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Mammography & Older Women

Approved for 9 Category A CE Credit

American Society of Radiologic Technologists (ASRT)
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Approved for Category 9 A CE Credits (00 –Technical)
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A Continuing Education Course for Radiation Operators

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Mammography and Older Women

Approved for 9 Category A CE Credits

Course Description

In the U.S. today, women comprise the majority of the older population. Older women face unique challenges to their health. Older women live longer; develop different chronic conditions and experience a higher prevalence of functional limitations than older men. Earlier diagnosis, improved treatment, and the overall increase in average lifespan continue to expand the number of breast cancer survivors who are 65 and older. Despite success of screening mammography, there are no standardized guidelines for women 65 years and older. Additionally, many studies indicate that few decision aids are available for physicians and women to use in regard to continuance of mammography screening after the age of 65. Further, questions have been raised about the adequacy of the healthcare workforce, and specifically radiologic technologists, to provide medical services to the elderly.

This course explores issues and concerns associated with mammography and older women. Highlights of this course include: mammography screening guidelines for women over 65 years of age, aging characteristics of the older woman, and suggestions for providing high quality breast imaging services to this population of women. The final sections of this course include quality improvements in imaging services and radiation protection in mammography.

Course Objectives

Upon completion of this course, the participant will be able to:

1. Recall facts and figures about the aging of the U.S. population and health risks and healthcare disparities that exist in this group.

2. Identify breast cancer risks associated with older women.

3. State facts and figures related to breast cancer, risk factors for breast cancer, and breast screening guidelines for older women.

4. Discriminate between common breast pathology.

5. Respond correctly to statements concerning patient communication in breast imaging examinations.

6. Select correct responses about providing care for older women during mammography examinations.

7. Describe how quality improvement actions relate to providing high quality breast images.

8. Recall facts about radiation protection in mammography.

Mammography and Older Women

"Age is an issue of mind over matter.
If you don't mind, it doesn't matter." Mark Twain

Introduction

In the U.S. today, women comprise the majority of the older population. Older women face unique challenges to their health. Older women live longer, develop different chronic conditions and experience a higher prevalence of functional limitations than older men.[1] Earlier diagnosis, improved treatment, and the overall increase in average lifespan continue to expand the number of breast cancer survivors who are 65 and older. Yet despite success of screening mammography, there are no standardized guidelines for women 65 years and older. Additionally, many studies indicate that few decision aids are available for physicians and women to use in regard to continuance of mammography screening after the age of 65. Further, questions have been raised about the adequacy of the healthcare workforce, and specifically radiologic technologists, to provide medical services to the elderly.

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Part 1 Introduction

Aging

A familiar statement about aging is that “humans begin to age the moment they are conceived.” Scientifically, this is a true statement; however, the boundary line between being middle aged and being old, elderly, or a senior is not so easily defined today. Due partly to advantages of preventative medicine and the emphasis on healthy lifestyles, today’s 60 year olds are often compared to being equivalent chronologically to 40 or 50 year olds. However, most developed world countries have accepted the chronological age of 65 years as a definition of “elderly” or “older person”.[2] Chronological time generally signifies certain important life milestones; such as the ages of 60 or 65 being roughly the equivalent to retirement ages.[2] In many parts of the developed world, chronological time has little or no importance in the meaning of old age. Some medical researchers propose that there are several levels of “old age” and have given them names such as the “young old”. A new class of individuals, known as the “centurions”, those living past the age of 100, is growing in number and is often the subject of numerous medical studies.

Healthy aging has emerged as one of the major public health opportunities of the 21st century.[3] Since the turn of the last century, there have been dramatic improvements in life expectancy. From 1900 through 1902, life expectancy at age 65 was 12 years; by 2005, life expectancy for this age group had increased to 18.7 years.[3] The proportion of the U.S. population aged 65 and over more than tripled from 1900 through 2000.[3] According to the U.S. Census Bureau projections, by 2030 adults aged 65 and over are expected to constitute 20% of the total U.S. population.[4]

Today, as adults in the U.S. live longer, there is growing emphasis on extending not just years of life, but years of quality life. Prevention, early diagnosis, and treatment of many of the diseases traditionally associated with older age have contributed to the extension of healthy years for many adults. Health disparities exist across subgroups of older adults and vary by age.[3] Community-based studies and studies of special populations have focused on a myriad of aging-related health issues, including disparities in physical and mental health status; disability and access to healthcare; associations among various health conditions and impairments in older adults; and the health benefits and consequences of personal health behaviors. Poor adults, near poor

adults, and adults with Medicaid were the most disadvantaged in terms of health status, physical and social functioning, healthcare utilization, and health behaviors.[3]

Overall, prevalence of fair or poor health, hypertension, heart disease, hearing impairment, vision impairment, and absence of all natural teeth increases as age increases.[3] Poor adults are more likely than adults who are not poor to be in fair or poor health. Adults with Medicaid coverage were more likely than those with private insurance to be in fair or poor health.[3] Among adults aged 55 to 64 and 65 to 74, those who were currently married were less likely than adults in other marital status groups to be in fair or poor health.[3]

United States Statistics

- Someone turns 50 years of age every 6 seconds.
- Those who have already reached age 65 can expect to live another 18.5 years.
- 88.5 million people 65 and older are expected in 2050, comprising 20% of the U.S. population.
- 55 million people in the U.S. are over 55 years of age and 34 million are over 65 years.
- Median age in the U.S. today is 43. By the year 2014, the youngest baby boomers will be 50 and the oldest will be 68 years of age.
- The over-85 age group is the fastest-growing segment of the U.S. population.
- By 2020, the senior population will number approximately 115 million.[4-6]

Workforce Readiness

In contrast to a traditional focus on the younger generations, the marketplace and especially the healthcare industry are scrambling to address the needs and concerns of its newest discovery: the aging population.[5] One of the most striking characteristics of the current senior population is the broad range of ages and lifestyles it encompasses.[5] In 1996, the baby boomer generation of approximately 78 million began turning 50 at the rate of 300,000 a month.[5] In an unprecedented paradigm shift, both parents and their children are now members of the senior population.[5]

Every aspect of the healthcare system is and will continue to be affected by this demographic shift, including medical imaging professions. Mammographers and other imaging personnel should be prepared to meet the challenges that this dramatic shift

represents. In 1998, a descriptive study was conducted to estimate the status of gerontology in American radiography, nuclear medicine technology (NMTA), diagnostic medical ultrasonography, and radiation therapy educational programs, and to determine whether there is a perceived need to expand gerontology instruction in the curricula of these professional programs.[7] Some of the unknown factors that the study attempted to answer was whether students currently enrolled in the above listed imaging programs were being prepared to:

- Be sensitive to cultural, economic and social influences involved in caring for the elderly;
- Adapt imaging and therapeutic procedures to accommodate the mental, emotional and physiological alterations associated with aging; and,
- Communicate effectively with this patient population.[7]

From the data collected from 205 viable responses (out of 442 surveys mailed), the researchers recommended that gerontology be presented prior to or concurrent with entry-level education in all professional imaging programs.[7] An overwhelming number of survey respondents (76%) (n=100) stated that 2 areas, pathology of aging and physiology of aging should be included in the curricula.[7] Approximately 102 respondents stated that they felt that clinical experience alone was sufficient for learning to care for elderly patients.[7] However, the researchers concluded that clinical experience often does not ensure that every student be presented with standardized information about the aging population and how best to care for them during imaging examinations.[7]

Part 2 Breast Cancer Statistics, Pathology and Risk

Breast Cancer Statistics

Breast cancer is the most common cancer among American women, except for skin cancers. A woman's chance of developing invasive breast cancer at some time in life is a little less than 1 in 8 (12%).[8] The American Cancer Society (ACS) estimates that in 2013, about 232,340 new cases of breast cancer will be diagnosed in women.[3] The ACS projects that in 2013, 39,620 women and 410 men will die of breast cancer.[8] Death rates from breast cancer have steadily declined in women since 1990, with larger decreases in women younger than 50 (a decrease of 3.2% per year) than in those 50 and older (2.0% per year).[8,9] The decrease in breast cancer rates represents progress in both earlier detection and improved treatment.[8,9]

Earlier diagnosis, improved treatment, and the overall increase in average lifespan continue to expand the number of breast cancer survivors who are 65 and older.[1] This population is already estimated to be one million of the total 2.3 million breast cancer survivors. This group of older women represents 17% of all older cancer survivors, yet the impact of breast cancer and its treatment on survivorship in these women has been poorly understood.[1] In 2002, the National Cancer Institute (NCI) funded efforts of a research team at Boston University to study breast cancer care and older women. The study named the Breast Cancer Treatment Effectiveness in Older Women (BOW 1) included 1,859 women aged 65 and older.[1] Data from the research indicated that variations in care have substantial consequences for older women.[1] The study found that less-than-standard treatment was associated with increased rates of disease recurrence and breast cancer-specific mortality, while mammography surveillance during the first 5 years after diagnosis was associated with a reduced rate of breast cancer mortality.

Researchers at the University of Texas M.D. Anderson Cancer Center in Houston published the results of a study, which is the first to specifically assess screening mammography in women older than 80.[10] The study was prompted by the lack of clear guidelines for screening mammography in older women.[10] The American Cancer Society (ACS) recommends annual mammography for women starting at age 40 with no age limit for women in good health.[8] The National Cancer Institute (NCI)

promotes breast screening after age 65 based on a woman's health status and longevity. The results of the study which included 12,358 women ages 80 and older showed a 12% decrease in the risk of breast cancer death for each mammogram.[10] Although the study had limitations, the researchers recommend that physicians should review each woman's situation to determine if a mammogram is in her best interest.[10]

Terminology

Most cancerous breast tumors are invasive, or infiltrating. These cancers start in the lobules or ducts of the breast but have broken through the duct or glandular walls to invade the surrounding tissue of the breast. Figure 1 lists common terminology used to describe breast cancer. Figure 2 lists the common types of breast cancer.

Invasive	Cancer that has invaded the surrounding tissues
In situ	Breast cancer that is confined to the ducts or lobules and does not spread to the surrounding tissues
Ductal	Cancer originating in the milk ducts
Lobular	Cancer originating in the glands that produces milk
Carcinoma	Cancer that begins in the skin or other tissues that Cover internal organs
Adenocarcinoma	Cancer of glandular tissue occurring anywhere in the body

Fig. 1. Common terminology used to describe breast cancer.[11]

One major way of defining breast cancer is whether or not it is a hormone receptor (estrogen or progesterone receptor) positive, HER2 positive, or triple negative (i.e., not positive estrogen, progesterone, and HER2). About 75% of all breast cancers are ER positive.[12] ER positive tumors grow in response to estrogen and older women often have small tumors that are ER-positive, without evidence of spread to the lymph nodes.[12] According to the ACS, nearly all cancers at this stage can be cured.[8]

Staging of breast cancer is an important key to determining the proper course of treatment and there are 2 main staging systems for cancer. The American Joint Committee on Cancer (AJCC) classification of tumors uses information on tumor size and how far it has spread within the breast and nearby organs.[8] For example, in the AJCC system, the letter (T) represents metastasis within the breast and nearby organs, (N) represents lymph node involvement, and (M) the presence or absence of metastases to distant organs.[8] Once the T, N, and M are determined, a stage of I, II, III, or IV is

assigned with stage I being an early stage and stage IV being the most advanced.[8] The AJCC staging system is commonly used in clinical settings.[8]

The second system for staging cancer, Surveillance Epidemiology and End Results (SEER) Summary Stage, is more commonly used in reporting to cancer registries and for public health research and planning.[8] This system uses terminology such as local-stage, regional-stage, and distant-stage to classify breast cancers.

Angiosarcoma	A rare type of breast cancer of the breast. It often occurs as a complication of radiation therapy with a latent period of about 5 to 7 years post-therapy.
In Situ	The detection rate of *in situ* breast cancer increased rapidly during the 1980s and 1990s, due to availability of screening mammography. The increased detection rate was observed in all age groups but was greatest in women aged 50 and older. There are 2 major types of *in situ* breast cancer; ductal carcinoma *in situ* and lobular carcinoma *in situ.*
Ductal Carcinoma *in situ* (DCIS)	DCIS is the most common type of noninvasive breast cancer. From 2002 to 2006, DCIS accounted for about 80% of diagnosed cases of noninvasive breast cancer. DCIS is detected by mammography, and the increase in its detection is a direct result of screening mammography.
Lobular Carcinoma *in situ* (LCIS)	LCIS is much less common than DCIS, accounting for only about 12% of female *in situ* breast cancers diagnosed from 2002-2006. Like DCIS, the overall detection rate of LCIS increased more rapidly than the incidence of invasive breast cancer, but this increase was limited to women over the age of 40 and mostly to postmenopausal women.
Invasive Ductal Carcinoma (IDC)	IDC is the most common type of breast cancer and is known to metastasize to other parts of the body.
Invasive Lobular Carcinoma (ILC)	Occurs in about 10% of invasive breast cancers but is considered more difficult to detect with mammography.
Medullary Cancer	Occurs in about 5% of breast cancers. The prognosis for this type of breast cancer is better than for other types of invasive breast cancer and its treatment is similar to ILC.
Mucinous Carcinoma	This is a rare type of invasive breast cancer that consists of mucus-producing cancer cells. It is also known as colloid carcinoma and has a prognosis better than for the more common types of invasive breast cancer.
Paget Disease of the Breast	Paget disease is rare and accounts for only 1% of all breast cancers.
Phyllodes Tumor	Phyllodes tumors develop in the connective tissue of the breast. Generally phyllodes tumors are benign but can be malignant, responding to the usual treatments for IDC and ILC.
Tubular Carcinoma	This is a special type of IDC and represents about 2% of all breast cancers. Tubular carcinoma are generally hormone receptor positive, but HER-2 negative.
Angiosarcoma	Angiosarcoma rarely occurs in the breast but may appear as a latent (i.e., 5 to 7 years) effect of breast radiation therapy.

Fig. 2. Common types of breast cancer.[11]

Pathology

Pathology is defined as the anatomic or functional manifestation of disease and may be either benign or malignant. A benign breast condition is any non-cancerous breast abnormality. According to the ACS, when breast tissue is examined under a microscope some type of abnormality is common in 9 out of every 10 women.[8] Although not life-threatening, benign conditions may cause pain or discomfort for some patients. Not all-benign breast conditions signal an increased risk for breast cancer. Depending on the type of benign breast condition and the patient's medical history, clinical presentation, and associated risk factors, treatment may or may not be necessary.

> ***Risk**, refers to the probability of a person developing or dying from a particular disease and is discussed as absolute and relative.*

Some breast changes can be associated with breast augmentation, postreduction mammoplasty, breast biopsy, surgery, or trauma. Regardless of the cause, breast changes are often first identified on mammography as a mass density. The density of a mass refers to the x –ray attenuation of the lesion relative to the expected attenuation of an equal volume of fibroglandular breast tissue.[13] Usually, low-density masses indicate benign lesions and high-density masses indicate malignancy.[13] Suspected lesions of the breast, whether benign or malignant, must be investigated with either additional mammography projections, magnification with or without spot compression, ultrasonography (US), or magnetic resonance imaging (MRI).[13] Clinical findings must be correlated with current and previous breast images and procedures.

Breast changes of significance include a new lesion, an enlarging lesion, a change in the margin of the lesion, a developing spiculation, or microcalcifications.[13] A change in the total number of calcifications is an important indicator of pathology and should be further investigated.[13] The correlation between breast cancer and calcifications was first made in 1913 by the German surgeon Salomon.[14] Nonpalpable lesions are usually first detected on mammography images as calcifications alone, calcifications associated with architectural distortion, or calcifications associated with a mass.[14]

Calcifications are formed by calcium salt deposits within the tissue, often as a result of a degenerative process that can be either benign or malignant.[14] Characteristics of calcifications can aid in diagnosis. For example, calcifications that are larger (greater

than 1 mm), smooth, round, dense, scattered over a large area or bilateral are classified as benign.[14] Certain types of calcifications in the breast are almost always benign; such as, popcorn-type calcifications, rim calcifications, milk of calcium, arterial and skin calcifications, Figure 3.[15]

Approximately 40-50% of calcifications represent malignant processes.[13] Malignant calcifications may appear as clustered, casting, linear, or granular.[13] Clustered calcifications (at least 4 to 5 calcifications in a 1-cm^3 area) are pleomorphic (of varying shapes) and/or punctate (consisting of tiny dots smaller than 1 mm and resembling salt).[14] Casting calcifications are produced when carcinoma in situ fills the ducts and their branches.[13] The shape of the cast is determined by the uneven production of calcifications and the irregular necrosis of the cellular content.[13]

	Benign	**Malignant**
Shape	Round, ring-like	Varying shapes
Density	Same density	Varying densities
Distribution	Scattered	Clustered
Definition	Well-defined borders	Poorly defined borders
Unilateral or bilateral	If the same type of calcifications occur in both breasts, they are more likely benign	If there is architectural or parenchymal distortion associated with calcium, malignancy must be considered
Surrounding tissue	If the calcium is seen within a benign-appearing mass or if the tissue surrounding the calcium appears normal, this is a benign indicator	If there is architectural or parenchymal distortion associated with calcium deposits, malignancy must be considered
Increasing in number from prior mammogram	Can be benign	Not an indicator alone but, when considered with other characteristics, can indicate malignancy
Size	Can be large or small	Most often small

Fig. 3. Mammographic Characteristics of Calcifications.

Calcifications that are neither clearly benign nor clearly malignant are considered indeterminate and must be treated as malignant until proven otherwise by biopsy.[14] Mammography is the imaging modality of choice for screening the entire breast for calcifications. Ultrasound imaging can demonstrate calcium deposits but is used only as a diagnostic tool after an abnormality has been detected on mammography.[14]

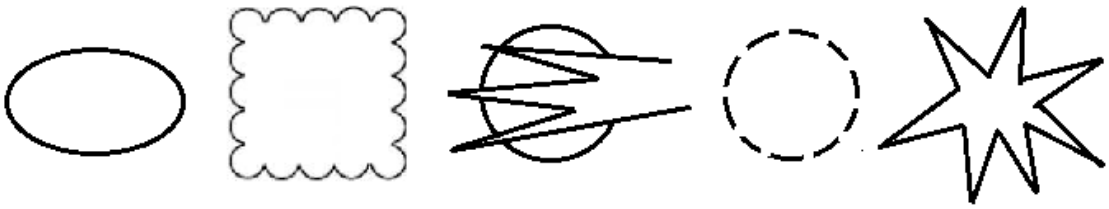
A detailed patient history and clinical breast examination are important to further evaluate calcifications. It is important to obtain information about any breast injury, previous surgery or radiation treatment to the breast. Also, deodorant, powder and certain creams or ointments may produce artifacts that mimic calcifications on mammography images.[14] Patients who have had gold treatments for arthritis may have deposits of gold in the breasts.[14] Skin lesions, which will be discussed in detail later in

this course, can mimic calcifications. Skin lesions such as moles, tattoos, and scars should be documented on the patient history form and in the case of moles and scars, marked directly on the skin with a radiopaque or semi-radiopaque marker.[14]

Characteristics of Benign and Malignant Breast Lesions

The Breast Imaging Reporting and Data System™ (BIRADS™), defines a mass as a space-occupying lesion seen in 2 different projections and a possible mass as a lesion seen in only one projection. Borders, margins, and the overall shape of breast masses are important diagnostic indicators as to whether the lesion is benign or malignant. The margins of a lesion may be circumscribed, microlobulated, obscured, indistinct, or spiculated, Figure 4. The shape can be round, oval, lobulated, or irregular, Figure 5. A circumscribed border of a lesion strongly indicates a benign condition whereas a spiculated border is an indication for malignancy.

> ***Spiculation*** *of a lesion usually represents a malignancy. A lesion with spiculations has a distinct solid center and sharp lines of variable lengths radiating in all directions away from the center. Usually the spicules are not bunched together and the larger the central core of the tumor, the longer the spicules.*



Circumscribed **Microlobulated** **Obscured** **Ill-Defined** **Spiculated**

Fig. 4. Examples of margins of breast lesions. Courtesy drawing DGM Consulting.

Round **Oval** **Lobular** **Irregular**

Fig. 5. Common shapes of breast masses. Courtesy drawing DGM Consulting.

Although the appearance of the margins and the shape of the lesion are important indicators of whether the lesion is benign or malignant, they are just indicators, until proven otherwise. Many benign lesions such as radial scars, abscesses, postoperative scars, fat necroses and hematomas can mimic malignant lesions. Likewise, some malignant lesions such as invasive ductal carcinoma (IDC), medullar carcinoma, mucinous carcinoma, fibrosarcoma, lymphoma, primary or secondary pseudolymphoma, and metastasis can mimic benign lesions.[13]

A capsule appears on mammography as a thin radiopaque line surrounding a mass. An encapsulated mass is most often benign.[15] The silhouette sign is another indicator of a benign process. A silhouette sign appears as lines running through the middle of a suspicious area of the breast. If the lines are seen to run into, through, and out of the lesion, this represents silhouetted structures in front of or behind the lesion. Recognizing a true silhouette sign also can help determine if a suspicious lesion has a spiculated border. If a mass is spiculated, the lines radiating from it will disappear in the middle of the abnormality, which is a strong indicator of malignancy.[15] A halo is a sign that appears as a thin, radiolucent curved line on the mammography image. A halo represents the edge of a mass compressing the surrounding fatty tissue.[15] A halo sign is strongly indicative of benign process. Although rare, the halo sign can occur in certain malignant processes.[15]

Many of the benign breast diseases are physically manifested by nipple discharge or pain while some are only detected during mammography, MRI, or US. Any history of nipple discharge and pain should be investigated.[7] Depending on the imaging modality, breast lesions will manifest with skin thickening, calcifications, asymmetric densities, or circumscribed masses.[13] Both benign and malignant breast lesions can be placed in one of 5 categories:

- Circular or oval;
- Stellate or spiculated;
- Calcifications;
- Thickened skin syndrome; and,
- Any combination of the 4 listed above.

The physical appearance of the breast can aid in the diagnosis of both benign and malignant lesions and the following summarizes the diagnostic implications of various physical presentations. Signs and symptoms of breast cancer include:

- Breast lump;
- Nipple discharge (new and spontaneous that is bloody, serosanguinous, serous but copious);
- New nipple inversion;
- Skin retraction or tethering; and,
- Peau d'orange skin changes.[8,9]

Erythema (redness) and edema (skin thickening) are both physical skin changes. Erythema of the skin may be localized to one area of the breast or include the entire breast. Erythema is associated with infection, abscess, and inflammatory carcinoma; however, it is also associated with other types of carcinomas and benign conditions. Edema is caused by the development of fluid within the skin and interstitial spaces and causes the skin to develop the appearance of an orange peel ('peau d'orange).

> ***Peau d'orange*** *describes the skin of the breast when the breast skin thickens and develops prominent pores resembling the skin of an orange. The condition is a secondary effect of obstruction of the axillary lymphatics and may be either a benign or malignant condition (i.e., inflammatory carcinoma).*

The presence of edema can indicate an infection, carcinoma, or a systemic disease, which manifests by fluid retention in the breast. Both erythema and edema may be present following radiation treatment for breast cancer.

Nipple inversion can be developmental; however, sudden inversion can indicate the presence of a tumor.[7] Eczematous changes such as reddening, flaking, and crusting

of the nipple may be benign but are also symptoms associated with Paget's disease of the nipple.

> ***Paget's*** *disease is an inflammatory disease of the nipple. The actual appearance of the nipple varies with the extent and stage of the disease. Paget's disease accounts for approximately 1-5% of all breast carcinomas.*[8,9]

Nipple discharge may vary in color from yellow to white, green, and brownish. The color of the discharge is less important than its occurrence in one or both breasts and whether the discharge occurs spontaneously or is expressed. Bloody or clear watery discharge may be indicative of either papilloma (benign tumor) or carcinoma. A clear watery discharge is more an indication of carcinoma than any other color. Any spontaneous nipple discharge always requires further investigation.

Normal architecture of the breast consists of ductal structures. These structures, while not individually evident on mammography, present a pattern of radial lines that converge at the nipple. Architectural distortion may be present with benign and malignant disease processes, occurring with both masses and calcifications.[15] Breast surgery, injury, resolving hematoma, and radial scar may also be evident as architectural distortion.[15] The parenchyma of both breasts should be smooth in outline, devoid of asymmetric bulging or "pulling in".[15]

The contour or shape of both breasts should be symmetrical. Any bulging, dimpling, or retraction of the skin can indicate an underlying pathological process, either benign or malignant.[17] The breasts should move symmetrically when the patient slowly raises the arms. Any differences in breast movement can indicate an underlying pathological process and require further investigation.

Breast pathology is seen on mammography as a mass, calcification, or diffuse accentuation of the glandular tissue.[17] These manifestations may only be apparent by indicators such as asymmetry, architectural distortion, and/or changes in contour of the parenchyma.[7] Secondary mammography signs may include dilated ducts, dilated veins, and skin thickening.[17] Their presence is an important diagnostic marker and requires further investigation.

Asymmetry of the parenchyma is the greatest aid in determining breast abnormalities, both benign and malignant.[15] The breasts are mirror images and the

distribution of glandular tissue should appear the same with only minor variation. A disproportionate amount of tissue in any area of the breast requires further investigation.

Findings of breast asymmetry are often encountered at screening and diagnostic mammography. Because there has been some confusion about proper use of the term asymmetry in describing this deviation, the 4th edition of the American College of Radiology Breast Imaging and Reporting and Data System (BI-RADS) has incorporated changes. In the BI-RADS lexicon for asymmetric breast findings, to correct any misuse and improve clinical standardization of reporting, the 4th edition has replaced the following:

- Asymmetric breast tissue with global asymmetry;
- Density seen in only a single projection with asymmetry; and,
- Focal asymmetric density with focal asymmetry.[18]

> ***Focal asymmetry*** *is visible as a confined asymmetry with a similar shape on two views but does not fit the criteria of a mass (i.e., lacks convex outer borders and conspicuity).*
>
> ***Global asymmetry*** *occupies a volume of less than one quadrant of the breast. This finding is almost always benign and requires no additional evaluation if there are no corresponding palpable abnormalities, architectural distortions, significant calcifications, or masses. This may indicate the presence of an underlying breast cancer if it corresponds to a palpable abnormality.*[18]
>
> ***Developing asymmetry*** *is a focal symmetry that is new, larger, or denser at current examination than at previous examinations. To identify such lesions, comparison with at least 2 years previous mammograms is critical. A developing asymmetry that cannot be accounted for by differences in imaging technique, positioning, or weight loss, HRT, surgery, trauma, or infection at the site should raise suspicion.*[18]

The American College of Radiology (ACR) recommends that once an asymmetric finding is seen, it should be determined whether it is due to a definite lesion.[19] Additional imaging studies such as straight lateral views, rolled views, and spot compression views at mammography, MRI, or US should be applied in a logical manner.

Exact breast positioning will vary from one examination to the next, but regions of asymmetry should be seen in at least one view on later examinations. The concern is that not all breast cancers form a mass visible at mammography and there is the potential for the radiologist to dismiss asymmetries because a mass is not evident. Conventional breast positions may not provide sufficient information for the proper evaluation of asymmetry findings.

For additional evaluation of asymmetry seen on one projection, it is recommended to return to that projection and alter it slightly to determine whether the finding is real. A real lesion is unlikely to change its appearance.[18] A straight lateral view should be obtained for an asymmetry seen only on a mediolateral oblique (MLO) view. A rolled view should be taken for an asymmetry seen only on a craniocaudal (CC) view. Spot compression views, rolled views, or views with altered x-ray tube angles may help spread or reorient tissue structures to help define and characterize asymmetries.[18]

To obtain a rolled view, the mammographer should gently rotate the breast around the axis of the nipple and recompress it in this new orientation. Using the rolled view to determine the presence of a lesion, the mammographer should direct the roll so that the area in question is rolled toward and projected over an area of fat and not over dense tissue, which may obscure the lesion.

Spot compression views with and without magnification is a common method used for evaluating asymmetry. By applying vigorous compression to a target area, normal fibroglandular tissue is more likely to spread apart whereas a true abnormality will retain its characteristics. It is always advisable to obtain two projections using spot compression, since even true abnormalities may disappear when compression is applied. There are some disadvantages to using the spot compression view and these include the following:

- It is generally obtained in the same projections as used in standard mammography, and may produce the same superimposition of structures; and,
- The focal compression can roll or squeeze the abnormality out of the field of view.

When mammography or palpation can determine the location of a lesion, targeted US is indicated and valuable. If the location cannot be established, ultrasonography is unreliable in evaluation of areas of breast asymmetry. The role of MRI for assessment of asymmetric breast findings has not been established.

Part 3 Mammography Screening

Early detection of breast cancer decreases mortality and facilitates breast-conserving therapy.[8,9] After continuously increasing for more than 2 decades, female breast cancer incidence rates decreased by 2.2% per year from 1999-2005.[8,9] Research studies continue to prove that mammography is the most effective method for early breast cancer detection.[8,9] Randomized clinical trials that have studied mortality have shown a reduction in mortality from breast cancer with the use of screening mammography, ranging from 18% to 30% depending on the age of the women.[8,9] The Digital Mammography Imaging Screening Trial (DMIST) results indicate that screening with digital mammography will detect at least as many breast cancers as screen film mammography over the whole population, and more advanced or serious breast cancers in women in the 3 subsets of women identified in the DMIST.[20]

The ACS guidelines for the early detection of breast cancer in asymptomatic women are found in Figure 6.

Age 40 and older

- Annual mammogram
- Annual clinical breast examination
- Monthly breast self-examination (optional)

Age 20-39

- Clinical breast examination every three years
- Monthly breast self-examination (optional)

Fig.6. American Cancer Society guidelines for the early detection of breast cancer in asymptomatic women.[8,9]

In recent ACS breast cancer screening guidelines, more emphasis has been placed on educating women, especially those at increased risk for breast cancer about the benefits and limits of mammography and adjunct imaging methods.[8] The ACS recommends that women known to be at increased risk may benefit from initiation of early detection testing and/or the addition of breast ultrasound and MRI.[19] The known risks associated with breast cancer include:

- Female;
- Increasing age;

- Personal history of breast cancer;
- First-degree relative with breast cancer;
- Early menarche;
- Late menopause
- Nulliparous;
- First birth after age 30;
- Atypical ductal hyperplasia;
- Positive for BRCA1 and BRCA2 genes;
- Radiation exposure to the chest area; and,
- Lobular carcinoma *in situ*.[8]

A family history suggesting an increased risk of breast cancer includes:

- More than 2 relatives with breast or ovarian cancer;
- Breast cancer in a relative less than 50 years of age;
- Relatives with breast and ovarian cancer;
- Relatives with 2 independent breast cancers or breast plus ovarian cancer;
- Male relative with breast cancer;
- Family history of breast or ovarian cancer and Ashkenazi Jewish heritage;
- Li-Fraumeni syndrome;
- Cowden's syndrome; and
- Ataxia-telangiectasia.[8,9]

Adjunct breast imaging including ultrasound, ductography, and MRI may be used to further diagnose breast disease and will be discussed further in the section titled *Imaging Modalities*.

Screening Guidelines for Older Women

The National Cancer Institute (NCI) provides screening mammography guidelines for special populations: women with limited life expectancy, elderly women, and women with thoracic radiation.[21] The NCI states that achieving balance between the benefits and harms of screening is especially important for women with life expectancy of no longer than 5 years. Such women might have end-stage renal disease, severe dementia, terminal cancer, or severe functional dependencies in

activities of daily living.[21] Early cancer detection and prompt treatment are unlikely to reduce morbidity or mortality within the woman's 5 years of expected survival, but the negative consequences of screening will occur immediately. Abnormal screening may trigger additional testing with attendant anxiety. In particular, the detection of low-risk malignancy would probably result in a recommendation for treatment, which could impair rather than improve quality of life, without improving survival. Despite these considerations, many women with poor life expectancy due to age or health status often undergo screening mammography.[21]

Screening mammography in women older than 65 years often results in additional diagnostic testing in 85 per 1,000, with cancer diagnosed in 9.[8,9] The testing is often accomplished over many months, which may cause anxiety due to diagnostic uncertainty. While screening mammography may yield cancer diagnoses in approximately 1% of elderly women, many of these cancers are low risk.[21] A study of California Medicare beneficiaries aged 65 to 79 years demonstrated this clearly. The relative risk (RR) of detecting local breast cancer was 3.3 among screened women.[21] A diagnosis of metastatic cancer was reduced among screened women, suggesting there may be benefit of mammography screening in elderly women, though it comes with an increased risk of over diagnosis.

