

INCREASING AWARENESS OF THE ROLE OF BREAST DENSITY AS AN
INDEPENDENT RISK FACTOR FOR BREAST CANCER: A PILOT STUDY

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Increasing Awareness of the Role of Breast Density as an Independent Risk
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ABSTRACT

Breast cancer is the second leading cause of cancer deaths among women in the United States (U.S.), affecting one in every eight women (American Cancer Society, 2017). Dense breast tissue can mask or hide breast cancer, delaying identification and early treatment (Lei, Yang, Zhang, Wang & Yang, 2013). Breast density (BD) is an independent risk factor for breast cancer. (Falcon, Williams, Weinfurter, & Drukteinis, 2017). A woman's mammogram determines BD. Current breast-screening guidelines vary from leading U.S. preventative organizations, making prevention education difficult for providers and patients to understand (Nguyen-Pham et al., 2014; Weaver & Gjesfjeld, 2014). Notification of BD legislation has increased awareness about BD. Gunn et al. (2018) found that BD notification letters are often written at a higher reading level. These issues cause barriers to understanding BD and confusion regarding how BD factors into screening recommendations as an independent risk factor for breast cancer. The purpose of this practice improvement project (PIP) was to increase awareness of dense breast tissue as an independent risk factor for breast cancer, assess current understanding of BD among rural women with known dense breast tissue, and to increase awareness of BD among healthcare professionals in rural healthcare.

Thirteen women with known dense breast tissue participated in the PIP. A questionnaire was used to assess rural women's knowledge and awareness of dense breast tissue. All participants (N=13) received personalized education on BD and risk for breast cancer. Almost all women acknowledged that having dense breasts does make it more difficult to see breast cancer on a mammogram (n=12; 92.3%), however only 46.2% (n= 6) recognize BD as a risk factor for breast cancer. Almost all women (n=12; 92.3%) did not feel knowledgeable about their dense breast tissue, however more than half (n=10; 76.9%) were comfortable about making

decisions regarding the type of screening to have with their dense breasts. Results were aggregated and disseminated to providers. Providers had an increased awareness of dense breast tissue and the risk for breast cancer. In addition, BD notifications were revised to reflect a seventh-grade reading level.

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DEDICATION

To all the strong and fearless women in my life especially my mother, Kimberly, and my grandmother, Mavis.

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CHAPTER ONE. INTRODUCTION

Breast cancer is the most common cause of cancer among women of all races in the United States (U.S.). One in eight women will be diagnosed with breast cancer within their lifetime, with a majority occurring after the age of 50 (Gentry, 2016). According to the American Cancer Society (ACS), even with the decreasing mortality rates, 40,610 women in the U.S. are expected to die from breast cancer in 2017 (American Cancer Society [ACS], 2017). Early detection and prevention are vital to reducing mortality associated with breast cancer (Lei, Yang, Zhang, Wang & Yang, 2013).

Background and Significance

Breast cancer screening recommendations vary from leading U.S. preventative oriented and cancer organizations. Major differences include the age to start and stop mammograms, frequency of mammograms, and need for supplemental screening. Numerous risk factors have been associated with breast cancer occurrence. Dense breast tissue is an independent risk factor for breast cancer. Women with dense breast tissue have an increased relative risk of 1.2 to 2.1 times that of women without dense breast tissue (Falcon, Williams, Weinfurter, & Drukteinis, 2017). In the U.S., 43% to 46% of women older than age 40 have dense breast tissue (Monticciolo et al., 2018). Due to multifactorial risks for breast cancer, it is imperative for women to understand how their breast density (BD) can increase their risk for breast cancer. The more informed women are about their breast anatomy, the better able they are to make an educated decision about breast cancer screening and if warranted, added supplemental screening (Jones & Stevens, 2014).

According to Weaver and Gjesfjeld (2014), rural women are less likely than urban women to follow preventative guidelines. Multiple factors influence rural women's compliance

with guidelines, including low socioeconomic status (SES), lack of insurance coverage, inconsistent primary care, and a greater geographical distance to healthcare (Weaver & Gjesfjeld, 2014). Individuals with low health literacy often also have low SES and educational level. Rural areas are associated with lower health literacy, which in return is linked with under-utilization of preventive health care services, such as mammography screening (Halverson et al., 2013). Rural women tend to be in the later stages of cancer at the time of diagnosis; the later diagnosing can be correlated to difficulty accessing or decreased awareness of preventative screening (Nguyen-Pham, Leung, & McLaughlin, 2014; Weaver & Gjesfjeld, 2014). Unfortunately, breast-screening guidelines are not succinct, making prevention education difficult for providers and for patients to understand (Nguyen-Pham et al, 2014; Weaver & Gjesfjeld, 2014). Understanding the screening beliefs, practices, and knowledge of rural women can help guide public health messages, and tailor clinical interventions to increase breast cancer screening (Davis et al., 2012).

Statement of Problem

Informed women make educated decisions about preventative screening. Awareness of dense breast tissue and types of screening modalities is vital to early detection of breast cancer. Notification of BD legislation has increased awareness about BD. Medical information should not be withheld; a woman should have the right to know about personal BD. As of May 2018, 35 states have BD notification laws. Minnesota (MN) currently has a law and North Dakota (ND) previously had an enacted law, however, the law expired July 31, 2017 (Are You Dense Inc., 2018). Most breast density legislation includes a requirement that radiologists inform women in writing of dense tissue in some areas on mammogram. The information included in the written BD notification varies from state to state. How women are interpreting BD

notifications is concerning, particularly rural women with possible low health literacy levels (Gunn, Bataglia, Paasche-Orlow, West, & Kressin, 2018).

Purpose of Project

The purpose of this project was to assess current knowledge and understanding about BD among rural women with known dense breast tissue. Also, to increase healthcare professional's awareness of BD and the increased risk for breast cancer in rural healthcare. The project objectives include:

1. Assess awareness and knowledge about breast density in women presenting for an annual mammogram at two Midwestern rural clinics.
2. Increase awareness about breast density in women presenting for an annual mammogram at two Midwestern rural clinics
3. Inform providers about breast density in women presenting for an annual mammogram at two Midwestern rural clinics and educate providers about breast density risk.
4. Increase readability of breast density notifications by providing feedback of dense breast notification letters at two Midwestern clinic sites.

