotherapy is fairly well-tolerated by most elderly patients and is recommended in the absence of other serious health conditions.

Several chemotherapy agents are available for the treatment of colon cancer. The most commonly used chemotherapy drug is 5-Fluorouracil (5-FU) and is often given with leucovorin which helps it work better. These drugs may be combined with other chemotherapeutic agents such as Irinotecan (Camptosar) or Oxaliplatin (Eloxatin). Capecitabine (Xeloda) is a pill form of chemotherapy.

Targeted Therapies – These are newer drugs developed to target the gene and protein changes in cells that cause cancer. They work differently from standard chemotherapy drugs and are currently given either along with chemotherapy or alone when chemotherapy is no longer effective. These drugs have different and less severe side effects. Targeted therapies attack the tumor and surrounding tissue and spare most of the normal tissue from damage. These drugs include the man-made types of immune system proteins called monoclonal antibodies such as bevacizumab (Avastin), panitumumab (Vectibix), and cetuximab (Erbix).

Targeted therapies act in different ways to stop cancerous cells from growing. Bevacizumab (Avastin) targets vascular endothelial growth factor (VEGF), a protein that helps tumors form new blood vessels to get nutrients. It acts by starving the tumor. It is most often used for advanced colorectal cancer.

Panitumumab (Vectibix) and cetuximab (Erbix) target the epidermal growth factor receptor (EGFR), a molecule that helps cancer cells grow. These drugs slow down or prevent cancer cell growth. They are usually given for metastatic colorectal cancers.

Testing for a mutation in the BRAF gene would also indicate that cetuximab would not be effective. BRAF is a protein that in humans is encoded by the BRAF gene. The BRAF protein is involved in sending signals in cells and in cell growth. It may be mutated and the protein altered. Mutations in the BRAF gene can cause disease in two ways. First, mutations can be inherited and cause birth defects. Second, mutations can appear later in life and cause cancer, as an oncogene.

Treatment Comparison to National Cancer Database

Colon Cancer- Diagnosed 2006 - 2007

Treatment by Stage Comparison - National Cancer Data Base vs Mercy Hospital Anderson

Treatment Type	NCDB	MHA	NCDB	MHA	NCDB	MHA	NCDB	MHA	NCDB	MHA	NCDB	MHA	NCDB	MHA
	Stage 0		Stage 1		Stage 2		Stage 3		Stage 4		Stage N/A		Stage Unknown	
Surgery Only	87%	100%	88%	94%	65%	58%	24%	0%	17%	9%	30%	0%	44%	33%
Surgery and Chemotherapy	1%	0%	2%	0%	17%	21%	56%	72%	39%	64%	14%	0%	10%	0%
Other Specified Therapy	7%	0%	8%	6%	15%	13%	18%	28%	17%	9%	19%	0%	15%	0%
No 1st Course Rx	5%	0%	3%	0%	3%	8%	3%	0%	27%	18%	36%	0%	30%	67%
% of Cases for Stage Group	7%	1%	19%	22%	24%	29%	23%	30%	17%	13%	0%	1%	11%	4%

Source: ©2010 National Cancer Data Base (NCDB) / Commission on Cancer (CoC)

Findings:

Stage 0 – there was only 1 patient and surgery was performed which made the percentage at 100%. This compares favorably to national and exceeds national treatment guidelines.

Stages 1 – 94% of our stage 1 patients were treated with surgery only. This compares favorably to national and exceeds national treatment guidelines.

Stage 2- fewer of our patients received surgery only and 4% more had surgery with adjuvant chemo. This was felt to be an acceptable difference because chemotherapy for stage 2 colorectal cancers is not widely recommended.

Stage 3 – significantly more of our stage 3 patients received adjuvant chemo (72% compared to 56% nationally). We also had a significant difference in patients treated with “Other Specified Therapy” (28% compared to 18% in the U.S.). None of our patients received chemotherapy, radiation or palliative treatment only.

Stage 4 - we had significantly more patients who received surgery only or surgery with adjuvant chemotherapy (73% compared to 56% nationally). We had fewer patients (18% at MHA compared to 27% nationally) who had “No 1st course of treatment. All of these modalities are felt to be acceptable treatment for this stage.

For both stage 3 and stage 4, compared to NCDB, we have more patients who received chemotherapy. This may simply be related to our concerted efforts to obtain information on treatment done elsewhere. Our performance in the Commission on Cancer, American College of Surgeons CP3R colon study indicates we have an average 2006-2007 concordance of 100% for adjuvant chemotherapy. Other Community Hospital Cancer Programs have an average of 86% and the state of Ohio has an average of 92% concordance for these years.

Colon Cancer Survival by Stage

The most recent data on relative survival for colon cancer indicates that five year survival for localized colon cancer (for patients diagnosed between 1996 and 2004) is 90%. For patients diagnosed at the regional stage it is 68% and for distant stage, 11%. In the late 1980s, the introduction of 5-fluoroucil adjuvant chemotherapy for resectable stage 3 colon cancer was a significant advance in treatment and reduced mortality by about 30%.

