

**Boston Medical Center**

**2010 Cancer Program Annual Report**

**THYROID CANCER**

with 2005-2009 Cancer Registry Data



EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Dear Friends:

This cancer program annual report focuses on Boston Medical Center's activities in thyroid cancer from 2005 through 2009.

The largest safety net hospital in New England and the primary teaching affiliate of the Boston University School of Medicine (BUSM), Boston Medical Center (BMC) is at the forefront of clinical practice, teaching and research in thyroid cancer.

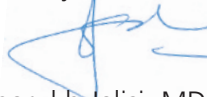
In our highly supportive and collaborative environment, renowned experts in thyroid cancer and related specialties provide patients with the most advanced, coordinated and comprehensive medical care available anywhere—treatment that is aggressive and innovative in controlling the cancer and managing its impact on the patient's quality of life.

A major provider in the Northeast for primary and tertiary referrals of patients with thyroid malignancies, BMC evaluates and manages both routine and aggressive cancers. Our resources include expertise in initial and revision thyroid cancer surgery, innovative treatments that incorporate translational research, and one of the two dosimetry programs in New England capable of giving maximal-dose radioactive iodine to patients with life-threatening thyroid cancer.

With its concentration of highly specialized expertise and resources, BMC achieved outstanding five-year survival rates for patients with advanced thyroid cancer (stages III and IV) compared with National Cancer Database outcome data.

At BMC, our mission is to deliver exceptional care, without exception. We are proudly and passionately advancing the standard of thyroid cancer diagnosis and treatment as we strive to improve our patients' outcomes.

Sincerely,



Scharukh Jalisi, MD, FACS  
*Editor, 2010 Cancer Program Annual Report  
Director, Head and Neck Surgical Oncology  
and Skullbase Surgery, Boston Medical Center*



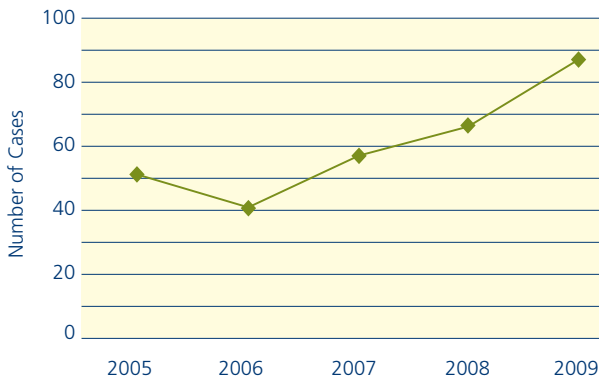
Lisa Kachnic, MD  
*Chair, Radiation Oncology and  
Chair, Cancer Care Committee,  
Boston Medical Center*

## THYROID CANCER AT BOSTON MEDICAL CENTER FROM 2005 TO 2009: OUTCOME DATA

The Boston Medical Center (BMC) Cancer Care Committee reviewed all thyroid cancer cases dating from January 1, 2005 through December 31, 2009, which includes five years of data, and compared this data with the National Cancer Database (NCDB).

The annual number of new thyroid cancer diagnoses at BMC has increased from 51 in 2005 to 87 in 2009, with a total of 301 cases over this five-year period (Figure 1).

**Figure 1**  
*Thyroid Cancer at BMC 2005 – 2009*

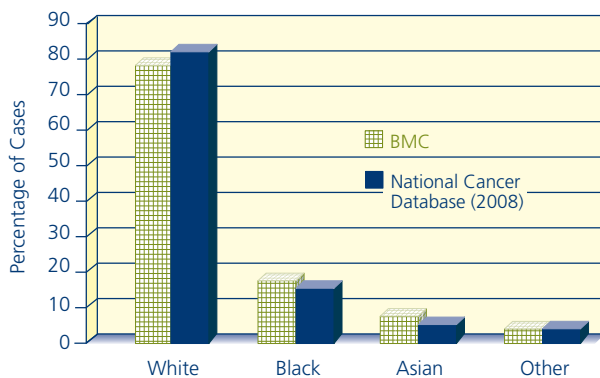


BMC has steadily expanded its clinical care and research in thyroid cancer over the past several years and provides comprehensive services to a growing number of patients who reside within and beyond Metropolitan Boston.

BMC’s patient population is more diverse than the population documented in the NCDB data (Figure 2). African Americans and Asians comprise about 20 percent of the patients diagnosed with thyroid cancer at BMC, but only 15 percent of the population in the national comparative data.

Nationwide and at BMC, the most common type of thyroid pathology is papillary thyroid cancer. BMC also diagnoses and treats patients with rare thyroid cancers, including follicular, hurthle cell and medullary thyroid cancers and thyroid lymphoma as well as poorly differentiated and anaplastic thyroid cancers.