CHAPTER TWO. LITERATURE REVIEW

The female breast is composed of adipose tissue and fibroglandular parenchyma. On mammography, the fibroglandular parenchyma will appear radiodense, or white, while adipose tissue is radiolucent, or black. Radiodense or white areas are defined as BD, or mammographic dense (MD) breast tissue (Falcon et al., 2017; Vinnicombe, 2017). The BD on mammographic imaging cannot be detected during a clinical breast examination. There can be variations of BD from woman to woman without correlation to breast size, breast texture, or fibrocystic changes (Green, 2016). The degree of BD can mask underlying lesions and is an independent risk factor in the development of breast cancer (Nazari & Mukherjee, 2017, Maimone & McDonough, 2017).

Dense Breast Classification

Radiologists examine mammograms and qualitatively rate dense breast tissue using the American College of Radiology's (ACR) Breast Imaging Reporting and Data System (BI-RADS). A BI-RADS assessment is used to classify BD. Heterogeneously dense and extremely dense breast tissue can obscure a breast mass and compromise the sensitivity of the mammogram. The denser the breast, the greater the chance a breast mass is obscured (D'Orsi et al., 2013).

Radiologist use an A-D scale to grade breast composition and visually estimate the content of fibroglandular-density tissue within the breasts on mammogram (D'Orsi et al., 2013).

The four BI-RADS categories (see Figure 1) of breast composition are:

- Category A Fatty. Denotes breast tissue composed almost entirely of adipose (fatty) tissue with density in the 5-24% range. Ten percent of women in the U.S have BD classified as Category A. The breast tissue appears dark grey or black

with scant light grey or white (fibroglandular tissue) markings on the mammogram.

- Category B Scattered Fibroglandular Density. Encompasses mammograms in which breast tissue is primarily adipose tissues with scattered areas of fibroglandular density. Forty percent of U.S. women have a Category B mammogram. Breast cancer that is similar in appearance to normal breast tissue or is within an area of high BD may be unidentified on mammogram.
- Category C Heterogeneously Dense. Refers to heterogeneously dense tissue with little adipose tissue. Of U.S. women, 40% have mammograms classified as Category C. Category C mammograms raise concern as the large percent of fibroglandular tissue could obscure small masses.
- Category D Extremely Dense. Comprises those mammograms where the breast tissue is extremely dense without or with scant adipose tissue. The remaining 10% of U.S. women of have category D mammograms. Category D density reduces the mammogram sensitivity by as much as 50%, secondary to a “white out” effect on mammogram images.

The term *dense breast* often refers to the breast tissue classification in Category C or D mammograms. There has been no change in the distribution across density categories from 1996 to 2008. (Densebreast-info.org, 2018; D’Orsi et al., 2013; Falcon et al., 2017; Nazari & Mukherjee, 2017; Sprague et al., 2014).

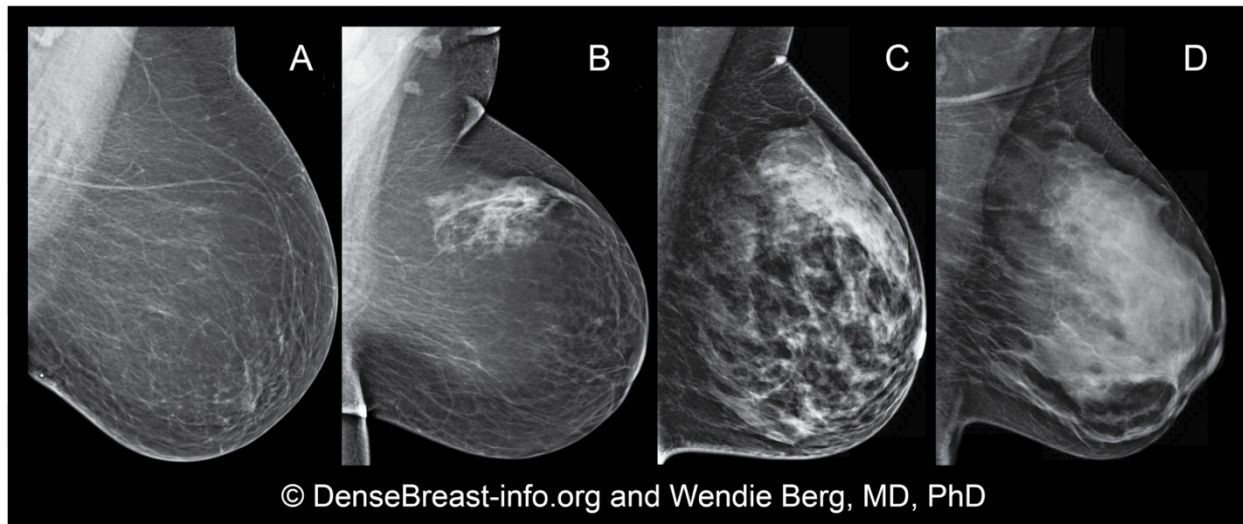


Figure 1. Mammographic Images Representative of the Four Categories of Breast Density. (A) Fatty; (B) Scattered Fibroglandular Density; (C) Heterogeneously Dense; (D) Extremely Dense. Breasts which are (C) heterogeneously dense, or (D) extremely dense are considered “dense breasts”

Risk Factors

An independent risk factor for developing breast cancer is BD. Only two other factors increase the risk of breast cancer more than BD; age and genetic mutations of BRCA1 and BRCA2 genes (Kerlikowske, 2007). In the mid-1970’s, Wolfe (1976) was the first to identify the correlation of BD with an increased risk of breast cancer. Wolfe’s retrospective study revealed that women in the high BD group had a greater incidence of breast cancer than those in the predominantly adipose group. Wolfe found a 3- to 4- fold increased breast cancer risk in women with the densest breasts (Falcon et al., 2017; Green, 2016; Kerlikowske, 2007; Nazari & Mukherjee, 2017; Wolfe, 1976). A study by Boyd et al. (1995) found that women had a 43% increase in relative risk (RR) between categories of BD such as A to B, B to C, and C to D (Boyd, et al., 1995). When comparing BD in women in the highest category to the lowest category, researchers found a 6-fold increased risk of breast cancer (Green, 2016). Boyd et al. adjusted for the effects of other risk factors such as age at menarche, number of live births, maternal age of first child, height, weight, and family history of breast cancer. Boyd et al. also

completed a meta-analysis of 42 studies and found an increased risk of breast cancer associated with BD independent of other known risk factors. However, the study was confounded by age and body mass index. Women in the study were in their late 30's and 40's, younger than women typically screened with mammography; furthermore, researchers did not account for body mass index (BMI) in postmenopausal women. BMI is an important variable, as obesity is an independent risk factor for breast cancer. The risk of breast cancer in women with BD is comparable to that of having a first-degree relative with a history of postmenopausal breast cancer (Densebreast-info.org, 2018; Throckmorton, Rhodes, Huges, Degnim & Dickson-Witmer, 2016).

