

## **Mammography in Pennsylvania**

### **Mammography and Female Breast Cancer**

A mammogram is a safe and effective procedure where X-ray images of the breast are taken. Mammography is a complement to, not a replacement for, regular breast self-exams and periodic clinical exams by a physician. However, a high-quality mammogram is currently the most sensitive medical tool for detecting breast cancer early. Early detection of breast cancer may allow for more treatment options. It could even mean saving your life.

Mammography is performed using an X-ray system designed specifically for imaging the breasts. Each breast is compressed between two flat plates with an X-ray image recorder placed underneath. Compressing the breast helps by spreading the breast tissue out resulting in a clearer picture and less radiation. X-rays pass more easily through the compressed breast, and abnormalities are more easily detected. Some patients may experience minor discomfort from compression, but with modern equipment and radiographers specially trained for mammography, this should be minimal for the typical patient.

The breast is made up of fat, fibrous, and glandular tissue. During mammography, as the X-rays pass through the breast, they are absorbed differently depending upon the type of tissue they encounter. Fat is light and easily penetrated by X-rays. It appears as black regions on a mammogram.

Benign and cancerous breast masses are denser and appear as white regions. Everything else, including fibrous tissues, glands, and abnormalities such as microcalcifications, appear as various levels of white. Microcalcifications are tiny specks (less than 0.5 mm) of calcium in the breast. In the majority of cases, these specks of calcium are due to benign breast changes. However, when many microcalcifications are seen in one area, they are referred to as a cluster and may indicate a small cancer. Microcalcifications are the most common mammographic sign of ductal carcinoma in-situ (DCIS). Sometimes DCIS may be described as pre-cancerous, pre-invasive, non-invasive, or intraductal cancer.

In general, it is difficult to see a clear difference between normal functioning fibrous and glandular tissues and cancerous tissue in the firmer, denser breasts of younger pre-menopausal women. In older women, the fibrous and glandular tissues diminish, leaving more fatty tissues. Mammography is most effective on fatty breasts that can be easily compressed.

As with other medical diagnostic methods, there are limitations to mammography. The first is that not all cancers of the breast can be seen using mammography. Also, interpreting mammograms can be difficult because of differences in the appearance of the normal breast for each woman. Mammography cannot always distinguish cancerous from non-cancerous tumors. Screening women under 50 is more difficult. However, it is recommended that routine mammography screening begin at age 40. Breast implants also can affect the accuracy of mammography, because silicone implants block a clear view of the tissues in front and behind them. Most importantly, even having routine mammograms performed at the recommended schedule using the best technology and read by the most competent interpreting physicians is not a guarantee that all clinically significant findings will be discovered. Identifying clinically significant pathology in mammography is difficult at best and, for younger women with dense breast tissue, interpretation may be more difficult. Breast cancer risk is also higher for women who have a close blood relative with this disease. Patients should always discuss their personal risk factors with their physician.

### **Mammography and Male Breast Cancer**

Male breast cancer is still among the rarest cancers in men. Once an abnormality is suspected, men often are slow to seek medical guidance. Enlargement of the male breast due to the growth of surrounding ducts and supporting tissues is known as gynecomastia. Gynecomastia is a benign condition; however, it does increase a man's risk for breast cancer. Because breast cancer in men is almost always clinically apparent, mammography is usually performed to evaluate gynecomastia rather than to diagnose or screen for breast cancer. Patients who seek medical care within six months of discovering a change in breast tissue experience a significant survival advantage. Early detection is particularly important for men, because they

have little breast tissue; therefore, malignant growth will reach the skin covering the breast or the muscles underneath the breast more quickly than in women. When mammography is used to image the male breast, the procedure and positioning are basically the same as for the female breast.

### **Regulatory History**

The Mammography Quality Standards Act of 1992 (MQSA) is a federal law that ensures every mammography facility meets rigorous quality standards. The regulations regarding MQSA can be found in Title 21, Code of Federal Regulations, Part 900. The mammography facilities covered include breast clinics, radiology departments in hospitals, mobile vans, private radiology practices, and other doctors' offices. The Food and Drug Administration (FDA) ensures that facilities all around the country meet MQSA standards. These standards apply to the following people at a facility: the technologist who takes the mammogram; the interpreting radiologist who reads the mammogram; and the medical physicist who tests the mammography equipment. To work in mammography, all of these professionals must have special training and education. Because technology is always improving, these professionals must remain current with any changes through ongoing education. MQSA also makes sure that mammography equipment is tested regularly and maintained to operate properly. State inspectors are also required to have special training and continuing education to inspect mammography facilities.

In 2013, Pennsylvania passed the Breast Density Notification Act. This Act requires mammography providers to inform patients of their breast tissue density. Patients must be made aware that dense breast tissue is a common finding and can make detecting small cancers more difficult. It could also increase the risk of a late-stage diagnosis.

### **Agency Roles**

The FDA requires that all facilities performing mammography attain accreditation. This process may take six months or longer. An accreditation body, such as the American College of Radiology, that has the expertise to recognize the qualities of an acceptable mammography program performs this function for Pennsylvania facilities. The FDA does not certify a facility for mammography until after the facility and its personnel have been accredited and have satisfactorily passed an inspection. The FDA maintains a list of certified facilities on its website. Men and women should feel confident that a facility listed as certified has in place equipment, personnel, policies, and procedures necessary to ensure a high quality mammography exam.

The Bureau of Radiation Protection (BRP) contracts with the FDA to perform annual inspections of mammography facilities in Pennsylvania.

As noted above, MQSA inspectors must meet and maintain specific FDA qualifications that include continuing education and experience requirements. All inspectors must pass a series of tests prior to independently performing inspections. Continuing education for inspectors includes specialized training in radiation physics, physics related to mammography equipment, and inspecting mammography facilities' compliance with MQSA regulations. In addition, the FDA has an audit program to assure that quality inspections are being performed by the contracting states.

To find out more about mammography, talk with a radiologist, a mammography technologist, or a doctor. Individuals can also call the National Cancer Institute's Cancer Information Service at 800-422-6237. Check out FDA's mammography website at [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm) to locate an FDA-certified mammography facility near you, or visit [www.dep.pa.gov](http://www.dep.pa.gov), or call the BRP at 717-787-3720.