Screening has been recommended for women exposed to therapeutic radiation, especially if exposed at a young age. Screening mammography and magnetic resonance imaging (MRI) can identify early-stage cancers, but the benefits and risks have not been clearly defined.

Screening Mammography for Frail Older Women

The elderly population is growing and the number of frail older adults who have multiple chronic illnesses is increasing as well.[22] A study of 216 women with a mean age of 81 years was conducted to determine potential benefits and harms of screening mammography in frail older women. Results of the study showed that 178 women (82%) had a normal mammogram, while 38 (18%) had an abnormality for which further work-up was recommended.[22] It is well known that the likelihood of benefit from screening mammography declines as life expectancy decreases. Benefit of screening mammography in this population of women is difficult to ascertain, because it only occurs in patients who get breast cancer and it takes several years before a reduction in mortality may occur.[22]

The recognized operational definition of screening burden for the study previously mentioned was a patient who was worse off for having been screened. A patient was considered to have experienced burden from breast cancer screening if they had any one of the following events:

1) Additional diagnostic procedures due to false-positive results;
2) Identification of an abnormality on screening exam but further work-up was declined; or,
3) Identification of a clinically unimportant cancer.[22]

False-positive results are defined as abnormal screening results for which work-up did not reveal cancer or a false-positive results subjects the patient to physical and psychological discomforts from additional testing and procedures that would not have been necessary if they had not been screened.

A patient is considered to experience a burden if screening leads to the identification and treatment of a cancer that would not have become symptomatic in the patient's lifetime. The mean duration that a mammography detectable breast cancer remains asymptomatic is approximately 3.4 years for women aged 70 to 74.[22] Patients in the study were considered to have potentially benefited from mammography if they were diagnosed with cancer as a result of the screening test and lived more than 2 years after detection and treatment. Data from the study found that screening mammography in frail older women frequently necessitates work-up that does not result in benefit.[22] Also, in the population of frail older women, many of the burdens of screening mammography were related to severe comorbid conditions and functional impairments, which supports the assumption that physicians or other healthcare providers should consider longevity and quality of life factors when making screening decisions rather than focusing on chronological age alone.[22]

Mammography screening may be effective in reducing breast cancer mortality in certain populations. As with any medical intervention, it has limitations, which can pose potential harm to women who participate. These limitations are best described as false-negative, false-positives, over diagnosis, and radiation risk.[23]

> ***False negative*** *refers to a missed diagnosis. This occurs when the mammography results indicate that no breast disease was present but the breast*

disease was actually present (i.e., often found during cytology and histology examinations).

False positive *refers to a mammography result that indicates the presence of a breast condition when the breast condition is not present.*

The sensitivity of mammography ranges from 70% to 90%, depending on a woman's age and density of her breasts, which is affected by her genetic predisposition, hormone status, and diet. Assuming an average sensitivity of 80%, mammograms will miss approximately 20% of breast cancers that are present at the time of screening (false-negatives).[23] If a woman does not seek medical attention for a breast symptom or if her physician is reluctant to evaluate that symptom because she has a "normal" mammogram, she may suffer adverse consequences. Whereas the medical community has been carefully educated that a negative diagnostic mammogram should not deter work-up of a palpable lump, the medical and lay communities should be made aware that a negative screening mammogram misses 1 in 5 cancers.[23]

Radiation Exposure

Because radiation exposure is a known risk factor for the development of breast cancer, it is ironic that ionizing radiation is our best screening tool. The major predictors of risk are young age at the time of radiation exposure and the radiation dose.[23] For women older than 40 years, the benefits of annual mammograms may outweigh any potential risk of radiation exposure due to mammography. It is speculated that certain sub-populations of women may have an inherited susceptibility to ionizing radiation damage, but mammography has never been shown to be harmful in these, or any, subgroups. In the U.S., the FDA regulations require that the mean glandular dose for screening mammography not exceed 1 mGy to 2 mGy (100-200 mrad) per view or 2 mGy to 4 mGy (200-400 mrad) per standard 2-view examination.[23]

Anxiety and Overdiagnosis

Because large numbers of women have false-positives tests, the issue of psychological distress-which may be provoked by additional testing-has been studied.[23] Several studies, however, show that the anxiety following evaluation of a false-positive test leads to increased participation in future screening examinations.

Over diagnosed disease is a neoplasm that would never become clinically apparent prior to a patient's death without screening.[23] An example is a tumor that is found by mammography screening that would never be evident otherwise. It is difficult to determine the proportion of image-detected cancers that are over diagnosed via a surveillance breast-screening program. A widely accepted estimation method is to compare breast cancer incidence over time in a screened population with that of an unscreened population.[23] Randomized screening trails are the most credible, but the period of screening versus control is limited in all trials.[23]

Breast Cancer Screening Adherence

Breast cancer screening has been shown to be an effective means for reducing breast cancer mortality.[8] While screening rates are improving, a significant number of women are not screening at nationally recommended rates.[23] Mammography use rose steadily in women aged 40 and older until 2000 and was stable until 2003, and dropped slightly in 2005.[24] The 2010 target of 70%, for all women, was not met in 2000, and the proportion of women fell to 67% in 2005.[24] Rates fell for white non-Hispanic, Black non-Hispanic, and Hispanic women.[24] Disparities remain for immigrants and those with lower incomes with less education, without insurance and lacking a regular health care provider.[24]

In November 2009, an announcement by the U.S. Preventive Services Task Force (USPSTF) caused what some consider a major set-back for screening mammography.[25] The USPSTF did not recommend routine mammograms for low-risk women aged 40 to 49, stating that the decision for this age group to have them, should be an individual choice.[25] To add further insult to injury the USPSTF stated that women over 50 need mammograms only every 2 years, not annually and that women should not self-examine their breasts.[25] Many claim that economic consideration rather than patient care motivated the USPSTF announcement.[25] Those supporting the USPSTF announcement emphasize that mammograms have a significant false-positive rate, which leads to unnecessary biopsies (i.e., harm from screening).[25] Most individuals involved with breast imaging agree that mammography does have its limitations but acknowledge that great strides have been made in breast cancer mortality due to increased surveillance.

One of the greatest fears of those who have been long time advocates of regular mammography screening programs is that because the USPSTF announcement has

been made public, it may become the standard for government and private healthcare reimbursement decisions.[25] For example, the California Department of Public Health has decided to deny mammography coverage to low-income women ages 40 to 49.[25] Other states such as New York, Florida, Illinois, and Michigan have also redesigned their breast cancer screening programs based on the USPTSF announcement.[25]

In July 2010, the U.S. Department of Health and Human Services (HHS) issued guidelines requiring new private health plans to cover preventive medical services, including mammography screening for women 40 and older.[26] Financial barriers have been cited as a reason for women to opt out of screening mammography and the new USPSTF guidelines are expected to increase this problem. Some mention that even if screening mammography is free, other barriers remain. For example, an important factor has been whether a woman's physician personally recommends the mammogram to her. Geographic availability can also affect a woman's ability to comply with screening mammography.[26]

Regular use of mammography screening followed by timely treatment can help reduce the chances of dying from breast cancer.[8] Strong evidence indicates that screening lowers the risk of death from breast cancer in women between the ages of 50-69 by 30%.[24] In 2010, 66% of women aged 40 and above had a mammogram within the past 2 years, a statistically significant drop from 70% (1998-2003).[24] Among racial/ethnic groups 64% of Hispanics (down from (65% in 2003), 66% of African Americans (down from 70% in (2003), and 70% of Caucasians (down 71% in 2003), had a mammogram in the past 2 years.[24]

Decision Aid

Many women who have participated in mammography screening are now approaching 70 years of age. Mammography screening reduces mortality from breast cancer, but it also has important downsides, including over-detection (and over-treatment) of *in situ* and invasive breast cancer. Over-detection is associated with additional imaging examinations and biopsies for abnormalities that may be proven to be benign (false positives).[27] As such, screening is generally recommended for women aged 50 to 69 years, but for women 70 years or older, in whom the benefit declines and the harms increase, the recommendations are less clear.[27] Older women are advised to carefully consider both the benefits and harms of continuing to be screened. According to the U.S. Preventative Services Task Force a mortality benefit from screening is still

likely for women older than 70 years, if life expectancy is not compromised by cormorbid disease.[27]

Informed decision making for preventive and screening services in primary care is receiving increased emphasis, yet the actual practice of informed decision making in clinical settings is limited.[28] Lack of training, time and standardized approaches to engage patients in decision making have been cited as barriers.[28] Many believe that a simple decision aid should be developed for women and/or women and their physicians to use in the decision-making process to continue or discontinue breast screening after age 65.[29] Based on the need for such an aid, Mathieu and colleagues developed and field tested a decision aid for clinicians and women to use to support decision-making regarding continuance of breast screening after 65 years of age.

Data from the clinical use of a breast screening decision aid found that having such an aid proved to be an effective way to assist women to make a decision about continuing mammography screening and seems to be a feasible intervention that can be used in population screening programs.[27,28] Researchers have learned that using a decision aid increased the percentage of women (i.e., from 49% to 73%), who were able to make an informed decision to either continue or stop screening.[28] Analysis of the data also showed that adequately informing women about these issues did not have any effect on breast screening participation rates.[28] This may be reassuring for countries with publicly funded screening programs that previously have provided information to encourage women to attend.[28]

Some researchers have studied the use of breast screening aids involving women in consultation with their physicians. It has been found that although women may discuss breast screening with their physicians, many women will make the final decision about whether to be screened independently of their physicians' advice.[28] The results are relevant to countries that provide population-screening programs, such as Canada, the United Kingdom, and many European countries. In countries without population screening programs, women are increasingly likely to make decisions about breast screening in the absence of input from their physicians as the trend toward more active consumer involvement in healthcare decision making increases.

Schonberg and colleagues conducted a cohort study of 2,011 women without a history of breast cancer who were age > 80 years between 1994 and 2004. They examined the outcomes of mammography screening and in this cohort study found that the majority of women > 80 years had been screened with mammography but few

benefited.[29,30] About 12.5% of the women experienced a burden from screening. Data from the Schonberg study can be used by physicians to provide elderly women with decision-making information about the benefits and burdens of screening mammography. Potentially informed decision-making may lead to more rational use of screening mammography resources.[29,30]

Guidelines exist to assist physicians in considering a woman's life expectancy before referring the woman for screening mammography. A study of 200 women found that while a physician's recommendation is the most important factor influencing elderly women's mammography screening decisions, habit and reassurance also strongly influence decision-making.[30] Interventions aimed at improving physician's counseling about screening mammography, which include discussions around habit and reassurance, may result in better decision-making.[30]

Screening rates have been linked to a wide range of social factors including variables such as age, socioeconomic status, education, as well as other factors such as medical insurance, marital status, physician recommendations, and minority status.[8,9] Fear, anxiety, or worry relates to breast cancer screening behavior.[8,9] The nationwide economic recession is affecting all aspects of daily life including healthcare.[31] Medical care once considered routine, preventive, and necessary may be delayed or cancelled altogether due to lack of money and/or insurance coverage.[31] The 2000 to 2006, Centers for Disease Control and Prevention epidemiological data shows that the number of women getting mammograms dropped in 34 states by 5.3%.[31]

One might expect that since 2006, with high unemployment, and other economic problems, that many women may have to forgo mammography screening and other preventative measures. Some contend that instead of coming in yearly, women have started pushing their screening mammograms to 18 months or longer due to lack of insurance or money to pay co-payments, and/or deductibles.[31] Some breast imaging facilities report that because women are putting off their screening mammograms, there has also been an increase in the number of diagnostic breast examinations being performed.

Various studies have been conducted about the reasons for non-compliance in mammography screening programs.[31] Fear of the medical establishment, pain associated with mammography, and embarrassment have all been cited as reasons for non-compliance.[31] Opinion polls taken of the general public have shown that there is a widespread fear of radiation exposure and a link to the risk of developing cancer.[31,32]

This fear has also been cited by women as a barrier to breast cancer screening. [31,32] Further complicating the issue are the actual known risks associated with radiation exposure. Thus it has become important that physicians understand and be able to convey the risk versus benefit of radiation exposure from mammography examinations to patients.

Breast cancer is an important health issue for older women. The benefits of mammography in women 50 to 70 years of age are clear. However, the benefits of mammography after age 70 years are less clear.[33] After age 70 years, breast cancer is common, but so are other diseases. Some women are likely to die of another condition before dying of breast cancer. To determine the relationship of health status and use of mammography and Papanicolaou (Pap) smears among women 70 years of age or older a telephone survey about health was conducted.[33] Approximately 4792 California women who were at least 70 years of age were asked to rate their own health and whether health decreases their ability to do certain activities.[33] The study researchers then determined whether recent mammography (within 2 years) or recent Pap smears (within 3 years) were associated with age and health status.[33] More than 3/4ths of the women in the study reported having had recent mammography, Pap smear, or both. The older women in the study were less likely to report having had the tests than were younger women.[33] In all age groups (70 to 74 years, 75 to 79 years, and 80 to 84 years and at least 85 years who reported worse health were no less likely than those with better health to have had the tests.[33] One of the flaws of this telephone survey was that researchers relied on women's reports of their last mammogram, which may not be completely accurate. However, the study indicates that there may be opportunities to better target screening mammography and Pap smears to women who are most likely to benefit from these tests.

Wealth and Screening Mammography

A cohort study of 4222 women 65 years or older, published in the Archives of Internal Medicine in 2008, sought to determine if wealthy women have higher rates of screening mammography than poor women do.[34] The study was designed to examine the relationship between wealth and screening mammography use in older women according to life expectancy (with substantial life expectancies and with limited life expectancies).[34] Data from the study indicated that poorer older women with favorable prognoses are at risk of not receiving screening mammography when they are likely to

benefit. Wealthier older women with limited prognoses (> 5 years) are often screened when they are unlikely to benefit.[34] Low socioeconomic status (SES) is also associated with decreased utilization of screening mammography even among women with Medicare.

Studies have also been conducted that consistently demonstrates economic disparities in screening mammography use by older women regardless of prognosis. Greater wealth is often associated with higher screening rates among women with good prognoses, and wealth is also associated with higher screening rates among women with limited prognosis.[34] Special attention has been focused on poor women, with good prognoses who are at risk of low screening rates when they are likely to benefit from screening; and, wealthy women, with limited prognoses who have high rates of screening even though guidelines indicate that they are unlikely to benefit.[34] The greatest association was made between a woman's wealth (net worth > $100,000) and higher screening rates.[34] This association was not only among wealthy women with good prognoses but also among wealthy women with limited prognoses, who are unlikely to benefit from screening.[34]

Radiation and Risk Associated with Screening Mammography

Scientists through the years have proposed radiation risk estimates from epidemiological, animal, and theoretical radiobiological studies and much is known about the consequences of such exposures.[35-37] In some situations, health physicists have extrapolated the risks from low level radiation exposures from data gathered about high levels of radiation exposure. The fact that data is scarce about the biologic effects from very low levels of exposure presents a major cause of uncertainty for the scientific community.[35]

> ***Absolute risk*** *refers to a person's chance of developing a specific disease over a certain time period. The absolute risk of disease is estimated by examining a large number of people who are similar in some respects (in terms of age, for example), and counting the numbers of individuals in this group who develop the disease over the specified time period.*
>
> ***Relative risk*** *is a comparison between the risk of disease among people with a particular exposure to the risk and people with that exposure. While*

relative risks are useful for comparisons, they do not provide information about the absolute amount of additional risk experienced by the exposed group.

Risk may be defined as the likelihood of injury, ailment, or death resulting from an activity. For those in medical radiology, risk is viewed as the possibility of developing cancer or a genetic defect after radiation exposure. Risk is also assigned to various occupations since the government has worker protection standards for each industry. The occupational risk associated with radiation exposure is on a par equal with the occupational risk in other industries that are generally considered safe.

Risk estimates for radiation workers were first evaluated by scientific committees starting in the 1950s.[34] It is difficult to estimate risks from radiation, since most humans receive very close to background radiation levels.[34] Natural background radiation accounts for 82% of human environmental radiation exposure and consists of terrestrial radiation from radioactive materials in the earth's crust, cosmic radiation from the sun and solar system, and internal radionuclides that make up a small percentage of the body's tissue.

Benefit versus Risk of Mammography Screening

"Medical imaging has transformed medicine … and is the standard of modern medical care for diagnosis of most conditions and diseases.[38] While imaging was once thought of primarily as a diagnostic tool, today it is used on the front line of treating, managing, and even predicting disease."[38] "The ability of medical imaging to provide physicians with new information and new vision inside the human body has created dramatic improvements in the quality and length of lives."[39] At the same time "…the use of radiation exposure from medical imaging brings potential risk…"[39]

According to the FDA and other federal agencies, the benefit from the use of radiation in medical diagnostic imaging and for therapy purposes normally outweighs the small potential risk posed by such radiation.[39] Despite this conclusion, the agencies expect referring physicians and radiologists to use prudent judgment when evaluating the risks versus the benefits when requesting medical imaging examinations. It is expected that the benefits and cost-effectiveness of medical imaging examinations relative to the patient's condition should guide medical decisions.[39]

Physicians licensed in the healing arts bear the responsibility of using their knowledge and judgment to determine the benefits versus the risks of using ionizing radiation for each patient's particular situation. The physician is responsible for determining the diagnostic efficacy of a x-ray procedure.[40]

> ***Diagnostic efficacy*** *is defined as the degree to which the diagnostic study accurately reveals the presence or absence of disease in a patient.*[33]

Once the decision has been made to perform a diagnostic imaging examination, the physician, radiologist, and the radiographer further accept the responsibility for protecting the patient from unnecessary and excessive radiation exposure. This concept of responsibility is known as ALARA, which is an acronym for **A**s **L**ow **A**s **R**easonably **A**chievable. ALARA encompasses all radiation safety measures, which as a whole minimize radiation dose.[39-40]

There has been controversy among medical experts about subjecting healthy asymptomatic women to the low-dose of radiation received during mammography. The majority of medical experts conclude that the risk of breast cancer for women under age 35 is not high enough to warrant the risk of radiation exposure.[40] The debate is not only based on the amount of radiation exposure but also on the fact that younger women have denser breast tissue than the average older woman. The increased breast tissue density of younger women reduces image contrast and sensitivity of screening mammography. As previously mentioned, the DMIST concluded that digital mammography was significantly better in screening women who were under age 50, of any age with heterogeneously or extremely dense breasts, and pre- or perimenopausal of any age.[41] Furthermore, the study stated that digital mammograms required approximately three quarters the radiation dose of screen film mammography.[41]

In February 2010, the American College of Radiology Imaging Network (ACRIN) conclusively confirmed that the mean glandular dose per patient was 17% lower for women undergoing FFDM compared to screen film mammography.[42] However, in the study, the differences in compression force and compressed breast thickness in FFDM and screen film mammography were shown to be minor.[42]

Incidental radiation exposure of breast tissue in young women significantly increases the risk of breast cancer compared to expected rates in the general population.[43] For example, women who have had thoracic nodal irradiation for Hodgkin's

disease have an increased risk of developing secondary breast cancer at an unusually young age.[43] In general radiography, performing repetitive scoliosis examinations when the x-ray beam enters the posterior surface of the patient's body instead of the anterior surface may reduce the radiation dose to the breasts of young patients.

The largest mammography study of radiation risk concluded that for women 40 years of age or older the risk of radiation-induced breast cancer was miniscule compared to the potential benefit of screening mammography.[44] The results of other studies also support the conclusion that the benefit of mammography outweighs the risk, especially for women 50 years of age and older. Mammography screening guidelines reflect this fact; however young women who have a family history of breast cancer are advised to begin mammography screening at an earlier age.[8,9] The age at which the mammography-screening program should begin still remains a controversial issue. Results published from a German Screening Mammography Program show an increased risk of breast cancer for those who begin mammography screening from the age of 40-45 years.[3] In this study the question was raised whether breast cancer screening by means of mammography (from a radiation hygiene viewpoint) is justified for women under 50 years of age. The excess lifetime risk to incur or die from breast cancer of a 40, 45, and 50-year-old woman was assessed.[43] The models used to establish risk included the Life Span Study of the Atomic Bomb survivors and the risk model given in the Biologic Effects of Ionizing Radiation (BEIR) VII Report. The benefit risk ratio was defined as the ratio of the number of "saved lives" due to screening to the number of deaths due to "radiation induced breast cancer". All estimations were based on the assumption that screening is ongoing up to the age of 69 years with screening performed annually up to age 50 and every 2 years from age 50 and beyond.[43] The glandular dose per 2-view mammogram was assumed to be 4 milligray (mGy). The benefit due to mammography screening was assumed to be 25% for all age groups and that screening began from the age of 45-45 years of age. The study concluded that excess lifetime risk (ELR) of breast cancer is on average about 3.5 or 2 times as high compared to the ELR associated with screening starting from age 50 years.[43] In comparison to the benefit risk ratio which results for women participating in screening from the age of 50 years, the benefit risk ratio for women starting with screening from the age of 40 or 45 years is reduced by a factor of 3 or 2.[43] With present data in regard to both the benefit and the risk of radiation exposure, this study indicated that it is not

justified to expose women at 40 years of age to the additional radiation exposure associated with a mammography screening program.[43]

Today, under MQSA regulations, the radiation dose to the breast is controlled and the average glandular dose delivered during a single view of a 4.2-cm thick, compressed breast consisting of 50% glandular and 50% adipose tissue must not exceed 0.3 rad (3 mGy).[45] This standard applies to both screen film and full-field digital mammography.[45] Compton scattering and photoelectric effect cause most of the x-ray absorption in soft tissue and the radiation risks associated with mammography are generally those related to late effects of radiation-induced cancer, particularly to the glandular tissue.[45]

Part 4 Imaging Modalities

Digital Mammography: Technical Aspects

Both screen film and digital mammography examinations involve the exposure of the breast to x-ray energies. A major difference is that in digital mammography the image is acquired as an electronic signal in digital format. The decoupling or separation of the functions of image acquisition, display, and archival allow independent optimization of each process. Routine clinical application of any digital approach to screening or diagnostic mammography requires that the images obtained be substantially equivalent to, or better than, high-quality screen film mammograms in portraying clinically significant image detail.[18] A major feature of digital mammography that may ultimately prove to be advantageous is its ability to provide improved image contrast over all regions of the breast. In addition, the ability to display, archive, and transmit digital mammography images may facilitate:

- Telemammography, the transmission of digital images to remote sites for purposes of off-site monitoring of diagnostic work-ups, interpretation, consultation, and conferencing;
- Computer-aided detection and diagnostic assistance to radiologists;
- Reduction in the number of repeats for technical reasons;
- More efficient storage and retrieval of images;
- Interventional techniques; and,
- Digital tomosynthesis.[46]

Digital mammography has been used as a tool for breast cancer detection and diagnosis since the early 1990s when the National Cancer Institute (NCI) funded the International Digital Mammography Development Group. Digital mammography has the potential to overcome the known limitations of screen film mammography. The greatest advantage of digital mammography is that the steps of recording, displaying, and archiving an image is decoupled, providing the radiologist and mammographer the opportunity to optimize each task independently. Full-field digital mammography (FFDM) fulfills the following 3 critical needs in breast imaging today:

- Provides quality images that result in detection of a high percentage of early stage breast cancers (i.e., has an acceptable recall rate and an acceptable biopsy rate and yield);

- Provides cost-efficient breast imaging service; and,
- Offers access for many eligible women.[47]

FFDM provides improvements in several key areas when compared to screen-film mammography. These areas include interpretation, viewing conditions, high-contrast resolution, increased detection and diagnosis of occult disease, and reader performance.

The Food and Drug Administration (FDA) approved the first clinical digital mammography system in 2000 but the adoption of this new technology has been slow to gain acceptance due to several factors. These include the initial high cost of acquisition, installation and acceptance testing and the recognized need for additional staff training. An early hindrance to widespread adoption of FFDM was lack of data supporting improved diagnostic accuracy.[48,49] Now data from several digital mammography studies are available and the results have brought renewed interest in the technology.
As of July 1, 2013, the total number of MQSA certified facilities in the U.S. was 8,670, with a total of 12,800 accredited imaging units.[50] The number of MQSA certified facilities with FFDM units was 7,827 and a total of 11,705 accredited FFDM units.[50] From January to July 2013, 8,896 facilities were inspected with 85.8% having no violations on inspection.[50]

The advantages of digital mammography will have to be weighed against the potential disadvantages and technical challenges. Some of the challenges involve image display monitors, workstation efficiency, large data storage requirements, and system costs.[51,52] Also during the initial transition from screen film to digital mammography, imaging centers have experienced high volume of recall examinations as interpreting physicians and mammographers become competent with the technology.[52] The need for additional staff training and the additional time required for physicians to gain efficiency in interpretation time also add to the increased cost of transitioning to digital mammography.[52]

The MQSA requires personnel to receive specific training in digital mammography in addition to meeting the initial MQSA mammography training qualifications. Interpreting physicians and mammographers are required to obtain 8 hours of initial training related to FFDM. The MQSA specifies that this should include practical (hands-on) training in all aspects of FFDM that are within the mammographer's and interpreting physician's area of responsibility.[53] The FDA strongly recommends that

interpreting physicians and mammographers whose 8 hours of FFDM training did not include any training in soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently manipulate and interpret soft copy images.[20] Medical physicists who conduct surveys or mammography equipment evaluations of FFDM/ CR FFDM systems must also meet the requirement for 8 hours of training in conducting such surveys or equipment evaluations.[53]

Studies of Importance to Digital Mammography

There have been 2 large studies that have impacted the acceptance and gradual acceptance and adoption of digital mammography. These are the Oslo II Trial and the Digital Mammography Imaging Screening Trial (DMIST).[41] The DMIST data has the most relevance to breast screening in the U.S. The primary goal of the DMIST study was to determine the effectiveness of various forms of mammography (i.e., screen film and digital) in the early detection of breast cancer.[41] Secondary goals included measuring the relative cost-effectiveness of both digital and screen film technologies, and the effect on participant quality of life due to the expected reduction of false positives.[41]

> *A **false positive** is a test result that indicates that a person has a specific disease or condition when the person actually does not have the disease or condition.*

The following women were ineligible to participate in the DMIST study:

- Pregnant women;
- Women with breast implants;
- Women who had undergone a screening mammogram in the past 11 months;
- Women with a focal dominant lump, which is defined as a single lump felt by a women or her doctor;
- Women with a bloody or clear nipple discharge; and,
- Women with a history of breast cancer treated with lumpectomy.[20]

DMIST showed that, for the entire population of women studied, digital and screen film mammography had very similar screening accuracy.[20,41] Digital mammography was significantly better in screening women who fit 3 particular categories:

- Under age 50 (no matter what level of breast tissue density they had);

- Of any age with heterogeneously (very dense) or extremely dense breasts; and,
- Pre- or perimenopausal women of any age (defined as women who had a last menstrual period within 12 months of their mammograms).[20,41]

There was **no** apparent benefit of digital over screen film mammography for women who fit **all** of the following 3 categories:

- Over age 50;
- Those who do **not** have dense or heterogeneously (very dense) breast tissue; and,
- Those who are **not** still menstruating.[41]

In addition, there was no statistically significant difference in the accuracy of digital mammography compared to screen film according to digital mammography machine type, race, or breast cancer risk.[20,41] These results suggest that for women who fall into 3 subgroups (women under age 50, women with heterogeneously dense or extremely dense breasts, and pre-and perimenopausal women), digital mammography may be better at detecting breast cancer than traditional screen film mammography. Approximately 65% of the women in the DMIST fit into one of the 3 subsets that showed a benefit with digital mammography.[20,41] Some earlier studies had suggested that digital mammography would result in fewer false positives than screen film mammography, but the rates of false positives for digital mammography and traditional mammography were the same in the DMIST.[20,41]

Breast Tomosynthesis

Breast tomosynthesis is possible due to technologic innovations in digital mammography, primarily the development of FFDM breast detectors.[54] Breast tomosynthesis produces breast images in numerous thin slices to potentially provide an earlier, more accurate cancer diagnosis. It provides 3-D breast information by acquiring images using different angles of the x-ray tube while the detector is stationary. As a result, objects located at different distances above the detector are shifted against each other in the images. This technique provides an increase in lesion conspicuity and highlights lesion morphology by minimizing the overlap of breast tissue.

In breast tomosynthesis, the breast is compressed as in conventional mammography. Each breast is compressed only once for a complete view. The tomographic breast images can be reconstructed from the limited number of projection

images obtained at various angles. The final 3-D data set depicts the breast as a series of 1-mm slices and each can be read without the interference of superimposed structures. Breast tomosynthesis minimizes the noise and artifacts common with conventional mammography.[54] The clinical benefits of breast tomosynthesis include enhancement of lesion detection, improved visualization of lesion margins and a reduced number of false positives requiring patient callbacks for re-examination.[54]

For digital breast tomosynthesis (DBT), a mediolateral oblique (MLO) projection of each breast has been suggested by some researchers as the only view required for DBT because the examination produces a 3-dimensional (3-D) image.[55] Presenters at the 2006 Radiological Society of North America (RSNA), reported that 9% of breast cancers were seen only in the CC tomosynthesis projection and not in the MLO.[55] Although acquiring both the CC and the MLO adds to image data storage needs, most suggest that a CC and MLO be acquired in DBT.[55]

Proper breast positioning is critical for any mammography study and mammographers will need additional training in the DBT application and positioning. Of special concern is the safety of the patient associated with a moving x-ray tube. Patients with special needs and those who have conditions that do not allow them to remain motionless, will require additional attention before and during the DBT examination.

DBT with a MLO projection results in about 11 to 15 image captures per examination. The number of images taken depends on breast size and thickness. Because DBT is a new imaging modality, the exact radiation dose to the breast from a particular system is not definitively known at this time.[55] A very important question is what difference could tomosynthesis make to a woman with latent breast disease or symptoms of possible cancer?[56] Early research has shown that tomosynthesis is clearly superior, statistically significantly, better in detection, and staging breast cancer, in the selected series of patients.[29] A research study currently being conducted by radiologists at the Malmö University Hospital in Sweden is analyzing a population-based single-arm data involving 15,000 screening candidates being examined with 2D mammography as well as tomosynthesis.[56] The images will be evaluated separately as well as together to determine sensitivity and specificity. The characteristics of any additional detected cancers will be studied, along with a cost-benefit analysis.[56] In a prior study of 98 women using DBT as an adjunct to FFDM, researchers found that the use of DBT reduced the recall rate by 52%.[56]

In regard to time consumption, it takes approximately 15 minutes to perform a combined 2-D and tomosynthesis examination and between 5 and 10 minutes to evaluate and report the findings.[57] It is expected that the tomosynthesis reading protocol will be improved and the time needed to reconstruct the images will be reduced.[30] Access to a single workstation that could synchronize images from different modalities would also allow for a reduction in reading time.[57]

Ultrasonography

Breast ultrasonography (US) is an adjunctive test, not a replacement for high quality mammography. According to Dr. Deborah Levin, in a recent article published in the Radiological Society of North America (RSNA) magazine (*RSNA News)*, radiology practices should ensure that their laboratories have US accreditation.[58] She further states that US is the ultimate "image gently" modality because there is a total absence of radiation exposure with US.[58] Also, Dr. Levin states that US is a patient-centered modality, and many advocate a patient-centered approach to radiology.[59]

Breast US has an important recognized role in the detection and evaluation of breast disease. It has become the preferred method for differentiating between solid and cystic breast lesions and is also commonly used in image guided breast biopsy procedures. A major advantage of US is that images are produced without radiation exposure. This is a very important benefit for use in the examination of the breasts of young females and pregnant women. The accuracy of US in distinguishing between a solid and cystic lesion is between 96-100%.[60] Like MRI, US is more sensitive than mammography for imaging women with dense breasts. MR imaging is dependent on contrast uptake by the lesion while US is not. Also, US is less expensive than MR imaging but is highly dependent upon operator expertise.