Authors found that women with a Category D mammogram had a 4- to 6- fold increased risk of breast cancer in comparison to women in Category A (McCormack & dos Santos Silva, 2006). Again, only 20% of women fall into Category A and D whereas 80% of women fall into Category B and C. Therefore, studies compare Category C and D to Category B. When comparing Category C to B the RR is 1.2 and Category D to B the RR is 2.1 (Berg, Pushkin, & Henke-Sarmiento, 2017; Falcon et al, 2017).

A BD of 50% or more may be linked to 16% of breast cancers (Boyd, 2013). The biological process linking mammographic density to the risk of breast cancer is still unknown (Lisanti et al., 2014). One such theory is that fibroblasts promote breast cancer by creating an inflammatory microenvironment, secondary to activated JNK1 stress kinase signaling (Lisanti et al, 2014; Throckmorton et al, 2016). An alternate theory is that extracellular matrix (ECM) proteins affect breast tissue density (Nazari & Mukherjee, 2017; Throckmorton et al, 2016). *Collagen type I* is a major component of the ECM. The increase in collagen increases the stiffness of the breast, thus, inducing proliferation and expansion of normal and abnormal

epithelial cells (Nazari & Mukherjee, 2017; Throckmorton et al, 2016). A third theory hypothesizes that the relationship between fibroblast and epithelial cells in dense breast tissue leads to the development of breast cancer (McCormack & dos Santos Silva, 2006; Nazari & Mukherjee, 2017). Breast cancer begins in the epithelial cells, which may be hidden in the areas of greater fibroglandular (dense) tissue. The areas of density may reflect a greater number of cells that are at risk for carcinogenesis or increased rate of epithelial proliferation (McCormack & dos Santos Silva, 2006; Nazari & Mukherjee, 2017). Understanding the importance of the relationship between BD and the increased risk of cancer for diagnosis and prevention will be important for the future (Lisanti et al., 2014).

Many factors affect the density of breast tissue. In studies of monozygotic and dizygotic twins, heredity played a role in density of breast tissue. Having a mother with dense breasts increased a woman's likelihood of dense breast tissue (Areyoudense.org, 2018; Nazari & Mukherjee, 2017). One study found parity status affects BD. Women who were parous with a larger number of live births under the age of 20, had predominately-fatty breasts, whereas women who were nulliparous or bore children later in life had higher rates of BD (Jones & Stevens, 2014; Nazari & Mukherjee, 2017). Women of Asian descent have higher rates of BD, whereas researchers have found evidence to suggest that women of African American descent have the lowest rates of BD; however, there are conflicting studies that found African American women do not have the lowest rates of BD (Areyoudense.org, 2018; Nazari & Mukherjee, 2017).

In women with different diet patterns, BD can differ. Women who consume a westernized diet pattern had higher BD than those who followed other diets. Also, there is an association between protein and fat intake and increased BD. Women who have an intake of seven alcohol servings per week and a BMI < 25kg/m², have 17% higher BD than non-drinkers.

Women with higher BMI's may have fattier breast tissue, however obesity does not change the percentage of fibroglandular tissue in the breast. Women with lower a BMI were more likely to have denser breast tissue than those with higher a BMI. Furthermore, BMI and BD are separate risk factors. Prior to menopause, a woman with a low BMI will have an increased risk for breast cancer. Post-menopausal women with an increased BMI have an increased risk for breast cancer. The increased risk is thought to be due to higher levels of estrogen produced by fatty tissue (Jones & Stevens, 2014; Nazari & Mukherjee, 2017; Vinnicombe, 2017).

Hormone replacement therapies (HRT), specifically combined HCT (estrogen/progestogen) therapy, are associated with higher BD after treatment in premenopausal and postmenopausal women. The Women's Health Initiative Trial found women had a 1% increase in BD one year after HRT discontinuation. Moreover, breast cancer risk increased by 3%, and women in the study with extremely dense breast tissue had a 3-fold increased risk of breast cancer (Nazari & Mukherjee, 2017; Vinnicombe, 2017).

A woman's age also affects BD. Younger females are more likely to have dense breasts due to the predominance of fibroglandular tissue. As a woman ages, adipose tissue replaces the atrophied fibroglandular breast tissue. In women <50 years old, breast tissue is approximately 56% fibroglandular, and BD decreases to 40% in women ages 50 to 59, and 25% in women 60 or older (Berg et al., 2017; Boyd, 2013; Jones & Stevens, 2014; Sprague et al., 2014; Vinnicombe, 2017).

Screening Recommendations and Options

Various imaging modalities are used to screen dense breast tissue. Mammography is the current gold standard for breast cancer screening in all women since the 1980's. Mammography is the only proven modality to reduce breast cancer related mortality with an average sensitivity

rate of 85% in detection of breast cancer (Falcon et al., 2017). Mammography uses low-dose x-rays of the breast. During a mammogram, a woman's breast is compressed in two distinct positions while x-rays of the breast are taken. The images consist of a craniocaudal (CC) view wherein the horizontally compressed breast is viewed from above and the mediolateral oblique (MLO) view in which lateral compression of the breast is viewed from the center of the chest toward the outer chest. Radiologic images are better when the breast tissue is compressed. (Densebreast-info.org, 2018; Jones & Steven, 2014). The standard mammogram is a 2-D mammogram and in the form of film (analog) or digital (full field digital). The difference is that digital uses an electronic detector system to computerize and display the image (Densebreast-info.org, 2018). Digital mammography (DM) is preferred over film. However, in women with predominately-adipose breast tissue, the digital mammography can obscure 12-22% of breast cancers and the percent rises to 50% in women with extremely dense breast tissue (Falcon et al, 2017; Freer et al., 2015). A 2-D mammogram detects two to seven breast cancers per 1000 women screened using ionizing radiation with a recall (women who need more testing) number of 100 (Densebreast-info.org, 2018).

