

## Position Paper for Health Care Providers

# Digital Mammography: Comparison with Screen Film Mammography

Mammography remains the best method of early breast cancer detection. Studies have shown that screening mammography reduces the rate of death from breast cancer among women who are 40 years of age or older. Among women age 50-69, the reduction in the mortality rate was between 16-35 percent; women age 40-49 had a reduction of 15-20 percent. However, traditional screen-film mammography is limited in its ability to detect some cancers, especially those occurring in women with radiographically “dense” breasts. For this reason, extensive research efforts to improve mammography have occurred.

Digital mammography was developed in part to address some of the limitations of screen film mammography for cancer detection. The results of the Digital Mammographic Imaging Screening Trial (DMIST), conducted from 2001 to 2005 by the American College of Radiology Imaging Network, adds important information that health care providers can use to assess the value of full field digital mammography (FFDM) as compared to screen film mammography (SFM).

Currently, only 8 percent of all U.S. mammography machines are digital. As of this report, there are 23 facilities in Michigan with digital mammography equipment, mostly located in southeast Michigan. Although current access to this type of technology is limited, during the next few years, the number of facilities purchasing FFDM systems is expected to increase.

### *Has the DMIST study shown that FFDM is superior to SFM in terms of detecting breast cancer?*

The Food and Drug Administration (FDA) regulates performance standards for all mammography equipment. The FDA approval process for digital mammography equipment requires manufacturers to show that their equipment performs at least at the level of screen film mammography. There is no requirement that the digital systems be superior. Several manufacturers have now met the FDA requirements and offer full field digital systems, which should perform at least as well as screen film mammography.

Although there have been scientific reasons to expect superior performance of digital systems, the DMIST study, which evaluated 42,760 asymptomatic women undergoing screening mammograms with both screen film and digital systems, suggest advantages of digital over film

mammography in some subgroups of women. However, the data for the entire population show no advantage of one technique over the other.

In subgroup analyses, screening with digital mammography had a significant advantage among women who were younger than 50 years of age, were pre-menopausal or peri-menopausal, and/or had radiographically dense breast tissue on film mammography.

However, a review of the data from DMIST, suggests that, in women 50 years of age or older, postmenopausal women, and women with less dense breasts, film mammography found more cancers than digital mammography, although the difference was not significant. This result is in concordance with those of other published studies (Lewin, Oslo I, and Oslo II). The higher specificity of digital mammography reported in DMIST is also supported by other data (Skaane P, Balleyguier C, and Diekmann F). Further analysis will determine if this benefit persists beyond the first digital mammogram since the screenings in this trial were a combination of first screenings and subsequent screenings.

Five types of digital mammography systems were used in DMIST. The study does not report whether certain brands of digital systems were superior to others. Overall, there was no significant difference. Therefore, mammographic facilities cannot determine from DMIST whether the advantages of digital imaging identified in some subgroups apply to equipment from all manufacturers.

The advantage offered by digital mammography appears to be limited to a minority of the women who undergo screening. Since routine screening is recommended for women 40 years of age or older, most women who undergo screening are postmenopausal and at least 50 years old, excluding them from at least two of the three subgroups that benefited from digital mammography in DMIST. Future data may determine if significant benefit is found for recommending FFDM in other sub groups of women as suggested from previous studies for film mammography.

### *What are the advantages of FFDM compared to SFM?*

FFDM offers potential and practical advantages over SFM. These include:

- Improved contrast and signal to noise ratios – may allow better cancer detection
- Real time interpretation of mammograms at distant sites with the use of teleradiology and computer-aided detection equipment
- Ability to place images in a window, level them, and electronically magnify them
- Elimination of film processing, storage, copying, and retrieval
- In women who were younger than 50 years of age, women who were premenopausal or perimenopausal, and those with radiographically dense breast tissue on film

mammography, the accuracy of digital mammography was significantly higher than that of screen-film mammography.

- Lower radiation dose. The DMIST data showed a 24 percent overall reduction in dose compared to film.

### *What are the potential disadvantages of FFDM?*

- Spatial resolution, the ability to visualize fine detail, is somewhat better on SFM
- Difficult to compare digital images with older film studies
- The costs of FFDM systems are often one and one half to four times as expensive as film mammography systems. Additional on-going costs of maintenance and image storage compound the price differential.
- Reimbursement rate for digital mammography by payers varies. The Center for Medicaid and Medicare Services reimbursement rate is not the same for other third-party payers. The potential cost of digital mammography to the patient can vary significantly but is higher than that of SFM.
- Manipulation of FFDM images (window and level settings and magnification) could require more expertise and time from the radiologist for optimal interpretation
- There was no demonstrated benefit in using digital mammography over screen film mammography in women 50 years of age or older.

### *Conclusion*

The most important message providers can give their patients is that good quality screening mammography saves lives, by diagnosing cancer early. The availability of high-quality images and skilled interpretation and the screening of all women who are eligible for it will yield optimal benefits regardless of the type of mammogram performed. Although digital mammography can detect cancers that might be missed by film mammography, the opposite will be true for some women. All women of the appropriate age should be regularly screened. When both types of equipment are available, the decision to use digital or film equipment should be tailored to the individual woman. If only one type of equipment is available, women should recognize that most of the benefit of mammographic screening is derived from the test itself and not from the way the image is stored.