National Cancer Database-Diagnosed 1998-2002

	Year					
	0	1	2	3	4	5
Stage 0	100%	95%	92%	88%	85%	81%
Stage 1	100%	95%	91%	86%	82%	77%
Stage 2	100%	92%	86%	79%	73%	67%
Stage 3	100%	87%	75%	65%	58%	53%
Stage 4	100%	51%	27%	16%	11%	8%
Overall	100%	84%	74%	67%	61%	56%

Source: ©2010 National Cancer Data Base (NCDB)

Mercy Hospital Anderson-Diagnosed 1998-2002

	Year					
	0	1	2	3	4	5
Stage 0	100%	75%	75%	75%	75%	64%
Stage 1	100%	90%	88%	82%	75%	71%
Stage 2	100%	91%	86%	80%	68%	65%
Stage 3	100%	84%	69%	57%	54%	47%
Stage 4	100%	41%	25%	16%	9%	7%
Overall	100%	79%	71%	63%	55%	51%

Source: Mercy Anderson cancer registry database

Comparison of Mercy Hospital Anderson to National Survival

Findings: Comparison of survival data for our patients diagnosed in 1998 through 2002 shows that our survival is lower than national survival. This may be explained because of the advanced age, precluding optimal cancer treatment of the patients. This breakdown by stage is as follows. Stage 0 had 12 cases and 6 of those cases were between the ages of 74-82. Stage 1 and 2 cases were comparable to national averages. Stage 3 cases had 61 cases and 8 of those cases were between the ages of 80-92 with 5 receiving surgery only with no additional adjuvant treatment. Stage 4 there were 44 cases and 9 of those cases were between the ages of 80-99, with 4 receiving no surgical or adjuvant treatment.

Summary of Findings and Recommendations:

- **Gender Comparison:** Our male/female incidence is the opposite of the national distribution. We have seen more males than females. Since there were only 3 more males than females in our study group of 83 patients, this was not felt to be a significant difference.
- **Colon Histologies:** We have slightly more adenocarcinomas and less other specified types, likely due to the small number of patients in our study.
- **Age:** Our age distribution compares favorably to what was seen nationally.
- **Stage:** We had 12 stage 0 cases and this fared slightly less especially at 5 years than the national average, which may be due to the small number of cases in the group. Our stage 1 and 2 cases were comparable to what was seen nationally. We had more stage 3. This was thought to possibly be related to patients having inadequate insurance coverage for screening colonoscopy or a lack of knowledge about screening guidelines. Our incidence of stage 4 was similar to that seen in the U.S. We also had significantly less stage unknown, likely related to our having more adenocarcinomas and less unstageable histologies.

Recommendation: Promote legislation for insurance coverage. According to the 2010 Colorectal Cancer Legislation Report Card, Ohio is among the 18 states that do not require insurance coverage for screening colonoscopies. The ACS is working to change this. We should promote working with the ACS and our state representatives to support legislation for insurance coverage for colorectal screening tests.

Recommendation: Promote diagnosis at earlier stage and increase awareness. Continue to have a Colon Rectal Awareness Day to promote Colorectal Cancer Month. Work with the American Cancer Society to promote legislation to require adequate insurance coverage for colon screenings. Work with staff physicians to promote and recommend colorectal screening in their offices.

- **Survival:** Our survival for all stages was lower than national survival.

Recommendation: Since almost half of the patients in this group were over age 70 at diagnosis and our study group was small, there were no recommendations. However, earlier stage at diagnosis and better treatment will improve colorectal survival so we will continue to promote colon cancer awareness and clinical trials through our Community Outreach activities.

Clinical Trials

For information on access to clinical trials in your area:

Call the American Cancer Society, Clinical Trials Matching Service (a free, confidential program) at 1-800-303-5691 or visit www.cancer.org

Visit the National Cancer Institute (NCI) website at: www.cancer.gov/clinicaltrials/search

Visit the Coalition of Cancer Cooperative Groups at: www.cancertrialshelp.org

References

American Cancer Society - www.cancer.org

National Cancer Institute – www.cancer.gov

American Medical Network – www.health.am

Genomic Health - <http://www.genomichealth.com/Pipeline/ColonCancer.aspx>

KRAS Information - <http://www.kras-info.com/default.aspx>

Connecticut Dept. of Public Health - <http://www.ct.gov/dph/cwp/view.asp?a=3134&q=436320>

<http://www.legislature.state.oh.us/bills.cfm>

<http://emedicine.medscape.com/article/1690010-overview>

<http://cancerres.aacrjournals.org/content/66/8/3992.abstract>

<http://online.wsj.com/article/SB124233922745621053.html>

Illustrations

Fig 1 - <http://health.allrefer.com/pictures-images/the-large-intestine.html>

Fig 2 - Recent Advances in the Molecular Diagnosis and Prognosis of Colorectal Cancer, miller, micheal. Available from: <http://knol.google.com/k/micheal-miller/recent-advances-in-the-molecular/2qtpmllakdowr/8>.