Digital breast tomosynthesis (DBT), or 3-D mammography, is an emerging technology in screening for breast cancer in women with BD. The FDA approved DBT in February of 2011 as an adjunct breast cancer screening tool (Falcon et al., 2017). DBT is a specially equipped digital mammography machine that compresses the breast like standard mammography, however, instead of a single image, the machine arcs over the breast to capture multiple images of the breast tissue in thin 1-mm slices. The thin image slices are reconstructed into 3-D images, which allows for better discrimination of breast tissues structures and lesions (Phi, Tagliafico, Houssami, Greuter & deBock, 2018). Currently, DBT is performed as supplemental imaging

with 2D mammography, resulting in twice the radiation dose. If DBT is used alone, the radiation dose is comparable or lower than a 2D mammogram (Jones & Stevens, 2017). Many studies have shown the increased sensitivity and specificity of 2D mammography with DBT screening in women with dense breast tissue. For instance, the Oslo Tomosynthesis Screening Trial of 3D mammography found a 27% increase in cancer detection rates (CDR) in all categories of BD and a 15% decrease in false-positive recall rate using combined DBT +2D mammography (Skaane et al., 2017). A population-based STORM-2 screening study found a 34% increase in CDR across all age groups and categories of BD and a 17% decrease in false-positive recall rates using combined DBT +2D mammography (Bernardi et al., 2016). Another population-based Malmö breast tomosynthesis screening trial found a 15% increase in sensitivity with combined DBT +2D mammography and an increase in recall rates from 2.6% to 3.8% (Lang, Nergarden, Andersson, Rosso, & Zackrisson, 2015). Friedewald et al. (2014) conducted a retrospective study in the U.S. that compared performance before and after the introduction of DBT +2D mammography and found a 29% increase in CDR (Friedewald, 2014). Another retrospective study, the TOMMY trial showed a 2% improvement in CDR with DBT + 2-D and an increase in 11% specificity (Gilbert & Selamoglu, 2018). A systematic review and meta-analysis conducted by Phi et al. (2018) found that the CDR of DBT was superior to digital mammography (DM). Additionally, the authors noted that DBT with or without DM increased sensitivity but did not change specificity. A significant reduction in recall rates were found when using DBT with DM. The 2-D mammogram plus DBT found three to nine breast cancers per 1000 women using ionizing radiation with a call back number of 70 (Densebreast-info.org, 2018). Overall, an improved CDR and reduced recall rate from DBT may suggest a more effective screening method for women with dense breast tissue (Phi et al, 2018).

Whole breast ultrasonography (WBUS) is another option for women with BD that is widely available, reproducible, and cost-effective. WBUS uses high-frequency sound waves to form an image of internal structures of the breast. Screening ultrasound examinations are performed using two methods. One method is by a trained technologist or radiologist who moves the transducer by hand; this type is referred to as hand-held ultrasonography. In the second method, the technologist uses an automated device referred to as automated whole breast ultrasound (ABUS). The FDA approved ABUS in September 2012 to be used as an adjunct with mammography. A multicenter study ASTOUND trial evaluated CDR of tomosynthesis and radiologist performed hand-held WBUS after negative findings on 2-D mammogram among women with Category C and D breasts. Adding tomosynthesis found an additional 13 breast cancers per 1000 screens whereas WBUS found 23 additional breast cancers per 1000 screens. WBUS has a low false-positive recall and biopsy rates (Tagliafico et al, 2016). The ASTOUND trial found that false-positive recall rates for tomosynthesis and ultrasonography were 1.7% and 2.0% respectively and false-positive biopsy rate was 0.7% for both groups (Tagliafico et al, 2016). WBUS offers an affordable option for detection of small masses without using added radiation or intravenous contrast. Literature strongly supports WBUS; however, the use of WBUS is still limited due to operator variability, shortages of trained personnel, and reduction in radiologist efficiency for image acquisition (Falcon et al, 2017). 2-D mammogram plus WBUS found four to eleven breast cancers per 1000 women using sounds wave with a call back of 170 to 230 (Densebreast-info.org, 2018).

The most sensitive imaging modality for dense breast tissue is magnetic resonance imaging (MRI). A breast MRI requires gadolinium-based intravenous contrast and creates a cross-sectional image that differentiates soft-tissue contrast between adipose, fibroglandular

tissue, and lesions in the breast (Densebreast-info.org). An MRI will show blood flow. Cancerous tumors usually have an increased abnormal blood flow (Densebreast-info.org, 2018; Falcon et al, 2017). Falcon et al. (2017) in a systemic review suggest there is a benefit for obtaining MRI in high-risk women with a >20% lifetime risk for breast cancer (Falcon et al., 2017). Falcon et al. (2017) reported a specificity rate of 86% for MRI with a callback rate of ten times higher and biopsy rates 5 times higher than with mammography alone. Benefits of MRI screening should be weighed against risk and limitations. Some women are unable to have an MRI due to gadolinium allergy, compromised renal function, or pregnancy. Contraindication to MRI imaging includes presence of a pacemaker/defibrillator or any metallic foreign body, and claustrophobia (Falcon et al, 2017; Densebreast-info.org, 2018). Cost is another barrier to MRI, with an average of an added \$1200 to the cost of annual screening. MRI is 2.5 times more expensive per life-year gained (Falcon et al, 2017; Gentry, 2018). 2-D mammogram plus MRI found 12-17 or more breast cancers per 1000 women using magnetic field and intravenous contrast with a callback rate of 160 to 220 (DenseBrest-info.org, 2018).