Some of the known strengths of US are:

- It images muscle and soft tissue very well and is particularly useful for delineating the interfaces between solid and fluid-filled spaces;
- It renders "live" images, where the operator can dynamically select the most useful section for diagnosing and documenting changes, often enabling rapid diagnoses;
- It shows the structure of organs;
- It has no known long-term side effects and rarely causes any discomfort to the patient;

- The equipment is widely available and comparatively flexible;
- Scanners are small and easily carried, and examinations can be performed at the bedside; and,

The procedure is relatively inexpensive compared to other modes of investigation (e.g., CT, x-ray tomography, and MRI).[59]

Some of the weaknesses of US imaging are:

- US devices have trouble penetrating bone;
- US performs very poorly when there is gas between the transducer and the organ of interest;
- The depth penetration of US is limited, even in the absence of bone or air, making it difficult to image structures deep in the body;
- The method is operator-dependent. A high level of skill and experience is needed to acquire diagnostic quality images; and,
- There are no scout images, so once an image has been acquired there is no exact way to tell which part of the body was imaged.[59]

The ACR has published guidelines for the performance of US examination of the breast. In these guidelines, the ACR provides appropriate indications for breast US including but not limited to:

- *Evaluation and characterization of palpable masses and other breast related signs and/or symptoms;*
- *Evaluation of suspected or apparent abnormalities detected on other imaging studies, such as mammography or MRI;*
- *Initial evaluation of palpable masses in women under 30 years of age and in lactating and pregnant women;*
- *Evaluation of problems associated with breast implants;*
- *Evaluation of breasts with microcalcifications and/or architectural distortion indicative of malignancy or highly suggestive of malignancy in a setting of dense fibroglandular tissue;*
- *Detection of an underlying mass that may be obscured on the mammogram;*
- *Guidance for breast biopsy and other interventional procedures; and,*
- *Preparation of treatment plans for radiation therapy.*

Currently there are several additional uses of breast US that are under research and not yet approved for clinical application. These include evaluation of the axilla for occult lymph node metastasis in women with newly diagnosed breast cancer and detection of occult masses in dense fibroglandular breasts of high-risk women with newly diagnosed or suspected breast cancer. As with any imaging procedure, the ACR recommends that the written or electronic request for a breast US examination provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.[58,59] All US images should include a permanent identification label.[58,59]

The ACR also suggests that breast US images be correlated with clinical signs and/or symptoms and with other prior examinations (i.e., mammography, MRI).[59] The images under investigation should be viewed in 2 perpendicular projections, and real-time scanning by the interpreter should be considered. Additionally, orthogonal plane images are recommended, along with at least 1 set of images of a lesion obtained without calipers.[55] Breast images should be labeled as to right or left breast, location of lesions, and the orientation of the transducer with respect to the breast.[59] The location of the lesion should be documented using clock face notation and distance from the nipple.

The ACR Breast Imaging Reporting and Data System® (Bi-RADS®) US categories should be used in characterizing breast masses.[59] This includes the categories of size, shape, orientation, margin, echogenicity, lesion boundary, attenuation, special cases, and surrounding tissue. The equipment used in breast US should be a high-resolution scanner with gain settings, focal zone selections, and FOV that allows optimization of the images. The scanner should be capable of operating at a center frequency of at least 10-megaHertz (MHz) and preferably higher.[59] Availability of a standoff device is necessary for evaluation of lesions in, on, or just beneath the skin.

Magnetic Resonance Imaging

MRI detects breast cancer in the contralateral breast for postmenopausal women better than clinical or mammography examinations.[61] Elderly women in good health potentially benefit from earlier detection and breast imaging experts believe that screening the undiagnosed breast with MR imaging should be considered. MR imaging of the breast is a dynamic imaging technique that uses gadolinium–DTPA to improve sensitivity and enhancement for the detection of breast cancer.[62] MR breast images

effectively reveals multifocal breast disease, aids in staging and follow-up of breast cancer, and helps determine which treatment options are most appropriate for a particular case.[48] With breast MR imaging nearly all malignancies of the breast enhance after intravenous contrast injection.[62]

Breast MRI data provides information based on the signal intensity of breast tissue in the presence of gadolinium DTPA. Malignant breast lesions produce a pattern of enhancement that is mapped onto a visual spectrum and delineated by contrast uptake and washout. When a confirmed diagnosis of malignancy is made, the contralateral breast can also be evaluated with MRI.[62-64] Breast MRI was originally used to detect breast implant ruptures, however is now also used as a breast cancer tool to verify the characteristics of lesions detected by mammography or US to assess treatment effectiveness and guide breast biopsies. One of the challenges of breast MRI is lack of specificity demonstrated in many studies. Low specificity can result in high false-positive rates, high recall rates, and unnecessary biopsies.[62-64] Current efforts are to increase specificity and develop techniques to improve diagnosis; however, the increase cost of MR imaging may be a prohibitive factor. There are advantages and disadvantages to breast MRI as well as factors that may compromise image quality.

MRI of the breast is used in the detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization. Breast MRI should be bilateral except for women with a history of mastectomy or when the MRI is being performed to further investigate or follow findings in only one breast. MRI findings should be correlated with clinical history, physical examination results, and the results of mammography and any other prior breast imaging examinations.[61]

The ACR lists current indications for breast MRI to include, but are limited to:

- Screening of high-risk patients;
- Screening of the contralateral breast in those with a new breast malignancy. MRI has been shown to detect occult malignancy in the contralateral breast in at least 4-5% of breast cancer patients;
- Evaluation of breast augmentation, postoperative construction, and free silicone breast injections;
- Determine extent of breast disease (i.e., metastasis, etc.); and,
- Evaluate clinical or imaging findings.[61]

The ACS concurs with the ACR in their recommendation that certain women with an especially high-risk of developing breast cancer should get MRI scans along with their yearly mammogram.[62]

MRI is used to determine the extent of disease more accurately than standard mammography and physical examination of the breast. The imaging modality allows a better understanding of the relationship of the breast tumor to the fascia and its extension into the pectoralis major, serratus anterior, and/or intercostal muscles. Demonstration of the relationship between the tumor and other tissues provides useful information in determining candidates for mastectomy and breast conserving surgery. MRI may also be useful before, during, and/or after chemotherapy to evaluate treatment response and the extent of residual disease prior to surgical treatment. It has also proved useful in the evaluation of suspected cancer recurrence in those with transfer flap reconstruction of the breast. MRI of the breast is not recommended as a screening modality for the general population.[62] MRI is more sensitive than mammography having a reported sensitivity to breast cancer of close to 96%. The increased sensitivity may not always be a good attribute since it detects abnormalities, which may or may not be clinically significant.[62] This may lead to higher false positive results than other breast imaging modalities. Surgical decisions should not be based solely on MRI findings because not all-suspicious lesions found during MRI are cancers. All suspicious lesions should be biopsied before a surgical plan is developed.[65]

MRI has the following advantages:

- Acquires patient information without the use of ionizing radiation;
- Produces excellent soft tissue contrast;
- Can acquire images in the transverse (axial), sagittal, coronal, and oblique planes; and,
- The quality of the images is not affected by bone.[62,66]

MRI has the following disadvantages:

- Any contraindication that would present a detrimental effect to the patient or health care personnel;
- Long scan time compared to CT; and,
- Cost.[62,66]

Current Considerations

Today, breast MR imaging offers the advantage of greater sensitivity compared with either mammography or US. Breast MRI is excellent in imaging dense breasts, small lesions, and multifocal breast cancer and as an aid in staging and follow-up on breast cancer therapies. Breast MRI also plays a decisive role in determining the course of treatment for breast cancer. For example, a MRI guided breast biopsy can help determine whether a lumpectomy or mastectomy is the most appropriate course of treatment, after the initial breast cancer diagnosis has been rendered. MRI has also proven effective in identifying residual disease after lumpectomy or chemotherapy, and distinguishing between postoperative scarring and active disease process, and remains the most effective imaging modality in detecting suspected rupture of breast implants.[63]

Fibroadenomas, radial scars, areas of inflammation can all show enhancement on the MR images. MRI is also unable to adequately image microcalcifications. Since MRI has a very high sensitivity, it has proven beneficial in excluding cancer and reducing the number of biopsies due to false positive mammograms. Although MRI has proven useful as a breast-imaging tool, it's use as a diagnostic and screening tool is the subject of controversy and debate.[63] Disagreements involve the lack of a history of proven efficacy (i.e., in randomized clinical trials), a high number of false positive results, and its high cost.[63] Currently there is lack of substantial data to confirm the effectiveness of breast MRI as a screening modality and because there is no standardized technique for breast MRI, research studies can produce different effects.[63] As with any new imaging technique, there is always a need for radiologists and mammographers to become proficient in using the modality and this is seen in variations of proficiency in procedural outcomes.

The high sensitivity of MRI gives it the leading edge in detection of abnormal areas of tissue; however the low specificity results in a high false positive rate. Most breast MRI examinations are conducted as an adjunct to other imaging modality examinations. MRI does not really qualify as a standard breast-screening tool because the ideal screening modality must have sensitivity, specificity, reproducibility, and be cost-effective. Since the current state of breast MRI does not satisfy all of these requirements, it is currently only recommended as a screening examination of very high-risk women and as a diagnostic tool in those with dense breast tissue, or those with suspected breast abnormalities previously demonstrated by other imaging modalities.

Breast MRI is a costly procedure compared to mammography or US examinations and is not widely available, especially in rural areas and may not be accessible to certain minority populations. The high cost of MRI examinations stems from the high cost of the initial purchase, installation, and operation of the equipment as well as staffing required. The cost of a single MRI is between $1,200 and $1,500 whereas, the cost of an average mammogram is approximately $100.[63] Over the past 10 years, many improvements have been made in MRI systems, including the use of higher-field strength magnets, dedicated breast coils, and availability of gadolinium. Combined, all of these improvements add to the overall cost of providing MR imaging services.

Most MRI magnets are superconductive and the magnetic field is always on. Any ferromagnetic material, oxygen tank, wheelchair, scissors, etc., may become a projectile object. Before entering a high magnetic field, individuals should be screened for contraindications including biomedical devices/implants or a device that is electronically, magnetically, or mechanically activated such as pacemakers, cochlear implants, certain intracranial aneurysm clips, and orbital metallic foreign bodies. These devices may move or undergo a torque effect in the magnetic field, overheat, produce an artifact on the image or become damaged or functionally altered. In 2009, the FDA issued a public health advisory that certain transdermal drug patches may deliver skin burns during a MR examination. The warning noted that some patches contain aluminum or other metals in their non-adhesive backing, and while not attracted to the scanner magnet, the metal can conduct electricity, generating enough heat to cause burns. Additional information may be obtained at http://ww.mrisafety.com/safety_article.asp?subject=56.

There is always the concern about claustrophobia. Due to the construction of closed MRI scanners, they are potentially unpleasant for someone who cannot bear the feeling of being closed within a structure. To compound problems associated with claustrophobia, MRI bore size and table weight restrictions must be considered for individuals who are overweight and obese. Breast MRI is conducted using a 1.5 tesla magnet with dedicated breast coils. Pre and post contrast imaging is performed after intravenous administration of gadolinium-DPTA. The patient lies face down on the table with the breasts placed into the breast coils. The patient should be thoroughly informed about what to expect during the procedure and the importance of no “motion” during the scan. Once the patient is secured in the final position, the table is inserted into the

gantry. The examination consists of a series of two to six sequences with each sequence lasting between 1-15 minutes. Images are then sent to the computer for processing.

The actual MR images may be obtained in the transaxial and sagittal view, which is most common; however, coronal images may also be obtained. After administration of the ferromagnetic contrast agent, tumors usually will demonstrate rapid contrast enhancement, usually within 5 minutes of the injection. The imaging sequences most commonly used include fat-saturated T2-weighted fast spin-echo (FSE) images, sagittal short T1 inversion recovery images, and fat saturated spoiled gradient-echo. The basic types of pulse sequences are proton (spin) density, T1 relaxation time, and T2 relaxation time. Each type of pulse sequence demonstrates the anatomy differently and helps differentiate between normal and abnormal structures. For a complete diagnostic evaluation, a combination of these pulse sequences is usually required.

Although there are many advantages to breast MRI, certain factors may compromise image quality. These relate to hardware, software, technologist performance, and patient cooperation. Motion artifacts on MR images are commonly due to patient swallowing, pulsatile flow motion, and respiration and can be minimized by proper instructions to the patient prior to image acquisition. Pulsatile flow motion artifacts can be minimized by using saturation pulses and can be applied to inferior and superior images. Any amount of patient motion produces misregistration of data on the image and reduces conspicuity of lesions. A few of the issues that contribute to motion are patient discomfort, claustrophobia, and incomplete or inadequate patient instruction prior to the scan. Failure of the contrast agent to perfuse adequately is usually due to poor or improper venous access. To overcome this problem, once the venous line is properly obtained, the patient's arms should be partially extended so the blood flow will not be blocked.

Aliasing artifacts occur when the part being imaged is outside the field of view (FOV) but within the RF excitation range. When this occurs, the radiofrequency (RF) excitation range signals are not properly interpreted. Body shape conductivity and extension artifacts are metallic-like artifacts appearing at the edge of the area being examined.

A chemical shift artifact appears as a bright rim of signal at one interface and a dark rim on the opposite side of the area. Chemical shift artifacts are caused by slight differences between the Lamour frequencies of similar protons (i.e., fat and water).

Ferromagnetic material artifacts are caused when metallic artifacts either on or embedded in the patient block the MRI signal. These cause a complete loss of signal at the site and a wrapping distortion of the area. Inadequate fat saturation results from the presence of the metal objects in or near the tissue being examined. Examples of indwelling metal objects include metal markers or ports for chemotherapy treatment.

Incorrect placement of local shim markers during the scan setup can lead to magnetic susceptibility artifacts on MR images. Improper patient positioning of the breasts in the coil is considered the most common cause of artifacts on the MR image.[67] The breasts should be in the center of the coil openings. Also, the tissues should be away from the chest wall to extend the Cooper's ligaments. Misregistration of data results when the breast tissue is compressed against the inner edge of the MRI coil.

A positron emission mammography (PEM) unit is a high-resolution breast positron emission tomography (PET) unit. PEM imaging demonstrates the metabolic phase of a lesion and is used to determine the extent of disease in newly diagnosed breast cancer patients.[68] PEM may be used prior to preoperative chemotherapy and after post-surgical chemotherapy to determine response to treatment.

Data from a National Institutes of Health (NIH) sponsored, multi-site study of approximately 400 women with newly diagnosed breast cancer shows that positron emission mammography (PEM) may reduce unnecessary breast biopsies.[68] Results of the study indicate that PEM was significantly more precise at identifying benign and malignant lesions, referred to as positive predictive value (PPV).[63]

> ***Positive predictive value*** *is the proportion of patients with positive test results who are correctly diagnosed. It is the most important measure of a diagnostic method as it reflects the probability that a positive test reflects the underlying condition under investigation.*[63]

One of the most important results of the study was that PEM was found to be an acceptable alternative to magnetic resonance imaging. Approximately 16% of women cannot tolerate MRI due to claustrophobia, obesity, sensitivity to gadolinium, and ferromagnetic devices such as a pacemaker or a metallic implant.

Molecular breast imaging (MBI), a nuclear medicine-based technology uses a gamma camera designed for imaging the breast.[26] MBI is a functional study as opposed to mammography, which is an anatomical study. Because MBI is a functional study, the

behavior of abnormal cells may be imaged.[69] The procedure requires that the patient be given an injection of technetium-99 sestamibi, a radiotracer.[69] MBI may be used for patients for whom breast MRI would be recommended, but due to certain contraindications cannot undergo a MR imaging examination.[69]

Although still new to the average breast imager, MRI has been used as an adjunct to mammography and ultrasound in diagnostic breast imaging and its use will continue to be further refined as a tool in the breast-imaging arsenal.[69]

Part 5 A Review: Breast Anatomy and Physiology

Normal Breast Composition

The adult female breast is a well-differentiated apocrine sweat gland located over the pectoral muscles and attached to the chest wall by Cooper's ligaments.[14,17]

> ***Cooper's ligaments****, also called suspensory ligaments, are strands of connective tissue running between the skin and deep fascia. These ligaments serve to support the lobes of the breast beginning at the most posterior portion or base of the breast and extending outward to attach to the anterior fascia of the skin.*

The apocrine glands have evolved into an organ that produces and secretes milk during lactation.[14] The breast is composed of:

- Milk glands (lobules) that produce milk;
- Ducts that transport milk from the milk glands (lobules) to the nipple;
- Nipple;
- Areola (pink or brown pigmented region surrounding the nipple); and,
- Connective (fibrous) tissue that surrounds the lobules, ducts, and fat.

External Appearance

The size and shape of the breasts vary considerably. Factors that may influence breast size includes:

- *Age;*
- *Family history;*
- Volume of breast tissue;
- Weight loss or gain;
- History of pregnancies and lactation;
- Thickness and elasticity of the skin over the breast;
- Degree of hormonal influences on the breast; and,
- Menopause and hormone replacement therapy (HRT).

Breast shape and appearance undergo a number of changes as women age. As a woman ages her breasts become less dense and the space is filled with fatty tissue. On breast images, lesions may appear white whereas fat appears as black regions with all other components of the breast appearing as shades of white. In general, the younger the woman, the denser her breast tissue composition. After menopause, the glandular tissue, which has been kept firm so that the glands could produce milk, shrink and are replaced by fatty tissue. The breast also tends to increase in size and sag because the fibrous connective tissue loses its strength.

According to many cosmetic surgeons, many older women are opting for breast augmentation surgery.[70] This group of older women includes those who are opting for breast augmentation as part of a "rejuvenation process", women who have undergone bariatric surgery, and those who simply won't let age and gravity take their youth without taking action.[70] Women may also undergo breast augmentation because of other changes in their lifestyle. There are women who are breast cancer survivors and for them breast reconstruction offers improved quality of life and self-image.

External Landmarks

The external landmarks of the breast include the nipple, inframammary fold, and axilla.

> ***Inframammary fold*** *refers to the most inferior aspect of the breast where it meets the anterior abdominal wall.*

Of the structures mentioned, the only fixed point of reference in the breast is the nipple and it is an important landmark in describing any breast abnormality, Figure 7.

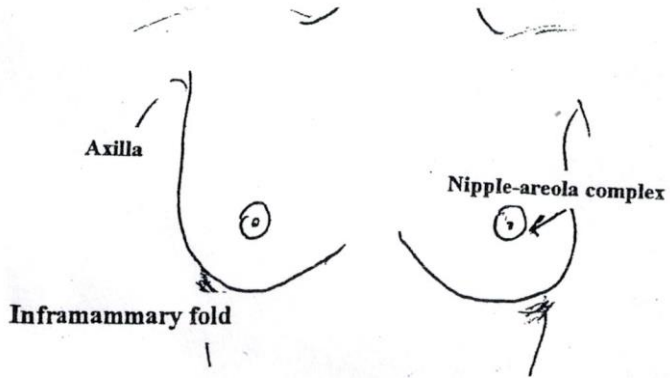


Fig. 7. External landmarks of the breast.

Two methods are used to subdivide the breast into smaller areas for localization of lesions. The quadrant method divides the breast into four areas, Figure 8.

- Upper-outer quadrant (UOQ)
- Upper-inner quadrant (UIQ)
- Lower-outer quadrant (LOQ)
- Lower-inner quadrant (LIQ)

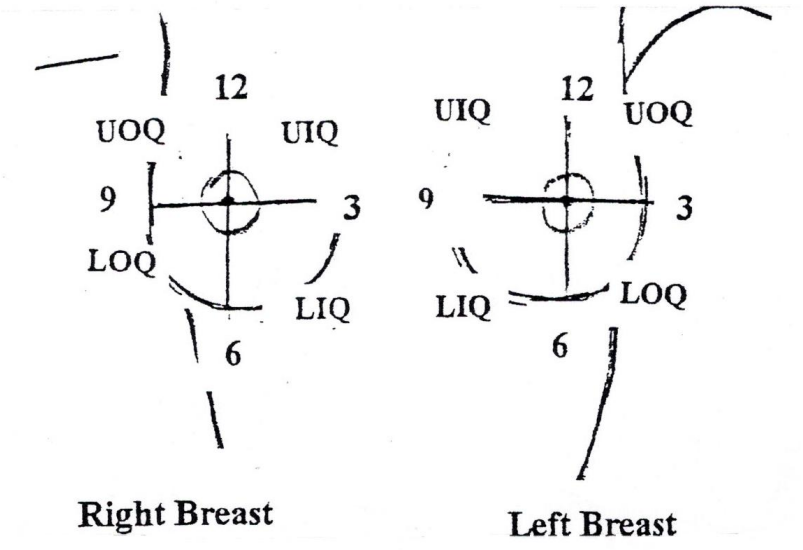


Fig. 8. The quadrant and clock system.

The clock method as illustrated in Figure 8, is also used and helps to describe the location of abnormalities in the breast. The clock method can be confusing since the 4 o'clock position in the right breast represents the LIQ while 4 o'clock in the left breast represents the LOQ.

Skin

The skin at the base of the breast is about 2 millimeters (mm) thick and becomes thinner as it approaches the nipple (0.5 mm).[17] The skin covering the breast contains sweat glands, sebaceous glands, and hair follicles that open to form skin pores.

Sebaceous glands *are oil-secreting glands located in the skin.*

The sebaceous glands are prone to infection and the inflammatory process may mimic carcinoma on the mammography image.[7] The skin pores may also be visualized on mammography as tiny multiple lucencies.[17]

Changes in the skin of the breast represent common conditions and developments that occur as women grow older. Changes in the connective tissue reduce the skin's strength and elasticity. The blood vessels of the dermis become more fragile which in turn leads to bruising, and bleeding under the skin. The subcutaneous fat layer thins thus increasing the risk of skin injury and reducing the ability to maintain body temperature. Rubbing or pulling the skin can cause skin tears. Bruises, flat collections of blood (purpura), and raised collections of blood (hematomas) may form after minor injury.

Nipple-Areola Complex

The nipple and areola are located at the most distal point (apex) of the breast. The areola contains erectile and smooth muscles and the Montgomery glands surround the nipple.

> *The **Montgomery glands** are specialized sebaceous glands that provide lubrication during lactation. These glands secrete a thick, protein type substance during lactation for lubrication and protection of the nipple.*

The size and characteristics of the nipple varies among women but the nipple is the center point of the breast and provides a reference to describe location of normal anatomy and pathology. The shape of the nipple can be flat, round, or cylindrical and generally protrudes from the breast. Patients may present with developmental variations such as; inversion, retraction, or enlargement of the nipple, which may be caused by either a benign or a malignant condition. Any sudden change in the nipple itself or to the skin around the nipple is significant and is indicative of an underlying malignancy and requires thorough investigation.

> ***Inversion** refers to a case in which the entire nipple is pulled inward. The turning inward may be far enough so that the nipple lies below the surface of the breast.*

Retraction *of the nipple means that only a slitlike area is pulled inward. Both inversion and retraction may be either congenital or acquired and may be either unilateral or bilateral.*

The nipple has 5 to 7 crevices (collecting ducts) that transfer milk from the lactiferous ducts during lactation. Immediately inside the nipple, the collecting ducts widen to form the lactiferous sinuses. Morgagni's tubercles are protrusions or rounded elevations on the surface of the areola. Morgagni's tubercles are the openings for the Montgomery's glands (sebaceous and rudimentary mammary glands).

Supernumerary nipples or polythelia, can affect both sexes. These accessory nipples are more commonly found just below the normal breast, but can be located anywhere along the milk line that runs from the axilla to the groin. Those with polythelia may have associated breast tissue that undergoes physiological and pathological changes like those observed in normal breast tissues. The condition is associated with other congenital disorders such as renal agenesis, renal cell carcinoma, supernumerary kidneys, and cardiac abnormalities.

Internal Anatomy

The breast is situated anteriorly to the pectoralis major muscle and the pectoralis minor muscle. These muscles aid in controlling upper arm movements. Adipose tissue and connective fascia separate these muscle layers from breast tissue creating the retromammary space.

The ***pectoral muscles*** *consist of the pectoralis major and the pectoralis minor. The pectoralis major muscle is a large, thick, fan-shaped muscle that covers the upper parts of the chest. The pectoralis minor muscle is a thin, flat, triangular muscle lying below the pectoralis major.*

The ***retromammary space*** *separates the breast tissue from the pectoral muscles.*

The fascia encapsulates the breast anteriorly and posteriorly and encloses the lobes, lobules, acini, nerves, blood vessels, and support structures of the breast, Figure 9.

The breast tissue itself is held in position by the Cooper's ligaments and fibrous connections that run from the fascia, up between the lobes, to the skin. These criss-crossing fibrous structures first described by Cooper in the 1880s, run between the deep and superficial layers of the fascia resulting in semi-compartmentalization of the structures. The area of the breast adjacent to the chest wall is the base or juxtathoracic. The breast tissue can reach as far superiorly as the clavicle (level of the second or third rib), and inferiorly to meet the abdominal wall (i.e., the area referred to as the inframammary fold or crease), at the level of the sixth or seventh rib. The breast reaches into the axilla (tail of Spence) and may also extend laterally to the edge of the latissimus dorsi muscle, which forms a portion of the axilla.

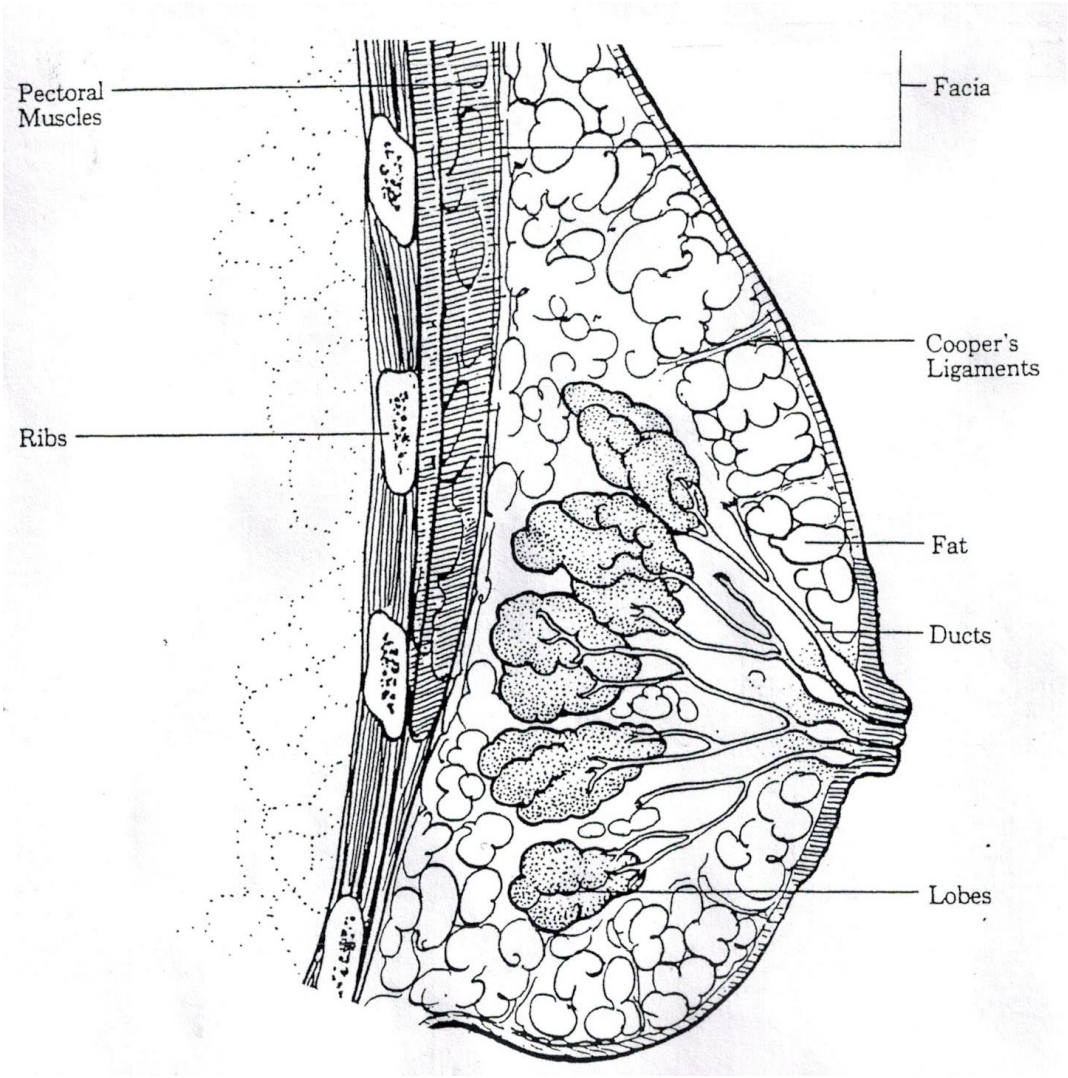


Fig. 9. Sagittal section of breast tissue. Courtesy of the National Institutes of Health, National Cancer Institute.

*The **tail of Spence** refers to the upper outer quadrant of the breast, which extends toward the axilla. The tail of Spence is the thickest portion of the breast structure.*

Cooper's ligaments bridge the superficial and deep pectoral fascial planes and provide a framework around various areas where glandular stroma and adipose tissue are deposited. These ligaments determine the firmness of the breast and may appear on mammography images as dense curvilinear structures in the anterior portion of the breast. Radiographic changes in the appearance of these structures may be due to tissue retraction associated with benign and malignant breast diseases. The superior and medial attachments of the breast to the thorax are the most rigid, which allows the inferior and lateral portions to be the most mobile.

The internal breast consists of varying amounts of fatty tissue and parenchyma. The parenchyma includes glandular components, lymphatic networks, blood vessels, connective and supportive stroma. The extralobular and intralobular stroma are specialized tissue that provides support for the larger ductal structures. The intralobular stroma gives the lobule its shape and definition. An extensive capillary network allows the exchange of hormones, into and secretions out of the lobules.

Glandular Tissue

Glandular tissue is generally concentrated in the central and upper outer quadrant of the breast. The quantity of this tissue varies with each individual but is influenced by genetic predisposition, age, and hormonal levels. The pattern and distribution of glandular tissue is normally the same bilaterally. Involution or atrophy of glandular tissue begins in the medial portion and extends posteriorly (from the base to the nipple).

***Involution** refers to a process that begins at menopause. During the involution process the breast loses its supportive tissue to fat and results in either a smaller breast or one that is larger and pendulous.*

***Atrophy** refers to an abnormal "wasting away" of, or diminishing in size of normal tissues, organs, or the entire body.*

Breast Architecture

The parenchyma of each breast consists of 15 to 20 lobes.
The lobes extend from the nipple and are arranged like spokes around a wheel, extending outward in a radial pattern. The ductal flow follows this radial pattern forming the normal architecture of the breast. Any change in breast architecture on the mammography image indicates pathology and requires further investigation, Figure 10.

