



Physician Update

Maine Research Associates and Central Maine Medical Center announce collaboration **A1**

A Quality Indicator: Needle Biopsy vs. Open Surgical Biopsy for Image Detected Breast Abnormalities **A2**

Central Maine Comprehensive Cancer Center is accredited by American College of Surgeons **A4**

Maine Research Associates and Central Maine Medical Center announce collaboration



Maine Research Associates and Central Maine Medical Center recently announced a new collaboration that will make emerging medicines more widely available in Maine.

In a press release issued at a gathering with Maine media representatives, Robert Weiss, M.D., founder of Maine Research Associates (MRA), and executives from CMMC said the new relationship between the organizations will “bring the medicines of tomorrow to the patients of today.”

Through more than 500 clinical research trials spanning some 25 years, Dr. Weiss has led research activities from offices at Two Great Falls Plaza in Auburn, Maine. At the heart of the practice’s work is the volunteer relationship between patients and a medical researcher that advances care, provides for new therapies, and eventually delivers medical opportunities worldwide.

The MRA-CMMC collaboration will immediately permit over 200 care providers to enroll potential study volunteers into clinical trials of possibly groundbreaking drugs. CMMC care providers represent some 30 medical and surgical specialties, which will broaden the base of potential clinical research activities and offer new opportunities to Maine patients, including those living with diabetes, arthritis, and emphysema. The alliance between MRA and CMMC will allow study volunteers to have greater access to leading edge medications at no cost.

Maine Research Associates has played a key role in the development of nearly every heart-related drug that has been prescribed in the last 15 years and that will be used in the next 10 years. Clinical trial research improves the treatment of acute and chronic illness.



NEW RESEARCH VENTURE – Robert Weiss, M.D., announces the affiliation of Maine Research Associates, a company he formed in the late 1980s, and Central Maine Medical Center. See accompanying story for details.

Dr. Weiss began Maine Research Associates in 1987, focusing on studies related to heart health. Today, with over 45 studies in progress and a team of 14 medical professionals, MRA is among the most trusted clinical research sites in the country.

Access to clinical research trials is typically available in large, academic medical centers. The MRA-CMMC collaboration creates an opportunity to expand clinical trial availability in Maine.

A Quality Indicator: Needle Biopsy vs. Open Surgical Biopsy for Image Detected Breast Abnormalities



By Gregory D'Augustine, M.D.

In the 20th century the diagnostic standard of care for breast abnormalities in the U.S. was open surgical biopsy. In 2005 Dr. Melvin Silverstein chaired an American College of Surgeons Consensus Conference that established a new paradigm in the diagnostic workup of image detected breast abnormalities.

The many drawbacks of open surgical biopsy were noted. These included a higher complication rate, a potentially disfiguring scar, a tendency to complicate surgical planning after cancer diagnosis (requiring a return to the operating room for additional surgery), as well as greater inconvenience, anxiety, and cost.

There was general agreement that some surgical biopsies were appropriate due to safety and patient preference issues, among others. Acceptable reasons for performing surgical biopsies included image detected lesions in hazardous or otherwise difficult locations. Stereotactic biopsy of deep lesions near the chest wall present risk of bleeding, increased pain, and even pneumothorax. Conversely, small superficial lesions can also be quite difficult to accurately biopsy with image guided needle technique. I should also stress that going to the operating room to obtain more tissue for further microscopic study after a needle biopsy showing “discordant” or high risk findings is not considered inappropriate.

The consensus statement established a new “gold standard” consisting of percutaneous needle biopsy as the best initial diagnostic step in evaluating such lesions. Soon thereafter, the American Society of Breast Surgeons issued a supportive consensus statement and embarked on an educational and training program to help breast surgeons bring this new concept into general practice. It was believed that greater than 90 percent of breast biopsies would soon be performed by percutaneous needle biopsy.

To the dismay of many, the following years saw only gradual incremental changes in breast biopsy techniques used across the country. In 2008 and 2009 several studies indicated a 30 percent to 40 percent open surgical biopsy rate was still present in the U.S. One study at Beth Israel Medical Center proved that this problem was not limited to rural settings or non-academic centers. These surprising results led Dr. Silverstein, in February 2009, to issue a call for activism entitled “Where is the Outrage?” in which he decried the ongoing misuse of open surgical biopsy and called for women to become informed and to demand better care.