In the U.S., major guideline organizations differ about the method of breast cancer screening in women with dense breast tissue. The Screening recommendations for women at average risk for breast cancer from the leading U.S. organizations are summarized in Figure 2. Organizations include The American College of Radiology (ACR)/Society of Breast Imaging (SBI), American Cancer Society (ACS), American College of Obstetricians and Gynecologist (ACOG), American Medical Association (AMA), National Comprehensive Cancer Network (NCCN), and United States Preventative Task Force (USPTF). Preferably, the when and how of breast cancer screening is a joint decision made by the provider and the informed patient. A joint

decision-making model incorporates the patient’s feelings as well as personal and familial risks for breast cancer.

Breast Cancer Screening Guidelines – Comparison

	ACR/SBI	ACS	ACOG	AMA	NCCN	USPSTF
Age to Start Mammography ^a	40	45 Option to start at age 40	Offer at 40, not later than 50	40	40	50
Age to Stop Mammography	No age limit; tailor to individual health status	When life expectancy is < 10 years	Age 75, then shared decision	Not stated	Not stated	74 years
Mammography Interval	Annual	Annual 45-54; Every 1 or 2 years 55 and older	Every 1 or 2 years	Annual	Annual	Every 2 years
View on Tomosynthesis (3D) Mammography	Improves cancer detection, reduces recall rates	Improvement in detection, lower chance of recall	Not stated	Not stated	Improves cancer detection, reduces recall rates	Insufficient evidence to support routine use; grade “I” © DenseBreast-info.org

Rev. March 2018

^a In a 2018 analysis from Harvard*, not considered in the current guidelines, black, Hispanic, and Asian women have peak incidence of breast cancer in their 40s and should begin screening at least by age 40. *Stapleton SM, Oseni TO, Bababekov YJ, Hung Y, Chang DC. Race/Ethnicity and Age Distribution of Breast Cancer Diagnosis in the United States. *JAMA Surg.* Published online March 07, 2018. doi:10.1001/jamasurg.2018.0035

Resources

- ACR/SBI** [Breast Cancer Screening for Average-Risk Women: Recommendations From the ACR Commission on Breast Imaging, 2017](#)
See also: [Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR, 2018](#)
- ACS** Oeffinger KC, Fontham ET, Etzioni R, et al. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. *JAMA.* 2015;314(15):1599-614. <https://www.youtube.com/watch?v=6SKh6Tm2HZs&feature=youtu.be>
- ACOG** <https://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Breast-Cancer-Risk-Assessment-and-Screening-in-Average-Risk-Women>
- AMA** Action of the AMA House of Delegates 2012 Annual Meeting: Revisions to AMA policy H-525.993 "Mammography Screening in Asymptomatic Women Forty Years and Older". Adopted 06-19-2012. Available at: <https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-science-public-health/a12-csaph6-screeningmammography.pdf>
- NCCN** NCCN Guidelines Breast Cancer Screening and Diagnosis Guidance PDF v.2.107, 6/2/17
- USPSTF** Siu AL, on behalf of the U.S. Preventive Services Task Force. Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2016;164:279-296. doi:10.7326/M15-2886

Figure 2. Screening Guide Comparison by Densebreast-info.org

Dense Breast Notification Legislation

The intention of breast density notification legislation is to inform women of their breast density, so they are better informed to make decisions on whether to undergo supplemental screening (Jones & Stevens, 2014). Nancy Cappello, PhD was diagnosed with stage III breast cancer within a few weeks after a normal mammogram (Cappello, 2013). Dr. Cappello was a healthy woman who exercised daily, had yearly mammograms, and no family history of breast cancer. Her diagnosis came as a shock and upon further investigation, learned that her

mammogram showed she had extremely dense breast tissue. Dr. Cappello initiated a grass roots movement to notify women of their dense breast tissue after mammogram and the limitations of mammography. In 2009, Connecticut was the first state to pass the *Breast Density Notification Law* (Cappello, 2013). Now there are 35 states, which have passed dense breast notification laws. MN passed their law on July 1, 2014. ND's law was passed on April 9, 2015 however expired on July 31, 2017 due to a sunset provision (Areyoudense.org, 2018). ND currently has efforts for breast density reporting and education despite not having the require notification (Densebreast-info.org, 2017).

If a woman has either Category C or D breasts, a state-mandated notification letter is sent to the woman with the principal message that increase breast density can obscure signs of malignancy on a mammogram. Notification content varies from state to state. Inconsistencies exist as dense breast notifications do not have a standard in letter wording, utilization of supplemental screening, counseling of patients, and recommendations for follow-up (Maimone & McDonough, 2017). Notifications include information that dense breast tissue may increase the risk of breast cancer however do not show to what extent, leaving women to interpret the notification for themselves (Yeh et al., 2015). MN and ND do not mandate specific language in their notification letters to women who have dense breast tissue. Most notifications have language to the effect that dense breast tissue can mask "cancer" or "abnormality" and that density is a risk factor for breast cancer. Both states do not include a personal breast density category or mention supplemental screening tests (Densebreast-info.org, 2018).

The Breast Density and Mammography Reporting Act was introduced on October 25, 2017 with an aim to standardize the communication of dense breast tissue and recommend that women talk to their health care provider whether they might benefit from added screening. As of

October 2018, the bill is not legislated (Areyoudenseadvocacy.org, 2018). Breast density laws aim to empower women with knowledge about the significance of breast density. One concern with legislative notification is an increase in women's anxiety, which could lead to rash decisions, distress, and increased medical costs (Stevens & Jones, 2014). Yeh et al. (2015) found that women's anxiety was a major factor in the intention to screen for breast cancer. A survey conducted by Trinh et al. (2015) found that most women do not know about their breast density and would want to be informed if they had dense breasts. The study also reported that women are interested in knowing about their dense breast tissue despite the increase likelihood of undergoing procedures, an increase in false-positive tests, and out-of-pocket expenses, as most supplemental exams are not covered by insurance (Trinh et al., 2015; Cappello, 2013). Another issue is that breast density interpretation is subjective. BD is reported by radiologists using 2-D digital or film mammography and using the ACR's BIRADS system (Cappello, 2013).

