Mount Sinai Hospital Cancer Program
2014 Annual Report

“The human spirit is stronger than anything that can happen to it”
C.C. Scott
Mount Sinai Hospital Cancer Program
2014 Annual Report

Proud members of Sinai Health System

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Contents

A Message from the Chief of the ............... 2
Hematology-Oncology Division

2015 Cancer Committee ....................... 3

2014 Cancer Case Information ............... 4

Clinical Trials ................................. 5

Rapid Quality Reporting System ............. 6

Colon Cancer Screening ..................... 8

KRAS Testing ................................. 11
A Message from the Chief of Hematology Oncology

It is my privilege to introduce the 2014 Mount Sinai Hospital Cancer Program Annual Report. The primary goal of the report is to provide an overview of the many activities our Cancer Program has realized over the past year. One improvement has been our involvement with the Rapid Quality Reporting System.

The primary objective of the RQRS is to promote evidence-based cancer care at the local level through real clinical time compliance monitoring and assessment of four National Quality Forum endorsed measures and two surveillance measures for cancer care for breast and colorectal cancer patients. It offers a systematic data collection and reporting system for promoting evidenced-based treatments.

Our quality data reported through RQRS demonstrates our commitment to bring the highest standard of evidenced based cancer care to the community we serve.

Our program analyzed colon cancer for this past year. We looked at our data from Mount Sinai Hospital, as well as performed a quality study on KRAS testing for patients with metastatic colorectal cancer. The analysis is contained within this Annual Report.

I hope you enjoy reading the selected activities presented in this report, as we look forward to serving our community with the highest quality, patient centric cancer care that we can possibly provide.

Pam Khosla, MD
Chief of Hematology/Oncology
Department of Internal Medicine
Mount Sinai Hospital
2014 Cancer Committee Membership

At Mount Sinai Hospital Oncology Services, our Cancer Committee oversees activities of the cancer program and is responsible for ensuring quality care and facilitating advancements. The multidisciplinary cancer committee is composed of medical, allied health and administrative personnel. We also are proud partners with the American Cancer Society.

<table>
<thead>
<tr>
<th>Member Name</th>
<th>Discipline</th>
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<tbody>
<tr>
<td>Khosla, Pam MD</td>
<td>Cancer Committee Chairperson</td>
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<tr>
<td>Ying, Shan-Ching MD</td>
<td>Pathology</td>
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<tr>
<td>Lorimer, Monica MD</td>
<td>Radiation Oncology</td>
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<tr>
<td>Kuznetsova, Marina MD</td>
<td>Community Outreach Coordinator</td>
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<tr>
<td>Jones, Anngell MD</td>
<td>Surgeon</td>
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<tr>
<td>Stephen Wise MD</td>
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<td>Kassem, Mohammed MD</td>
<td>Medical Oncology</td>
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<tr>
<td>Gross, Robert MD</td>
<td>Diagnostic Radiology</td>
</tr>
<tr>
<td>Veres, Christine MD</td>
<td>Palliative Care &amp; Hospice</td>
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<tr>
<td>Delves, Denise RN</td>
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<tr>
<td>Imelda Unto, RN</td>
<td>Cancer Program Administrator</td>
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<tr>
<td>Patel, Niraj</td>
<td>Clinical Research Coordinator</td>
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<tr>
<td>Sunina Chacko, APN</td>
<td>Genetics/Risk Assessment Coordinator</td>
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<tr>
<td>Imelda Unto, RN/Smith, George RN</td>
<td>Oncology Nurse</td>
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<td>Stephanie Bradley RN</td>
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<tr>
<td>Arreola, Maria CTR</td>
<td>Certified Tumor Registrar</td>
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<td>Josephson, Laura RN</td>
<td>Performance Improvement/Quality</td>
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<td>Issac, Devonne</td>
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<td>Caroselli, Valerie, Pharm D</td>
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<td>Gutierrez, Adriana</td>
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<td>Kanoon, Jacqueline</td>
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<td>Manching, Romulo</td>
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<td>Marcouiller, Nicole, MSW</td>
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<tr>
<td>Suzette Mahneke RN</td>
<td>Chief Nursing Officer &amp;</td>
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<td>Vice President of Patient Services</td>
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<td>Vaca, Lorena</td>
<td>Cancer Conference Coordinator</td>
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<td>Sarah Little</td>
<td>American Cancer Society</td>
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<td>Zabinsky, Beth RCD</td>
<td>Clinical Dietician</td>
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2013 Cancer Case Information