In February 2011, an editorial in the New York Times drew attention to the fact that a high percentage of breast biopsies were still being done in the operating room. Particular attention was given to a recent Florida database study of 172,342 breast biopsies over the past several years. The open surgical biopsy rate of 30 percent was deemed “outrageous” by Dr. Silverstein. Commentary to the effect that the “reason for the overuse of open biopsies is not known” prompted speculation about inadequate surgeon education as well as potential financial explanations.

My initial response to such comments was something on the order of “That can’t be accurate”. But the more I learned, the more disturbing the data became. The current study, then, compares our practice at the Bennett Breast Center to the new standards outlined above.

Methods and Results: In 2010, 288 breast biopsies were done at the Bennett Center. The preponderance of these followed detection of abnormalities on imaging studies such as mammography, ultrasound or magnetic resonance imaging (MRI). Image guided needle biopsies were performed by six radiologists and three surgeons who practice at the Bennett Center. One hundred and twenty malignant lesions were identified. Virtually all surgical biopsies were performed by the three surgeons who ascribe to the Bennett Breast Center's educational guidelines and treatment protocols.

Most surgical biopsies had been preceded by needle biopsy. Indications for surgical biopsy following needle biopsy included the finding of "high risk" lesions on needle biopsy. These included radial scar, papillomas, and atypical lesions, all of which are felt to raise concerns over the possibility of nearby cancer cells or high risk of cancer development over time.

Only 14 open surgical biopsies were carried out without prior needle biopsy. Seven of these were carried out because the lesion was deemed "too small and superficial" to accurately biopsy with image guided needle technique. Two open surgical biopsies were carried out for abnormalities seen only on galactogram study (thus precluding accurate image guided needle biopsy). All 14 of these biopsies proved to be benign by microscopic exam.

One surgical biopsy was carried out, as called for under Bennett Center management protocol, to assess a "complex cyst" seen on ultrasound exam. Pathology report confirmed a malignant lesion. One surgical biopsy case involved a lesion which lay adjacent to an augmentation implant. Pathology report confirmed malignancy.

There were four "problem cases" where initial surgical biopsy might reasonably have been avoided. The first entailed "patient preference" for an open surgical biopsy. The second related to a 21-year-old patient with a presumed benign fibroadenoma. The third involved a lesion at the site of prior fibroadenoma excision in 2005. The final case involved a suspicious density seen at the site of tylectomy for breast cancer in 2005. Stereotactic biopsy was felt to be technically impossible because of the presence of multiple surgical clips in the area in question. No ultrasound exam was performed, however,

so the feasibility of ultrasound guided core biopsy was not considered. All four of these cases were proven to be benign findings on surgical pathology assessment.

Conclusions: The data indicates that an open surgical procedure was the initial biopsy in only five percent of cases seen at the Bennett Center in 2010. Most of these represented appropriate use of the operating room for diagnosis. This confirms my belief that our surgeons and radiologists maintain an excellent standard of care when determining the safest and best approach to diagnosis of suspicious abnormalities seen on breast imaging studies. Use of needle biopsy as the initial diagnostic maneuver in such a high percentage of cases emphasizes the importance of high educational and ethical standards among our surgeons. These three surgeons maintain a high volume of breast cases in their practices and have demonstrated a vested interest in providing the best care possible for patients presenting with breast related problems.

Gregory D'Augustine, M.D., is co-medical director of the Sam and Jennie Bennett Breast Care Center at Central Maine Medical Center in Lewiston, Maine.

References:

American Society of Breast Surgeons Consensus Statement on Percutaneous Needle Biopsy for Image Detected Breast Abnormalities. June 12, 2006.

Clarke-Pearson, Emily, et al: Quality Assurance Initiative at One Institution for Minimally Invasive Breast Biopsy as the Initial Diagnostic Technique. JACS 2008. 75-77. (Commentary: "Where's the Outrage" by Dr. Silverstein).

Grady, E. Study of Breast Biopsies Finds Surgery Used Too Extensively. The N.Y. Times. Feb. 18, 2011.