Women's Knowledge of Dense Breasts and Cancer

In the U.S. 27 million women, aged 40 to 74 have dense breast tissue (Gunn et al, 2018). The majority of state notifications inform women that having dense breasts increases cancer risk and all notifications mention that having dense breasts can mask breast cancer on mammogram. Does legislation increase the awareness of breast density and knowledge? One survey noted that 42% of women reported they were not aware of the significance of the term "breast density" (Rhodes, 2018). Gunn et al (2018) found that awareness varies by patient factors such as race/ethnicity, income, health beliefs, and the setting such as academic versus county hospitals (Gunn et al, 2018). A common research finding is that women without a college degree, non-Caucasian women, and women living in areas with lower median incomes were significantly less likely to have knowledge about BD (Gunn et al., 2018; Manning et al., 2013; Moothathu et al,

2016; Rhodes, 2018). A survey by Rhodes (2018) found that when comparing knowledge of BD by U.S. regions, the Midwest women were the least informed (55.9%). Connecticut women had the highest BD awareness (81.4%) than any other residents of the U.S. Rhodes (2018) suggested that BD “awareness” does not translate to women’s knowledge about how BD reduces mammography sensitivity or increases breast cancer risk (Rhodes, 2018).

Rural Women and Breast Cancer

Rural women are less likely than urban women to use preventative services as recommended by national guidelines. One of those preventative services is cancer screenings. Research has consistently shown that low socioeconomic status (SES), a lack of insurance coverage, not having a usual source of care, and geographic distance to care are associated with underutilization of preventative health services (Weaver & Gjesfjeld, 2014). Rural residents have lower incomes, are less educated about health-related issues, are more likely to be underinsured or uninsured, and often travel longer distances for health care than urban women residents (Depke, Boreen, & Onitilo, 2013; Peppercorn et al., 2015). Due to the reasons listed above, rural women are less likely than urban women to receive preventative services (Weaver & Gjesfjeld, 2014). When it comes to knowledge and awareness of breast cancer, research indicates that the majority of rural women have heard of breast cancer. However, rural women were not clear about what age to begin or how often to have mammography. According to Davis et al. (2012) if rural women had a breast cancer diagnosis, they would want to know. For rural women, the main barriers to screening were the physical discomfort of the mammogram or a perceived lack of time in their busy schedule or have the mammogram. Interestingly, one in three rural and urban women denied receiving information or education about breast cancer screening with mammography and were unclear at what age to start screening (Davis et al, 2012;

Peppercorn et al., 2015). According to Peppercorn (2015), the fear of discomfort and the perception of “too busy” are modifiable behaviors improved through education and screening reminders.

Health Literacy

Health literacy is a key factor in decision making about preventative screening tests. Individuals with low health literacy have difficulty understanding, obtaining, and recalling health information (Halverson et al., 2013). Low health literacy is associated with a decreased probability of mammography screening and an inadequate understanding of the complex information about breast cancer (Halverson et al., 2013). Health literacy has been associated with lack of insurance, lower SES, and lack of usual source of care (Halverson et al., 2013). BD notification letters are often written at a higher reading level. Using the Flesch-Kincaid readability scoring, Gunn et al. (2018) found that BD notification letters were written at a mean grade of 10.5, while letters in Minnesota averaged a grade of 12.6. The recommended readability for health information is grade 7-8; however, 20% of the population reads below a grade 5 level (Kressin, Gunn, & Battaglia, 2016). Health information written at greater than a grade 8 level can result in misinterpretation that may influence the women’s beliefs, attitudes, knowledge, and participation in follow-up care. Gunn et al. (2018) surveyed 58 women from Boston Medical Center in Massachusetts and found that women had little understanding of the concept of BD despite the notification (Gunn et al., 2018). Women in the survey admitted to making up their own definition of dense breast tissue. The definitions were often inconsistent with current medical knowledge (Gunn et al, 2018). Rural women are at higher odds of having lower health literacy, which may result in decreased preventative breast screening and inadequate knowledge of BD.

Women prefer verbal communication with their primary care provider. However, research has shown that providers do not feel prepared to discuss BD and supplemental screening (Gunn et al., 2018). A multisite survey of all Mayo Clinics (Minnesota, Arizona, and Florida campuses with 70% from Minnesota) found that 68% of providers were aware of BD notification (Maimone et al, 2017). Seventeen percent of providers felt “very comfortable,” 36% “moderately comfortable,” 30% “slightly comfortable,” and 17% were “not comfortable” answering questions about breast density. Forty-four percent of providers reported a formal education or directive from an employer about interpreting BD notification and ordering supplemental screening... Providers participating in the study showed a clear desire to gain more knowledge about BD. Additionally, 50% of providers were unaware if their patient had returned for the recommended supplemental screening, which may suggest a lack of patient understanding, failed patient-provider communication, system flaw in arranging follow-up, or the cost of supplemental screening (Maimone et al, 2017).

Theoretical Framework

Nola Pender’s Health Promotion Model (HPM) is a framework for understanding an individual’s major determinates of health and how to motivate an individual to engage in healthy behaviors. Pender first published the HPM in 1982 and revised the model in 1996. HPM’s philosophical roots are based on how individuals interact with their environment and how they shape their environment to fit their goals and needs. Pender used the expectancy value theory and the social cognitive theory for HPM’s theoretical roots. Five key concepts of HPM are person, environment, nursing, health, and illness. The three main components are individual characteristics and experiences, behavior-specific cognitions and affect, and behavioral outcomes. HPM’s central focus is on eight beliefs that are accessible points of interventions to

improve healthy behaviors. The eight beliefs are prior related behavior, perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related affect, interpersonal influences, situational influences, and commitment to a plan of action. The HPM model as adapted for assessing rural women’s knowledge of dense breast tissue as illustrated in Figure 3. (Pender, 2011; Pender, Murdaugh, & Parsons, 2015).