Mount Sinai Hospital was involved in the diagnosis and/or treatment of more than 386 cancer patients in 2013. Over ninety-eight percent (379) of those cases were considered analytic cases directly diagnosed and/or treated with the health network.

<table>
<thead>
<tr>
<th>YEAR</th>
<th>MOST TREATED</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
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<td>Hematology</td>
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<td>Hematology</td>
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<td>2009</td>
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<td>Prostate</td>
<td>Bronchus/Lung</td>
<td>Colon</td>
<td>Hematology</td>
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Commonly Used Terminology

**American Joint Committee on Cancer (AJCC) Staging:** A classification system used for describing the extent of disease progression based on the evaluation of the tumor size/invasiveness (T), nodal status (N) and metastasis (M) at the time of diagnosis. AJCC stage is important in considering treatment plans.

**Analytic Cancer Case:** analytic cases are cases for which the facility provided the initial diagnosis of cancer and/or for which the facility contributed to all or part of the first course of treatment.

**Collaborative Staging:** Collaborative Stage is a unified data collection system designed to provide a common data set to meet the needs of all three staging systems:

- (TMN)
- Surveillance, Epidemiology and End Results (SEER) Extent of Disease (EOD)
- Summary Stage (SS)

It provides a comprehensive system to improve data quality by standardizing rules for timing, clinical and pathologic assessments, and compatibility across all of the systems for all cancer sites. The Collaborative Stage project is sponsored by the American Joint Committee on Cancer (AJCC) in collaboration with several standard-setting organizations, including the SEER Program.

**National Cancer Database:** The nationally recognized National Cancer Data Base (NCDB)—jointly sponsored by the American College of Surgeons and the American Cancer Society—is a clinical oncology database sourced from hospital registry data that are collected in more than 1,500 Commission on Cancer (CoC)-accredited facilities. NCDB data are used to analyze and track patients with malignant neoplastic diseases, their treatments, and outcomes. Data represent approximately 70% of newly diagnosed cancer cases nationwide and 30 million historical records.
Clinical Trials
Niraj Patel
Clinical Trial Coordinator

Clinical trials are studies in which people volunteer to take part in tests of new drugs or procedures. Doctors use clinical trials to develop new treatments for serious diseases such as cancer.

Frequently asked Questions about Clinical Trials

• **Who can participate in a clinical trial for cancer?**
  To qualify for a particular study, participants must meet a carefully defined set of criteria. These usually relate to age and gender, cancer type and stage, and the types of treatments they have already received.

• **What information do participants receive about clinical trials?**
  Before agreeing to participate, patients learn about possible risks and benefits of the therapy being studied. As the trial progresses, participants are given new information that may affect their willingness to stay in the trial. Participants may withdraw from the trial at any time.

• **How are patients protected?**
  Before any clinical trial begins, it must be approved by its host institution's Institutional Review Board (IRB), which includes researchers and physicians. The IRB considers whether proposed studies are safe and well planned and whether they will ultimately advance patient care. It also reviews studies to ensure patients are adequately informed about the risks of participating in clinical research. In all studies, the health of each patient is closely monitored during the course of the trial.

• **What are the different phases of a clinical trial for cancer?**
  Cancer clinical trials are divided into three distinct stages. Only when the third stage has been successfully completed, and the Food and Drug Administration has given its approval, can a new treatment become part of standard therapy.