Silverstein, MJ, Lagios MD et al: Image Detected Breast Cancer: State of the Art Diagnosis and Treatment. JACS 2005; 201. 586-597.

Central Maine Comprehensive Cancer Center is accredited by American College of Surgeons



The Central Maine Comprehensive Cancer Center at Central Maine Medical Center has been approved by a national healthcare quality review organization.

The cancer center has once again been recognized by the American College of Surgeons (ACoS) as a Community Hospital Comprehensive Cancer Center – the highest level of approval granted to community hospitals.

“The commendations are gratifying for us because they highlight the careful focus we place on getting all the details right,” said Dr. Erickson. “Not only do we provide a high-quality service, but we do all the things that make our cancer program truly comprehensive.”

Hematologist-oncologist Nicholette L. Erickson, M.D., chairman of the medical center’s Cancer Committee, said the accreditation included commendations in seven areas: outcomes analysis; data management, including timely data abstracting; observing College of American Pathologists guidelines; prevention and early detection activities; staff education; and quality improvement.

“The commendations are gratifying for us because they highlight the careful focus we place on getting all the details right,” said Dr. Erickson. “Not only do we provide a high-quality service, but we do all the things that make our cancer program truly comprehensive.”

To gain ACoS approval a hospital must offer the four major components of an approved cancer program: a multidisciplinary cancer committee that provides the cancer program with leadership; cancer conferences that facilitate consultations among service providers; a patient care evaluation system; and a cancer registry for tracking and managing information regarding cancer patients.

Commission on Cancer approval is awarded only to those facilities that have voluntarily committed to provide the best in diagnosis and treatment of cancer and undergo a rigorous evaluation process and performance review. To maintain approval, facilities must undergo an on-site review every three years.

Dr. Erickson said the approval “demonstrates the high quality services offered at CMMC. Our program is reviewed every three years and has received approval since 1937.”

The cancer program has research affiliations with nationally-recognized cancer programs, which means that patients and families are assured the care they receive at CMMC is the best cancer care available.

Cancer conferences at CMMC provide educational opportunities for the medical staff and promote consultations between cancer care providers. The conferences cover most cancers, and are attended by physicians from all medical disciplines, nurses, social workers, cancer registrars and other healthcare professionals.

CMMC's patient care evaluation system identifies ways in which patient care can be improved. The ACoS Commission on Cancer requires that approved programs conduct annual studies to assess treatment processes and outcomes.

The CMMC Cancer Registry collects and manages the data base used to evaluate the cancer program's effectiveness in treating patients. Each confirmed cancer case is entered into the registry with detailed information on diagnosis, extent of disease, treatment and demographics.

A history of medical, family and occupational-industrial factors, and personal habits is maintained. This system provides information on changes in a person's disease. The registry's statistical reports enable physicians to

evaluate the success of specific cancer treatments and are a valuable resource for cancer researchers. Information collected through the CMMC Cancer Registry allows CMMC to participate in national studies designed to improve patient care. The Cancer Registry at CMMC was started in 1954.

"CMMC's cancer program works to decrease the incidence of disease and mortality of patients with cancer, improve the medical center's comprehensive cancer control efforts, and enhance the care of terminally-ill patients," said Dr. Erickson.



Central Maine Healthcare's cancer care physician team includes, from left, Daniel C. Rausch, M.D., Sue A. Mandell, M.D., Courtney A. Jensen, M.D., Nicholette L. Erickson, M.D., and David C. Caldwell, M.D. Absent from photo are Hans L. Boedeker, M.D., and Trudi A. Chase, M.D.

Ocean. Lakes. Mountains.
Boating. Kayaking. Fishing. Skiing.
A professional culture that values your clinical skills.
A competitive salary, skilled colleagues and excellent quality of life.

What more could you want?



Choose your ideal practice from a variety of clinical positions
affiliated with the Central Maine Medical Family.

Emergency Medicine
Endocrinology
Endovascular Surgery
Family Practice in rural settings
Gastroenterology
General Surgery in rural setting
Internal Medicine in rural settings
Regional Hospitalist
Neurology
Neurosurgery
Otolaryngology
Trauma/General Surgery/Surgical Critical Care
Urology

Visit www.cmmc.org/jobs/physjobs.taf or call 800-445-7431