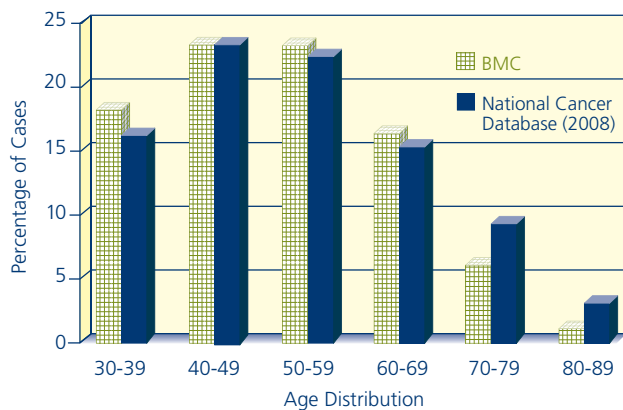
**Figure 2**  
*Thyroid Cancer Distribution by Race: 2005-2009*



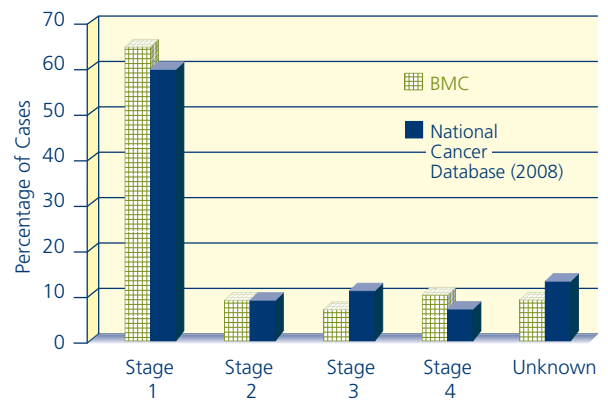
At their time of diagnosis, BMC patients with thyroid cancer encompass a broad range of ages (Figure 3). BMC parallels nationwide data in the percentage of patients who are older than age 40 when diagnosed with thyroid cancer. However, at BMC, a substantial number of patients—31 percent in contrast to 24 percent nationwide—are between 20-to-39 years of age at the time of diagnosis.

BMC’s higher percentage of patients who are younger than age 40 at diagnosis corresponds with its larger portion of early-stage thyroid cancers—73 percent versus 69 percent according to nationwide American Joint Committee on Cancer (AJCC) data (Figure 4).

**Figure 3**  
*Thyroid Cancer Age at Diagnosis: 2005-2009*

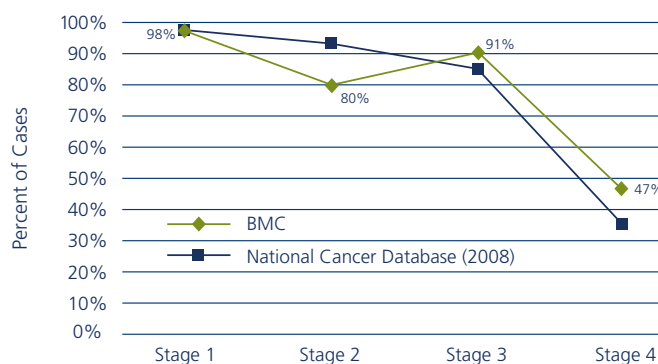


**Figure 4**  
*American Joint Committee on Cancer Thyroid Cancer Stage at Diagnosis 2005-2009*



This concentration of early-stage cases could partly reflect BMC’s excellent diagnostic services. They begin in an outpatient setting at a community health center or primary care office and continue at the hospital via advanced techniques such as ultrasound and fine needle aspiration (FNA) biopsy that enable early detection of thyroid cancer.

**Figure 5**  
*Thyroid Cancer 5-Year Survival Rate 2005-2009*



As a consequence of the close collaboration between BMC’s experts in diagnosis and its specialists in surgical and adjuvant therapies, BMC achieved outstanding five-year survival rates when compared with NCDDB data for advanced stage cancers. BMC’s survival rates significantly exceed nationwide averages for Stages III and IV cases.

At BMC, the five-year survival rate for patients with Stage III thyroid cancer is 91 percent versus 86 percent nationwide. The five-year survival rate for patients with Stage IV thyroid cancer is 36 percent nationwide; but at BMC, their survival rate is 47 percent (Figure 5).

## COLLABORATIVE APPROACH TO PATIENT CARE

A major provider in the Northeast for primary and tertiary referrals for the management of thyroid malignancies, BMC provides comprehensive, state-of-the-art services to patients with thyroid cancer.