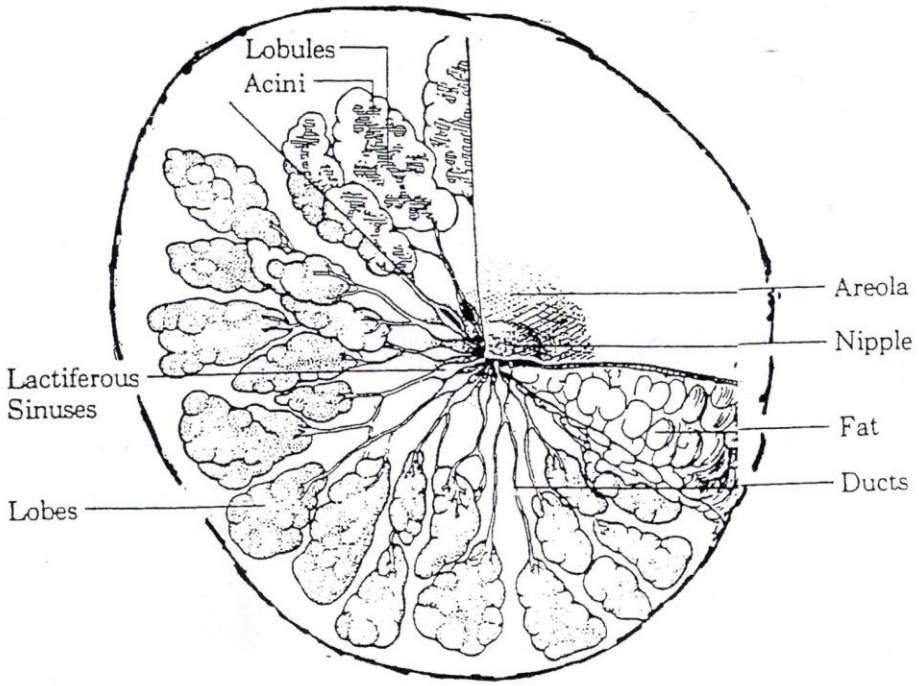


Fig. 10. Breast parenchyma. Courtesy of the National Institutes of Health, National Cancer Institute.

Lobes and Ductal Features

The ducts begin at the nipple and widen into lactiferous sinuses (ampulla), which in turn branch off into many medium-sized subsegmental ducts.

*An **ampulla** is a sac-like dilation of a canal or duct.*

The larger subsegmental ducts further divide until coming to the lobule. The number of lobules varies among women, and even at different times in the same woman. Nearly all breast cancers originate in the ducts or lobules of the breast. Tumors arising from

glandular breast tissue are called adenocarcinomas with the two main types being ductal and lobular carcinoma.

The extralobular terminal duct is the small duct just outside of and leading to the lobule. Once inside the lobule, extralobular terminal ducts further divide into intralobular terminal ducts, which ultimately end in terminal ductals (the number varies from 10 to 100 in any lobule). The portion of the ductal structure starting at the extralobular terminal duct and ending at the terminal ductules is the terminal duct lobular unit (TDLU). The TDLU increases and decreases in size and number depending on life cycle changes, menstrual cycle, and hormone fluctuation. The TDLU is responsible for milk production and hormonal and nutritional exchange.[17] Most breast pathology, including various types of cancer, arises from the TDLU.[17]

The spaces around and between the lobules are filled with adipose tissue. The lobes, lobules, and acini are connected to the nipple by a complex network of ducts. During pregnancy and lactation, the lobes increase in size due to an increase in the size and number of acini. Following menopause, the lobes involute and are replaced by adipose tissue.

Breast Lymphatics and Sentinal Node Mapping

The lymphatic system is an essential part of the immune system, which helps the body fight infections. The lymph network is made up of fine capillaries that merge to form lymph vessels. Cellular waste and lymph fluid is transported via lymph nodes, ducts and specialized organs to the bloodstream. Lymph nodes are usually present in clusters in the axilla, on either side of the neck, and in the groin, Figure 11.

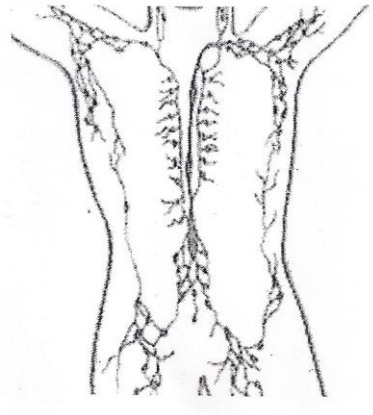


Fig. 11. The lymphatic system. Courtesy of the National Institutes of Health, National Cancer Institute.

In the embryo, the breast and its lymphatic system develops from a central breast bud.

Lymph fluid is a clear white-yellow fluid that contains white blood cells (lymphocytes), proteins, and some red blood cells. Lymph nodes are usually located in the upper outer quadrant of the breast and tend to follow the route of the blood vessels, but can occur anywhere in the breast, including the medial and inferior portions.[60] Lymph nodes can fluctuate in size but most normal lymph nodes are less than 2 centimeters in size and have a kidney-bean shaped appearance.[60] Superficial lymphatic drainage beneath the skin of the breast goes to the pectoral and infraclavicular lymph nodes and to the deep plexus. Deep drainage goes to the pectoral nodes and the subscapular nodes and then to the lateral axillary, apical nodes, and deep cervical nodes.

The lateral half of the breast tends to drain into the pectoral group of axillary lymph nodes and the medial half of the breast drains into the internal mammary lymph node. The internal mammary nodes drain toward the mediastinal nodes, Figure 12. Approximately 97% of the lymphatic drainage of the breast pass to the axillary nodes and about 3% drains to the internal mammary nodes.[60]

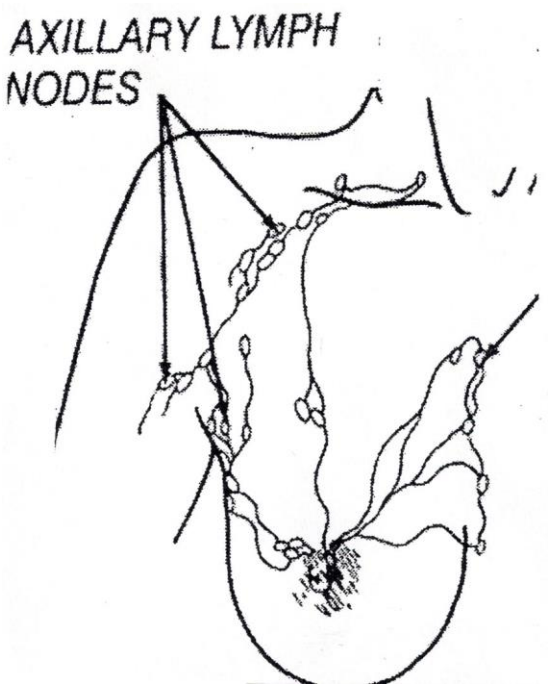


Fig. 12. Axillary lymph nodes. Courtesy of the National Institutes of Health, National Cancer Institute.

Lymph drainage from the breast is significant because it is by this route that malignant cells may leave the breast and spread to other areas of the body.[13] Because the lymph drainage routes are similar to that of the blood flow, the breast has a predictable pattern for lymphatic drainage.[71]

On mammography images, the lymph nodes can vary in size between examinations, sometimes going away completely only to reappear on subsequent studies.[60] If a benign appearance is maintained, lymph nodes that demonstrate small increases in size can be followed by mammography.[60] There is a high association with malignancy in dense lymph nodes that are ill-defined or have spiculated margins.[60] If on mammography, there is a loss of the fatty hilum around a lymph node, loss of margin definition, spiculation, rounding, and/or increasing density, a biopsy should be considered.[60]

The term “sentinel lymph node” (SLN) has been coined to describe the condition in which certain lymph nodes are first in line to receive lymphatic drainage from a tumor. SLN mapping is a diagnostic procedure used to locate and mark the SLN before biopsy and to confirm the presence of cancer in the lymph nodes. Once a malignant tumor has been identified, the primary drainage for the entire breast can be determined via sentinel node mapping. The procedure consists of injecting the breast with either a radiocolloid preparation or a blue dye. When radiocolloids are used, SLN mapping is referred to as lymphoscintigraphy. After the tracer has been administered, a gamma detector is used to identify areas of radioactive uptake and a computer is used to create images of the lymph flow.

The SLNs are identified, excised and examined by a pathologist for the presence of cancer. Just because a lymph node shows uptake of the tracer material does not mean that the lymph node contains cancer cells. SLN mapping is recognized as an acceptable alternative to axillary node dissection and can establish which patients require node dissection and additional treatment.[71] The procedure is not indicated in those with high-risk lesions, non-invasive cancer, and non-palpable breast masses.[71] Also poor candidates for the procedure according to the Health Canada’s Canadian Breast Cancer Initiative, include women with:

- Palpable lymph nodes;
- Locally advanced breast cancer;
- Multifocal breast cancer;
- Previous breast surgery; and,

- Previous radiation therapy.[72]

Breast Blood and Nerve Supply

The blood supply to the breast is via the anterior cutaneous or perforating branches of the internal mammary and the lateral mammary branch of the lateral thoracic arteries. The thoracic branches of the axillary artery, the posterior intercostal branches of the descending thoracic aorta and the internal mammary artery also supply blood to the breast.

Perforating branches from the 2nd through the 4th intercostal arteries supply blood to deep portions of the breast. Of these, branches of the internal thoracic artery supply the medial portion of the breast. The lateral portion of the breast receives its blood supply from branches of the subscapular artery, arising from the 3rd portion of the axillary artery. The superior thoracic artery arising from the first part of the axillary artery supplies the pectoralis major muscle. The acromioclavicular artery arises from the 2nd portion of the axillary artery and supplies blood to the pectoralis major and minor muscles. The breast is supplied with sensory and sympathetic nerves by the anterior and lateral cutaneous branches of the 4th through the 6th intercostal nerves.

Physiology of the Breast

In most women, the breast is in a constant state of change brought about by hormonal fluctuations associated with the menstrual cycle. The breast is referred to as "resting" when there is no pregnancy or lactation. The menstrual cycle prepares the body for pregnancy, which in turn causes changes to the breast tissue. These changes range from proliferation of the cells of the ductal structures to involution, regression, and atrophy.[1]

Initial Breast Development

Breast tissue initially develops in the 6th week of fetal life, along the milk ridgeline. By the 9th week of fetal development, the milk ridgeline regresses to the chest area, leaving two breast buds on the upper half of the chest. The male and female breasts in human beings develop from the same embryological tissue. In females, columns of cells grow inward from each breast bud, becoming separate glands with ducts leading to the nipple. Both male and female infants have very small breasts and may actually experience some nipple discharge during the first few days after birth.

Breast Changes over the Female Hormonal Life Cycle

Female breasts generally begin to grow at puberty (i.e., around age 10 or 11), when a variety of physiologic changes occur in preparation for reproduction, Figure 13.

Before puberty	Early puberty	Later puberty
The breast is flat except for the nipple that sticks out from the chest.	The areola becomes a prominent bud; breasts begin to fill out.	The amount of glandular tissue and fat increases in the breast, and the areola becomes flat.

Fig. 13. Hormonal influence on breast development.

Breast development results from ovarian stimulation at puberty, which is regulated by hormones, produced by the anterior pituitary gland. Estrogen, produced by the Graafian follicle cells of the ovary, stimulates duct elongation and branching and increases the volume and elasticity of connective tissue, deposition of adipose tissue, and increased vascularity.

Estrogen *is a hormone produced by the Graafian follicle cells of the ovary. Estrogen stimulates the development of the reproductive organs, including the breast and secondary sex characteristics such as pubic and axillary hair.*

A ***Graafian follicle*** *is a mature vesicular follicle cell of the ovary. Beginning with puberty and continuing until menopause, except during pregnancy, a graafian follicle develops at approximately monthly intervals.*

Progesterone *is a hormone obtained from the corpus luteum and placenta. It is responsible for changes in uterine endometrium in the second half of the menstrual cycle that are preparatory for implantation of the blastocyte. It is also responsible for the development of the maternal placenta after implantation and the development of mammary glands. It is used in the treatment of menstrual disorders such as ammenorrhea and dysmenorrhea.*

Corpus luteum *refers to the yellow endocrine body formed in the ovary at the site of a ruptured ovarian follicle immediately after ovulation.*

The hormone prolactin, also secreted by the anterior lobe of the pituitary gland, is present only during initial breast growth, pregnancy, and lactation. With menarche (i.e., onset of menstruation), the breasts grow rapidly and the ducts and lobules subdivide and mature. Each month during a woman's reproductive lifetime, breast size may fluctuate with the menstrual cycle, as the body prepares for a possible pregnancy, Figure 14. During each menstrual cycle, the milk glands and ducts enlarge, causing the breasts to retain water. Females report that during this time their breasts feel swollen and lumpy and are often tender.

Menstrual Cycle Effects on the Breast	
Days 3-7	Estrogen rise leads to epithelial proliferation.
Days 8-14	Differentiation of epithelial cells.
Days 15-20	Progesterone rises which lead to an increase in size of the acini lumen and ducts.
Days 21-27	Epithelial cells in the lumen produce secretions; intralobular stomal edema and venous congestion occur.
Days 27-2	Decrease in secretion with resultant decrease in stromal edema and a decrease in lumen size.

Fig. 14. Menstrual Cycle Effects on the Breast

Breast Changes after Menopause

At menopause (typically late 40s or early 50s), a woman's body stops producing estrogen and progesterone. In some women, the loss of these hormones causes a variety of symptoms including hot flashes, night sweats, mood changes, vaginal dryness and difficulty sleeping. During this time, the breasts also undergo change. For some women, the breasts become more tender and lumpy and develop cysts. Approximately 3 to 5 years after menopause, the breast tissue begins to atrophy and the supportive breast tissue is gradually replaced by fat. The lobules involute and the epithelium flattens and secretory activity is diminished. Over time the epithelial layers disappear. Menopausal atrophy begins medially and posteriorly, then laterally to the nipple and is not always equal in both breasts.

The glandular breast tissue, which until menopause has remained firm so that the glands could produce milk, shrinks and is replaced with fatty tissue. The breasts also tend to increase in size and sag because the fibrous, connective tissue loses its

strength. The last areas to involute in the menopausal breast are the retroareolar regions and the upper outer quadrant. These areas are demonstrated on mammography as radiolucent structures.[60]

> *The term **radiolucent** refers to an anatomic structure or body tissue that allows the x-ray beam to pass through with little or not attenuation (interaction) between the x-ray beam and the structure or tissue. For example, when the patient fills their lungs with air on inspiration, the lungs are radiolucent structures (i.e., appearing dark on the radiographic image).*

Influence of Post-Menopausal Hormone Replacement Therapy

Hormone replacement therapy (HRT) is taken by millions of women to ease hot flashes, night sweats, vaginal dryness, brittle bones, and other symptoms of menopause. An estimated 6 million women take the drugs estrogen and progestin to replace the hormones lost at menopause.[73,74] In July 2002, the National Heart, Lung and Blood Institute stopped the Women's Health Initiative (WHI) study of combined hormonal replacement therapy (HRT) 3 years early due to questions about the safety of long-term HRT (estrogen-progestin) use.[8,11,12]

A similar study designed to determine the influence of estrogen-alone was stopped at the end of February 2004 because of an increased risk of stroke and no significant effect on heart disease. After further analysis of the estrogen-alone data, researchers announced that taking estrogen-alone does not increase the risk of breast cancer in postmenopausal women but increases the risk of blood clots in the legs, reduces the risk of hip fracture and had no significant effect on colorectal cancer. Researchers noted that longer follow-up is needed to fully explain the reduced number of breast cancers in women, in the trial group, who were taking estrogen. The new analysis also found that participants taking estrogen had 50% more abnormal mammograms that required follow-up and underwent 33% more breast biopsies (747 compared to 549).

Mammography of women on HRT, demonstrates an increase in the density of the breast parenchyma as well as fibrocystic changes. Studies indicate that ERT probably does not affect the sensitivity of the mammography study, but may reduce specificity.[14,73,74] Additionally, the U.S. Preventive Services Task Force has

recommended against the routine use of estrogen and progestin for the prevention of chronic disease in postmenopausal women.[16,75]

> ***Sensitivity*** *in breast imaging refers to the probability of detecting breast cancer when cancer is present. The goal of mammography is that sensitivity should exceed 85%. Sensitivity is often difficult to calculate because in most clinical settings an accurate false negative rate is difficult to obtain. Access to tumor registry data helps determine the false negative result rate.*
>
> ***Specificity*** *in breast imaging is the quality of being precise rather than general. An imaging system that is highly specific can effectively differentiate between normal and abnormal changes within the breast.*
>
> ***False negative*** *refers to a missed diagnosis. This occurs when the mammography results indicate that no breast disease was present but the breast disease was actually present (i.e., often found during cytology and histology examinations).*
>
> ***False positive*** *refers to a mammography result that indicates the presence of a breast condition when the breast condition is not present.*

Breast Classifications

There are 3 classifications or categories of breast tissue; glandular, fibrous or connective, and adipose. All breast tissue has low inherent subject contrast; however, fatty tissue is less dense than either glandular or fibrous. The breast tissue is in a constant state of change due to hormonal fluctuations and the female reproductive cycle. The breast changes or evolves from a structure consisting of dense tissue in the early stages of life to one that is mostly fatty tissue after menopause. These changes have significance since the density of the breast tissue determines the amount of radiation exposure required during mammography.

The fibro-glandular breast has very little fat but is dense and is more common in women 15 to 30 years of age who are childless. Pregnant and lactating females in all age ranges are also placed in the fibro-glandular breast category. From about 30 to 50 years of age, the female breast tissue changes to a more equal distribution of fat and

fibro-glandular tissue (fibro-fatty). Young women with 3 or more pregnancies are also placed in this category. The fibro-fatty breast is not as dense as the fibro-glandular breast and requires less radiation exposure during mammography.

The 3rd type is the fatty breast, which occurs as the breast atrophies (involutes), after menopause, beginning at about age 50. Of the 3 types of breast tissue, the fatty breast is the least dense and requires less radiation exposure during mammography. Children and males are also placed in this breast category since their breasts contain mostly fat. The breast glandular tissue has a high degree of radiosensitivity.[76] Radiation dose to the breast of a young patient should be maintained as low as reasonably achievable (ALARA).[76]

> ***Radiosensitivity*** *refers to the impact of radiation exposure on living tissue. Each type of cell differs in its sensitivity to radiation. The Law of Bergonié and Tribondeau attempts to explain the basis of cell radiosensitivity. The law states the following:*
>
> - *Immature, nonspecialized cells are the most radiosensitive of the cells (i.e., lymphocytes);*
> - *Mature, specialized cells are the most radioresistant of the cells (i.e., nerve cells);*
> - *Cells that are rapidly growing and dividing are radiosensitive; and,*
> - *Immature tissues and organs are radiosensitive.*

> ***As low as reasonably achievable (ALARA)*** *is the basic philosophical principle of radiation protection concerning the use of ionizing radiation. The ALARA principle emphasizes the need to maintain exposure to ionizing radiation at a level that is as low as reasonably achievable.*

Cultural Status of the Breasts: Art, Religion, and Legend

Historically, breasts have been regarded as fertility symbols, because they are the source of life-giving milk. Certain prehistoric female statuettes, so-called Venus figurines, often emphasized the breasts. In historic times, goddesses such as Ishtar were shown with many breasts, alluding to their role as protectors of childbirth and mothering.[77] The legendary tribe of Amazons bared their breasts, and in some accounts removed one breast to allow better combat and archery.[77]

Some religions afford the breast a special status, either in formal teachings or in symbolism. Islam forbids public exposure of the female breasts.[77] In Christian iconography, some works of art depict women with their breasts in their hands or on a platter, signifying that they died as a martyr by having their breasts severed; one example of this is Saint Agatha of Sicily**.** [77]

Breasts are secondary sex organs and sexually sensitive. Cultures that associate the breast primarily with sex (as opposed to with breastfeeding) tend to designate bare breasts as indecent, and they are not commonly displayed in public, in contrast to male chests. Other cultures view female toplessness as acceptable.[77] Opinion on the exposure of breasts is often dependent on the place and context, and in some Western societies exposure of breasts on a beach may be acceptable, although in town centers, for example, it is usually indecent. In some areas, the prohibition against the display of a woman's breasts generally only restricts exposure of the nipples.

Women in some geographical areas and cultures are approaching the issue of breast exposure as one of sexual equality, since men (and pre-pubescent children) may bare their chests, but women and teenage girls are forbidden.[77] In the U.S., the top free equality movement seeks to redress this imbalance. This movement won a decision in 1992 in the New York State Court of Appeals (People v. Santorelli) where the court ruled that the state's indecent exposure laws do not ban women from being bare breasted.[77] A similar movement succeeded in most parts of Canada in the 1990s. In Australia and much of Europe it is acceptable for women and teenage girls to sunbathe topless on some public beaches and swimming pools, but these are generally the only public areas where exposing breasts is acceptable.

When breastfeeding a baby in public, legal and social rules regarding indecent exposure and dress codes, as well as inhibitions of the woman, tend to be relaxed. Numerous laws around the world have made public breastfeeding legal and disallow companies from prohibiting it in the workplace.

Part 6 Mammography: The Examination

Patient Perceptions

Patients arrive for their breast imaging appointment with varying ideas of what mammography entails. Women who are established patients with a breast-imaging center may arrive with some prior experience as to what to expect. Some may even request a specific mammographer, who they feel particularly comfortable with. However, new patients to the imaging center and those having their first mammogram may be apprehensive and may have fears that encompass aspects of physical, emotional and intellectual concerns.

As the overall U.S. population ages, mammographers can expect to be serving older women. According to current health statistics, about 2.9% of older adults experience serious psychological distress.[3] Adults aged 55 to 64 are more likely than those aged 65 and over to exhibit signs and symptoms of serious psychological distress. Psychological distress may be expressed by abnormal fears and has been documented to be generally highest among adults who are non-Hispanic black, Hispanic, poor or near poor, covered by Medicaid, and not currently married.[3]

Physical fears usually relate to inaccurate accounts of pain resulting from breast compression. Psychological fears may come from popular press announcements that warn women about receiving too much radiation to their breasts during mammography. These announcements caution women that the radiation from a mammogram may actually initiate breast cancer.

Emotional fears involve such things as the fear of finding cancer or the embarrassment of having the breasts exposed and handled by another person during the examination. Intellectual fears involve the actual examination and may include such concerns as the various positions used during the examination. Also, an intellectual fear involves the imaging report. For example the woman may ask, “What is the next step if they find a mass?”. In research studies and surveys, a patient’s experience during the breast imaging examination is directly linked to the service (i.e., care, empathy, etc.) given by the mammographer and ancillary staff.

Patient Preparation

The patient’s preparation for breast imaging begins with the first telephone contact. Every breast imaging facility has established mammography protocols for

scheduling screening mammograms. During the scheduling telephone contact, the patient should be given simple preparation instructions. Some breast imaging centers recommend that the patient wear either a blouse or shirt with either a skirt or a pair of slacks so that they will not feel "totally exposed" during the examination. Patients should also be advised to avoid using powders, deodorants and perfumes the day of the examination. Also during the initial scheduling contact, it is necessary to ask about the need for any special help or items such as, a wheelchair, cane, walker, etc., or if the patient has other requirements. A very important question is whether the patient has breast implants. This is a routine question of anyone scheduling a mammogram because additional time must be allotted to obtain extra breast views. Any patient being imaged because of a declared "mass" may also require additional scheduled time to allow for special views such as magnification.

If the patient is "new" to the breast imaging center, it is important to obtain prior breast images, if possible. Copies of "priors" may be obtained as "hard copy" or may be electronically transmitted. According to the ACR comparison with available prior breast imaging studies is an important part of mammography.[46] Digitized images of previously obtained screen-film mammogram may be used for comparison purposes if the interpreting physician deems that acceptable. If previous breast imaging studies are needed for assessing mammography findings an attempt should be made to obtain them. Published practice standards indicate that facilities must be able to provide breast images to new mammography facilities or referring physicians with the original diagnostic quality.[46] Further, upon written request of the patient, original films and copies of the report must be transferred to a healthcare provider or to the patient directly. For digital examinations, the facility must be able to provide the medical institution, physician, healthcare provider, patient, or patient's representative with hardcopy films of final interpretation quality or, when it is acceptable to the recipient, with original or lossless electronic compressed images.[46] Digital mammograms provided on computer discs may not be optimal for diagnostic purposes when viewed on non-high resolution monitors.[46] Laser hardcopy printers for digital mammography images should support the Integrating the Healthcare Enterprise (IHE) Mammography Image Profile and the IHE Consistent Presentation of Images Profile.[46] In addition, the ACR states that it is helpful to have the Secure Node or Secure Application actor: IHE Audit Trail and Node Authentication.[46]

Greeting the Patient

It is often said that, “The first impression is a lasting impression.” Patients arriving for their appointment should be immediately acknowledged and welcomed. When a patient arrives at the reception area and is ignored or not greeted, this sends a non-verbal message to the person that they are “not important”.
Everyone should be greeted immediately by a cheerful hello and a welcoming attitude that reflects patient-centered customer service.

Mammographers are frequently responsible for acting as a patient advocate, taking the patient history and explaining post-examination care. Mammographers should give explicit instructions and answer questions promptly and completely. They should also participate in the coordination of patient care and efficiently work with the patient, ancillary staff, and healthcare personnel to deliver quality care.

A new study suggests that health literacy directly affect a person’s health status and healthcare use. Researchers suggest that improving health literacy may be the most effective and direct approach to improving health status and reducing hospital and emergency room use among elderly patients.[78] One method suggested accomplishing by design a more reader-friendly media with simple illustrations and culturally sensitive examples and enhancing patient’s understanding of health information by communicating in simpler language and instructions.[78]

In an increasingly multilingual, multicultural society, providing safe, high-quality healthcare requires overcoming certain barriers (i.e., language and cultural barriers and low health literacy).[78] Current regulations and guidelines are in place to address the language needs of patients (i.e., the patient’s rights to be fully informed about his or her care).[78] Today, the need to communicate effectively is recognized as an element of quality of patient care. Thus, in the healthcare setting, effective communication is a method of interacting that takes into account individual differences in language, culture, and health literacy. The Joint Commission cites communication problems as the most frequent root cause of serious adverse events reported to the Joint Commission’s Sentinel Event Database.[78] Additional information will be provided about the Joint Commission later in this section of the course.

According to Schyve on behalf of the Joint Commission, as a providers of medical care and imaging services focuses attention on improving the safety and quality of patient care, a set of principles begin to emerge that include the following statements.

- Providing safe and high-quality patient care is dependent upon effective communication between healthcare professionals, patients, and patient's families.
- Effective communication requires the recognition and amelioration of 3 key barriers: language differences, cultural differences, and low health literacy.
- There is a growing body of evidence-based practices that addresses these 3 key barriers (and of evidence that certain practices are ineffective or unsafe).
- For the implementation of these practices to be effective, reliable, and sustainable, the practices should be incorporated into the redesign of the relevant work processes in the healthcare delivery site (e.g., medical offices, clinics and hospitals), not just bolted into the current system.
- Changes in the site's systems and processes are likely to produce unintended consequences: a prospective identification of these potential consequences should be undertaken before implementation, and vigilance for these consequences should follow implementation.[78]

Health Literacy & Minority Disparities

Patients who have low literacy levels or who cannot read may be limited in their access to healthcare information. Patients with low literacy typically have difficulty understanding the name of prescription medications, their indications for use, and dosing instructions.[79] Northwestern University researchers found that patients with low literacy missed doses or wrongly timed doses of prescribed medications.[79] After adjusting for age and income, less literate patients were nearly 3 times less able than their more literate counterparts to name any of their antihypertensive medications.[79]

A study conducted by the University of Michigan Comprehensive Cancer Center in Ann Arbor found that minority women were less likely to be aware of their odds for survival after 5 years post mastectomy or breast conserving surgery.[80] Out of 1,132 breast cancer survivors, only 51% responded correctly to the survival questions, but the numbers varied significantly for minorities: 57% of Caucasians answered correctly, 37% of Latinos did, and only 34% of African Americans knew their survival odds.[80] This points to the fact that minorities may not have received accurate information of the risks and benefits of the options available to them at the time of the initial diagnosis of breast cancer.[80] Therefore, they were unable to do make a high-quality decision about the best treatment for their breast cancer.[80]

A study by the Michigan State University of 341 women including African American, Arab American, and Hispanic women, found that more than two-thirds of those subjects believe that healthcare organizations sometimes mislead or even purposely deceive patients.[81] Yet another study of 150 lesbian/bisexual and 400 heterosexual women measured their attitudes about screening mammography.[81] The study revealed negative beliefs about mammography, lower levels of provider trust, and less perceived risk of breast cancer among lesbian/bisexual women.[81]

Patient-Centered Mindfulness

Executives from the Studer Group asked their employees what they would want for a family member if they were hospitalized. The responses received consistently mention respect, communication, appreciation, and confidence in the skill of the caregivers.[82] The Studer Group uses the acronym "AIDET" (acknowledge, introduce, duration, explanation, and thank you) to help employees remember the 5 fundamentals of service. The AIDET in action means:

- **Acknowledge:** The mammographer and ancillary staff should acknowledge the patient by name. Make eye contact, Ask: "Is there anything I can do for you?"
- **Introduce:** The mammographer should introduce herself and tell the patient about her professional certification and experience.
- **Duration :** The mammographer should give an accurate time expectation for tests and in the case of mammography, when the patient might expect the results of the imaging examination.
- **Explanation:** The mammographer should explain step by step what will happen during the imaging examination, answer questions, and leave a telephone number in case the patient should have questions after they leave the facility.
- **Thank:** The mammographer should thank the patient for choosing "the hospital/imaging facility", and thank the patient for their cooperation. Also, if the family is in attendance, the mammographer should thank the family for assistance and being there to support the patient.[82]

According to the Studer Group, organizations who have hardwired the 5 Fundamentals of Service through consistent use by all employees find this practice correlates closely with high ratings on patient satisfaction surveys.[82]

Patient-centered care focuses on the needs of the patient and patient satisfaction and not on the treatment itself. This type of care management philosophy does not especially focus on the disease or condition but rather, on the patient and the patient's psychological, spiritual, and emotional needs.[83] One of the major objectives of patient-centered care is to empower patients and their families by providing them with information and education about the patient's health condition and encouraging them to be active participants in the decision-making process.[83]

The patient-centered care management process involves effective practices to include possessing good communication skills, providing the patient with clear and useful information and including the patient in the decision-making process.[83] Regulations and practice guidelines provide the framework for ensuring patient safety in imaging examinations. "Not answering the patient's questions or rushing treatment diminishes trust.[83] Good communication not only helps to minimize patient complaints, image retakes, and potential litigation but also is an important part of the healing process.[83]

According to the Institute for Healthcare Improvement most individuals desire care that considers their cultural traditions, personal preferences, values, family situations, and their lifestyles.[84] Patient-centered care ensures that transitions between providers, departments, and healthcare settings are respectful, coordinated, and efficient. When care is patient-centered, unneeded and unwanted services can be reduced. The Robert Wood Johnson Foundation is working to identify best practices and promising system changes that enable patient-centered care in 3 areas:

- Involving patient and families in the design of care;
- Reliably meeting patient's needs and preferences; and,
- Informed shared decision-making.[84]

Patient-centered care puts responsibility for important aspects of self-care and monitoring in the patient's hands, along with the tools and support they need to carry out that responsibility.[97] Clear communication between healthcare providers, ancillary staff, patients, and their families is essential for patient-centered care to be successful.

The Medical Record and Documentation

Once the patient welcome has been accomplished, the next most important task is registration and the medical history. The medical record, health record, or medical

chart is a systematic documentation of a patient's medical history and care.[85] Medical records are uniquely personal documents and there are many ethical and legal issues surrounding them, such as who has access to them and the proper storage and disposal of the records.[85] The medical record allows communication among healthcare providers, and contains critical evidence of the type and quality of care provided to the patient.[86] The 3 most recognized reasons for the medical record are:

- To document the diagnosis, treatment and progress of the patient;
- For business purposes; and,
- For use as a legal document.

