Congressional Update: *Report from the Biomedical Imaging Program of the National Cancer Institute*

American College of Radiology Imaging Network:

The Digital Mammographic Imaging Screening Trial—An Update[1]

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A major, 3-year multicenter study of digital mammography, the Digital Mammographic Imaging Screening Trial (DMIST), was launched on October 29, 2001. This study, sponsored by the National Cancer Institute and conducted by the American College of Radiology Imaging Network (ACRIN), is designed to compare digital mammography with standard mammography for the detection of breast cancer *(http://www.dmist.org).* Principal Investigator for this ACRIN study is Etta Pisano, MD, University of North Carolina.

Although film mammography is still the "gold standard" for early detection of breast cancer, digital x-ray mammography may offer substantial improvements. The primary aim of the DMIST is to compare the diagnostic accuracy of digital mammography with that of screen-film mammography for breast cancer screening. Secondary aims will address issues associated with the cost-effectiveness of digital mammography and the impact of false-positive results on health-related quality-of-life issues. These include (*a*) determining the diagnostic accuracy of digital compared with screen–film mammograms through four retrospective reader studies; (*b*) assessing the effects of patient characteristics—including age, lesion type, pathologic diagnosis, menopausal and hormonal status, breast density, and family history—on measures of diagnostic accuracy for digital mammography; (*c*) using accuracy, resource utilization, and quality-adjusted life-year data to model the cost-effectiveness of digital mammography versus that of screen-film mammography in a screening population; (*d*) assessing the effect of decreased false-positive mammogram interpretations that are expected with digital mammography on the health-related quality of life and personal anxiety of women undergoing the screening mammography experience; (*e*) conducting retrospective reader studies to assess the relation between the diagnostic performance of digital mammography and the rate of cancer in the set of cases utilized; (*f*) conducting retrospective reader studies to determine the effect of soft-copy versus printed film display on the diagnostic performance of digital mammography; (*g*) conducting retrospective reader studies to determine the effect of breast density on the diagnostic accuracy of digital mammography versus that of screen-film mammography; (*h*) determining differences in image quality and breast radiation dose in digital and screen-film imaging among all participating study sites; and (*i*) assessing temporal variations in image quality, breast radiation dose, and other quality control parameters at all participating study sites during the course of the screening trial.

A total of 49,500 asymptomatic women will be prospectively enrolled into the trial at 18 centers in the United States and Canada, across four different machine types, over an estimated 18 months (Fig 1). Enrollment is currently in line with study projections. Women are entered into the study at the time of their regular screening mammographic examination and are followed up annually for 2–3 years. They will undergo both a standard and a digital mammographic examination. In each examination, two views per breast will be obtained, for a total of eight views. For some women, additional views or studies may be required. For additional information on the DMIST, refer to the study Web site *(http://www.dmist.org).*

The four digital technologies (and thus machines) being tested include those from GE Medical Systems, Fischer Im-

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Figure 1. ACRIN DMIST sites.

Cancer Information Service
Toll-free: 1-800-4-CANCER (1-800-422-6237)
TTY (for deaf and hard of hearing callers): 1-800-332-8615

NCI Online
http://cancer.gov

CancerFax
Fax-on-demand service for both health care providers and patients or families. Dial 1-800-624-2511 or 301-402-5874 and follow the voice-prompt instructions.

Figure 2. Sources of National Cancer Institute information.

aging, Fuji Medical Systems, and Lorad. Both the GE and Fischer systems have Food and Drug Administration approval. The four existing digital mammography systems will be tested to assess the effects of technical parameters including display type, machine type, and detector spatial and contrast resolution on measures of diagnostic accuracy for digital mammography.

ACRIN is the National Cancer Institute cooperative group of imaging physicians, scientists, and medical institutions conducting the DMIST. ACRIN is designed to conduct clinical trials focused on the rigorous testing and validation of standard and emerging medical imaging technologies. ACRIN and DMIST represent activities by the National Cancer Institute that are aligned with the recommendations of the March 2001 Institute of Medicine Committee on Technologies for the Early Detection of Breast Cancer. These recommendations fell into two major categories: to improve the development and adoption processes for new technologies and to make the most of technologies currently available for breast cancer detection (1).

The promise of digital mammography includes not only better detection of cancer, especially in breasts with dense parenchymal tissue, but also potentially enhanced patient throughput and higher productivity for mammographers. Improvement in throughput may be critical in allowing mammography centers to provide digital mammography screening services at an acceptable cost.

Benefits, other than those predicted from the primary and secondary DMIST aims, may result from digital mammography. First, the digital nature of the mammograms will allow for the electronic transmission of images. This could allow remote areas of the country or world to have access to experienced mammographers. Also, this would facilitate the opportunities for breast imaging radiologists to consult with each other and aid in the training of future mammographers. Second, the digital images generated by digital mammography will provide a ready source of data that can be used in computer-aided detection systems.

DMIST represents the first large, multicenter clinical trial for ACRIN, and it is off to a solid start. The sites are established, equipment is in place, and accrual is proceeding at projected rates. ACRIN stands poised to move breast cancer detection technology forward through this ambitious collaborative trial. Figure 2 provides information about how to contact the National Cancer Institute. For further information on National Cancer Institute initiatives applicable to breast cancer research, refer to *http://www.nci.nih.gov/bci.html,* and for more information on imaging priorities at the National Cancer Institute refer to *http://www.cancer.gov/initiatives/grp-image.html.*

REFERENCE

1. Committee on Technologies for the Early Detection of Breast Cancer; Nass SJ, Henderson IC, Lashof JC. Mammography and beyond: developing technologies for the early detection of breast cancer [Institute of Medicine, National Academy of Science Web site]. Available at: *http://www.iom.edu.* Accessed 2001.