Our Cancer Services Program participates in screening trials, treatment trials, quality of life trials (supportive care) and other trials. For 2013, our total clinical trial accrual was 76 patients for an accrual rate of 16.8% per an estimated analytical case load of 450.

Our accrual rate of 16.8% exceeds the Commission on Cancer minimum standard for clinical trial accrual percentage of 2% for our Community Cancer Center Program. In fact, our Mount Sinai Hospital Cancer Services Program well exceeds the percentage for commendation which is set by the Commission on Cancer at 4%.
Rapid Quality Reporting System (RQRS)

Pam Khosla, MD
Chief of Hematology/Oncology
Department of Internal Medicine

Introduction

The Rapid Quality Reporting System (RQRS) provides valuable incentives and benefits to hospitals implementing it, including improved patient outcomes, the ability to negotiate favorable reimbursement with payers by demonstrating their quality of medical practice, and commendation for Standard 5.2 of the American College of Surgeons (ACoS) Commission on Cancer’s (CoC) Cancer Program Standards.

Challenges can be expected with any new system implementation, including staffing, training and I.T. infrastructure upgrades; therefore, all hospitals must weigh the benefits and challenges of RQRS participation. Those moving forward can take steps to significantly increase their odds of success. The RQRS provides the next logical step in utilizing the cancer registry to positively impact patient outcomes and the quality of medical practice.

As defined by Standard 5.2 of the CoC Cancer Program Standards 2012, Version 1.2.1: Ensuring Patient-Centered Care, the CoC developed the RQRS to: “… facilitate quality improvement by encouraging evidence-based care in CoC-accredited programs for select quality measures. RQRS enables accredited cancer programs to report data on patients concurrently, receive notifications of treatment expectations, and presents year-to-date concordance rates for each measure as compared to the state, other hospital groups, and hospitals at the national level.”

The primary objective of the RQRS is to promote evidence-based cancer care at the local level through real clinical time compliance monitoring and assessment of four National Quality Forum endorsed measures and two surveillance measures for cancer care for breast and colorectal cancer patients. It offers a systematic data collection and reporting system for promoting evidenced-based treatments.

As a web-based system, RQRS also provides alerts to support the anticipated scope of care coordination required for breast and colorectal cancer patients at local facilities. The RQRS reports the same quality measures for breast and colorectal cancer care as those endorsed by the National Quality Forum or identified through collaboration with other national medical and oncology organizations and societies. CoC accredited cancer programs currently receive reports of these measures but rely on the collection and analysis of retrospective data, often more than 18-24 months old. The RQRS provides a significant advantage by reporting these data in real clinical time.

In 2014, the RQRS standard became one of seven criteria for the CoC Outstanding Achievement Award. This standard is currently valid for programs previously accredited by the CoC and is for commendation only.
RQRS (continued)

In 2013, our program entered 126 applicable patients into the Rapid Quality Reporting System. Our results, meeting the evidence-based cancer care at Mount Sinai Hospital, were above national average.

Specific 2013 results are as follows:

<table>
<thead>
<tr>
<th>Metrics</th>
<th>Description of Metric</th>
<th># Patients</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HT (Quality Improvement)</td>
<td>Tamoxifen or third generation aromatase inhibitor is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1c or stage IB-III hormone positive breast cancer</td>
<td>36/36</td>
<td>100%</td>
</tr>
<tr>
<td>MAC (Quality Improvement)</td>
<td>Combination chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0, or stage IB-III hormone receptor negative breast cancer</td>
<td>4/4</td>
<td>100%</td>
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<tr>
<td>BCS (Surveillance)</td>
<td>Breast conservation surgery rate for women with ACC clinical stage 0, I, or II breast cancer</td>
<td>43/44</td>
<td>97.7%</td>
</tr>
<tr>
<td>BCSRT (Accountability)</td>
<td>Radiation is administered within 1 year (365 days) of diagnosis for women under the age of 70 receiving breast conservation surgery for breast cancer</td>
<td>30/30</td>
<td>100%</td>
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<tr>
<td>Colon Cancer</td>
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<tr>
<td>ACT (Accountability)</td>
<td>Adjuvant chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer</td>
<td>4/4</td>
<td>100%</td>
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<tr>
<td>12RLN (Quality Improvement)</td>
<td>At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer</td>
<td>8/8</td>
<td>100%</td>
</tr>
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Colon Cancer Screening
Monica Lorimer, MD
Clinical Liaison Physician