According to several sources, electronic personal health records are likely to replace handwritten notes.[87] During Barack Obama's presidency, he vowed to make electronic medical records a priority.[89] One of the major roadblocks is finding the right technology to handle the transition to paperless medical records. Among the many challenges are the storing, accessing, and updating of records so that the patient's privacy is maintained yet the information is accessible across a wide network of medical providers.

The medical record serves as the basis of the quality and timeliness of the care provided to the patient. The record also serves as a legal document, and is often cited in malpractice litigation. In the first two-thirds of the 20th century, the most common reasons for malpractice were negligent acts of commission (i.e., physicians did something wrong).[89] Medical care providers were often charged with the failure to order radiologic studies in a timely manner. The litigation involved what is referred to as "omission of care." Defensive medicine, in which medical care providers ordered tests and procedures that were not indicated medically, but which, if absent, might render the physician vulnerable in malpractice litigation, became the norm.[90-91] The annual cost to the nation for defensive medicine has been estimated to range from $25 billion to $126 billion.[89-91]

Radiologists specializing in breast imaging are subject to litigation for "failure to diagnose cancer" and "failure to follow up," or "failure to obtain additional diagnostic studies" and to clarify or confirm the tentative diagnosis, when appropriate.[89] It is anticipated that as the sophistication of radiologic and nonradiologic procedures and tests continues to expand, the errors caused by physicians' omission in ordering or using this technology will increase.[104] Radiologists can expect an increase in litigation not only

for failing to recommend imaging tests, but also for failing to recommend other diagnostic procedures as well.[90] One may also speculate that in the not-so-distant future, radiologists will likely be subject to litigation for errors in omitting the use of technology that is not yet the standard of care, such as computer-assisted detection (CAD) and teleradiology, when obtaining expert consultations.[90]

According to legal experts Full-field digital mammography (FFDM) has already created issues for which no easily prescribed rules exist to avoid legal exposure.[91] They point to the ability of FFDM to better identify microcalcifications. This introduces a dilemma for the interpreting physician as to whether stable calcifications seen previously on screen film images have truly increased or are seen with improved FFDM clarity.[91] Conscientious review of the patient's medical history, clinical findings in conjunction with the mammography request, and prior breast images is a first step in providing quality patient care, and hopefully, in reducing future litigation.[91]

The mammographer plays a critical role in reviewing the patient's medical history and clinical symptoms prior to mammography. The mammographer documents information in the patient's medical record and is the liaison between the patient and the radiologist. Radiologists have a duty to acquaint themselves with the pertinent clinical information concerning patients whose mammograms they will be interpreting.

In many breast imaging centers, it is the mammographer who questions the patient and completes a preprinted questionnaire form.[90] If this is the procedure used, the mammographer should have the patient or her advocate review, sign, and date the questionnaire form. Risk management experts recommend that a written form on which the patient must provide (i.e., write) pertinent clinical information, is the most reliable source document.[89,90] Although it is acceptable practice for the mammographer to complete the information on the questionnaire form, there may be less likelihood of misunderstanding if the patient herself fills out the form.[90] The mammographer can then go over the completed form and obtain additional verbal confirmation from the patient. If the patient fills out the form, the mammographer should document that the completed questionnaire was reviewed, and that the patient confirmed the answers. Such notations in the record should be signed and dated.

A system that ensures that every patient undergoing mammography provides a complete medical history, possible symptoms, and clinical signs is critical to obtaining high quality breast images. Risk management experts also suggest that the questionnaire form ask a question about the patient's understanding of why she is

having the mammography procedure.[90] By asking these pertinent questions, the mammographer is able to determine if the mammography request properly matches the patient's clinical signs and symptoms, or if the procedure is merely a screening examination. To reduce the possibility of a missed cancer, every effort must be made to distinguish diagnostic patients from screening patients. Risk management experts suggest that this should be done repeatedly, beginning at the appointment setting, when the patient arrives at the reception desk, and finally by the mammographer before the examination begins.

In the *Practice Standards for Medical Imaging and Radiation Therapy: Mammography Practice Standards*, the American Society of Radiologic Technologists (ASRT) provides guidance about the mammographer's involvement in documentation.[92] Standard One Assessment states that the practitioner (i.e., the mammographer) should collect pertinent data about the patient and the procedure. The ASRT Standard 2, Analysis/ Determination, and Standard 8, Documentation, further address the mammographer's role and responsibility.[92] The mammographer is generally the first to review the reason for the mammography examination and to determine if the request is appropriate based on the presenting facts. In this capacity, the mammographer has a professional responsibility to confer with the radiologist about the appropriateness of the imaging request, and to decide if additional projections are required. There are 3 recognized ways that a mammography examination can be designated diagnostic rather than screening. These include:

- History from the referring physician;
- History from the patient; or,
- Conversion of a screening mammogram into a diagnostic mammogram by the radiologist because of the presence of abnormal findings.[90]

Patient Communication & Examination Preparation

Communication between the mammography staff and the patient is vital for ensuring the successful outcome of any imaging examination. Patients present for imaging procedures with various levels of apprehension and knowledge, or the lack thereof. Patients have the right to know the details of their imaging examination and have the legal right to be informed about the potential risks and benefits. Most facilities providing diagnostic imaging services will require the patient or their legal guardian to

complete an informed consent form. If adequately informed patients may be more at ease and cooperative.

Breast imaging examinations require that the patient disrobe. The mammographer should give clear disrobing directions and provide for privacy. Retake examinations often result when the patient has not properly disrobed or has failed to remove all items. During the preliminary examination period, the mammographer can explain the examination and tell the patient how they may help during the examination.

Successful communication also includes critical listening skills. As the patient provides details about their condition, the mammographer should be attentive and evaluate the information and determine how it may impact the selection of technical and related imaging factors. Questions that the mammographer may ask about include:

- The patient's reason for the current examination;
- Past history of breast disease, if present, what was the diagnosis and treatment;
- History of previous breast surgery;
- Facts about breast scars or skin lesions (i.e., also noted on history breast diagram);
- Family history of breast or ovarian cancer; and
- History of hormone replacement therapy, duration and type.

Communication during breast imaging examinations may be difficult if the older woman has impairments related to hearing, speech, vision, and cognitive status. The following briefly describes these impairments and provides suggestions for effective communication.

Hearing Loss

Presbyucisis is age-related hearing loss caused by the cumulative effects of aging on hearing.[93]

> ***Presbycusis*** *is defined as a progressive bilateral symmetrical age-related sensorineural hearing loss most often at higher frequencies.*[93]

The prevalence of hearing impairment increases with age but hearing loss can affect women of any age. According to national health statistics, overall nearly one-third of adults aged 55 and over (31.6%) have some level of hearing impairment with women over aged 85 having the greatest percentage of hearing loss at 62.1%. Not all hearing

loss or deafness is a result of aging. According to the March of Dimes, hearing impairment is one of the most common birth defects, occurring in about 12,000 babies (3 in 1,000) each year in the U.S.[94] About 90% of babies with congenital hearing impairment are born to parents with normal hearing.[94]

The mammographer will encounter women of all ages who have various levels of hearing loss; however, the effects of age can exacerbate this loss. Increasing age affects a person's ability to hear high frequencies more than low frequencies and is more pronounced in men than women. Over time, the detection of high-pitched sounds becomes more difficult and speech perception may be altered. Factors responsible for presbycusis include atherosclerosis, diabetes, noise trauma, hypertension, and ototoxic drugs such as aspirin that may hasten the process of presbycusis.[93]

Sound waves vary in amplitude and in frequency. Amplitude is the sound wave's peak pressure variation. Frequency is the number of cycles per second. Loss of the ability to detect some frequencies, or to detect low-amplitude sounds that a person normally detects, is considered a hearing impairment. A hearing impairment exists when an individual is not sensitive to the sounds normally heard. The severity of a hearing impairment is categorized according to *how much* louder a sound must be made over the usual levels before the listener can detect it.[95] There is another aspect to hearing that involves the quality of a sound rather than amplitude. This is usually measured by tests of speech discrimination, which measures that the sound is detected but also understood.

Conductive hearing loss results when sound is not normally conducted through the outer or middle ear or both.[95] Women with conductive hearing loss will generally have adequate speech discrimination, when sounds are amplified. Sensorineural hearing loss is due to insensitivity of the inner ear, the cochlea, or to impairment of function in the auditory nervous system.[95] Sensorineural hearing loss may be mild, moderate, severe, or profound to the point of total deafness.[85]

When hearing loss involves the upper frequency ranges of speech, sounds are distorted and parts of words are lost.[95] Upper frequency words involving the consonant letters such as s,z,sh,f, ph, and ch are often not discernable by women with sensorineural hearing loss. For example, when the mammographer asks the women to *move forward*, the woman hears *orward* or when asked to lift the *shoulder*, the woman hears *older*.

When talking with hearing impaired women, the mammographer should attempt to eliminate all extraneous noise and should use recognized communication methods.[95] Whenever possible, the mammographer should face the woman directly at a distance of 3 to 6 feet, and on the same level.[95] Positioning directions will be more easily understood if the mammographer is not eating or chewing and keeps her hands away from her face while communicating. There are many additional suggestions for communicating with hearing impaired persons and these include:

- Do not raise the volume of your speech because sound distortions will occur;
- Lower the pitch of your voice;
- Speak slowly and pause to assess the listener's understanding;
- If it's difficult for the listener to understand, find another way of saying the same thing, rather than repeating the original words;
- Move to a quieter location, if extraneous background noise exists;
- Be sure to have the listener's attention before you start talking;
- Speak in a normal fashion without shouting or showing impatience;
- See that room lighting is not shining into the listener's eyes;
- If the hearing impaired person wears a hearing aid, make sure that is has batteries installed, the batteries work, the aid is turned "on" and the aid is clean and free from ear wax;
- Sometimes a hearing impaired person has a "good" or "better" side. Ask them if they do;
- Avoid abrupt changes of subject in the conversation;
- Pronounce words clearly. If the hearing-impaired woman has difficulty with letters and numbers say: "M as in Mary", "B as in Boy", and say each number separately, like "five six", instead of "fifty-six", etc.
- Keep a note pad handy, and write your words out and show them to the hearing-impaired person if necessary.[95,96]

Mammographers may be able to recognize hearing-impaired women by some of the characteristics listed in Figure 15.

Characteristics of the Hearing-impaired

- Leaning forward or tipping head to one side to hear what has been said;
- Frequently asks for clarification of what has been said;
- Questions instructions more than usual;
- Inappropriately responds to statements; and,
- Speaks in an excessively loud voice.

Fig. 15. Characteristics of Hearing-impaired Women.

Visual Impairment

National statistics of adults aged 55 years and over indicate that the prevalence of vision impairment more than doubled between the age groups 55 to 64, and 85 and over.[3] Women are more likely than men to have vision impairment, except among adults aged 85 and over.[3] Rates of vision impairment were highest among poor and near poor adults and those with Medicaid coverage, with the differences by poverty and insurance status most pronounced among adults aged 55 to 64.[3]

Many mammographers may be unsure of how to communicate naturally with a blind or visually impaired women, or, whether to offer assistance.[97] When greeting women, who are visually impaired, the mammographer should identify herself before starting to speak. The mammographer should explain any noises related to the breast positioning device or the x-ray exposure and tell the patient if they are to be left alone in the room for any period of time.[98] It can sometimes be helpful to give the visually impaired woman information about the physical environment and let her feel the breast-imaging platform. A blind or visually impaired person may or may not use a white cane or stick.[98] The visually impaired may carry a cane only to advise others about visual difficulties. In the case of long canes, individuals use them to check the ground for obstacles ahead.[98] A cane or stick with a red band means the person also has a hearing impairment.[98] The mammographer should not move a blind person's cane without permission.[98]

In assisting a blind or visually impaired women, first and foremost, respect the person's ability to do things for herself.[98] The mammographer should not provide assistance without first asking. If help is accepted, the mammographer should offer the woman her arm and should never grab the woman's arm or attempt to direct her by pushing or pulling. The mammographer should walk one step ahead and tell the woman

about any changes in directions or terrain, obstacles, steps, etc. When assisting a blind or visually impaired women to their seat, place their hand on the back of the seat.

Loss of Speech

Asphasia is a total or partial loss of the power to use or understand words.[99] It is often the result of a stroke or other brain damage. Expressive aphasics are able to understand what is said; receptive aphasics are not. Some women may have a bit of both kinds of speech impediment.[99] When expressive aphasics try to speak it is like having a word "on the tip of your tongue" and not being able to call it out. Some suggestions for the mammographer in communicating with women who have aphasia includes:

- Be patient and allow time to communicate;
- Ask the woman how best to communicate, for example, what techniques or devices can be used to aid communication;
- Allow the aphasic to try to complete her thoughts, to struggle with words and avoid being too quick to guess what the person is trying to express;
- Encourage the person to write the word she is trying to express and read it out loud;
- Use gestures or pointing to objects, if helpful in supplying words or adding meaning;
- Use a pictogram to allow the aphasic to point to requests; and,
- Use touch to aid in concentration, to establish another avenue of communication, and to offer reassurance and encouragement.[99]

Dementia

The term dementia describes a group of symptoms that usually are caused by changes in the normal activity of very sensitive brain cells.[100] The 2 most common forms of dementia are multi-infarct dementia (vascular dementia) and Alzheimer's disease. Telltale signs of multi-infarct dementia include vision or speech problems, and/or numbness or weakness on one side of the body. In Alzheimer's diseases, nerve cell changes in certain parts of the brain result in the death of a large number of cells.[100] Symptoms of Alzheimer's disease begin slowly and become steadily worse. Both forms of dementia can exist together and both types are irreversible.[100]

Approximately 5.3 million Americans have Alzheimer's disease (AD) and many others suffer from various forms of dementia.[100] Alzheimer's disease affects the structure and function of the brain, causing progressive loss of memory, language, and

ability to care for oneself. Between 2000 and 2006, deaths due to heart disease, stroke, and prostate cancer declined by 12%, 19%, and 14%, respectively, whereas, deaths attributable to Alzheimer's disease increased by 47%.[100] Mammographers will most certainly provide imaging services to women with dementia and communication may be difficult to establish and maintain. Suggestions for communicating with women with Alzheimer's disease or related disorders include:

- Always approach the woman from the front, or within her line of vision, no surprise appearances;
- Speak in a normal tone of voice and greet the women as you would anyone else;
- Face the woman as you talk to her;
- Minimize hand movements that approach the woman;
- Be respectful of the person's personal space and observant of her reaction as you move closer to position the breast;
- Use a low-pitched, slow speaking voice;
- Ask only one question at a time; and,
- Nod and smile only if what the woman said is understood.

Those with dementia and related cognitive impairments may also suffer from paranoia. Paranoia is a common mental disorder characterized by self-consciousness, hypersensitivity and mistrust.[101] Women with paranoia are suspicious and believe they will be exploited and that others are plotting against them.[101] Often, they will be detached and reluctant to confide in others, leading to social isolation and often hostility toward others.

Mammographers may have advance notice that a woman has dementia, paranoia, or a cognitive impairment, but should always be alert to abnormal thinking patterns and be able to recognize them in order to deliver quality imaging services. Those with paranoid personality disorder tend to be suspicious and may misinterpret what the mammographer is saying.[101] Paranoid patients may frequently glance around the room and ask the mammographer such questions as "Why are you doing this to me?" and "Why are you torturing me by pressing my breast?" Because a paranoid patient's emotions can erupt in anger, hostility and even violence, the mammographer is encouraged to use simple, clear language and to refrain from arguing with the patient.[102] Information about the breast examination should be presented in simple phrases and during the procedure the mammographer should maintain simple verbal contact which

may help relieve the patients anxiety.[102] Also, when dealing with a paranoid patient the mammographer should face the patient and use direct eye contact when speaking and should not have conversations with co-workers out of the sight but within the hearing range of the patient.[102]

Screening and Diagnostic Projections & Positions

Patient communication and preparation is essentially the same for both screening and diagnostic mammography; however, diagnostic examinations require additional positions and projections. Screening mammography is indicated for asymptomatic women 40 years of age or older. Screening mammography consists of 2 projections of each breast; a craniocaudal (CC) and a mediolateral oblique (MLO). Diagnostic mammography provides additional information about patients who have signs and/or symptoms of breast disease, mammography findings of concern, or in situations deemed appropriate by the interpreting physician. A diagnostic mammogram is performed under the direct supervision of a physician qualified in breast imaging and may include additional breast imaging modalities and a variety of positions and imaging modalities and techniques (i.e., US, MRI, etc.).

Handling the Breast

Mammographers are generally female; however males are not excluded from this imaging specialty. If a male mammographer is on staff, some patients may request a female mammographer. The reasons for this request may be due to the patient's cultural or religious beliefs/traditions or personal preference and should be honored. The mammographer should explain to the patient that she will be resting her breasts on the imaging platform. Once the patient is in the appropriate position, the mammographer should firmly handle the breast during positioning. Cupping the breast with the thumb and fingers at the posterior wall allows the internal structures to be positioned, not just the overlying breast fat. Each mammographer should adapt and adjust their hold on the breast to best bring all of the internal breast tissue into the image. As in any imaging examination, the patient's body habitus must be considered during specific positioning. In breast imaging, the thin, small breast and the pendulous heavy breast each pose challenges to the mammographer.

All breast-imaging examinations have universal common elements such as image labeling, markers, and infection control. The ACR and others have provided

general guidelines that should be followed for such universal common elements. The ACR states that adequate documentation of pertinent patient and technical information is essential for high-quality patient care. All breast images should be labeled in accordance with the current ACR Mammography Quality Control Manual.[46] Both hardcopy and softcopy labeling must include specific information in a permanent, legible, and unambiguous manner, placed so as not to obscure anatomic structures. The minimum information that breast image should have includes:

- Facility name and location, including city, state, and zip code;
- Patient's first and last name;
- Unique identification number and/or date of birth;
- Examination date;
- Mammographer's initials (or identification number);
- Cassette (screen) number for nondigital and computed mammography images;
- Mammographic unit identification, if there is more than 1 unit in the facility; and
- View and laterality (placed on the image in a position near the axilla).[46]

Image markers may be used to identify areas of clinical concern, areas of prior intervention, skin abnormalities, etc. and to help correlate them with ultrasound findings. The visualization of surface markers may provide positioning guidance for routine views, spot compression, tangential, and other views. Such markers are visible on the image; however, a notation should be included in the report about the location or placement of marker(s) and the type of lesion(s) marked. Such information is essential when breast imaging reports and mammograms are released to other facilities.[46]

Explaining the Procedure

Successful communication includes critical listening skills. As the patient answers basic questions about their recent breast health the mammographer should be attentive and evaluate the information and determine how it may impact the selection of technical and related imaging factors. Specifically when taking the patient's medical history or confirming what the patient has written, the mammographer should use the information about risk factors, as well as the "red-flag" indicators of breast disease to initiate further health history questions. Such factors include a family history of breast and ovarian cancer, previous breast surgery or interventional procedures, previously diagnosed benign or malignant breast lesions, skin changes, or changes in the palpable

consistency of the breast. During the breast imaging examination, the mammographer should observe the breasts and record any significant clinical signs, such as lumps, skin tethering or dimpling, recent nipple inversion, eczema of the nipple, and nipple discharge. These signs may indicate an underlying condition that may not be demonstrated on the breast images. Also, it is important for this information to be conveyed to the radiologist. Mammographers should also be observant for signs of elder abuse. Information on this topic will be presented later in the course.

During this preliminary period, the mammographer should show the patient the machine that will be used and should explain the importance of breast compression. Some suggested phrases used during the explanation might include:

- Compression may be uncomfortable rather than painful;
- If the pressure becomes too uncomfortable, please tell me;
- The compression per view does not last long, only a few seconds;
- Compression is important to produce a quality image; and,
- The pressure will not harm your breasts.

The mammographer should assure the patient that the compression may be uncomfortable for a few seconds but it should never be painful. Further, the patient should be told to let the mammographer know if the procedure becomes painful so that it can be stopped. Cooperation and teamwork between the mammographer and the patient is needed to produce high quality diagnostic breast images. Also during the preliminary examination period, the mammographer should inform the patient about the number of views to be taken. For screening patients, they should be told that occasionally additional views may be needed to complete the examination but she should not be alarmed that something is wrong. Finally, all patients should be asked if they have any questions about the examination. Patients may ask such questions as:

- When will I know my imaging results;
- Will someone call me if something wrong is discovered;
- Who will look at my breast images;
- Will you send a report to my family doctor; and,
- What is the next step if a mass is found?

The answers to any and all patient questions should be given according to protocols established by the breast-imaging center. Once the breast images have been obtained

the mammographer should tell the patient that the images would be evaluated by the radiologist. Further, the patient should be told about how they would receive the imaging report. An advantage that FFDM has over screen-film imaging is that the mammographer can immediately determine if all of the required breast anatomy is visible and if the image quality is acceptable. Receiving imaging results in a timely manner has been shown to closely related to high level patient satisfaction.

The MQSA requirements are quite specific about communication of mammography results to healthcare providers (i.e., when the patient has a referring provider) and to the patient (either referred or self-referred).[46,103] The facility must send or give directly to all patients a written summary, in lay terms, of the results of the breast study no later than 30 days from the date of the examination. In cases where the assessment is a BI-RADS® category 4 or 5, the facility should make a reasonable attempt to communicate the results to the patient as soon as possible.[46,103] This should occur within 5 working days from the date of the interpretation. The actual or attempted communication should be documented. For self-referred patients, facilities must have a system to refer such patients to a healthcare provider when clinically indicated. Reports with an assessment of BI-RADS® category 0,3,4,or 5 should be communicated as soon as possible to the self-referred patient within 5 working days from the date of the interpretations.[46,103] All attempts to communicate such information should be documented. The effect of timely delivery of breast imaging results and other factors affecting patient satisfaction, quality care, and improvements in breast imaging will be discussed later in a section of this course titled “Improving Quality”.

Breast Imaging Nomenclature

The projections and positions used for breast imaging are those that are universally accepted to demonstrate particular anatomy. The following is a brief review of the standard nomenclature and positions used in mammography. Mammographers use the following universal labeling codes for positions used in breast imaging.

R right
L left
CC craniocaudal
MLO mediolateral oblique
ML 90˚ mediolateral
LM 90˚ lateromedial

M magnification
XCCL exaggerated craniocaudal
CV cleavage
AT axillary tail
TAN tangential
RL+ roll (laterally)
RM+ roll (medially)
FB caudiocranial (from below)
LMO lateromedial oblique
SIO superolateral to inferomedial oblique
ID implant displaced

Screening and Diagnostic Projections & Positions

The projections and positions used for breast imaging are those that are universally accepted to demonstrate particular anatomy. Special adaptations of these are often required due the patient's individual body shape, size, or needs and to accommodate requests by the interpreting physician.

Traditionally, mammography has been performed with the woman in a standing position. Mammography may be performed with the patient in a sitting position to accommodate certain groups of women, such as those with cognitive impairment, loss of physical strength, and those in wheelchairs. The prevalence of difficulty with functioning in physical and social activities generally increases with age, with the greatest increase occurring between the 2 oldest age groups.[3] According to national health statistics reports, 1 out of 4 adults aged 55 and over have difficulty walking 1/4th mile, ranging from 17.3% of those aged 55 to 64 and over half of those aged 85 and over.[3] About 1 out of 4 adults aged 55 and over had difficulty standing for 2 hours, with prevalence increasing nearly 3-fold between the age groups of 55 to 64 and 85 and over. Across the activities studied, women were more likely than men to have difficulty with physical and social activities, with the largest differences noted in those aged 65 and over. The mammographer should anticipate and try to accommodate declines in the patient's ability to walk great distances. For example, frail and unsteady patients may be accommodated by wheelchair transport between the waiting area and the examination room.[3] The mammographer can strategically position a bench or chair to provide frail, ambulatory patients a place to rest.

The aging process increases the chances that women will have arthritis or other muscle or bone issues that limit mobility. Osteoarthritis is a very common chronic condition affecting older women. By age 65, more than half of all women will have radiological evidence of osteoarthritis (OA). The disease affects the cartilage that covers the ends of the bones at the joints and causes bony overgrowths to occur, resulting in stiffness and pain. Surgical replacement of joints (i.e., knee, hip, and shoulder, etc.) improves mobility, quality of life, and longevity. In some cases, if the joints are severely affected, the mammographer may have to assist the patient in altering their arm movements during disrobing and breast positioning.

The National Osteoporosis Foundation (NOF) estimates that more than 44 million Americans have osteoporosis, or 55% of the people 50 years of age or older.[105] In the U.S, today, 10 million people already have the disease, and almost 34 million more have low bone mass (osteopenia), placing them at increased risk for osteoporosis.[105,106] Osteoporosis is an under-diagnosed and silent condition that has financial, physical, and psychosocial consequences. The World Health Organization (WHO) Study Group defined osteoporosis (1994) as a systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, resulting in an increase in bone fragility and susceptibility to fracture.[107]

Often, the physical changes that result from fractures make it hard to find clothing that fits properly. People with vertebral fractures lose height, and develop a curved back and protruding abdomen. Modification of clothing to accommodate the physical changes can make getting dressed and undressed easier for the person with osteoporosis. Additionally, the mammographer may need to provide help to the patient in dressing prior to and after the imaging examination.

Preventing falls is important for anyone with osteoporosis. Each year about one-third of all persons over age 65 experience a fall, which may result in a bone fracture, most often of the hip or wrist. The following are just a few indoor safety tips that can be used to fall-proof the inside and outside environment

- Keep floors free of clutter. Remove all loose wires and cords that are in high-trafficked areas.
- Use non-skid mats or rugs on the floor, and clean up spills immediately.
- Install grab bars on the bathroom walls.

To support the option of sitting versus standing during screening mammography, a research project was conducted in the United Kingdom (UK).[108] In the UK study 543 eligible women were divided between the 2 methods. For first-time patients (i.e., no prior mammography), there were no significant differences in the scores between the seated and standing groups as related to ease of positioning.[108] There was a significant difference for first-time patients in that more "inadequate" images were associated with the seated group than the standing group.[108] In the UK study, women who were seated during mammography reported that the procedure was easier in terms of positioning and more comfortable than women who stood.[108] This finding however applied only to women who had experience a previous mammogram and not for first-time patients.[108]

Screening Projections and Positions

The craniocaudal (CC) projection combined with the mediolateral oblique (MLO) position is the routine for all screening examinations of the breast. In the CC projection the majority of breast tissue is demonstrated with the exclusion of the extreme medial portion of the axillary tail. The CC projection should demonstrate the nipple in profile and pointing towards the center of the long axis of the image. The majority of the medial and lateral tissue with the exclusion of the axillary tail should be demonstrated. This is accomplished when the mammographer uses the "2-hand" technique. This maneuver gently pulls the breast tissue away from the chest, which maximizes the amount of breast tissue visualized on the image. Also, skin folds can be eliminated when the mammographer assists the patient to externally rotate the humeral head and to relax her arm by her side. In older women, the skin covering the breast may be thin and fragile and the mammographer should avoid excessive pressure that might cause a skin tear or bruise. If a patient is slightly unsteady, it helps when the mammographer assists her to externally rotate the humeral head, bend the elbow, and gently place the hand underneath the image receptor to gain a measure of support. This arm movement may be challenging if the woman has osteoarthritis in the elbow and shoulder joints.
If the nipple is not demonstrated in profile in the CC projection, the mammographer should follow the facility protocol in regard to acquiring additional images. In most cases, this requires an additional cone-down projection with the nipple in profile.

When viewing the CC projection, the depth of breast tissue demonstrated should be equal to or no more than 1 centimeter (CM) less than, the distance from the nipple to pectoral muscle on the MLO. As with all breast positioning, the mammographer should

control the patient's body and the breast until compression is complete, expose immediately, and release compression as soon as the exposure has ended. The mammographer should be ever vigilant to observe frail older women to evaluate their mobility and stability during the examination.

Some common CC positioning problems include the nipple pointing downwards and skin folds at the lateral aspect of the breast. In the CC projection, if the nipple is pointing downwards, the probable causes are the image receptor is too high, the skin on the underside of the breast is caught at the edge of the image receptor, or there is excess loose skin on the superior surface of the breast. Folds appearing at the lateral aspect of the breast image are usually caused by a pad of fat or skin above the upper quadrant or in some cases the breast may have been twisted.

Mediolateral Oblique Position (MLO)

When the patient has been properly positioned, the MLO is the single image that best demonstrates the entire breast. The MLO demonstrates the pectoral muscle down to the level of the nipple (i.e., ½ to 2/3 of the way down the breast). The nipple should be seen in profile, breast tissue away from the chest wall and not drooping, and inferiorly a small portion of inframammary tissue should be visible.

For the MLO, the mammographer angles the image receptor 30˚ to 60˚ from horizontal, placing the image receptor parallel to the pectoral muscle. A steeper angle of 55˚ to 60˚ may be required for patients who are tall and thin. Heavy or obese patients may require an angle of 45˚ to 60˚. The x-ray beam is directed from the superomedial aspect to the inferolateral aspect of the breast and the image receptor must be parallel to the pectoral muscle, or less breast tissue will be visualized on the image. The mammographer should use the "up-and-out" maneuver to hold the patient's breast up and away from the chest wall while applying compression. This positioning maneuver prevents inferior breast tissue from drooping down and being inadequately compressed because of the overlapping of breast tissue. If the patient's breast is large, the mammographer may ask the women to firmly hold the opposite breast out of the way. The image receptor should be placed firmly against the lateral border of the breast with the pectoral muscle on the image receptor and the latissimus dorsi muscle just behind it.

Improper breast positioning may result in the nipple being rotated toward the breast support platform, the nipple rotated toward the x-ray tube, or the inframammary angle not being visualized on the image. If the nipple is rotated towards the breast

support platform, the woman's skin may be caught on the support platform at the lateral aspect. If the nipple is rotated towards the x-ray tube, the patient's hips and/or feet may not be properly rotated or aligned. Inadequate or improper rotation of the patient's hips and/or feet may also result in the inframammary angle not being visualized on the image.

When positioning for the MLO and before applying compression, the mammographer should check that the pectoral muscle is across the image receptor by confirming that the compression plate will be adjacent to the thorax, from immediately beneath the clavicle to the inframammary angle. Also, the mammographer should confirm that the nipple is in profile, the inframammary angle is clearly visible, and that there are no skin folds. A properly positioned MLO image should demonstrate the inframammary angle, nipple in profile, nipple lifted to the level of the lower border of the pectoral muscle, and the pectoral muscle across the image at an appropriate angle for the individual patient.

Additional projections may be required if an abnormality is seen or to localize lesions for additional diagnostic examinations. Such projections include modified craniocaudal projections (i.e., cleavage, roll [medially and laterally], exaggerated craniocaudal, axillary tail, and caudocranial). Modified lateral positions include the 90˚ lateral view, which is the most commonly used additional view, whether mediolateral or lateromedial, lateromedial oblique, superiolateral to inferomedial oblique, and tangential. Special positioning may be requested for microcalcifications and small masses and includes spot compression with and without magnification. Visualizing the breast tissue of a mastectomy patient, biopsy specimens, and certain patient categories such as women with breast implants, males, adolescents, and special needs patients often requires special positioning adaptations and projections.

Patients with Special Needs

Patients with special needs are those requiring unique adaptations to the routine screening and/or diagnostic breast positions and projections. Special attention may be required due to the individual patient's body habitus (i.e., thin breasts, heavy breasts, and kyphotic stature), or handicapped status (i.e., wheelchair or stretcher bound), and includes patients who have undergone surgery such as a lumpectomy, mastectomy, or breast implants. Male and adolescent patients may also require special adaptations to breast imaging routines.

Very Small and Very Large Breasts

Some suggest that the secret to imaging small breasts, such as may be encountered with male and adolescent patients, is the proper selection of the angle and height of the imaging receptor. Likewise, positioning patients with large breast can be difficult for the mammographer. The mammographer may find that it is difficult to lift and control a large breast with just one hand or if the mammographer hands are small. In this case the "two-handed" method may be used to position the breast accurately.