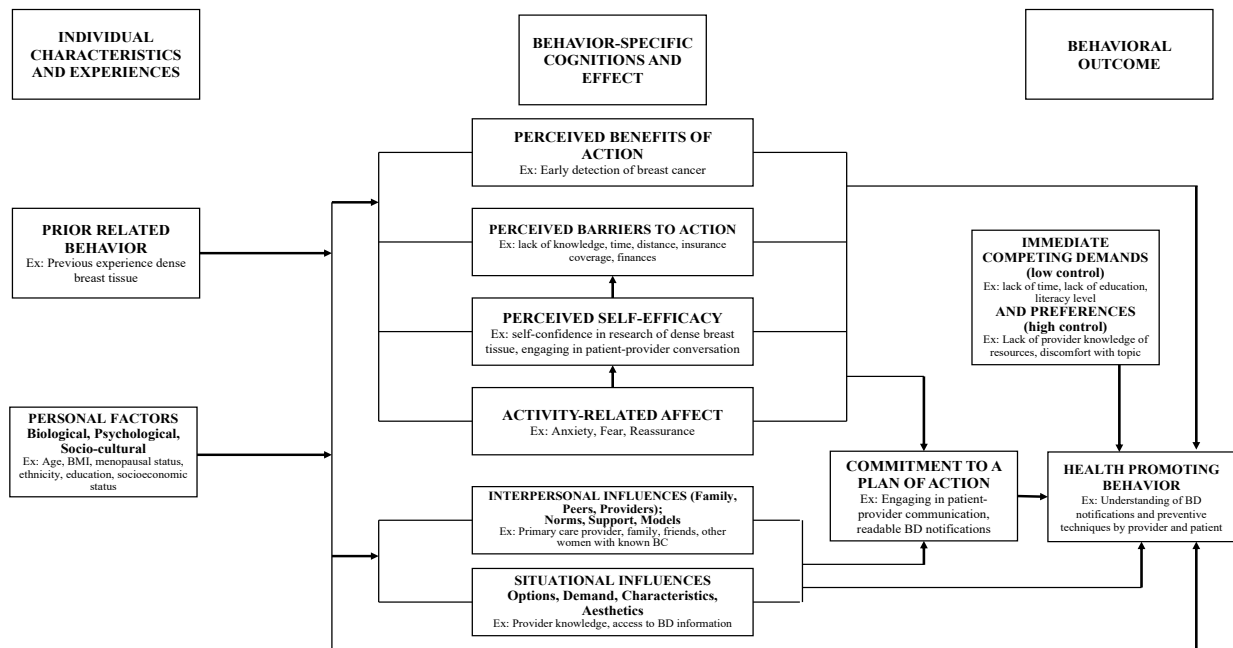


Figure 3. Nola Pender’s Health Promotion Model. Adapted for Assessing Rural Women’s Knowledge of Dense Breast Tissue. Used with permission from Nola Pender, PhD, RN, FAAN. Copyright 1996. For permission to use or reproduce the model, please contact the University of Michigan School of Nursing, or follow this link: <http://deepblue.lip.umich.edu/handle/2027.42/85351>.

Project Framework

A simple model for quality improvement projects is the Plan-Do-Study-Act (PDSA) developed by Associated in Process Improvement. The PSDA model is an effective and powerful tool used to guide projects and accelerate improvement in an organization. When

planning a quality improvement project using PDSA there are three fundamental questions one needs to ask. The questions consist of:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What change can we make that will result in improvement?

When the project team finds the answers to the three questions, project planning can begin. The first step is to *Plan*, the second step is to *Do*, the third step is to *Study* or Evaluate, and the fourth step is to *Act*, or revise based on the earlier three steps. The PDSA is cyclic and always occurs in a forward motion. (Donnelly & Kirk, 2015; Institute for Healthcare Improvement, 2018).

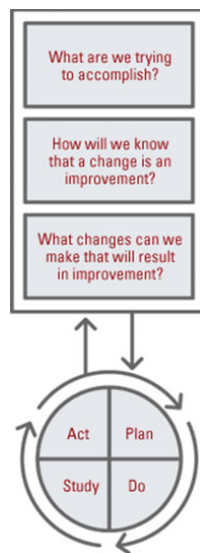


Figure 4. PDSA Model (AHRQ, 2015).

Fundamental Questions

What the PIP is trying to accomplish is an increased awareness about the significance of BD in rural women, knowledge, and awareness of BD, and how can to improve BD notifications. The change will be effective if there is a need for improvement of a more readable BD notifications, women are communicating with their providers about BD and their risk for breast

cancer, and an increase in knowledge and awareness of BD. The change could result in improved understanding of dense breast notification by rural women, improved patient-provider communication about dense breast tissue and risk for breast cancer and improve breast cancer screening in women with dense breast tissue.

PDSA Steps

The PDSA model is a four-step cyclic model, which can be repeated multiple times until the desired outcome is achieved. The first step is *Plan*. Project planning will include organizing the team, setting, and receiving institutional review board approval. During the Plan step, the objectives of the project are clarified for the team to help predict barriers and to plan the project. The second step is *Do*. The project will be completed on a smaller scale with a limited samples size at two different rural clinical sites. The clinic sites are in ND and MN. Step three is *Study*. During this phase, time will be set aside to analyze the collected information and feedback from the project. BD notifications will also be analyzed on content and readability. Analysis of the information from the team and patients will be compared to the predicted information. Next, the analysis of the information will be summarized and reflected on what was learned from the Do. The last step to make changes is the *Act* step. Project changes will be made based on what was learned from the Do. Modifications will be done during this phase along with plans to prepare for the next step (Donnelly & Kirk, 2015; Institute for Healthcare Improvement, 2018).

CHAPTER THREE. PROJECT DESCRIPTION

The overall project goals are to increase awareness and knowledge about BD for women and provider at two Midwestern rural clinics. Women who are presenting for their annual mammogram at the rural clinics were assessed about their awareness and knowledge. Afterwards, personalized education for each woman was completed by the co-investigator. Dissemination of the results were presented to the providers at each clinic. An educational session on BD risk was presented for providers at each rural clinic. Finally, BD notification for each rural clinic were assessed and revised as necessary for increased readability.

Project Design

The PDSA model was used to guide the project design. The *Plan* stage involves how to assess rural women's knowledge about BD, identifying stakeholders, approval of the North Dakota State University (NDSU) dissertation committee, Institutional Review Board (IRB) approval, and identification of the target population. Evaluating rural women's knowledge of BD was accomplished by a face-to-face interview with women with known dense breast tissue at two rural clinics located in ND and MN. Interview questions were taken from the Rhodes et al. (2015) Mayo Clinic Breast Density Awareness and Knowledge Survey and constructed by the co-investigator (Appendix A.). After informed consent, a face-to-face interview followed.