At BMC, the care of patients with thyroid cancer is a collaborative process. The patient makes a number of complex decisions in consultation with the primary care physician as well as specialists in thyroid cancer who communicate closely with referring physicians regarding diagnosis, treatment planning, and follow-up care.

Referring physicians include primary care providers on BMC's campus, local and out-of-state physicians, as well as the 15 community health centers that participate in Boston HealthNet, an integrated health care delivery network founded by BMC.

As the primary teaching affiliate of the Boston University School of Medicine (BUSM), BMC is at the forefront of clinical practice, teaching and research in thyroid cancer. BMC employs the most advanced methods of evaluating thyroid nodules for cancer and managing both routine and aggressive thyroid malignancies.

Treatments encompass both standard modalities and, as appropriate to each patient, novel methods that incorporate translational and patient-oriented research in innovative partnership with basic science discovery. For example, recent breakthroughs in the

molecular pathology of thyroid cancer are yielding new, molecular-based therapies for aggressive thyroid cancers and facilitating personalized and targeted cancer therapies.

BMC models its care of patients with thyroid cancer on the most current American Thyroid Association (ATA) Guidelines for the Management of Thyroid Nodules and Cancer as well as the latest National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology.

BMC offers patients excellent and highly integrated care that brings together the expertise of physicians in multiple disciplines associated with the diagnosis and treatment of patients with thyroid cancer. Participating specialists include endocrinologists, cytopathologists, thyroid and thoracic surgeons, nuclear medicine specialists, medical oncologists, radiation oncologists, and radiation physicists.

Members of these departments conduct multidisciplinary reviews of cases in BMC's monthly Thyroid Pathology Conference and Head and Neck Tumor Conference.

» As the primary teaching affiliate of the Boston University School of Medicine, BMC is at the forefront of clinical practice, teaching and research in thyroid cancer. «

## DIAGNOSIS AND STAGING

Nodules are evaluated based on well-defined sonographic characteristics and size criteria specified in ATA biopsy guidelines. If the nodule reaches the criteria requiring biopsy, this procedure is usually conducted under ultrasound guidance for the most accurate results.

Fine-needle aspiration (FNA) biopsy is the current standard of diagnosis for thyroid nodules. A patient whose biopsy is consistent with malignancy (including follicular lesions or indeterminate cytologies) is referred for surgery. Each patient has a diagnostic neck ultrasound prior to surgery to determine if a central or lateral lymph node dissection must be performed with the thyroidectomy.

BMC endocrinologists perform ultrasound exams and ultrasound-guided biopsies, which greatly facilitate the patient's evaluation and accelerate surgical referral.

### *Pathology*

The interpretation of an FNA biopsy is an essential step in the screening of thyroid disease. Antonio de las Morenas, MD, Director of Cytopathology and Professor of Pathology, reviews all tumors and leads BMC's monthly thyroid pathology conferences.

The BMC Pathology Department is equipped with up-to-date tools to provide important information for the diagnosis and prognosis of thyroid cancer. The specimens are processed and stained using standard methods. The residual tissue available after processing is paraffinized and sectioned as surgical excision samples.

### **Using FNA tissue to advance tumor typing and prognosis**

While yielding essential data for individual diagnoses, the specimens are also used for special studies that may improve detection of malignant from benign tissue and avoid unnecessary surgery. The material that remains in the paraffin blocks aids the typing of tumors and tumor prognosis through conventional immunohistochemistry and molecular analyses that detect rearrangements or mutations involving BRAF, RET and RAS genes.

Over the last four years, the number of thyroid FNA samples received by the Pathology Department has increased significantly from 465 in 2007 to 510 in 2009. During 2009-2010, 873 biopsies were performed and 93.5 percent rendered satisfactory diagnoses. This is a superior result compared to the standard of care which typically is 10-15% of biopsies do not yield sufficient cells for evaluation. Most of the specimens comprised benign hyperplastic nodules or thyroiditis (69.5%), follicular and atypical lesions (16%), and papillary carcinomas (8%). The balance of specimens consisted of medullary carcinomas, anaplastic carcinoma, lymphoma and metastatic carcinoma.

Partial or total thyroidectomies received by the department increased from 155 in 2007 to 241 in 2009. As of September 30, 2010, the department received 164 cases. The majority of diagnoses comprised papillary carcinoma (39.9%), benign multinodular goiter (33.0%), Graves disease (11.4%), chronic thyroiditis (7.6%) and follicular and Hurthle cell adenomas (6.3%). Other diagnoses—abscesses, Hurthle cell carcinoma and squamous cell carcinoma—each amounted to just 0.6 percent of all cases.