Obesity

Researchers indicate that obese women are less likely to undergo breast cancer screening than their normal-weight counterparts.[109] Obesity has a dramatic impact on mobility and quality of life. In 1993, only 14.1% of adults in the U.S. were obese; but, by 2008, the number of obese adults had risen to 26.7%, nearly a 90% increase.[3] Researchers have established a strong link between physical inactivity and mobility among obese women and this causes them to be unable to stand unassisted for any length of time. It is believed that obesity is a strong deterrent in adherence to breast screening guidelines.[109]

Obesity has been indicated as a risk factor in the development of and death from postmenopausal breast cancer.[109] In a meta-analysis of 17 studies comprising over 276,000 participants, to examine whether overweight and obese women are less likely to have had a recent mammogram than normal-weight women, the researchers found that severely obese women were 20% less likely to have had a recent mammogram than normal-weight women.[109] However, being overweight or obese was not a factor for lack of mammography adherence in African-American women. Researchers did find the following reasons why obese women may not undergo screening mammography:

- A delay in taking up medical care due to poor self-esteem and body image;
- Embarrassment;
- A perceived lack of respect from healthcare providers; and,
- Unwanted weight loss advice.[109]

Chest Wall Variations

Variations in the patient's chest wall skeleton may pose difficulty in positioning the breast. For example a patient with a prominent sternum, may require that the

mammographer rotate the body so that the thorax is more medial yet still preserving the nipple in profile. If the patient's chest wall variation is prominent lower ribs, this poses a more difficult challenge than a prominent sternum. There are several tips that the mammographer may use to overcome this challenge in the CC projection. First, a slight 10˚ elevation of the lateral side of the breast support has been shown to help in positioning patients with prominent lower ribs. Also, the mammographer can ask the woman to lean forward as much as possible, from the waist, without getting her head in the path of the x-ray beam. For the MLO, the mammographer should try flattening the image receptor to between 35˚ to 40˚, which will allow it to be placed between the inframammary angle and the prominent area of the ribs.

The postmastectomy patient is a special needs customer who may require imaging to demonstrate the retromammary area and the post-mastectomy axilla. These areas of anatomic concern are often imaged to detect recurrence of cancer. To accomplish this, the mammographer must adjust the x-ray tube to an angle that matches the patient's pectoral muscle. With the patient in a mediolateral position with the elbow bent and the arm extended across the image receptor at a 90˚ angle, the corner of the image receptor is positioned behind the patient's pectoral muscle with the latissimus dorsi muscle behind the image receptor. With the patient in this position, the mammographer gently rotates the patient forward onto the image receptor and activates compression. In post-mastectomy patients, the retromammary view demonstrates bone detail in the ribs, humeral head area, retromammary space and subcutaneous tissue. To accomplish this view, the mammographer rotates the x-ray tube to a 90˚ true lateral position.

Limited Mobility

Limited mobility patients require special positioning adaptations to obtain diagnostic quality breast images. Imaging those who are unable to stand or sit upright for mammography examinations may be accomplished by rotating the x-ray tube head. For patients confined to a wheelchair, mammography may be performed with the patient seated. In certain situations, it may be necessary for the mammographer to provide support with pillows so that the patient can lean slightly forward in the wheelchair. When conducting breast-imaging examinations on patients with limited mobility, the mammographer must lock any moving parts on a stretcher or wheelchair to avoid accidental mishaps.

Breast Implants

According to the American College of Radiology (ACR) in the *ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography*, asymptomatic women with breast implants may undergo screening mammography.[46] At the discretion of the facility, asymptomatic women with breast implants may receive a diagnostic mammogram."[46] The ACR highly recommends that facilities have procedures in place to inquire whether patients have breast implants prior to the actual mammography examination.[46] If the facility does not provide implant-imaging services, the patient should be provided with information about other facilities that provide such services. The ACR and other national breast imaging groups recommend that evaluation of the augmented breast should include, when possible, standard CC and MLO views as well as implant displacement views in both projections. Also, lateral images of the breast may be helpful in cases where the implant cannot be displaced.

Elder Abuse and Imaging Considerations

Mammographers and imaging personnel should be alert to signs of elder abuse. The mammographer is in a unique position to observe the patient's upper chest, neck, and face for unusual signs that may indicate physical abuse. According to the best available estimates between 1 and 2 million Americans age 65 or older have been injured, exploited, or otherwise mistreated by someone on whom they depended for care or protection.

Every year, an estimated 2.1 million older Americans are victims of physical, psychological, and other forms of abuse and neglect.[110] Approximately 1 out of every 14 cases of elder abuse is reported to authorities and typically the victims are 50 years of age and older and primarily women.[110] The perpetrators can be spouses, partners, adult children and grandchildren, other family members, caregivers or other individuals with ongoing, lasting relationships with the victim.[110] Studies show that up to 10% of the elderly population have been abused and the percentage of those abused increases as the age of the victim rises.[43] About 48% of substantiated cases of abuse involve older adults who are not physically able to care for themselves.[110]

Individuals suffering from dementia often experience poor judgment and impaired communication skills and may be more vulnerable to abuse and neglect.[111] Neglect is the most common form of elder maltreatment in domestic settings. Data collected from 2000 to 2004 showed that there was an increase of 19.7% in reports of elder and

vulnerable adult abuse and neglect cases.[112] Of these, there was a 15.6% increase in substantiated cases.[112] In 20 of the states reporting elder abuse, more than 2 in 5 victims (42.8%) were age 80 or older and most of the alleged perpetrators in 2003 were adult children.[112] Elder abuse is an umbrella term referring to any knowing, intentional, or negligent act by a caregiver or any other person that causes harm or a serious risk to a vulnerable adult.[112] The following is a brief list of generally accepted terminology related to elder abuse.[112]

- Physical abuse is inflicting, or threatening to inflict, physical pain or injury on a vulnerable elder, or depriving them of a basic need.
- Sexual abuse is the infliction of non-consensual sexual contact of any kind.
- Emotional or psychological abuse is the infliction of mental or emotional anguish or distress on an elder person through verbal or nonverbal acts.
- Financial or material exploitation is the illegal taking, misuse, or concealment of funds, property, or assets of a vulnerable elder.
- Neglect is the refusal or failure by those responsible to provide food, shelter, health care, or protection for a vulnerable elder.
- Self-neglect is characterized as the behavior of an elderly person that threatens his/her own health or safety.
- Abandonment is the desertion of a vulnerable elder by anyone who has assumed the responsibility for care or custody of that person.[110-112]

Federal laws exist on child abuse and domestic violence which fund services and shelters for victims but there is no comparable federal law on elder abuse.[113] The Federal Older Americans Act does provide definitions of elder abuse and authorizes the use of federal funds for the National Center on Elder Abuse (NCEA) and for certain elder abuse awareness and coordination activities in states and local communities, but it does not fund adult protective services or shelters for abused older persons.[113]

Legislatures in all 50 states have passed some form of elder abuse prevention laws. Laws and definitions of terms vary considerably from one state to another, but all states have set up reporting systems and generally, adult protective services agencies receive and investigate reports of suspected elder abuse. In all states but 8, certain types of professionals are designated as mandatory reporters of domestic elder abuse.[114] They are required by law to report suspected cases of abuse, neglect, and exploitation. In gathering information for this course most sources stated that the

greatest percentage of all domestic elder abuse reports originates from healthcare providers while service providers (i.e., staff of agencies providing services to the elderly) ranked second in reporting. Additionally, family members and relatives of victims were frequently cited as the source of reported cases of domestic elder abuse. Friends and neighbors, law enforcement personnel, clergy, banks/business institutions, and elder abuse victims also are cited as reporters of domestic elder abuse.[114]

With current medical advances and the adoption of healthier lifestyles, people are living longer. Older Americans now comprise the fastest growing segment of the U.S. population.[115] As a result of the sheer number of older Americans, the number of elder abuse cases will increase, and the impact of elder abuse as a public health issue will grow.[115] Victims of violence have twice as many physicians visits compared with the general U.S. population, allowing opportunities for discovery and intervention.[115] Emergency physicians, radiologists, and radiographers are in a unique position to affect diagnosis and management of this vulnerable population.[115] The American Medical Association (AMA) recommends that doctors routinely ask geriatric patients about abuse, even if signs are absent. Substantial evidence exists for the following risk factors of elder abuse:

- Shared living situation with abuser, likely due to an increased opportunity for contact;
- Dementia;
- Social isolation; and,
- Pathologic characteristics of perpetrators such as mental illness and alcohol misuse.[115]

Theories of the origin of mistreatment of elders can be divided into 4 major categories, as follows: physical and mental impairment of the patient, caregiver stress, transgenerational violence, and psychopathology in the abuser. Recent studies have failed to show direct correlation between patient frailty and abuse, even though it had been assumed that frailty itself was a risk factor of abuse.[116] Physical and mental impairment has been shown to play an indirect role in elder abuse, decreasing seniors' ability to defend themselves or to escape, thus increasing vulnerability.[116]

Caregiver stress is considered more as a trigger for abuse rather than as a cause.[116] Transgenerational violence is considered to be family violence that is a learned behavior that is passed down from generation to generation. The child who was once abused by the parent continues the cycle of violence when both are older. Family

members who have psychopathology tendencies many times become the caregiver because they may be home because of lack of employment or poor social skills. Drug and alcohol addiction, personality disorders, mental retardation, dementia, and other conditions can increase the likelihood of elder abuse.[116]

Healthcare providers should keep these “red flags” in mind in all interactions with elder patients. Some general recommendations when evaluating a patient for possible elder abuse include keeping questions direct and simple and asking in a nonjudgmental or nonthreatening manner. It is also helpful to interview the patient and caregiver together and separately to detect disparities offering clues to the diagnosis or abuse.[116] Accurate and objective documentation of the interview is essential since all findings may be entered as evidence in criminal trials or in guardianship hearings.

During the physical examination, the patient should thoroughly disrobe and should be evaluated for unexpected injuries. The size, shape, and location of all injuries should be documented, including photographing the injuries if possible.[116] Clinical findings and observations that make elder abuse a strong possibility, include the following:

- Several injuries in various stages of evolution;
- Unexplained injuries;
- Delay in seeking treatment;
- Injuries inconsistent with history;
- Contradictory explanations given by the patient and caregiver;
- Laboratory findings indicating under dosage or over dosage of medications;
- Bruises, welts, lacerations, rope marks, burns;
- Venereal disease or genital infections;
- Dehydration, malnutrition, decubitus ulcers, poor hygiene; and, signs of withdrawal, depression, agitation, or infantile behavior.[116]

For additional information on the subject of elder abuse contact the National Center on Elder Abuse at 1-202-898-2586 or visit www.ncea.gov.

Part 7 Quality Improvement in Medical Imaging

"Better health care is a result of effective process design and implementation as well as the use of up-to-date technology by highly qualified physicians."[117] "To improve the safety and quality care that radiologists provide, and to allow radiologists, mammographers and ancillary staff to remain competitive in an increasingly complex environment, it is essential that all imaging facilities establish and maintain managed, comprehensive, and effective performance improvement programs."[118] Many medical imaging facilities have been monitoring personnel performance (i.e., retake analysis and breast imaging interpretations compared to biopsy findings), and equipment operating parameters dating back to the 1930s.[119] The 1968 Radiation Control for Health and Safety Act was the initial impetus toward use of quality management in diagnostic imaging services. The U.S. Department of Health, Education, and Welfare (now called the Department of Health and Human Services) was responsible for the development and administration of standards that would reduce human exposure to radiation from electronic products. The Bureau of Radiological Health (BRH)(now called the National Center for Devices and Radiological Health) was given the responsibility of implementing the standards. The BHR began regulatory action in 1974 beginning with control of the manufacture and installation of medical and dental equipment. The enforcement regulations were published in the document Title 21 of the Code of Federal Regulations Part 1020 (21 CFR 1020). To assist diagnostic imaging providers understand the full scope of the regulations, the BRH published (1978) one of the first quality improvement references titled *"Recommendations for Quality Assurance Programs in Diagnostic Radiology Facilities".*

Today, medical imaging providers can no longer wait to initiate quality improvement programs because governmental policies and accreditation agencies are mandating such programs. Examples of governmental influence include the 1981 Consumer-Patient Radiation Health and Safety Act, which address factors closely related to excessive and unnecessary radiation exposure to the public. In 1996, the Health Insurance Portability and Accountability Act (HIPAA) was enacted to simplify healthcare standards, encourage electronic transactions and require safeguards to protect patient security and confidentiality. In the final HIPAA rules, all medical records and patient information, whether electronic or paper, or oral were covered.

In 2000, the Consumer Assurance of Radiologic Excellence (CARE) Act was introduced in Congress to mandate education and training for all persons performing imaging procedures; however, as of the printing of this course, the CARE Act has yet to be enacted. The original version of the CARE Act has undergone many changes and is now referred to as the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy bill.

The Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) has always been involved in mandating certain policies to protect the health and safety of Americans. In the mid-1980s, because of the prevalence of the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and most recently drug-resistant tuberculosis, OSHA amended existing federal regulations concerning infection control in the workplace and mandated a policy on blood-borne pathogens. Furthermore, in medical imaging, OSHA, EPA, and the FDA regulate a wide range of matters from disposal of supplies, chemicals, and radioactive materials.

The Safe Medical Devices Act (SMDA) of 1990 was implemented to require the FDA and device manufacturers to increase reporting of certain problems with medical devices. The MQSA, enacted in 1992, established standards of training and competency for breast imaging personnel as well as a very rigid quality control in all aspects of mammography imaging systems.

The aforementioned governmental actions are just a few of those that imaging facilities must comply with. Additionally, in the 1970s, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), now The Joint Commission, began requiring hospitals and other healthcare providers to perform and document specific quality management procedures in order to obtain and maintain accreditation. Among many other requirements that will be discussed later, the Joint Commission requires accredited institutions to have a process in place for correcting customer complaints (i.e., a process called service recovery) that involves improvements in customer service. Although the hospital and ambulatory care facility accreditation is voluntary, it is considered the basis for delivery of medical care, which is the standard by which reimbursements from Medicare, Medicaid, and others are managed, as well as for insurance liability purposes.

Healthcare Reform

"What does the healthcare law mean for R.T.s?", is a question posed by an April 2010 news article released by the ASRT.[120] An inescapable fact of the new health care reform law is that, more than ever before in the history of reimbursed medical care, reimbursement rates will be linked to provisions aimed at improving quality. "Policymakers appear to have recognized that there are goals that are so entangled they cannot be addressed by more incrementalism."[121] The central goals of the healthcare reform act are to cover millions of uninsured Americans, control spiraling healthcare costs, and improve the quality of patient care.[121]

Beginning in 2011, the healthcare reform law increases the utilization rate assumption from 50% to 75% on imaging equipment that costs one million dollars or more and is installed in non-hospital settings.[120] Currently the national average utilization rate is 54% and increasing the utilization rate assumption to 75% will have the effect of reducing Medicare reimbursement, mostly for MRI and CT examinations.[120]

Expanding healthcare coverage to as many as 32 million more Americans is expected to increase the number of patients requiring imaging examinations.[120] As demand for imaging services increases there may be a proportionate need for additional radiologists, radiographers and ancillary personnel.[120] To this end, the ASRT and other national radiation safety and quality improvement organizations continue to lobby for the passage of the Consistency, Accuracy, Reliability, and Excellence in Medical Imaging and Radiation Therapy bill (H.R. 3652).[120] The bill's primary goal is to ensure that individuals providing medical imaging services meet educational and certification standards.[120]

Historical Overview

The quality improvement movement had its origins in the early 1900's, when Frederick Winslow Taylor, an industrial engineer, proposed that the planning function and implementation stage be separate and various people be assigned specific tasks within a production process. For his work, Taylor has often been called the "father of scientific management". He believed that by dividing up a production process, the complexity of the task was minimized, thus increasing efficiency and reducing errors. Taylor's scientific management philosophy was used throughout American industry and in the delivery of healthcare until the early 1980s.

Beginning in the early 1980s, quality improvement principles that had been used in industrial manufacturing companies began a slow integration into improvement efforts in the delivery of healthcare. The roots of quality improvement are often tied to W. Edwards Deming and Joseph Juran, who used the quality improvement model to regenerate the economy of Japan after World War II. There are many quality improvement systems and management strategies that healthcare facilities and imaging centers can use to improve the process of delivering patient care and safety outcomes. Deming's 14 points for business includes the following modified concepts as translated to the delivery of medical care.

- To stay in business, the healthcare industry must focus on providing jobs through research, innovation and continuous improvement of products and services.
- Facility leaders must adopt and support the philosophy of continuous improvement through the empowerment of personnel.
- Personnel must be taught to assess their own work and progress during every phase of the service delivery process.
- Healthcare providers must work with manufacturers and suppliers to build trust and collaboration.
- Managers must maintain an environment in which all personnel are empowered to make continuous progress in product and service improvement while they reduce waste and inefficiency.
- Training programs must be provided for new personnel and continuing education programs for the continuous improvement of personnel.
- Facility leaders must provide coaching and mentoring to personnel in order to increase productivity.
- Facility leaders must develop ways to create cross-department and multi-level teams among personnel.
- Personnel must be empowered to be responsible for their department's progress toward quality improvement.
- Facilities must remove the systemic causes of personnel failure through close collaborative efforts.
- All facility personnel must be provided with incentives to support the culture and goals of quality improvement initiatives.[122]

Modern quality control was referred to by Dr. Deming as the "Shewhart cycle".[123] This cycle has also been called the Deming cycle, Deming wheel, or plan-do-study-act (PDSA).[123] The most common term used for Deming's quality concept is PDSA.[123] The concept of PDSA is based on the scientific method, which can be stated as "hypothesis", "experiment", and "evaluation" or plan, do, and check.[123] A fundamental principle of the scientific method and PDSA is iteration, once a hypothesis is confirmed (or negated), executing the cycle again will extend the knowledge further.[123] Repeating the PDSA cycle can bring the individual closer to the goal, usually a perfect operation and output.[123] Sometimes, one of the most difficult roadblocks in quality improvement is to determine where changes and/or improvements need to be made. Determining what areas require improvement often starts with what customers want. The following briefly explains each step of the PDSA concept.

- **PLAN:** Establish the objectives and processes necessary to deliver results in accordance with the expected output. By making the expected output the focus, it differs from other techniques in that the completeness and accuracy of the specification is also part of the improvement.
- **DO:** Implement the new processes. Often on a small scale, if possible.
- **Study**: Measure the new processes and compare and study the results against the expected results to ascertain any differences.
- **ACT**: Analyze the differences to determine their cause because each will be part of either one or more of the PDSA steps.

When a pass through these 4 steps does not result in the needed improvement, refine the scope to which PDSA is applied until there is a plan that involves improvement.

According to Deming's concept, PDSA should be repeatedly implemented in spirals of increasing knowledge with each cycle closer to refinement than the previous.[123] Rate of change, that is, rate of improvement, is a key competitive factor in today's world.[123] PDSA allows for major "jumps" in performance. The power of Deming's concept lies in its apparent simplicity.[123] Over time, other quality improvement systems were created based on the original work of Deming. An example is Six Sigma, which originated as a set of practices designed to improve manufacturing processes and eliminate defects.[124] The Six Sigma philosophy starts with a very simple and obvious idea: defects cost money.

The term Six Sigma comes from a field of statistics known as process capability studies.[124] The Six Sigma philosophy uses the application of science and data to drive organizational and system change. In Six Sigma, a defect is defined as any process output that does not meet customer specifications, or that could lead to creating an output that does not meet customer specifications.[124] Processes that operate with "Six Sigma quality" over the short term are assumed to produce long-term defect levels below 3.4 defects per million opportunities. Six Sigma's implicit goal is to improve all processes to that level of quality or better.[124] Many experts state that organizations undertaking a Six Sigma program need to change in 3 domains:

- The way people in the organization think: focusing on the individual through stated expectations and conclusions of the members of the organization;
- The norms: often referred to as corporate culture, every organization has standards, models, and patterns which guide behavior; and,
- Systems and processes: this is the core work of the Six Sigma practitioner, but cannot be sustained without the success of the prior 2 organizational changes.

Those who have been involved in using Six Sigma quality improvement caution that the average time to achieve benefits from a Six Sigma program can be more than 3 years, a timeframe that many healthcare providers simply cannot endure. Many say that Six Sigma is a proven methodology to quantify the impact of healthcare decisions and align them with healthcare outcomes.[125] Mark Chassin in his 1998 article "Is Health Care Ready for Six Sigma Quality?" proposes that in healthcare clinical processes, the underlying causes of quality defects have been linked to the overuse, underuse and misuse of clinical interventions.[125] In each situation, inappropriate clinical decisions and interventions lead to less than desirable results and errors occur when appropriate actions are taken but are inadequately implemented due to poorly performing support systems.[125]

Features that set Six Sigma's methods apart from previous quality improvement initiatives include:

- A clear focus on achieving measurable and quantifiable financial returns from any Six Sigma project;
- An increased emphasis on strong and passionate management leadership and support;

- A special infrastructure of “Champions”, “Master Black Belts”, “Yellow Belts”, etc. to lead and implement the Six Sigma approach; and,
- A clear commitment to making decisions on the basis of verifiable data, rather than assumptions and guesswork.

Factors involved with successful Six Sigma projects in healthcare organizations include:

- Establishing full physician and staff support and effective communication;
- Identifying problem areas from patient surveys, complaints and equipment failures;
- Brainstorming and selecting the most beneficial, cost effective, achievable project(s);
- Establishing teams with various backgrounds in order to promote creativity;
- Training physicians and staff in quality principles;
- Establishing clear goals and requirements;
- Delegating responsibilities and stressing accountability;
- Identifying the proper quality of Six Sigma techniques and tools to use;
- Setting objectives and metrics in order to track, measure and analyze data; and,
- Rewarding successes and achievements.[126]

Another quality improvement method referred to as ***Lean*** is often used concurrently with Six Sigma efforts. The major difference is that Lean concepts emphasizes removing waste from organizations and processes while focusing on and delivering more value to customers; whereas, Six Sigma focuses on variation reduction in processes, products and services. Hospitals and imaging centers use Lean and Six Sigma business management strategies in attempts to reduce costs and improve productivity. There is little data about how many hospitals and imaging centers either have used, are using, or are planning on using the Lean and Six Sigma management systems to improve. In 2007, the American Society for Quality (ASQ), conducted a study to investigate the implementation of Lean and Six Sigma in U.S. hospitals. Of the 77 hospitals responding to the survey, 53% report some level (i.e., minor, moderate or full) use of Lean methods and 42% reported some level of Six Sigma use.[127] The reasons that neither method has been used in hospitals include the need for resources (59%) of hospitals, lack of information (41%), and leadership buy-in (30%) with 11% responding that they were not familiar with either method.[127] In the survey, hospitals reported that the greatest challenges in implementing Lean or Six Sigma include

sustaining improvements, competition from other initiatives, leadership commitment and availability of resources.[127] According to ASQ survey data, hospitals reported a median investment of $25,000 for their 2007 Lean initiatives and a median investment of $96,485 for their 2007 Six Sigma initiatives.[127] In the 2007 ASQ study the locations most likely to have Lean and/or Six Sigma were in the broad areas of clinical deployment, ancillary/support services and non-clinical support. The adoption of quality improvement effort by areas included:

- **Clinical deployment**
  -Lean: 61% in surgery and 60% in emergency
  -Six Sigma: 72% in emergency and 66% in surgery
- **Ancillary/support services deployment**
  -Lean: 43% Admissions/discharge and 43% radiology/imaging
  -Six Sigma: 56% Admissions/discharge and 53% radiology/imaging
- **Non-clinical support deployment**
  -Lean: 36% Purchasing/supply, 24% information systems and 24% administration
  -Six Sigma: 53% Purchasing/supply, 24% information systems and 22% maintenance.[127]

Lean and Six Sigma quality improvement methods provides “tools” which assist healthcare providers in defining, measuring, analyzing, improving and controlling process performance. In a broad sense, each of the tools in the quality improvement “toolbox” support the acronym DMAIC (i.e., define, measure analyze, improve, and control). To review, the Six Sigma methodologies provides a foundation to help staff eliminate defects and reduce variation and Lean methodologies allow staff to examine the mechanics of a process to eliminate non-value-added waste or actions. Six Sigma trained healthcare teams define, measure and analyze the “as-is” process. Once the “as-is” process is known, Lean tools like 5S, layout analysis, process and work balancing, setup reduction, pull replenishment and inventory management controls may be used to create the basic ways and means of improvement.

The National Committee for Quality Assurance (NCQA), a private, not-for-profit organization recommends programs and services that reflect a straightforward formula for improvement which encompasses the actions of measure, analyze, improve, and repeat.[128] NCQA develops quality standards and performance measures for a broad

range of healthcare providers. NCQA's contribution to the healthcare system is regularly measured in the form of statistics that track the quality of care delivered by the nation's health plans.[128] Over the past 5 years, the NCQA's numbers have improved and quality care improvements translate into lives saved, illnesses avoided and costs reduced.[128] Additional information about NCQA quality improvement programs and services may be obtained on the organization's website www.ncqa.org.

In reference to the 2007 ASQ study, of the hospitals reporting, 87% of the medical imaging departments using Lean methods and 89% using Six Sigma rated the success of the programs as "somewhat" or "highly" successful. An example of Six Sigma in radiology can be illustration by changes made in the imaging department at Newton-Wellesley Hospital in Boston.[128] Under the direction of a Six Sigma consultant, the imaging staff began formal training of Green Belts and eventually, some Black Belts. The initial training spanned a 5–6 month time period.[128] Some of the changes made through the Six Sigma initiative included functional work layout changes that helped increase the efficiency of the actual workflow.[128]

At Newton-Wellesley Hospital prior to implementation of Six Sigma processes, there was not enough staff to provide imaging services to patients in a timely manner. Patient satisfaction and quality of care suffered because "…during the course of each day, there could be between 15-20 patients waiting for x-ray examinations."[128] So after initial training the Six Sigma team began to study the concern by defining what the problem was and studying the processes involved.

One of the old processes involved the way patients flowed from the registration desk, to disrobing, and being met by the mammographer. Often, when the mammographer picked up an imaging order, there would be discrepancies or other conflicting issues. The mammographer's time was often spent on resolving such concerns. One simple change was to have the mammographer pick up a correct order and to have the patient disrobed and ready for the imaging examination. This meant a change in the registration process. Because of changes made to the process, the time spent by the mammographer in performing non-imaging related duties decreased.[129] Another layout improvement involved relocating the lead technologist who had previously been located away from the day to day operation of the department. By relocating the lead technologist to an area where all department processes could be viewed, it allowed her to direct the workflow. This simple act was viewed by staff as a proactive move rather than a reactive one.[128] The Newton-Wellesley Hospital imaging

department wait time was reduced to nearly half by implementing various Six Sigma process improvement initiatives.[129] The increased efficiency also allowed the imaging department to save more than $700,000.[129]

A critical aspect of Six Sigma application in medical imaging centers, is the emphasis on the selection, prioritizing, and scoping of potential opportunities for improvement.[127] Not every imaging issue is a suitable candidate for a Six Sigma project. The scoping process helps to ensure that projects are aligned with organizational objectives and presents a clear opportunity for improvement.[127] Pexton, a quality improvement consultant, suggests that in selecting and scoping projects, healthcare organizations ask the following questions:

- Is the project aligned with strategic priorities;
- What will be considered in or out of scope (i.e., impatient versus outpatient);
- Will the project team have access to valid data;
- What are the potential benefits (qualitative and quantitative) for the organization;
- How long will it take to complete the project;
- Is the sponsor passionate about this issue;
- Are there opportunities for translation or "spread" of project results;
- Is there a significant gap between the current state and desired performance (including meeting regulatory specifications);
- Is there a sense of urgency to address the problem; and,
- Will the organization commit appropriate resources toward the project? [130]

Implementation of Quality Improvement in Scheduling

The medical imaging industry can learn a great deal from automotive manufacturing history. Many tools used in automotive engineering can cross over and be applied to solving problems in the medical imaging industry. Using these tools requires that medical imaging staff identify specific problems that are seen as important and can be measured. In most hospitals an important common problem in the surgery department involves first case-on-time starts. Medical imaging centers may be able to use the information from this example to improve processes related to utilization of highly specialized imaging suites, equipment and staff.

In utilization of specialized medical suites, equipment, and staff, the importance of starting the first case of the day on time impacts important aspects related to profitability. For example, the performance of first case-on-time start for surgeries

influences operating room utilization (i.e., empty rooms equal lower profit), staff schedules (i.e., overtime pay), and staff morale and patient satisfaction.

Issues related to first case-on-time performance can easily be related to scheduling medical imaging procedures such as image guided breast biopsies and interventional breast procedures. In most imaging centers today the ideal situation is where the number of examinations is growing at a significant rate. Poor performance in first case-on-time starts can significantly reduce an imaging center's bottom line revenue stream, interfere with patient satisfaction and lead to overall discontent among staff. During business growth periods, utilization of specialized imaging equipment, examination rooms and specialty staff are at a premium and any deficiencies equate to losses.

The following is an example in which an Ohio based medical center identified that the first case-on-time performance was a poorly performing process. One of the first steps in the quality improvement process at the Ohio medical center was to employ a quality improvement team to help them use the "tools" of the manufacturing process to improve the first case-on-time surgery process.[131] The outside team recommended a 5-week study of the Ohio center's pre-operative surgery area. An unbiased person was involved in making the observation.[131] Each morning during the study period, the representative observed all activities related to preparing the patient for surgery. All of the information listed in Figure 16 was recorded by the observer for every first start surgery case.[131]

Pre-operative room number
Operation room number
Scheduled surgery start time
Time the patient was taken into surgery
Surgeon's name and clinic
Pre-operative nurses' name
Patient arrival time
Time when the pre-operative paperwork was completed
Time of the pre-operative surgeon visit
Time of anesthesia delivered to the patient
Time the procedure was performed

Fig. 16. Information gathered by an unbiased observer in the pre-operative surgery area.

A case was labeled as a “late start” if the patient was taken into surgery more than 5 minutes after the scheduled time to start.[131] If a case that was designated as a “late start”, an investigation was conducted to determine the reasons for the late start. Both primary and secondary reasons were noted for each late start along with how late the surgery actually started.

In the Ohio study, 34.7% of the late cases were due to the surgeon not arriving early enough to perform the required tasks prior to the surgery start time.[131] In 17.3% of the late starts, the anesthesiologists were responsible and 8% were patient related.[131] The information indicated that certain surgeons consistently outperformed the majority. This fact proved that the basic system and processes used for scheduling surgery was working, at least in most cases. The next step in the quality improvement process is to analyze the data collected. In formulating a process record or report, a series of interviews were conducted with all the key people from every department that interfaced with the surgery scheduling process. Those interviewed were encouraged to provide suggestions for improving the scheduling the process and all suggestions were collected and considered in the improvement process.

After analyzing the data, the next step was to standardize the process. In the Ohio study, it was found that there were variations in staff compliance with completing the surgery schedule request. It became evident that the exchange information between clinics and the scheduling department needed to be standardized. It was found that most clinics faxed a copy of the request to the department responsible for scheduling surgery and that this method was error prone. In some cases, the faxed copy of the surgery request form was never received by the surgery department, was incomplete, or both and required additional staff time in follow-up and re-work. A solution to this inefficiency was to develop an electronic scheduling system.

The study data also showed that patients often would report to a scheduled surgery and not be properly prepared, late, and not at the right location for the surgery. During the standardization process, a tool, in the form of a patient information packet, was developed. This packet contained all of the vital information a patient would need to be properly prepared for the surgery, to report on time and to arrive at the correct location.

A major glitch in the first case-on-time process was that often the required pre-operative paper work was not started soon enough before the surgery start time. The key word here is “soon enough”. Soon enough is not a standardized, measurable

parameter. The quality improvement team worked with staff to determine a definite time to start the paperwork for the first case-on-time to become a reality of being on-time to start. To make this a reality, a pre-operative checklist tool was developed. The checklist contained all of the required pre-surgery tasks along with a designated time period (i.e., prior to surgery) for each task to be completed. All of the key resources needed to complete the pre-surgery paperwork and patient preparation were listed on the checklist.