Colorectal Cancer Defined

Colorectal cancer, often referred to as colon cancer, develops in the colon or the rectum, which is part of the digestive system or gastrointestinal (GI) tract. The digestive system processes food for energy and eliminates solid waste. Colorectal cancer usually develops slowly over many years. Most colorectal cancer begins as a noncancerous (benign) adenoma or polyp (abnormal growth) that develops on the lining of the colon or rectum. Polyps can be removed to significantly reduce cancer risk. Colonoscopy plays an important role in colorectal cancer prevention because precancerous polyps can be detected and removed during the same exam when they are discovered.

Colorectal Cancer Facts

- Colorectal cancer is the second leading cause of cancer-related deaths in the United States (when men and women are combined). It is the third leading cause of cancer-related deaths when men and women are considered separately (behind lung and prostate cancer in men, and behind lung and breast cancer in women).
- Nearly 137,000 people in the United States are diagnosed with colorectal cancer each year and over 50,000 die because of it annually.
- The majority of CRC can be prevented with proper screening, early detection and removal of adenomatous polyps (precancerous polyps). Screening helps prevent CRC by finding precancerous polyps so they can be removed before they turn into cancer.
- According to a 2013 report from the Centers of Disease Control and Prevention (CDC), about one in three adults (23 million) between the ages of 50 and 75 years old are not getting screened for colorectal cancer as recommended. Exercise and eating healthy foods such as vegetables and fruits can help decrease the risk of colorectal cancer, but screening is an essential part of colorectal cancer prevention.
- The incidence of CRC and the death rate from the disease has dropped for the past 15 years. Scientists believe that the decrease is probably because polyps are being found and removed by colonoscopy before becoming cancer. Also, CRC is being found earlier when it is easier to cure, and treatments for cancer once it has occurred have improved.
- There are approximately one million CRC survivors in the United States and that number is growing.
- According to American Cancer Society data released in 2014, colorectal cancer incidence rates have dropped 30 percent in the U.S. in the last 10 years among adults 50 and older due to the widespread uptake of colonoscopy.
• The five-year survival rate for people with CRC discovered early is greater than 90 percent. But only 39 percent of CRCs are found at that early stage. Five-year survival rapidly declines when the cancer has spread to nearby organs or lymph nodes.
• Individuals who have a family member (parent, brother or sister, or child) with colorectal cancer or polyps are at increased risk for developing the disease themselves and may need to undergo more aggressive screening starting at a younger age. Individuals who have more than one family member with colorectal cancer or with other types of cancers may be at even higher risk.

Symptoms of Colorectal Cancer

Certain symptoms might indicate this cancer:

• Blood in the stool
• Narrower than normal stools
• Unexplained abdominal pain
• Unexplained change in bowel habits
• Unexplained anemia

Screening Recommendations for those at Average Risk

Beginning at age 50, both men and women at average risk for developing CRC should have a colonoscopy every 10 years. The risk of developing CRC increases with age, with more than 90 percent of cases occurring in persons aged 50 or older.

Men and women should begin screening earlier and more often if they have any of the following CRC risk factors: a family history of CRC or polyps, a known family history of inherited CRC syndromes, a personal history of CRC, or a personal history of chronic inflammatory bowel disease (ulcerative colitis or Crohn's Disease).

Colonoscopy is considered the gold standard of colorectal cancer screening methods for its ability to view the entire colon and both detect and remove polyps during the same procedure.