The most common cancer in these resection specimens was papillary carcinoma. The microcarcinoma variant of papillary carcinoma, representing tumors under 1.0 cm, was the most common subtype, accounting for 49 percent of all papillary carcinomas seen at BMC.

## THYROID SURGERY

BMC brings together specialists in diverse disciplines to provide every patient with individualized treatment and deliver exceptional care without exception. Surgery plays a major role in the management of most thyroid cancers.

BMC offers a full range of surgical options, from standard total thyroidectomy and central neck dissections to procedures that treat locally advanced papillary thyroid and medullary thyroid cancer. These techniques include lateral neck dissections and extended cancer resections as well as endoscopic and minimally invasive thyroidectomy and laryngectomy as well as tracheal resections and reconstruction. BMC surgeons can conduct thyroid resections under local anesthesia in patients who are not candidates for general anesthesia.

Airway management of all types of thyroid cancer is a particular area of expertise at BMC. When treating advanced thyroid cancers that invade the trachea or larynx, the thyroid surgery team can perform laryngectomies and airway resections as well as reconstruction.

At BMC, special expertise is also available in revision thyroid cancer surgery, which tends to be more complicated than initial operations. Re-operative surgery has higher risks of permanent hypocalcemia from damage to the parathyroid glands or may induce temporary or permanent hoarseness from injury to the recurrent laryngeal nerves obscured by scar tissue.

BMC surgeons constantly seek to improve patient safety, reduce the likelihood of complications and enhance outcomes. BMC is a regional leader in endoscopic airway surgery. Other surgical techniques in use at BMC that reduce risk incorporate such technologies as flexible laryngoscopy to evaluate patients' airways and vocal cords; preoperative and

intraoperative ultrasonography to assess the thyroid gland and adjacent lymph nodes; and intraoperative monitoring of the laryngeal nerve.

BMC is fortunate to host a number of surgeons with considerable experience in thyroid surgery, including:

**Anand Devaiah, MD, FACS**, Director of Medical Student Education and Associate Professor, Departments of Otolaryngology-Head and Neck Surgery and Neurosurgery

**Gregory Grillone, MD, FACS**, Vice Chairman and Associate Professor, Department of Otolaryngology-Head and Neck Surgery

**Scharukh Jalisi, MD, FACS**, Director, Head and Neck Surgical Oncology and Skullbase Surgery and Assistant Professor in the Departments of Otolaryngology-Head and Neck Surgery and Neurosurgery

**David McAneny, MD, FACS**, Vice Chairman (for Quality and Patient Safety), Department of Surgery, and Associate Professor of Surgery

**J. Pieter Noordzij, MD**, Associate Professor, Department of Otolaryngology-Head and Neck Surgery

**Jennifer Rosen, MD, FACS**, Assistant Professor of Surgery and Molecular Medicine

**Mark Shrime, MD**, Assistant Professor, Department of Otolaryngology-Head and Neck Surgery

**Michael Stone, MD, FACS**, Chief, Section of Endocrine Surgery and Surgical Oncology, and Professor of Surgery

## POSTOPERATIVE CARE

Following a thyroid operation, the patient may go home later that day or after an overnight observation. Some patients require a longer hospital stay, such as a patient with a low calcium level or an individual recovering from a highly complex operation.

Early recognition and management of complications by the health care team is essential for the patient's safe recovery. Vigilant monitoring and management are collaborative processes that involve surgeons, nurses and other staff members. They observe patients for signs of low calcium levels, bleeding, airway compromise or other problems.

Administration of vitamin D before and after surgery can help the patient maintain normal calcium levels after a thyroid operation.

BMC nurses educate patients about thyroid hormone and calcium replacement and prepare

patients to recognize symptoms that may indicate complications. They also provide information regarding medications, wound care, and nutrition, as well as follow up visits with surgeons and physicians.

The surgeons and endocrinologists follow each patient and, together with the BMC Medicine Service, they co-manage patients with multiple medical problems. Close coordination among these specialties improves patient safety and outcomes, and enhances communication with patients and their families.

## ENDOCRINOLOGY

BMC is one of just two sites in New England capable of treating patients with maximal-dose radioactive iodine.

An individual with an aggressive iodine-avid tumor may be considered for maximal-dose radioactive iodine therapy, which administers the highest dosage of radioactivity that can be safely given to a patient. This large dose of radioactive iodine is calculated by our radiation physicist, Richard Behrman, PhD. After removal of the tumor by thyroidectomy and lymph node dissection, if necessary, the patient is staged with a radioactive iodine whole-body scan. The patient is prepared for the scan with a low-iodine diet. The tumor is stimulated to take up radioactive iodine by elevating thyroid stimulating hormone (TSH) using one of two techniques. Either the patient's thyroid hormone medication is stopped, which makes the

patient hypothyroid; or the patient is injected with recombinant human TSH.