The last frontier of the Ohio center's quest for quality improvement in the first case-on-time performance process was how to get the surgeons to report in sufficient time to complete pre-surgery tasks and be ready to perform the surgery on time. The most direct approach to this issue was revoking a surgeon's privilege of scheduling the first case block of time. It was suggested that this could be accomplished by developing a quality performance system for each surgeon that reflected a percentage score based on his/her on-time surgery starts. As with most quality improvement suggestions, the facility or organization leadership must be involved in order for the necessary remedial actions to be instituted.

Other general examples of successful implementation of Lean and Six Sigma methodologies in healthcare are illustrated in Figure 17.

Type of Facility	**Improvements & Results**
Regional medical center in the Southeast	Patient length of stay in the ER and delay in admissions was decreased resulting in $1 million in financial gains.
Healthcare delivery system in California	Increased throughput generated incremental revenue opportunities with $8.4 million in documented gains.
Health system in Midwest	Reduced the number of inpatient transfers resulting in $1.886 million in documented gains.

Fig. 17. Examples of successful implementation of Lean and Six Sigma methodologies in healthcare.

According to Pexton a number of factors have been identified as keys to the successful implementation of Six Sigma or other major change initiatives in healthcare.[130] A major key factor is that the people in leadership must have a clear vision for the initiative. They must invest in resources and make a long-term commitment and dedicate the best and brightest personnel to leading the charge. Leadership must measure and hold people accountable and be willing to change the systems and structures to support the effort. Change management tools should be used to identify cultural barriers, gain acceptance, and build momentum for projects selected. Members of the Six Sigma team must

establish a shared need, value, and vision and be ready to recognize, reward and celebrate successes.

A major roadblock in the quality improvement journey is a negative historical legacy, referred to by Kevin McManus as “culture wars”.[132] Past events related to an organizations culture or lack of it are often fact but may become distorted overtime. Over time, these events may even take on more myth than fact and thus becomes engrained in the heartbeat of the organization. In the healthcare industry such negative events may be related to massive employee layoffs, mergers of several hospitals/clinics, closure of satellite clinics or reduction in services offered.

Such events, if not managed properly, can leave indelible scars that may hinder attempts to implement performance improvement initiatives. According to McManus, culture scars exist to some degree in all organizations.[132] The effects of these scars are often demonstrated by employees who say that attempts to improve quality are just the “flavor of the month”, or by the attitude that “this too shall pass”.[132]

In today’s competitive business environment, healthcare administrators are pressed between the financial bottom line and the reality of the organization’s culture. Open and honest communication is one way to begin to heal old wounds. Experts suggest that employee interviews and surveys combined with efforts to improve relationships with employees can diagnose underlying culture scars that may inhibit adoption of quality incentives.

According to DJ Scheeres, a Six Sigma black belt advisor, certain levels of staff have certain responsibilities in the management of a quality improvement effort in any organization.[133] Scheeres provides the following examples of the team levels. The chief executive team (i.e., chief team) develops and supports the organization’s core mission, vision and values, setting goals and objectives to keep the organization on the quality improvement path. They acquire the funding, apply the resources and respond to the direction of governing boards and other oversight agencies. Mid-level chiefs are managers and directors who are usually most concerned with the operational and tactical deployment of healthcare products and services. They create, review, and react to periodic performance reports. The third major team involved in quality improvement efforts includes the point of service teams who are the staff who actually deliver the day to day services. Quality improvement experts emphasize that the members of the chief and mid-level teams are also responsible for maintaining the quality improvement momentum and suggest the following to re-energize a burdened work force.[134]

- Focus on people, not numbers.

  The moods, innovation, energy, thoughts and behaviors of the people who work there determine an organization's failure or success.
- Model good behavior.

  Leaders set the tone for how employees respond to almost every situation. They can inspire, or they extinguish.
- Practice positive leadership.

  Positive leadership means remaining purposeful in the face of adversity.
- Fill the void.

  As a leader, you must meet with your employees and continually communicate, communicate, communicate.
- Tell energy vampires, "It's time to get on the bus or off the bus."

  No matter how many pep talks you give or good behaviors you model, your efforts won't go far/unless everyone is on the same page.
- Forbid complaining.

  Let your employees know that they are not allowed to complain unless they offer solutions.
- Teach your people to be heroes, not victims.

  Both heroes and victims get knocked down. The distinction between the 2 groups lies in the fact that heroes get back up while victims simply give up.
- Focus on the small wins.

  Always place your attention on those little, ordinary, non-spectacular "wins" that add up to big successes.
- Make sure you have sharks in your key positions.

  Look at your team and figure out which people display the characteristics of driven, go-get-em, nice sharks. Sharks choose to swim ahead, believing that the best is yet to come. [134]

As industrial engineering techniques are gradually used in healthcare, proven methodologies for process improvement pose a tremendous challenge to application in the healthcare setting. The things that healthcare professionals must learn before the Lean processes can be fully integrated include such things as: how to identify and address the needs of clinical employees as Lean trainees; and, how to apply creative applications of traditional Lean tools in healthcare.

Most healthcare organizations have some degree of reluctance in accepting advice from industry outsiders. The demands of healthcare reform have pushed healthcare providers to be receptive to advice from non-clinical experts. According to current estimates, the amount of waste in the U.S. healthcare system costs as much as $700 billion annually.

An Example of Lean Tool Application in Healthcare

The Sisters of St. Francis Health Services Inc (SSFHS), have instituted a Six Sigma program at 13 hospitals and dozens of other facilities in Indiana and Illinois, including physician offices, medical laboratories, and a centralized pharmacy.[135] In the facilities the Lean tools used most by quality control consultants were 5S, waste (i.e., non-value added tasks, inconsistency, excessive stress and strain), pull systems, changeover reduction, kanban, and visual workplace. The Six Sigma tools used most frequently were simple graphical analytical methods such as run charts, scatter diagrams, Pareto charts, histograms, box-and-whisker plots, brainstorming, affinity diagrams and cause-and-effect diagrams. Before describing the quality improvement initiatives undertaken by SSFHS, the 5S tool will be briefly described.

5Ss Tool Implementation in Healthcare

5S is a "tool" or method used to reduce waste and optimize productivity through maintaining an orderly workplace. The 5S method uses visual cues to achieve more consistent operational results. Implementation of this method "cleans up" and organizes the workplace basically into its existing configuration, and it is typically the first Lean method which organizations implement.[136]

The 5S pillars, Sort, Set in Order, Shine, Standardize, and Sustain, provides a methodology for organizing, cleaning, developing, and sustaining a productive work environment. In the daily work of a medical imaging center, routines that maintain organization and orderliness are essential to a smooth and efficient flow of activities. The 5S method encourages workers to improve their working conditions and helps them to learn to reduce waste, minimize unplanned downtime, and improve in-process inventory.

A typical 5S implementation would result in significant reductions in the square footage of space needed for existing operations.[136] It also would result in the organization of tools and materials into labeled and color-coded storage locations, as

well as “kits” that contain just what is needed to perform a task. The 5S tools provide the foundation on which other Lean methods can be initiated.

Sort is the first S in the 5S toolbox and it focuses on eliminating unnecessary items from the workplace that are not needed for current production operations. An effective visual method to identify these unneeded items is called “red tagging”, which involves evaluating the necessity of each item in a work area and dealing with it appropriately. A red tag is placed on all items that are not important for operations and that are not in the proper location or quantity. Once the red tag items are identified, these items are then moved to a central holding area for subsequent disposal, recycling, or reassignment. Medical imaging facilities often find that sorting enables them to reclaim valuable floor space and eliminate such things as broken tools, scrap, and excess raw materials.

The Set in order tool focuses on creating efficient and effective storage methods to arrange items so that they are easy to use and to label them so that they are easy to find and put away. Set in order can only be implemented once the first pillar, Sort, has cleared the work area of unneeded items. Strategies for effective Set in Order implementation include painting floors (i.e., outlining work areas and locations), affixing labels and placards to designate proper storage locations and installing modular shelving and cabinets.

The Shine step is used once the clutter that has been clogging the work areas is eliminated and the remaining items are organized. The shine step is used to thoroughly clean the work area. Once the first steps have been implemented, the next pillar is to standardize the best practices in the work area. Standardization is used to maintain the first 3 steps and creates a consistent approach with which tasks and procedures are done. Some of the tools used in standardizing the 5S procedures are: job cycle charts, visual clues (e.g., signs, placards, and display scoreboards), scheduling 5-minutes 5S periods, and check lists. The second part of Standardize is prevention, which includes preventing accumulation of unneeded items, preventing procedures from breaking down, and preventing equipment and materials from getting dirty.

The sustain step is used to make a habit of properly maintaining correct procedures and it is often the most difficult S task to implement and achieve. Changing entrenched behaviors can be difficult, and often the tendency is to return to the status quo and the comfort zone of the “old way” of doing things. Proper discipline keeps the 5S circle in motion.[136]

Imaging centers, which have implemented the 5S method, recognize some of the following potential benefits:

- The removal of obstacles and the marking of main thoroughfares decreases the potential for accidents that could lead to spills and associated hazardous;
- Regular cleaning decreases the accumulation of dirt and other substances that can contaminate the work area; and,
- Organizing equipment, parts, and materials so that they are easy to find can significantly reduce unneeded consumption.[136]

To return to the example of the Sisters of St. Francis Healthcare Services (SSFHS), the quality improvement consultant typically began the improvement process by using the observation method, which leads to appropriate tool selection from the Lean and Six Sigma toolboxes.[135] It was recommended that staff should observe healthcare processes that they do not work in, or if observing their own work area, they should do so without their identification badge and should wear "street clothing". Process observation and documentation has proven effective in healthcare settings because it can serve as a real "eye-opener" for staff members.

In finding a practical way of teaching observation skills to the staff at SSFHS, the quality improvement consultants used folding scrub tops. A full-length exercise was developed that included constructing process flow charts and measuring times, followed by a group discussion. Two staff members were selected to fold the scrub tops and the remainder of the staff served as observers. The observers noted differences in the time needed to complete the required number of steps and also noted differences in the quality of the finished product. The observers were amazed at how such a simple task could require so many steps to complete and produce such variations in quality. This observation led naturally to a discussion about process waste identification and removal. A process waste discussion usually leads to an introduction to pull system.

> *A **pull system** is defined as a process that produces a product or service based on a real-time request for that product or service.*

Push systems often cause frequent bottlenecks in patient flow areas of the hospital like those requiring scheduling and in the emergency department wait time. For teaching the Lean method of changeover reduction, quality improvement consultants

often use examples related to emergency room bed turnover, operating room turnover, inpatient bed or room turnover, and specialized medical imaging room turnover. "Simple questions such as, "Do we need to wait until the patient is in the OR to start an intravenous (IV) line?" are used to get staff to ask similar questions about routine processes. Process observation is often used to answer this and similar type questions. Introduction of changeover reduction and pull systems often lead to kanban discussions.

> ***Kanban*** *is a signal that notifies upstream processes to send additional patient or material flow.*

Relocating supplies and resources often makes changeover reduction possible, and an effective kanban system ensures that those resources are available where and when needed. Kanban is almost a necessity in healthcare because of the abundance of storage locations. At the SSFHS facilities a color-coding system is used to identify supplies of a specific type. The color coding system consists of a 3-column chart with the color at the left, the meaning in the middle, and a visual symbol in the 3rd column. Figure 18 is an example of color coding system used at SSFHS facilities with the symbol in the 3rd column excluded.

Color	Meaning	Symbol
Red	IV supplies/needles	
Yellow	Urinary supplies	
Brown	GI/Ostomy supplies	
Purple	Respiratory supplies	
Orange	ADL supplies	
Green	Dressing supplies	
White	Miscellaneous	

Fig. 18. A summary of the SSFHS supply room color-coding system.

When teaching the supply color-coding to SSFHS staff, the trainer also teaches 5S which was previously mentioned. Some experts joke that before the 5S implementation, the 5S represented the conditions of scrounge, steal, stash, scramble, and search which often reflects conditions of many healthcare settings before proper application of 5S. At SSFHS, the 5S tool was successfully applied in the emergency room department, pharmacies, sterile processing units, equipment storage rooms, and diagnostic imaging departments and office areas.[136]

The Quest for Quality Improvement

In the *Essential Guide to Health Care Quality* published by the National Committee for Quality Assurance's (NCQA), the organization asks, "What is health care quality?".[128] In the NCQA's explanation they suggest that healthcare providers can be more effective in their quality improvement efforts if there is an understanding of a few important factors. A major factor is whether or not medical care providers make the most of the best available medical research. The NCQA states that despite the national investment in medical research and healthcare, the new findings about best practices often do not get translated into clinical practice. A second major concern is the need for improvements in the portability of patient medical records and coordination of patient care among multiple physicians.[128] Research proves that the quality of care is improved when communication and coordination exists among healthcare providers, patients, and patient families.[128] Research also proves that engaging patients in their care is an important factor in the delivery of quality healthcare.

Many factors contribute to healthcare quality. Organizations such as hospitals and medical imaging centers usually start with aligning quality and the organization's mission. From there, organizations usually identify areas that they wish to improve through various systems. Many healthcare organizations consider the outcomes of care very important and a parameter that must be constantly measured. Usually the parameter most frequently studied is the effects of care on patients.[137] Yet another aspect of care that is subject to constant scrutiny is the experiences of patients and their family members while receiving healthcare services.[94] Such experiences and opinions may be determined by asking patients about overall satisfaction with their care, the quality of communication with their care providers and their ability to get needed care quickly.[137]

There are many intricate pieces that must be identified, studied, and measured in any quality improvement program. As previously mentioned there are various aspects to measure and recognized standards of achievement. Such standards of achievement are derived from the best available evidence on what constitutes the "gold standard" of care for specific illnesses and health problems.[137] For example in diagnostic imaging, the American College of Radiology publishes various practice guidelines for the performance of imaging examinations. These practice guidelines cover a broad range of imaging procedures and may be accessed at the ACR website, www.acr.org. The ACR, FDA and other national organizations also publish accreditation program requirements

for various imaging modalities. To further aid physicians and healthcare providers, the ACR publishes ACR Appropriateness Criteria, which provides baseline guidelines in the proper selection of medical imaging examinations based on the patient's condition and/or disease.

While the aforementioned documents provides clinical application guidelines, medical imaging facilities may use benchmarking to determine their position in delivering medical services and care. Benchmarking is the process of comparing one's business processes and clinical performance metrics to industry bests and/or best practices from other industries.[138] Typical benchmarking methodology suggests:

1. Identify the problem areas;
2. Identify other industries that have similar processes;
3. Identify organizations that are leaders in these areas;
4. Survey companies for measures and practices;
5. Visit the "best practice" companies to identify leading edge practices; and,
6. Implement new and improved business practices. [130]

Benchmarking is a continuous measurement of a process, product, or service compared to those of the toughest competitor, to those considered industry leaders, or to similar activities in the organization in order to find and implement improvements. Internal benchmarking occurs when similar processes within the same organization are compared. Competitive benchmarking occurs when an organization's processes are compared with best practices within the industry. Functional benchmarking refers to benchmarking a similar function or process, such as scheduling, in another industry.

Lehigh Valley Health Network (LVHN) is a large academic integrated medical delivery network in Allentown and Bethlehem, PA. It employs 9,500 employees, and has the largest Level 1 trauma center in Pennsylvania with multiple critical care units, including pediatric, neonatal and intensive burn care units. The network was recognized by U.S. News & World Reports' "American's Best Hospitals" and has been identified as one of the best companies to work for by Fortune magazine. Since the late 1990s, LVHN has used operational and clinical benchmarking to identify areas of improvement. Cross-functional teams use total quality management and the Shewhart cycle to drive improvement efforts.

The Joint Commission

The Joint Commission is an independent, not-for-profit organization that accredits and certifies more than 17,000 healthcare organizations and programs in the U.S.[139] The mission of the Joint Commission is to continuously improve healthcare for the public, in collaboration with other stakeholders by evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.[139]

The Joint Commission has established monitoring and evaluating processes that are used by hospitals and ambulatory centers in meeting the requirements for accreditation. In essence, the process of applying for the Joint Commission accreditation is a guidepost for initiating a quality improvement plan. A few of the details of the monitoring and evaluating process will be briefly discussed.

One of the major first steps in a quality improvement initiative is for a person to be appointed as the leader. The leader may be the hospital president or the medical director; however, in larger complex healthcare facilities, a multi-disciplinary/multi-departmental team will conduct the tasks of monitoring and evaluating. The medical imaging supervisor or attending physician is usually responsible for monitoring and evaluating services rendered in the imaging department and a lead quality control technologist performs the required routine equipment testing. An accredited facility is required to identify the major types of services rendered and the patient population to be served. Additional information about the type of imaging modalities available, credentials of staff, and other accreditation must be documented and should also be published in the facility's literature and on the website, etc. Once the scope of services and target customers has been identified, the facility must identify indicators of performance and establish a means to trigger evaluation, collect and organize data. Facilities must also provide information about what triggers the evaluation process. The continuous monitoring and evaluation of healthcare processes requires that the organization evaluate the effectiveness of actions taken to correct deficiencies and indicate methods to best maintain proper levels of service and care after a deficiency has been determined. Organizations are also required to communicate results with affected individuals, customers, and groups.

In support of its mission to continuously improve the safety and quality of healthcare, the Joint Commission reviews organizations' activities in response to

sentinel events in its accreditation process. The Joint Commission defines a sentinel event as:

> *An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.*[140]

The Joint Commission's policy has 4 goals:

- To have a positive impact in improving patient care, treatment, and services and preventing sentinel events;
- To focus the attention of an organization that has experienced a sentinel event on understanding the causes that underlie the event, and on changing the organization's systems and processes to reduce the probability of such an event in the future;
- To increase the general knowledge about sentinel events, their causes, and strategies for prevention; and,
- To maintain the confidence of the public and accredited organizations in the Joint Commission's accreditation process.[138]

The Joint Commission requires each accredited organization to define "sentinel event" for its own purposes in establishing mechanisms to identify, report, and manage these events. According to the Joint Commission's guidelines, appropriate responses includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements.[138-140]

- ***Root cause*** *is the most fundamental reason for the failure or inefficiency of a process and root cause analysis is used as a tool in identifying the factors involved in the failure or inefficiency.*

- ***Root cause analysis*** *is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. In the root cause analysis, the organization may identify certain variations.*

The differences in results obtained in measuring the same phenomenon more than once is a variation. The sources of variation in a process over time can be grouped into 2 major classes: common causes and special causes.

- ***Common cause*** *is a factor that results from variation inherent in the process or system. The risk of a common cause can be reduced by redesigning the process or system; and,*
- ***Special cause*** *refers to a factor that intermittently and unpredictably induces variation over and above what is inherent in the system.*

Excessive variation frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services. Common-cause variation, also called endogenous cause variation or systemic cause variation, in a process, is due to the process itself and is produced by interactions of variables of that process, not a disturbance in the process. A common cause variation can only be removed by making basic changes in the process. Special-cause variation, also called exogenous-cause variation or extra-systemic cause performance variation results from identifiable causes. Special-cause variation is intermittent, unpredictable, and unstable. It is not inherently present in a system; rather, it arises from causes that are not part of the system as designed.

- *A **Near miss** refers to any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome.*

The Joint Commission requests that an organization transmits its root causes analysis, action plan, and other sentinel-event-related information to them electronically. An action plan is the product of the root cause analysis that identifies the strategies that the organization intends to implement in order to reduce the risk of similar events occurring in the future.[139] The Joint Commission definition of a sentinel event that requires review takes into account a variety of occurrences that are not limited to but may include any of the following:

- The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition; or,
- The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):
- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting, or, within 72 hours of discharge;
- Unanticipated death of a full-term infant;
- Abduction of any patient receiving care, treatment, and services;
- Discharge of an infant to the wrong family;
- Rape;
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;
- Surgery on the wrong patient or wrong body part;
- Unintended retention of a foreign object in a patient after surgery or other procedure;
- Severe neonatal hyperbilirubinemia;
- Prolonged fluoroscopy with cumulative dose > 1500 rads to a single field or any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose.[139-140]

Sentinel events are one of the prime reasons that healthcare organizations have a risk management program. Risk management personnel usually participate in quality improvement teams throughout the organization. Small clinics and imaging centers may have a designated staff person who serves as the risk management contact. The scope of a risk management program includes clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

Each accredited facility is encouraged, but not required, to report to the Joint Commission any sentinel event meeting the above criteria for an event requiring review.[139-140] The Joint Commission lists several reasons for self-reporting a sentinel event although self-reporting is not a requirement.[139-140] One of the most important reasons is that reporting an event enables the Joint Commission to add the "lessons learned" to the Joint Commission's Sentinel Event Database which provides general knowledge about sentinel events and the reduction of such events in other accredited facilities.[139-140]

Preventing Errors

Preventing errors in the diagnostic imaging arena requires that the mammographer remains vigilant and aware at all times. Hippocrates said, "do no harm" and to do no harm the mammographer must check and recheck all the steps required for a particular imaging procedure; and, if in doubt, ask for assistance. There are various ways to classify errors but most are either an error of commission or an error of omission; or a combination of both types.

- ***Error of commission*** *occurs as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood cross-matched to another patient.*

- ***Error of omission*** *occurs as a result of an action not taken, for example, when a delay in performing an indicated cesarean section results in a fetal death, when a nurse omits a dose of medication that should be administered, or when a patient suicide is associated with a lapse in*

carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes.

Other terminology commonly used by risk management specialists about errors include active failure, adverse event, causation, clinical pathway, complication, latent failure, local trigger, proximate cause, risk points, and underlying cause. An active failure is an error, which causes an action or actions leading to errors and violations. The commission of errors and violations are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, or disabling existing defenses. For example, when a technologist overrides an automatic collimator system, it is a breach of the existing safety defenses inherent in the imaging equipment.

Adverse events can and do occur in the delivery of medical imaging services. An adverse event is an untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in the healthcare facility. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient. There are many opportunities for adverse events to occur in medical imaging and includes adverse drug event and adverse drug reactions.

*An **adverse drug event** is any incident in which the use of a medication any dose, a medical device, or a special product may have resulted in an adverse outcome in a patient.*

*An **adverse drug reaction** is an undesirable response associated with the use of a drug that either compromises therapeutic efficacy enhances toxicity, or both.*

Causation refers to an act by which an effect is produced and the factors involved may be predisposing, enabling, precipitating, or reinforcing in their effect to the disease occurrence. In regard to malpractice especially in cases involving negligence and possibly criminal law, the doctrine of causation is important. When someone refers to a clinical pathway it basically means a treatment regime. Usually a clinical pathway is agreed upon by consensus that includes all the elements of care, regardless of the effect on patient outcomes. Sometimes when a clinical pathway has been determined, complications arise. A complication is considered a detrimental patient condition that

arises during the process of providing healthcare, regardless of the setting in which the care is provided. A complication may prolong a patient's length of stay in a hospital or lead to other undesirable outcomes.

In medical imaging during the delivery of sophisticated medical interventions a latent failure may occur.

- *A **latent error** is one that cannot be foreseen, but if detected, the error can be corrected before it contributes to system failure.*

In complex medical imaging systems, errors, which are caused as a result of managerial and organizational processes, pose the greatest danger to patients, staff, and visitors. Sometimes a local trigger, which is an intrinsic defect or atypical condition, creates failures of systems and safety defenses. An act or omission that naturally and directly produces a consequence is called the proximate cause. As will be discussed later in this course, treating only the "symptoms" may lead to short-term improvements, but it is not the solution to prevent the variation (i.e., problem) from recurring. Active quality improvement programs attempt to determine the proximate cause of an event. Underlying causes may involve special-cause variation, common-cause variation, or both.

- ***Variation** is the differences in results obtained in measuring the same phenomenon more than once. The courses of variation in a process over time can be grouped into 2 major classes; common causes and special causes. As previously mentioned excessive variation frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services. Special-cause variation is intermittent, unpredictable, and unstable and is not inherently present in a system; rather, it arises from causes that are not part of the system as designed.*

Errors in the delivery of imaging service leads to adverse patient outcomes, potential loss to the facility, and malpractice. Often malpractice results from negligence, which is the failure to use such care as a reasonable prudent and careful person, would use under similar circumstances.

- ***Malpractice*** *is improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position.*

When the term malpractice is applied to physicians, dentists, lawyers, and public officers it denotes negligent or unskilled performance of duties when professional skills are obligatory. Malpractice is a cause of action for which damages are allowed.

The mammographer is responsible for his/her own actions in regard to patient safety. It is the mammographer's responsibility to check and confirm each person's identity before proceeding with the imaging examination. By following the established protocols and procedures for a particular medical facility, the mammographer can reduce errors. Individual patient circumstances often require that the mammographer adapts the routine examination procedure but any extreme variation should be recorded in the examination documentation. In today's fast paced competitive healthcare industry, mammographers are increasingly required to assume greater workloads yet be efficient and effective. One should never become so overwhelmed that there is not enough time to check the technical factors, patient positioning, or apply radiation safety measures. Although time is of the essence during imaging examinations, especially trauma care, the mammographer should remember that the time spent on "doing the work right, the first time", will more likely result in images of diagnostic quality. To summarize the importance of preventing errors in imaging examinations, the mammographer should:

- Review and check all paperwork related to a imaging examination just finished to determine that all documentation is complete, before moving on to another patient,;
- Concentrate on the task at hand by focusing on one patient at a time;
- Read each imaging request thoroughly before preparing for the imaging examination;
- Develop a routine approach to preparing for each imaging examination; and
- Review the completed mammography images to determine if the required facility image quality standards have been met.

A simple yet effective way to limit errors in diagnostic imaging is to maintain communication between co-workers, patients, physicians, and all support staff. Today, social media recommends that consumers become involved in accessing healthcare and become responsible for their own health status. Patients and their family can and should become involved in helping to reduce the occurrence of medical errors. Recent data

indicates that the general population wants to be more involved with their care but may not know how to become involved in the process.

While consumers can play an important role in preventing adverse events, involving them in the process can be challenging. Patients and family members may not understand the value of their roles in the prevention of errors or be reluctant to participate. To engage the public in healthcare efforts to prevent errors, organizations and practitioners must understand and overcome the barriers that prevent patients and their families from becoming involved. Two of the most common barriers that must be overcome are language, (i.e., both non-English speaking and medical terminology) and literacy.

If a mistake is made, the mammographer should take responsibility, apologize, and act to mitigate or correct the error or concern. The mammographer's scope of practice and the facility's protocols must be followed in regard to the extent of the response and mitigation that the mammographer can extend. Facility policy may dictate that the mammographer notify the attending physician, imaging supervisor, and/or management of the error. The mammographer should avoid becoming defensive because it will not change the outcome and could increase the issues surrounding the mistake. The mammographer should respond to the patient with such phrases as: "Thank you for telling me. I am sorry this happened. I understand why you are upset. This is what I am going to do about it."

A new position paper from the American College of Physicians (ACP) provides ethical guidance to physicians for developing mutually supportive patient-physician-caregiver relationships. Many patients depend on caregivers for assistance with managing complex care and communicating with health care professionals and physician recognition of the value of the caregiver role may contribute to a positive care giving experience.[97]

Family caregivers are of vital importance to more than 30 million patients with acute or chronic disease.[97] Caregivers improve patient quality of life by helping with daily activities, managing complex care regimens, coordinating patient healthcare, and communicating with healthcare professionals.[141]

Patients who have received substantial amounts of radiation during imaging procedures (i.e., fluoroscopy and interventional procedures) are advised to be alert for signs of redness or rash and to report back to the facility.[141] Caregivers may be involved in the

pre-procedure informed consent and the post-procedure care process. In collaboration with 10 other professional societies, the ACP recommends that the physician should:

- Respect the patient's dignity, rights, and values in all patient-physician-caregiver interactions;
- Optimize appropriate patient autonomy and participation in decision-making in all clinical encounters;
- Routinely evaluate the patient's preferences concerning the nature and degree of caregiver participation in the clinical visit to provide the patient's desired level of privacy;
- Educate the patient, family caregiver, and other family members so that they share an accurate understanding of the patient's condition and prognosis; and
- Facilitate discussion of the patient's healthcare values and advance care planning, to provide both the family caregiver and physician with a clear understanding of the patient's wishes.[141]

Quality Assurance and Quality Control

In a literature search for what constitutes a quality improvement program for imaging facilities, it was found that there are various opinions. Kruskal, et.al. proposes that the basic components include patient safety, process improvement, customer service, professional staff assessment, and education.[118]

Quality consists of 3 levels; expected quality, perceived quality, and actual quality. Breast imaging providers and staff has the least amount of influence on the level of expected quality from customers and the public. Expected quality is the inherent value placed on goods or services by the customers. Customers who have received imaging services leave with a feeling or perception about their experience. This in turn becomes what is relayed to family and friends and today may even be posted on the Internet via blogs, etc. The exchange of information between a current customer or patient and the outside world becomes the "word of mouth" announcement about expected quality.

Perceived quality is the customer's perception or "feelings" about the goods or service and is highly subjective or uniquely individualized. Perceived quality is difficult to measure. The perception of breast imaging services is often influenced by factors such as the general cleanliness of the facility, friendliness of staff, if the wait period to receive services was longer than expected, etc. greatly influences perceived quality. The

mammographer's attitude and approach to patient care has a major impact on a patient's perceived quality of the imaging services delivered. Perceived quality is the factor most linked to repeat customer business. Actual quality is a measurable level based on statistical data of outcomes of factors that can influence outcomes ranging from image quality, accuracy of diagnosis, timeliness of report back to the referring physician, etc.

In the early days of quality management, the concepts of quality assurance (QA) and quality control (QC) (i.e., systematic monitoring and evaluation of various functions) were all that was used. These components are now incorporated into total quality improvement efforts. Quality assurance refers to the systematic collection and evaluation of data. Quality assurance consists of all the activities that supports the production of high quality images and patient care. A quality assurance program includes such areas as scheduling, management techniques, and department policies and procedures, technical effectiveness and efficiency, in-service education, and image interpretation with timeliness of reports.

Quality control is an integral part of the quality assurance program and deals with tests used in monitoring and maintaining the technical aspects of the systems that affect image quality. Certain quality control tests are mandated by the Mammography Quality Standards Act regulations and these will be specified later. Quality control tests in mammography consist of 3 levels; Level 1, which are noninvasive, simple tests; Level 2, noninvasive and complex; and Level 3 invasive and complex. Level 1 tests are usually performed by staff and may consist of such tests as the wire test for screen contact, darkroom safelight safety test, etc. In mammography, a designated technologist is responsible for performing Level 2 tests. Qualified equipment engineers and medical physicists usually perform Level 3 invasive and complex tests. Acceptance testing is performed on new equipment and on equipment that has undergone major repair. The purpose of acceptance testing is to evaluate whether the equipment is operating within the manufacturers' specifications. Generally, the data obtained during acceptance testing is used to establish operational baseline data that is a reference for future quality control testing.

Certain tests performed after the equipment has been in operation for a certain period of time is considered a component of routine performance testing. The purpose of such routine tests is to verify that the equipment is performing within recommended standards. Routine performance testing of imaging systems also can be used to

determine if any changes in performance have occurred. Once a malfunction has been identified in any part of the imaging system, further tests are performed to locate and verify the cause so that a repair or replacement can be made.

Each of these components requires strategies for implementing continuous programs to monitor performance, analyzing and depicting data, implementing change, and meeting regulatory requirements. It is suggested by Krushkal et.al., that for small imaging departments or facilities that they gradually introduce one or more of these components to ensure the safety and quality of their services.[142] Others (Johnson, et. al) propose that the 4 main areas of quality that need to be addressed for a complete quality and safety program in radiology include safety, process improvement, professional outcome assessment, and satisfaction.[142]

The Mammography Quality Standards Act (MQSA) which is enforced by the U.S. Food and Drug Administration (FDA) has published mammography quality control test requirements and the timing of such procedures. Figure 19 lists tests and frequency required by the MQSA.