Screening Recommendations for African-Americans

Although all men and women are at risk for CRC, some people are at higher risk for the disease because of age, lifestyle or personal and family medical history. According to studies, African-Americans are at a higher risk for the disease than other populations. Starting at age 50, everyone should begin routine screening tests. Research shows that African-Americans are being diagnosed at a younger average age than other people. Therefore, some experts suggest that African-Americans should begin their screening at age 40.
• The incidence of CRC is higher among African-Americans than any other population group in the United States.
• Death rates from CRC are higher among African-Americans than any other population group in the United States.
• African-Americans are less likely than Caucasians to have colorectal polyps detected at a time when they can easily be removed.
• African-Americans are more likely to be diagnosed with CRC in advanced stages when there are fewer treatment options available. They are less likely to live five or more years after being diagnosed with CRC than other populations.
• There may be genetic factors that contribute to the higher incidence of CRC among some African-Americans.
• African-American women have the same chance of getting CRC as men, and are more likely to die of CRC than are women of any other ethnic or racial group.
• African-American patients are more likely to have polyps deeper in the colon (on the right side of the colon).

**Colon Cancer Screening at Mount Sinai Hospital**

In 2013, there were 1,180 colonoscopies performed at Mount Sinai Hospital. Of those colonoscopies, 57% (672) were screening colonoscopies.

In 2014, total operative cases were as follows:
• Colon Cancers: 16
• Rectal Cancers: 4

In 2014, the breakdown of cases by months:
• July 2013 – December 2013: 6
• January 2014 – July 2014: 14
• Our cases are increasing.
• 17/20 (85%) of patients were symptomatic at time of screening
• 3/20 (15%) of cases founding of screening:
  o 2013: 1 cases
  o 2014: 2 cases

Demographics of operative cases:
• Symptomatic Patients Screened: Age range 47-85. Two patients under age 50
• Screened patients without symptoms: Ages 56, 59, 80
• Adequacy of lymph node sampling
  o Twelve lymph nodes required for adequate sample
  o 19/20 (95%) of specimens submitted noted to be adequate
Study of Quality: KRAS Testing
Mohamed Kassem, MD
Hematology/Oncology

Colorectal cancer is cancer that starts in the colon or rectum. The colon and the rectum are parts of the large intestine, which is the lower part of the body’s digestive system. During digestion, food moves through the stomach and small intestine into the colon. The colon absorbs water and nutrients from the food and stores waste matter (stool). Stool moves from the colon into the rectum before it leaves the body.

Most colorectal cancers are adenocarcinomas (cancers that begin in cells that make and release mucus and other fluids). Colorectal cancer often begins as a growth called a polyp, which may form on the inner wall of the colon or rectum. Some polyps become cancer over time. Finding and removing polyps can prevent colorectal cancer.

In metastatic colon cancer, tumors express the KRAS gene in two forms: mutated and wild-type. This discovery has essentially split colon cancer into two separate diseases. About 40% of patients with metastatic colon cancer have tumors with a mutated form of the KRAS gene, and these patients are unlikely to respond to treatment with cetuximab and panitumumab.

The other patients with the “normal” or wild-type, KRAS genes are likely to respond to the above mentioned drugs. In some patients, the addition of cetuximab or panitumumab to chemotherapy can produce a 10%-15% improvement in benefit, although not all patients respond.

The lack of response to EGFR inhibitors in patients with KRAS mutations is supported by the new National Comprehensive Cancer Network guidelines. In the guidelines, it strongly recommends KRAS genotyping of tumor tissue (either primary tumor or metastases) in all patients with metastatic colorectal cancer.

For 2014, our program tested patients with metastatic colorectal cancer who received anti-EGFR MoAb therapy. Six out of 19 patients had metastatic disease. Four out of six patients (66.6%) qualified for testing. 75% of the four patients were tested and positive. Two patients were treated with EGFR therapy.