As recommended by current ATA guidelines, the decision for treatment with radioactive iodine is based on AJCC staging of the tumor as well as risk of recurrence.

Radioactive Iodine treatment is administered at the BMC Department of Nuclear Medicine in close collaboration between our colleagues in the Section of Endocrinology, Diabetes, and Nutrition — Lewis Braverman, MD, Professor of Medicine; and Stephanie Lee, MD, PhD, Director of the Thyroid Health Center, Associate Chief of the section, and Associate Professor of Medicine — and our

colleagues in nuclear medicine, including: Gustavo Mercier, Jr., MD, PhD, Chief, Molecular Imaging and Nuclear Medicine Section, Department of Radiology, and Assistant Professor of Radiology; Rathan Subramaniam, MD, PhD, FRANZCR, Associate Professor of Radiology; and nuclear medicine technologists and radiation physicists.

The joint team conducts radioisotope scanning procedures that include radioactive iodine whole-body scans and positron emission tomography (PET) CT scans. They closely coordinate all components within the planning and implementation of each patient's treatment. These elements include diet, lab tests and recombinant human TSH administration as well as multiple measurements to estimate bone marrow exposure to radiation and total body retention of the isotope.

» BMC is one of just two sites in New England capable of treating patients with maximal-dose radioactive iodine. «

Boston Medical Center is fortunate to have many international and national experts in thyroid disease in the Section of Endocrinology, Diabetes and Nutrition, including:

**Sonia Ananthakrishnan, MD**, Assistant Professor of Medicine

**Lewis Braverman, MD**, Professor of Medicine

**Andrea Coviello, MD, MSc**, Assistant Professor of Medicine

**Alan Farwell, MD**, Director, Endocrine Clinics and Associate Professor of Medicine

**Philip Knapp, MD, MS**, Assistant Professor of Medicine

**Stephanie Lee, MD, PhD, FACE**, Director of the Thyroid Health Center, Director of the Thyroid Nodule and Cancer Research Group, and Associate Professor of Medicine

**Angela Leung, MD**, Assistant Professor of Medicine

**Elizabeth Pearce, MD, MSc**, Associate Professor of Medicine

**Sara Pietras, MD**, Assistant Professor of Medicine

**Joshua Safer MD, FACP**, Director of Endocrinology Fellowship Training and Endocrinology Education and Associate Professor of Medicine and Molecular Medicine



## MEDICAL ONCOLOGY

The role of the medical oncologist, previously limited in the care of patients with thyroid cancer, is becoming more important with the emergence of new, effective treatments designed to inhibit metastatic spread of the cancer.

At BMC, Omar Eton, MD, Associate Professor of Medicine, and his colleagues in the Section of Hematology and Medical Oncology specialize in finding new ways to treat advanced thyroid cancer using signal transduction inhibitors. These inhibitors target tumor vasculature as well as abnormally expressed receptors and enzymes produced by the thyroid cancers. BMC medical oncologists and pathologists work together to individualize care by identifying potential molecular targets in each patient's thyroid cancer tissue.

Many of these new drugs are pills that can be taken daily with water, and most have reasonable side effect profiles. When effective, these medications can control the growth and spread of the disease for a significant period of time while allowing patients to carry on their lives. BMC medical oncologists and nurses are skilled in preempting, mitigating, and managing the side effects of these medications to make the treatment experience as comfortable as possible for the patient.

In close collaboration with their peers in endocrinology, BMC oncologists help patients manage side effects that may be directly related to the thyroid cancer and associated hormonal over-secretions. They also work very closely with surgeons and radiation oncologists to coordinate the sequence of treatment interventions that achieves the best results without overburdening the patient and family.

Since thyroid cancer can grow slowly over several years, the medical oncologists use scans and other tests to monitor patients for new or worsening symptoms or acceleration in the growth rate of tumor metastases. They use this data to guide the optimal time to start treatment.

BMC medical oncologists have access to all FDA-approved agents and they also enroll eligible patients in appropriate clinical trials. If a specific trial of potential value to a patient is not open at BMC, oncologists will refer the patient to a site that offers the trial.

### *New treatments for aggressive cancer*

Research on a new treatment modality for aggressive thyroid cancer that is not iodine-avid has entered clinical trials in the last two years. Doctors Eton and Lee are co-principal investigators in a trial of Sorafenib (marketed as Nexavar®) for these patients, who have no other treatment options. This drug is a tyrosine kinase inhibitor shown to be effective at stabilizing growth of tumors.

Although it is unusual for an endocrinologist such as Dr. Lee to participate in an oncology trial, this collaboration recognizes the role of endocrinologists in managing treatment for the vast majority of patients with thyroid cancer and their skill in assessing appropriate opportunities to administer this treatment.