Timing of Test	Quality Control Test
Daily	Processor performance test
Weekly	Image quality evaluation test
Quarterly	Fixer retention in film Repeat analysis
Semiannually	Darkroom fog Film-screen contact Compression device performance
Annually	• Automatic exposure control performance • kVp accuracy & reproducibility • Focal spot condition • Beam quality & half-value layer • Breast entrance air kerma & automatic exposure control reproducibility • Dosimetry • X-ray field/light field image receptor/compression paddle alignment • Uniformity of screen speed • System artifacts • Radiation output • Decompression

Fig. 19. MQSA required quality control tests & timing.[108]

According to MQSA, for mammography imaging systems with image receptor modalities other than film-screen, the quality assurance program should be substantially the same as that recommended by the image receptor manufacturer.[108] In full film digital

mammography (FFDM), the equipment manufacturer designs and mandates the quality control program and these procedures are used with the MQSA requirements in mind. Additional quality control and assurance testing should be conducted whenever new mammography imaging equipment is installed, dissembled or reassembled or major components of the equipment are changed or repaired.[108]

The American College of Radiology in the ACR position statement on *Quality Control and Improvement, Safety, Infection Control, and Patient Education* (ACR Resolution 9, 1998 and revised in 2008 as Resolution Ie), also includes a statement about equipment quality control with ionizing radiation.[143] It is recommended that imaging facility have documented policies and procedures for monitoring and evaluating the effective management, safety, and operation of equipment involved in the use of ionizing radiation for imaging, diagnosis, and therapy. The quality control program should be designed to minimize patient, personnel, and public radiation risks and to maximize the quality of the diagnostic information or therapeutic benefit.[143] For example, simple physical checklists, diagnostic-decision support systems, or second looks at imaging examinations could help prevent some of the estimated 40,000 to 80,000 hospital deaths in the U.S. from diagnostic errors according to a John Hopkins University physician.[144]

The ACR and the Joint Commission stress that medical imaging equipment performance should be monitored and a qualified medical physicist should make estimates of radiation dose and should use this as a benchmark against recognized standards. The monitoring of equipment is a component of routine QC testing and should be conducted by properly trained individuals. Equipment testing usually begins with the initial acceptance testing of newly installed equipment, continues as dictated by regulations, and is performed whenever certain service and maintenance is performed.

Ongoing training and education is a key to improving delivery of healthcare and ensuring for the safety of patients and personnel. The ACR recommends that facilities have written policies about educating and informing patients about examinations and/or interventions to be performed by the facility staff. [143] This should include appropriate instructions for patient preparation and aftercare, if any. This information should be provided in an appropriate form to the patient and family.[143]

Imaging examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the

examination. Complications and adverse events or activities that may have the potential for sentinel events should be monitored, analyzed and reported as required, and periodically reviewed in order to identify opportunities to improve patient care. The data should be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.[143]

To summarize, quality controls are the actual tests, evaluations, inspections, etc., which are regularly scheduled to ensure that all systems are functioning properly. Professional service personnel, medical physicists, and radiographers usually share the responsibility of performing quality control tests. State and federal inspectors also are involved in examining and reviewing quality control tests to determine compliance with applicable laws. One can easily understand that if imaging systems are not in proper working condition, assurance that the facility is delivering quality services that meet ALARA requirements cannot be guaranteed.

Although quality assurance and quality control are very important aspects of delivering high quality diagnostic imaging services, these 2 aspects alone do not constitute a fully integrated approach to quality improvement. A major concern with quality assurance and quality control functions is that their activities are concerned with meeting recognized standard requirements or parameters and does not focus on continuous improvements beyond the expectations. Today, however, the Joint Commission and other national accrediting organizations expect efforts that demonstrate that quality assurance and quality control functions are part of a larger effort of quality improvement.

Quality improvement efforts are based on identifying errors or problems in the entire imaging process. It is based on the assumption that errors and variability with the process are the main causes of poor quality, waste, and inefficiencies. Some suggest that the 85/15 rule and the 80/20 rule prevail in errors in the delivery of imaging services.

- ***85/15 Rule*** *proposes that the process causes problems 85% of the time and personnel within the process are to blame 15% of the time.*

- *A* ***process*** *is an ordered series of steps that helped achieve a desired outcome.*

- ***80/20 Rule*** *proposes that the problems are the result of 20% of the causes.*

- *Personnel who function within the process usually know what is wrong and can suggest corrective actions.*

- *Use of **problem-solving** that is based on statistical methods result in better long-term fixes.*

- *Everyone in an organization is responsible for supporting and improving quality.*

A recent study conducted at the Mayo Clinic in Rochester Minnesota demonstrated that small process changes in mammography imaging could yield significant results.[145] The study analyzed diagnostic mammography processes and made minor adjustments that cut repeat examinations and patient examination time while improving patient and staff satisfaction.[145]

The Mayo Clinic study found that it took 72 minutes to collect and interpret a diagnostic mammogram. [145] After study of the entire process, it was decided to have a mammographer and a radiologist manage the imaging process from planning to interpretation.[145] Another change was having imaging parameters given the same day as the diagnostic examination rather than at the time of screening mammography.

After the changes were implemented the need to retake examinations decreased from 17% to 7% for the radiologist and from 32% to 20% for the mammographer.[145] The patient's time in the examination fell from 54 minutes to 38 minutes due to consolidation and elimination of process steps.[145] Patient satisfaction regarding wait time rose from 87% to 96%, and employee satisfaction according to surveys, improved from a rating of 2.95 out of 5 to a rating of 4.19 out of 5.[145]

Information Technology

U.S. healthcare spending is at a historic low for the third straight year, growing in line with the overall economy.[146] Although this is good news, there remains a gap in interoperability of healthcare information. Several of the technologies developed for the manufacturing sector for improving interoperability are potentially transferable or adaptable to the healthcare sector. The major enabler of healthcare information sharing is the electronic health record (EHR), containing all the relevant patient healthcare data in a sharable form.[147] A national survey of office-based physicians conducted in 2011,

reports that most of those who have adopted EHR systems are satisfied with their system and say it has improved patient care. According to the survey, 55% of responding physicians said they have adopted at least some EHR technology in their practices.[147] Despite these numbers, physicians In many small clinics continue to rely on paper based records and faxed-based communications. Available electronic health record systems are deemed too expensive for many small healthcare facilities.

Health Level Seven (HL7) provides messaging standards that allows disparate healthcare information systems to communicate with each other. Importing legacy patient healthcare information is expensive and time consuming but essential for medical and legal resources and for providing quality. Although there is acceptance of the HL7 standard, interoperability and interchange of healthcare information remains a barrier due to different degrees of adoption of the revision of the HL7 standard. HL7 is a registered trademark of the Health Level Seven, Inc., the non-profit standards developing organization that is accredited by the American national Standards Institute (ANSI).

Medical imaging is a multimillion-dollar industry and is making major strides into current medical diagnoses and treatment. There are key barriers that are hampering progress in medical imaging, including lack of standards for data collection and analysis across different commercial imaging platforms; lack of validated and robust software methods for measurement of change in extracted features and lack of technical interoperability. Health information technology (HIT) allows comprehensive management of medical information and the secure exchange of such information between healthcare consumers and providers. Broad use of HIT will:

- Improve healthcare quality;
- Prevent medical errors;
- Reduce healthcare costs:
- Increase administrative efficiencies;
- Decrease paperwork; and,
- Expand access to affordable care.[148]

Interoperable HIT will improve individual patient care, but it will also bring many public health benefits, including:

- Early detection of infectious disease outbreaks around the country;
- Improved tracking of chronic disease management; and

evaluation of healthcare that is based on value enabled by the collection of de-identified price and quality information that can be compared.[148]

The 2009 breast screening announcement from the Centers for Medicare & Medicaid Services (CMS) coupled with the lingering economic recession may cause many breast imaging centers to delay equipment purchases and decisions about expanding information technology infrastructure.[149] As previously mentioned, information is an important key to improving productivity and the framework for timely submission of reimbursement claims, patient invoices, and imaging reports. Prompt reporting of breast imaging examinations has been closely implicated in surveys of patient satisfaction.[149]

Improving efficiencies in the delivery of healthcare is the buzzword today. Breast imaging centers strive to reduce the time required to create a diagnostic report and put it in the hands of those who need it.[150] Precision reporting can help reduce turnaround times by streamlining radiologist workflow and facilitating creation of accurate, structured reports. Advances in voice-recognition are allowing radiologists to read studies for multiple facilities regardless of location.[150] In addition, it narrows the number of routines the doctor is presented by utilizing a predictive user interface to match relevant study information with the appropriate templates and routines.[150] Full-report speech recognition and editing slows radiologists.[150] Newer systems tightly integrate speech recognition with other automation tools to limit the amount of actual speech recognition, resulting in improved productivity and reporting.[150]

Bar-code technology added to an electronic medication administration record has been shown to dramatically cut hospital transcription and medication errors according to researchers at Brigham and Women's Hospital in Boston.[151] The researchers documented a 41% reduction in nontiming drug administration errors and a 51% reduction in potential drug-related adverse events associated with this type of error.[151]

Manufacturers are now providing a single database for RIS, PACS, and billing which provides for a one-stop location for information like patient demographics, insurance card images, referring physician's order, and the image report.[151] This type of data management is expected to increase efficiency and cut down on data entry, thus reducing the number of personnel needed to perform these tasks.[152]

Part 8 Radiation Protection in Mammography

Obligations to Protect

The mammographer has moral, ethical, and legal obligations to protect the public, patients, co-workers, staff, and self from harm while in the service of providing imaging services. "From harm", is an all-encompassing concept that sometimes may seem overwhelming to the individual mammographer; however, when put into perspective, one realizes that he/she is part of a healthcare team, where each member shares a portion of the burden of safety. The American Registry of Radiologic Technologists (ARRT), American College of Radiology (ACR), and the Mammography Quality Standards Act (MQSA), provide guidelines for mammographers about safe practices, professional behavior, and the scope of imaging practice.

The ARRT Standards of Ethics is a professional document that provides registered technologists (i.e., mammographers), registered radiologist's assistants, and candidates with guidelines for acceptable ethical conduct in ensuring protection, safety, and comfort while providing imaging services.[153] Specifically, item 7 of the ARRT Code of Ethics states that a "radiologic technologist uses equipment and accessories, employs techniques and procedures, performs services in accordance with an accepted standard of practice, and demonstrates expertise in minimizing radiation exposure to the patient, self, and other members of the healthcare team." [153]

ASRT, the premier organization for imaging professionals, provides further guidance to mammographers in the form of practice standards. For example, Standard 4 of the ASRT *Radiography Clinical Performance Standards* section states that quality patient services are provided through the safe and accurate performance of a deliberate plan of action.[153] Specific criteria associated with this standard further emphasize that mammographers use radiation shielding devices and set "…technical factors according to equipment specifications to minimize radiation exposure to the patient."[153] Additionally, ASRT Standard 8 is based on the specific criteria that mammographers document radiation exposure parameters.[154]

The *Radiography Quality Performance Standards* component of the ASRT *Practice Standards* further states that the mammographer must:

- Maintain controlled access to restricted areas during radiation exposures;
- Follow federal and state guidelines to minimize radiation exposure levels;

- Maintain and perform quality control on radiation safety equipment such as aprons, thyroid shields, etc.;
- Develop and maintain a technique chart for all equipment; and,
- Participate in radiation protection, patient safety, risk management, and quality management activities.[154]

Additional information about the ASRT *Practice Standards for Medical Imaging and Radiation Therapy* is available on the ASRT Web site (www.asrt.org).[154]

For all diagnostic imaging procedures there are universal practices that must be followed by all personnel. [155,156] The ACR has issued detailed universal practice guidelines that support personnel actions during imaging procedures. [155,156]The ultimate goal of the practice guidelines is to minimize radiation exposure to patients, staff, and the public while delivering high-quality diagnostic images. The ACR practice guidelines for general radiography that relate to breast imaging procedures are paraphrased in the following broad statements:

- *The written or electronic request for mammography should provide sufficient information to demonstrate the medical necessity of the examination, and to allow for the proper performance and interpretation of the examination.*
- *All breast-imaging studies should be permanently labeled with patient identification and the date of the examination.*
- *All facilities performing breast imaging should have protocols for standard views of each anatomic area that will be imaged.*
- *All facilities performing breast imaging should have technique charts listing exposure factors that will reliably produce diagnostic radiographs, in order to minimize the need for repeat exposures.*
- *Repeat rates should be part of the routine quality control process.*
- *All breast images should be reviewed for positioning and diagnostic quality at the facility before the patient is released.*
- *All facilities producing breast images should have policies and procedures for the appropriate shielding of patients.*
- *All facilities should have immobilization and assistance procedures that are appropriate for the age and size ranges of patients to be imaged. These should be available to ensure that images of diagnostic quality can be obtained in patients who*

are unable either to cooperate or to be positioned in an usual manner due to age or physical limitations, and without unnecessary irradiation of healthcare workers.

- *Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.*
- *The diagnostic imaging equipment and facility should meet all applicable federal and state radiation standards.*
- *In facilities where digital imaging is used, the equipment should meet the specifications described in the ACR Technical Standard for Digital Image Data Management.*
- *Automated processing is preferred.*
- *Radiologists, mammographers, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, staff, and society as a whole while maintaining the diagnostic quality.*
- *Facilities, in consultation with the medical physicist, should have policies and procedures in place and adhere to them in accordance with ALARA. They* should also have documented policies and procedures related to quality, patient education, infection control, and safety. These should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety Infection Control, and Patient Education Concerns appearing in the ACR Practice Guidelines and Technical Standards *Handbook.*[155,156]

Radiographer Non-Compliance

The philosophical concepts of radiation safety and ALARA become real when, in everyday practice, mammography personnel implement universal practice standards. Although ALARA universal practice standards are easy to perform, there exists widespread concern that radiological personnel are not performing them on a consistent basis. Variations have been found to range from strict adherence to shielding and collimation to no compliance.[157] Several studies (i.e., Tilson and Lemley) and national reports (i.e., *The Challenges and Potential for Assuring Quality Health Care for the 21st Century)* have provided information about the reasons for lack of ALARA compliance.[156] Data from a study conducted in 2003 (i.e., Slechta and Reagan) of the factors related to radiation protection practices indicate that there is poor compliance with radiation safety practices, especially safety practices designed to reduce unnecessary exposure to

personnel.[156] Slechta and Reagan based their research on variable factors such as the type of initial professional education, work site type, and years of employment.[155] The results showed that the type of initial professional education was not significantly related to compliance with ALARA practices, although it had a small, significant association with knowledge of safety practices.[156] The type of work site and years of employment in medical imaging were found to be the more important variable factors in determining compliance with ALARA practices. Specifically, a higher rate of ALARA compliance was found to exist in large hospitals than in any other type of work site.[112] Reagan and Slechta conducted a recent survey with 2 primary objectives:

1. To ascertain whether key findings of the 2003 national study of radiologic technologists' radiation safety practices would be replicated with a revised instrument and with the California-based population of ARRT radiologic registrants; and,
2. To determine whether there was a significant difference between compliance with personnel safety practices and compliance with patient safety practices.[156]

The findings from the recent study support the findings of the 2003 national study and support predictions that compliance would be higher for patient safety practices than for personnel safety practices, and that years in practice and type of work site would be related to safety compliance.[157] The major findings from the national and the current study are as follows for those surveyed:

- Participation in continuing education (CE) was high, yet compliance with safety practices was low;
- Knowledge of safety practices was higher than compliance with safety practices.[157]

After analyzing the research data, Reagan and Slechta conclude that additional research is needed to address certain questions.[157] For example, continuing education (CE) is required for radiographer compliance with certain state statutes and ARRT registration and yet there is low compliance with safety practices. Also, the researchers question why compliance with safety practices is greater for patients than for personnel.

Appropriateness of Imaging Examinations

The current literature focuses on potentially medically-unnecessary imaging examinations as the cause of the rapidly rising costs of healthcare in the U.S. and the ever increasing radiation exposure to Americans.[158,159] There are several moves to curb both the cost and the additional radiation exposure. Because sophisticated medical imaging examinations now accounts for 60% of radiology costs and 80% of cost increases, third party payors are tightening the requirements for pre-authorization of the examinations. [158,159] One of the challenges has been the lack of a commercially available, research-driven guide for physicians on how to quality the appropriateness of imaging examinations for patients. The ACR has published appropriateness criteria, which serves as foundation guidelines based on the patient's condition or disease. The ACR appropriateness criteria ranks imaging examinations from 1 to 9 based on certain specified conditions.

Recently researchers at Massachusetts General Hospital in Boston found that an electronic system when used consistently prevents nurses or office assistants from ordering low-yield CT, nuclear medicine scans or MR imaging. Use of the decision support software allowed for a drastic reduction in the rate of such examinations and markedly increased the percentage of tests personally ordered by physicians. An advantage of Web-based software is that it offers physicians suggestions for a better examination in the event of a low score or inappropriate examination.[158,159] With the continued improvement in such decision making tools, it is anticipated that physician ordering of unnecessary and/or inappropriate medical imaging examinations will decrease and this will result in an overall reduction in exposure to ionizing radiation.

Factors Impacting ALARA

Recognized ALARA practices consist of simple yet effective measures that can be applied in all imaging procedures. These include those items directly related to the imaging procedure, such as patient communication, examination preparation, motion control, and reduction in repeated examinations. Other items that contribute to the overall goal of ALARA include the design of the x-ray room, structural protective shielding, protective barrier requirements, and equipment design.

Retake Exposures

When a breast image must be retaken, the radiation dose received by the patient increases. The ultimate goal of all imaging procedures is the production of high quality images, without retake examinations. A retake of an image may be required whenever the image quality fails to provide adequate diagnostic information. The reasons for retake examinations range from simple mammographer forgetfulness to complex technical errors. The most common causes of retakes include improper positioning of the part or patient, inaccurate selection of the technical factors (over or underexposure of the image), patient motion (voluntary and involuntary), and improper film processing techniques. The observant mammographer can correct many of these errors beforehand, thus minimizing the number of x-ray exposures and reducing the patient radiation dose.

If in doubt about the need to retake a particular image, the mammographer should consult with a supervisor to determine whether the image provides sufficient diagnostic information. Since additional exposures result in increased radiation dose to the patient, each image should be thoroughly evaluated for diagnostic integrity prior to the decision to retaking an examination. Factors such as either the patient's condition or the technical factors can be improved upon during the retake examination must also be considered prior to actually subjecting the patient to additional radiation exposure. In many cases, these factors cannot be easily changed, and the outcome of the retake examination may not yield any improvement in image quality, so should not be attempted.

A retake analysis program can easily be incorporated into the overall quality control program. Whether performed by an individual or the supervisor, analysis of the number and causes of retake examinations can result in heightened awareness of areas needing correction. Such information can be used to design staff in-service training and customized continuing education. Further, information about an individual mammographer can be used during personnel evaluations as a way to begin a self-improvement plan, or at worst, to begin the documentation for punitive action and eventual termination of employment.

ALARA in Action

The concept of ALARA is best explained as actions the mammographer performs in every imaging examination to provide maximum radiation protection to the patient,

public, and self. Some of the simplest ALARA actions performed by the mammographer can be the most effective. Examples of these include when the mammographer/radiographer:

- Uses the lowest exposure factors that will produce a high-quality diagnostic image;
- Performs the procedure correctly the first time to avoid retake examinations;
- Properly shields the patient with gonadal shields; and,
- Limits the primary radiation beam to the area of clinical interest.

There are many factors contributing to the overall goal of ALARA. Each of the following will be briefly reviewed: cardinal principles, structural design, protective apparel, primary beam limitation, filtration, selection of technical exposure factors, film-screen combinations, grids, and equipment design.

The cardinal principles of radiation protection are time, distance, and shielding (TDS). If used together, these principles can effectively minimize radiation exposure. The cardinal principles were first introduced for nuclear-energy employees who had the potential to be exposed to high levels of radiation in the workplace. Individuals employed in breast imaging are not expected to receive such high levels of radiation; however, the cardinal principles have practical application to everyday medical imaging and special procedures.

The T in TDS refers to the fact that radiation exposure is proportional to the length of time exposed to radiation. A 5-minute radiation exposure would result in a radiation dose five times as great as a one-minute radiation exposure. This has several implications that can be related to minimizing radiation exposure. The mammographer has a responsibility to:

- Reduce the amount of time exposed to radiation. The mammographer should stand behind the protective barrier during the exposure, and should not allow visitors in the room during the exposure.
- Make the x-ray exposure only when the imaging room doors are closed. This practice provides a substantial degree of protection for patients and staff who may be walking past the imaging room.
- Reduce the amount of time that the patient is exposed to radiation. The mammographer should reduce retake examinations, which subsequently reduces the total quantity of radiation dose received.

- Use a fast exposure-time whenever possible. A fast exposure time helps minimize patient motion. Motion results in image blurring, which reduces image quality and increases the need for retake examinations.

Exposure Control

There are many factors that influence the amount of radiation that the patient receives. Of these, there are only a few within the mammographer's control. The correct selection of exposure factors is under the direct control of the mammographer, and if performed consistently can reduce radiation exposure to patients and staff. There are various systems available for the selection of technical exposure factors; these include both manual and automatic variables on computed and direct mammography equipment.

Automatic exposure control (AEC) systems limit the length of the exposure, and thereby have some impact on overall radiation dose. AEC devices are also referred to as phototimers, and are programmed to terminate the radiographic exposure time at a predetermined value. Mammographers are advised to continually review current technical and positioning references in regard to proper selection of AEC chamber(s), and correct positioning when using them.

The D in TDS is for distance as it relates to the distance between the patient, mammographer, and the radiation source. One of the most effective methods that radiographers can use is to put as much distance between themselves and the radiation source as possible. The inverse square law applies to point sources of radiation, and can be used to demonstrate the effect of distance on radiation intensity. The distance principle as applied to patient protection refers to the fact that every breast imaging procedure should be performed with the x-ray tube or source positioned at the proper distance from the patient or part being examined.

The S in TDS is for shielding. When x-ray travels through living tissue, the quantity and energy of the x-ray decreases as a result of attenuation by the tissue. The degree to which the quantity and energy of the x-ray beam is decreased depends upon the following 3 factors:

- Original quantity and energy of the x-ray;
- Type of absorber material, or atomic number of the tissue; and,
- Thickness of the absorber material in centimeters or inches, and consideration of any existing pathology.

Structural Design for Radiation Protection

A breast imaging room must be designed to ensure that placement of the equipment is proper, and that the structural protective shielding meets recommended protective guidelines. A qualified medical physicist must survey the prospective room design and determine the exact requirements for structural shielding. Whether the prospective breast imaging room is already in existence or is part of a new construction, appropriate thickness of lead structural shielding must be installed according to the physicist's specifications, which are usually mandated by state and/or federal laws. The physicist provides recommendations for both primary and secondary protective barriers.

Primary structural protective shielding provides protection from the primary x-ray beam. Primary radiation emerges directly from the x-ray tube window, and moves without deflection toward a wall, door, etc. A wall in the path of the primary radiation requires the most protective shielding. For x-ray equipment capable of operating up to 150 kVp, the protective primary structural shielding should contain of 1/16th inch of lead and extend as high as 7 feet from the imaging room floor.[160] Primary structural protective shielding is installed perpendicular to the primary x-ray beam.

Secondary radiation occurs when the primary x-ray beam is deflected or re-directed by the object being irradiated. Radiation leakage around the x-ray tube and scatter radiation generated by the patient and other objects receiving radiation comprise secondary radiation. Secondary protective structural shielding should consist of 1/32nd inch of lead, extend to the ceiling, and be located parallel to the primary beam.[113] Secondary protective shielding is also installed in the control console shield and structural barrier window through which the mammographer can observe the patient. The window is required to contain 1.5 mm of lead equivalency.[160]

Protective apparel for Radiation Protection

Protective apparel is used for the patient and mammographer whenever additional protection is desired or necessary. Protective apparel consists of lead-impregnated vinyl gloves and aprons. If the x-ray tube operating capacity is in the 100-kVp range, the lead gloves and aprons should contain at least 0.25-mm of lead equivalent; however, a lead apron is typically lined with 0.5-mm of lead or its equivalent.[160]

Gonadal shielding protects the patient's gonads from direct exposure to the primary radiation beam. Gonadal shields should be used in addition to collimation.

Gonadal shielding should be provided for all persons having reproductive potential, including adults of reproductive age and children. The anatomic location of the testes in the male generally allows for adequate shielding while not obscuring important anatomic structures; however, the ovaries are located near the vertebral spine, ureters, and the small and large intestines, and pose a shielding challenge. Gonadal shields should meet the following specifications based on the kilovoltage range of the radiography equipment being used:

- 0.25 mm of lead equivalent for 100 kVp or less;
- 0.5 mm of lead equivalent for 100 to 150 kVp; and,
- 1.0 mm of lead equivalent for 150 kVp and above.[160]

Protective gloves, aprons, and gonad shields impregnated with lead should be handled and stored with care. Protective apparel should not be folded during storage since cracks may result from bending. If cracks occur, radiation may leak through and diminish the protective characteristic. Protective apparel should be checked at least every 3 months for cracks.[160]

Primary beam limitation

Primary beam limitation is one of the most effective methods that can be employed to reduce unnecessary radiation exposure to the patient. Limitation of the primary x-ray beam has a twofold benefit: it reduces the amount of radiation dose to the patient by reducing the amount of scatter radiation while also producing a high quality image. As the amount of primary radiation is reduced, the quantity of secondary scattered radiation is also reduced.

Filtration

Filtration of the primary radiation beam is another method that contributes to the overall goal of ALARA. A filter removes low-energy, long-wavelength photons from the primary radiation beam. The two major functions of a radiographic filter are (1) protecting the patient's skin and superficial tissue, and (2) improving the quality of the radiation beam. [159] The purpose of the filter is to remove the longer wavelengths, or the lower energy photons, from the primary radiation beam, resulting in a primary radiation beam that is more homogeneous in nature.

Quality assurance and quality control are very important aspects of an active ALARA-based radiation safety program. Quality assurance consists of all the activities that support the delivery of high-quality breast imaging and patient care. Quality assurance is the broad umbrella of evaluation and monitoring which encompasses all the systems that affect the delivery of breast imaging services and patient care. This includes the patient information data systems, personnel policies and procedures, and overall operating procedures (clerical, technical, support, administrative, etc).

All imaging systems and accessory equipment, such as cassettes, viewboxes, and darkroom environmental features, are subject to regular required inspection, maintenance, and testing protocols that must be performed to assure the integrity of the system. Mammographers are encouraged to continue to expand their knowledge and understanding of quality assurance and quality control by consulting specific references on these subjects.

Imaging Equipment Design for Radiation Protection

Use of computerized software in digital mammography allows for post-processing and optimization of the digital images that is not possible in screen-film radiography. For example, images that may be underexposed or overexposed can be corrected with software applications. Because of ongoing innovations in digital mammography software programs, system manufacturers typically issue updates or revisions to the system software.[161] These must be installed and tested to ensure ongoing compliance and quality. Such software upgrades are considered part of the ongoing quality control program in digital mammography, and are often highly specific to a particular system. [161]

Sharing of digital breast images is important in the timely delivery of radiology services, and in the delivery of high-quality medical care. The ability to share prior images may result in fewer imaging examinations for the patient, and ultimately, a reduction in radiation exposure.

Radiation Detection and Monitoring

Radiation detection and monitoring are important to the overall radiation protection program in any facility. Monitoring of personnel provides important information regarding the amount of radiation exposure received. Information gathered from personnel monitoring is generally reviewed by the radiation safety officer (RSO) to determine if it is within the acceptable exposure guidelines. After review, corrective

actions may be required to reduce or eliminate the radiation exposure. It should be noted that monitoring is not considered a protective method; rather, the data gathered from monitoring provides information about the wearer's personal radiation safety habits and the imaging environment. Radiation monitoring is recommended for those who are exposed occupationally on a regular basis to ionizing radiation, and who are at risk of receiving 10% or more of the annual occupational effective dose limit of 5 rems in any single year.[116]

Regardless of the company supplying personnel radiation monitors and reporting, there is a certain amount of information that is commonly contained in a report. This information is listed as follows:

- Personnel identification, usually by a number (name, birthdate, and sex);
- Type of dosimeter;
- Radiation quality (e.g. X-rays, beta particle, neutron, combined radiation exposure);
- Equivalent dose data for the entire reporting period; and,
- Notation of the starting date that the monitoring company began keeping records for the individual.[161]

Mammographers should maintain a copy of their accumulated permanent equivalent dose record. This information can then be conveyed from employer to employer throughout the person's work life.

The optically-stimulated luminescence (OSL) dosimeter combines the best features of the traditional film badge monitor and thermoluminescent dosimeter, while eliminating some of their disadvantages. The OSL dosimeter can be worn for up to one year, but in actual practice is usually only worn for a two month period.[162] A disadvantage of the OSL dosimeter is that it must be shipped to the radiation monitoring company for reading, so determination of exposure is delayed.[162] The OSL dosimeter has a sensitivity reading as low as 1 mrem for x-ray and gamma ray photons, and is considered the monitor of choice for monitoring both personnel.[161]

The Safety Manual from the Office of Safety and Environmental Health at Johns Hopkins offers the following additional tips regarding personnel radiation monitoring:

- *Individuals who may receive an occupational radiation dose in excess of 10% of the allowed limits shall be required to use a personnel monitor.*
- *The monitor is a measure of the individual's personal exposure. It should not be given to other people to wear.*

- *Once a month, the films within the monitor must be changed. Failure to change the film at the proper time negates the monitor's usefulness.*
- *Monitors should not be put in radiation sources for experimental purposes.*
- *The personnel radiation monitor is issued to document exposure to the head and trunk of the body. The monitor should be worn at the waist or chest level, never at the extremities. When wearing a protective apron, the personnel radiation monitor should be worn outside the apron at the collar level.*
- *If a monitor is lost or damaged, a new monitor must be obtained before continuance of activities involving possible radiation exposure. There is a charge for exchange of damaged holders.*
- *Technologists should take care of the personnel radiation monitor as it is also sensitive to heat, moisture and pressure. Appropriate precautions should be observed.*
- *A personnel radiation monitor should never be worn when receiving radiation exposure as a patient.*
- *An annual record of radiation exposure should be provided to the technologist at his/her request.*[162]

Radiation protection procedures for patients, staff, and the general public require that mammography personnel be knowledgeable about the nature of ionizing radiation, and constantly attentive to all safety measures. Mammography personnel are challenged to apply a variety of methods, techniques, skills, and knowledge in an effort to practice ALARA in every imaging procedure.

Conclusion

Mammography is an important aspect of preventative healthcare for older women. Although, some guidance exists relative to increasing age and continuance of mammography screening, there is very little research in the area of mammography in women over age 80. Current guidance suggests that physicians should counsel women regarding the benefits and harms of screening mammography over the age of 65; however, there are few decision-making aids available to assist in this consultation.

In the U.S., the population is aging and mammographers can expect that the number of older women seeking breast-imaging services will continue to increase. Some speculate as to whether the initial training of radiologic technologists is sufficient

to adequately serve the vast number of aged that are expected over the next 20 years. Currently, mammographers can begin to prepare to be able to recognize and assist older women during breast imaging examinations. Mammographers must be prepared to adapt routine positioning methods to accommodate physical and cognitive limitations in older women. Also mammographers have an important role in recognizing and reporting signs and symptoms of elder abuse that may be evident during breast imaging examinations.

It is also expected that as the U.S. population ages, that the demands on all imaging professionals will increase. Not only will the population of patients be older but also in many instances they may be more gravely ill and require specialized services. Mammographers and radiologic technologists have always accepted the challenges of providing high quality images despite less than ideal circumstances. It is expected that they will continue to do so and that providing services to the aging population will be no different than the all the challenges that have come before.

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