

Mammography in Pennsylvania

Mammography and Female Breast Cancer

A mammogram (also called a mammography exam) 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 more treatment options. It could even mean saving your breast or 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 women 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 other abnormalities such as microcalcifications, appear as various levels of white. Microcalcifications are tiny (less than 0.5 mm) specks 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 important, even having routine mammograms performed at the recommended schedule using the best technology and read by the most competent interpreting physicians are 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 harder-to-image breasts, the possibility of faster, more aggressive growths developing in between routine exams may occur more frequently than in the elderly. Young women with a family history of breast cancer should consult their physician for other possible medical screening tests.

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 usually is 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

In the past, mammograms were performed using high doses of radiation and produced poor diagnostic quality X-ray images. A survey of mammography facilities by the Bureau of Radiation Protection (BRP), in the mid 1970s, illustrated this fact and began a national review by the Food and Drug Administration (FDA). Technological advances over the years have made it possible to substantially reduce radiation dose and increase image quality. With the technological issues resolved, the federal government and many state governments, including Pennsylvania, passed legislation requiring strict quality standards to ensure that mammography will continue to be a safe and effective procedure.

The Mammography Quality Standards Act of 1992 (MQSA) is a federal law that makes sure 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 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 your mammogram; the interpreting radiologist who reads your mammogram; and the medical physicist who tests the mammography equipment. To work in mammography, all of these professionals must have special training and education. In addition, because technology is always improving, these professionals must keep up 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.

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 (ACR) that has the expertise to recognize the qualities of an acceptable mammography program, performs this function for Pennsylvania facilities. Not until after a facility and its personnel have been accredited and have satisfactorily passed an inspection does the FDA certify that facility for mammography. The FDA maintains a list of certified facilities on their Web site, as does the DEP at www.dep.state.pa.us/brp under Radiation Control Division. 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.

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 hands-on 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.

The BRP contracts with the FDA to perform inspections of mammography facilities in Pennsylvania. All BRP MQSA inspectors have received extensive training, attend refresher courses annually, and are responsible for inspecting mammography facilities in Pennsylvania.

To find out more about mammography, talk with a radiologist, a mammography technologist, or your doctor. You can also call the National Cancer Institute's (NCI) Cancer Information Service at 1-800-422-6237. Check out FDA's mammography Web site at www.fda.gov/cdrh/mammography to locate an FDA-certified mammography facility near you, or visit www.depweb.state.pa.us, keyword: Mammography, or call the Bureau of Radiation Protection at 717-787-3720.