## RADIATION ONCOLOGY

Physicians in the BMC Department of Radiation Oncology are key participants in the multidisciplinary care of patients with thyroid cancer.

These physicians include Minh Tam Truong, MD, Clinical Director and Assistant Professor of the Department of Radiation Oncology; and Lisa Kachnic, MD, Chair and Professor of the Department of Radiation Oncology.

External beam radiation therapy has applications in the management of thyroid cancer at BMC, such as when treating locally invasive, well-differentiated tumors that do not concentrate radioactive iodine. Such tumors, as well as those that demonstrate extrathyroidal extension of disease, may pose high risk of recurrence, and external beam radiotherapy can improve local control.

External beam radiotherapy also plays a major role in the management of anaplastic thyroid carcinoma, another tumor that does not concentrate radioactive iodine. A regimen comprising upfront surgical debulking followed by a combination of adjuvant radiotherapy and concurrent chemotherapy may offer the best chance of cure.

Factors that increase the technical challenges of delivering radiotherapy to the thyroid bed and regional lymph nodes include the unique anatomy of the thyroid gland in the head and neck region as well as the potential lymphatic spread to the bilateral neck and upper mediastinum. Advances in radiation technology allow the use of intensity-modulated radiotherapy for thyroid cancer. This highly precise technique optimizes the dose to the tumor while sparing surrounding normal tissues and minimizes the patient's risk of acute and late toxicities from treatment.

At BMC, novel radiation modalities such as stereotactic body radiosurgery using the CyberKnife® Robotic Radiosurgery System remain investigational tools to be studied on protocol. These techniques may have a future role in the management of thyroid cancer in patients with solitary malignant nodules who are not candidates for surgery.



## INTEGRATIVE MEDICINE

Integrative medicine practices have been shown to reduce cancer-related symptoms such as pain, anxiety, nausea and fatigue. The Program for Integrative Medicine and Health Care Disparities in the Department of Family Medicine at BMC combines conventional medical treatments with evidence-based complementary therapies.

Led by Robert Saper, MD, MPH, Director of Integrative Medicine and Associate Professor, Department of Family Medicine, the program offers patients and staff a spectrum of traditional and alternative approaches to care.

BMC is conducting ongoing research into the benefits of integrative care to patients with cancer. With support from the Massage Therapy Foundation, free therapeutic massage has been offered to cancer patients and staff. Further support from this foundation has enabled surgical oncologist Jennifer Rosen, MD, to study the effectiveness of massage as a tool to decrease pre-operative anxiety and post-operative pain in patients undergoing surgical procedures for cancer.

At the Moakley Building, where BMC conducts much of its cancer care, registered yoga teacher Anna Dunwell holds a free weekly yoga class and licensed acupuncturist Ellen Highfield offers free acupuncture to patients with cancer. Participants in these sessions have gained notable clinical benefits, reporting decreases in nausea, pain, depression, anxiety and fatigue.

Services to individual patients complement group activities. Paula Gardiner, MD, MPH, Assistant Director of Integrative Medicine and Assistant Professor, Department of Family Medicine, offers consultations to patients that focus on stress management, nutrition and coordination of complementary therapies.



**Weekly Yoga practice at the Moakley Building produces clinical benefits in our patients.**

» BMC is conducting ongoing research into the benefits of integrative care to patients with cancer. «

## PATIENT SUPPORT SERVICES

A diagnosis of cancer can be a life-altering experience. The BMC Cancer Support Services Program provides a comprehensive set of services to help patients focus their energy on combating and coping with their disease. Designed to improve long-term outcomes and survivorship, these services address a range of medical, social, economic and emotional needs.

Resources available to patients include support groups, educational activities and classes from Chi Gong and Zumba to yoga as well as access to social workers and interpreters, assistance in navigating the steps in treatment, and counseling in nutrition, diet and lifestyle changes.

The program also offers services to patients who have completed treatment such as the BMC Survivorship Program. In 2010, financial assistance from this program enabled 50 patients to attend the Stowe Vermont Weekend of Hope for Cancer Survivors.

### *Patient Navigators*

The BMC support program includes the services of patient navigators, advocates who help patients and their families manage cancer diagnoses and overcome barriers to obtaining timely and appropriate treatment. These barriers include lack of transportation or childcare, insurance difficulties, financial stresses, literacy and language issues, and the complexities of appointments and treatment plans.

BMC began its patient navigator program a decade ago, and in 2005 became one of eight institutions to receive a five-year National Cancer Institute grant to develop a patient navigator research program. A subsequent grant from an anonymous donor has enabled BMC to expand its navigation program to reach even greater numbers of patients.

Patient navigators help to coordinate care and guide patients through diagnostic and treatment plans that involve diverse medical personnel. They may schedule appointments with caregivers, develop treatment calendars, arrange translation or interpretation assistance or childcare services during appointments, or facilitate transportation to and from medical visits. They provide encouragement and support to patients and call or visit those who have skipped appointments.

While helping patients identify and cope with obstacles to treatment, BMC patient navigators improve treatment compliance, decrease the “no show” rate, and develop disease algorithms that streamline and expedite patient care.

## RESEARCH TO ADVANCE DETECTION, DIAGNOSIS AND CURE

### *Translational research*

BMC participates in the Boston University Medical Campus Thyroid Nodule and Cancer Research Group, a newly formed collaboration of experts to support research in thyroid cancer and thyroid diagnostics. The director of this group is Dr. Stephanie Lee of the Section of Endocrinology. Its multidisciplinary efforts in thyroid ultrasonography, thyroid cytology, molecular diagnostics and diagnostic nuclear imaging by PET/CT will expand the scope of translational research at BU with direct clinical relevance to reducing unnecessary surgery and treatment of thyroid neoplasms.

### *New technology to reduce need for diagnostic surgery*

The current standard of diagnosis for thyroid nodules — FNA biopsy — yields indeterminate results in 10- to-25 percent of its applications. As a result, twice as many thyroidectomies are performed for further diagnosis. BMC researchers have been developing new technologies to improve differentiation between benign and malignant tissue and avoid surgery for the purpose of diagnosis alone. One of these tools is optical spectroscopy.

Elastic scattering spectroscopy (ESS) is a new, minimally invasive optical-biopsy technique. Mediated by fiber-optic probes, ESS is sensitive to cellular and subcellular morphological features. BMC researchers, Doctors Rosen and Lee assessed the diagnostic potential of ESS to differentiate benign from malignant thyroid nodules as determined by histology and found it to be both

sensitive and specific. Now, in collaboration with the BU Department of Biomedical Engineering, they are minaturizing the ESS probe for use in thin needle aspiration biopsies of thyroid nodules in the Endocrine clinic in an IRB-approved protocol.

BMC researchers are also developing another diagnostic tool, microRNA array analysis. Recently discovered to play a key role in cell regulation, microRNA are very small pieces of gene products. Using Genome Science Institute and BU Bridge awards, Doctors Rosen and Lee have established an IRB-approved thyroid tumor registry that now contains more than 400 thyroid FNA biopsy and surgical specimens. The two physicians performed microRNA microarray analysis of 20 surgical specimens (10 from malignant thyroid cancers and 10 from benign thyroid nodules) using two novel platforms and then used complex models to analyze the data.

They identified 43 microRNA with a pattern of expression that could reliably differentiate benign from malignant thyroid nodules. Five of these microRNA were significantly altered in expression. They successfully reduced the expression of one microRNA in cancer cells in the clinic, reducing that cell line's malignant potential.

Doctors Lee and Rosen are applying for an R21 NIH grant to use the profiles in combination with novel microfluidic sample preparation technology developed by Dr. Rosen with the BU Department of Biomedical Engineering. They have published their initial findings and presented their work at national and international scientific meetings.

» ...developing new technologies to improve differentiation between benign and malignant tissue and avoid surgery for the purpose of diagnosis alone. «

### *Clinical trials*

BMC is a leader in the enrollment of underrepresented populations in clinical trials, which bring the most advanced care to patients with cancer. At BMC, nine percent of newly diagnosed patients enroll in cancer clinical trials, a rate that exceeds the national average by 300 percent. Of the enrollees, 39 percent are minorities, while nationwide, minorities comprise just 17 percent of the participants in clinical trials for cancer patients.

The BMC Clinical Trials Program is co-directed by Kathleen Finn, NP, and Timothy Cooley, MD, Physician Director, Cancer Clinical Trials Program, Section of Hematology and Oncology, and Associate Professor of Medicine. Its Cancer Clinical Trials Program is administered by Salli Fennessey, CCRP.

Patients with thyroid cancer are evaluated for clinical trial eligibility in a multidisciplinary conference that convenes biweekly throughout the year.

BMC is currently conducting the following clinical research studies on thyroid cancer:

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**WIRB #2009-1598: Bayer Healthcare #14295** A Double-Blind, Randomized Phase III Study Evaluating the Efficacy and Safety of Sorafenib Compared to Placebo in Locally Advanced/Metastatic RAI-Refractory Differentiated Thyroid Cancer

*BMC Co-Principal Investigators: Omar Eton, MD, and Stephanie Lee, MD, PhD*

This multi-center study sponsored by Bayer Healthcare seeks to enroll patients with thyroid cancer. Participants will be randomly assigned with equal probability to receive either Sorafenib (marketed as Nexavar®) or a placebo. If there is progression of disease at any time, those on placebo may be switched to Sorafenib.

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**IRB #H-26261** Molecular Markers in Thyroid Pathology from Fine Needle Aspiration

*Principal Investigator: Jennifer Rosen, MD*

This single-center, investigator-initiated study seeks to enroll patients undergoing fine-needle aspiration of the thyroid. Consenting patients permit researchers to use leftover samples from this procedure to evaluate specific genes that are present in different thyroid diseases and to use these tests to distinguish various thyroid conditions without needing to do surgery. The goal is to prevent unnecessary surgery in patients without thyroid cancer. To date, 171 participants have enrolled in this study. Of the 114 patients whose race was known, 42 percent were from minority groups.

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**IRB #H-28135** The Role of an Optical Probe in the Detection of Thyroid Cancer

*Principal Investigator: Jennifer Rosen, MD*

This single-center, investigator-initiated study seeks to enroll patients undergoing thyroid surgery. Consenting patients permit researchers to use leftover samples from this procedure to evaluate the effectiveness of an optical biopsy system. The tip of the optical probe will be placed in gentle contact with the leftover tissue sample to obtain a reading. The diagnosis from the optical biopsy system will be compared with the official pathology diagnosis. To date, 40 patients have enrolled in this trial. Of the 33 participants whose race was known, 79 percent were from minority groups.

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**Patients with thyroid cancer may also participate in the following relevant clinical trials:**

**IRB #29430** Qualitative Research: Conceptualizing Cancer-Related Fatigue or Tiredness in Patients with Cancer

**IRB #H-28725/RTOG #R0841** Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy

## CANCER REGISTRY DATA: TOP CANCER SITES IN 2009

One of the components of a teaching hospital cancer program is the Cancer Registry, the data collection unit designed to accession and abstract all new cancer cases diagnosed and/or treated at BMC. The Registry, managed by Ruth Flaherty, CTR, also conducts yearly follow-up of all living patients in its database.

Overseen by the BMC Health Information Management Department, the BMC Cancer Registry contains data for both internal and external uses on the more than 13,000 patients who have been diagnosed with cancer since January 1, 1999.

The Cancer Registry works closely with the BMC Cancer Care Committee to maintain BMC's accreditation as a Teaching Hospital Cancer Program and to monitor its compliance with the American College of Surgeons Commission on Cancer Standards.

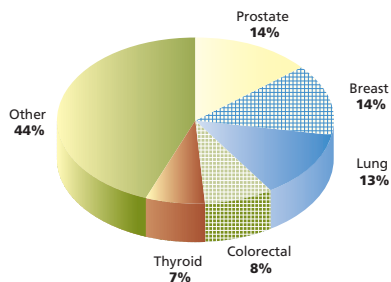
A participant in the annual National Cancer Data Base (NCDB) Call for Data, the BMC Cancer Registry also reports its cancer data to the Cancer Registry of the Massachusetts Department of Public Health.

In 2009, the BMC Cancer Registry accessioned 1,230 analytic cancer cases, of which 641 were male and 589 were female. Prostate, breast, lung, colorectal and thyroid cases continue to comprise the major sites at BMC.

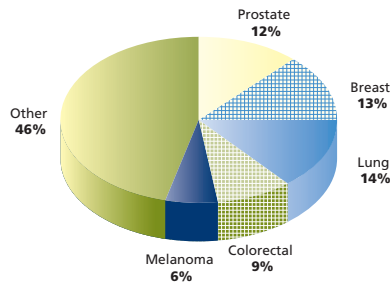
### Top Cancer Sites In 2009

|            | <b>Boston Medical Center</b> | <b>Mass</b> | <b>American Cancer Society</b> |
|------------|------------------------------|-------------|--------------------------------|
| Prostate   | 14% (173)                    | 12%         | 13%                            |
| Breast     | 14% (167)                    | 13%         | 13%                            |
| Lung       | 13% (159)                    | 14%         | 15%                            |
| Colorectal | 8% (97)                      | 9%          | 10%                            |
| Thyroid    | 7% (85)                      | n/a         | n/a                            |

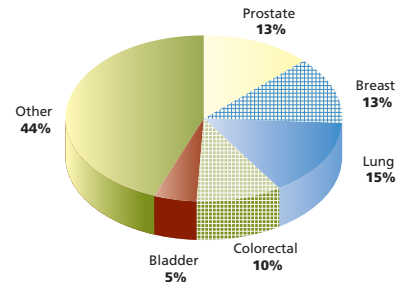
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