The project stakeholders included the co-investigator, clinic administrators, and three primary care providers currently practicing at rural clinics in Fosston, MN and Northwood, ND. The provider stakeholders consisted of a PA-C and two FNP-C. A radiology manager at each of the rural clinics were provided information on BD notification. Other supporters were the radiology staff, ancillary staff, such as clinic nurses and aides, and patients at each rural facility.

The *Do* stage involved assessing rural women's knowledge about BD via an interview from women in rural healthcare facilities. The interview consisted of demographics and open-ended questions to obtain information about women's knowledge of BD. Participants are women, aged 40 to 80 years, with known dense breast tissue who presented to the rural clinics for a scheduled mammogram. The co-investigator traveled to the two rural clinic sites to recruit and interview rural women who had appointments or were at the clinic for mammography. The interviews transpired via paper format questionnaire with predetermined questions (Appendix A). One interview question was open-ended allowing personalized responses. Interviews were planned over three 8-hour days in each rural facility with the goal of interviewing 25 to 50 women. An appreciation gift was given to women upon completion of the interview. The gift promoted breast cancer screening in the form of a pink pen and monthly pocket calendar obtained from Positive Promotions and paid for by the interviewer. The BD notifications for each clinic were reviewed using two different scales (Flesch-Kincaid Grade and Flesch Reading Ease score).

The *Study* step consisted of analyzing and summarizing the information collected through the interviews. The analysis and summary of the data was planned and completed within a month of data collection. The objectives were evaluated to determine if they were met by the co-investigator. Project outcomes are evaluated and revised in the last step of the PDSA model, *Act*.

Setting

The physical setting for the project included two rural clinics in Midwestern communities. The clinic sites are family-oriented primary care rural clinics. Participants were women aged 40 to 80 years with known dense breast tissue who consented to an interview with the co-investigator. Face-to-face interviews consisted of predetermined and impromptu yes/no

questions, along with open-ended questions about BD. Educational information was provided to participating women that consisted of a pamphlet from Densebreast-info.org. Provider education included a presentation over the noon break. The coinvestigator provided a PowerPoint presentation, a printed list of online resources, and informational pamphlets from densebreastinfo.org.

Timeline

The timeline was outlined as such:

- November 2018 to December 2018: Collected information via face-to-face interviews from rural women. Educated women during the interviews on BD.
- January 2019: Analyzed collected information from rural women.
- February 2019: Disseminated information collected and educated providers on BD at the two rural clinics. If applicable, provided revised BD notification to each rural clinic.

CHAPTER FOUR. EVALUTION

The PDSA model was used for a framework to plan, execute, analyze, and act on what was learned in the PIP. The PIP went through one cycle of the PDSA model. Evaluation of the project involved a determination of objective outcome.

Objective One Evaluation

Objective one: assess awareness and knowledge about BD in women presenting for an annual mammogram at two Midwestern rural clinics. The evaluation of objective one was through a questionnaire and a face-to-face interview with women presenting for an annual mammogram. Participating women's BD knowledge was assessed through a series of prepared questions. The BD questionnaire had 37 questions. There were eight demographic, nine breast history, two knowledge of breast density masking effect on breast cancer, seven sources of dense breast information, and 11 opinions related to breast density questions (Appendix A). Interview questions were taken from the Rhodes et al. (2015) Mayo Clinic Breast Density Awareness and Knowledge Survey and modified by the co-investigator. Permission was granted from the authors to use the Rhodes et al. (2015) survey (Appendix D). According to Rhodes et al (2015), the authors were among the first to provide a U.S. representative estimate of BD awareness and knowledge among women who are eligible for mammogram screening. The questionnaire consisted of yes or no questions, multiple-choice answers, and one open-ended question regarding BD. The questionnaire was presented to participants in a paper format on a clipboard with a pen/pencil. At the completion of data collection, the results were analyzed using simple inferential statistics due to the small sample size. Results and interpretation can be found in Chapter 5 & 6.

Objective Two Evaluation

Objective two: increased awareness about BD in women presenting for an annual mammogram at two Midwestern rural clinics. The co-investigator provided educational material and resources on BD for women at ND and MN clinic sites. Education and distribution of BD information occurred after completion of the questionnaire. The co-investigator provided personal education on BD based on the woman's risk factors and history found from the questionnaire. Data was presented in aggregate form to providers and stakeholders to protect participant anonymity. Participants received a two-page handout regarding facts on BD and internet resources (Appendix L). If women had further questions, women were given internet resources for independent education on dense breasts. Internet resources included links for Susan G. Komen, Densebreast-info.org, Center for Disease Control (CDC), and the ACS (Appendix L). The co-investigator provided each rural clinic with copies of the handout, which could be used for further use and distribution if so desired by the providers to other patients. Evaluation of learning was completed via the teach-back method to assure understanding of where to find education and resources on BD.

Objective Three Evaluation

Objective three: inform providers about BD in women presenting for an annual mammogram at two Midwestern rural clinics and to educate providers about BD risk. The co-investigator increased providers' knowledge and awareness of rural women's knowledge regarding BD through a PowerPoint presentation on dense breast tissue, dissemination of questionnaire results/feedback, and by providing a dense breast fact sheet. A forty-five-minute PowerPoint presentation was given to the providers and stakeholder over the noon break at each rural clinic. The presentation included the information from the questionnaire and the face-to-

face interviews with rural women participants. Invitations were sent to stakeholders and flyers were posted in the clinics for notification of the presentation. Evaluation of the presentation included feedback from providers after the educational presentation. Disseminating the information on rural women's knowledge of BD provided discussion on how to improve patient-provider communication about BD and preventative screening techniques. The educational handout (Appendix K) and a copy of the PowerPoint presentation (Appendix J) on BD were provided for healthcare professionals at the rural clinic sites as resources for future use.

Objective Four Evaluation

Objective Four: evaluate the readability of BD notification letters at two Midwestern rural clinics. The co-investigator completed clinical hours within each rural clinic for which the PIP was being conducted. Professional contacts at each clinic included previous and current preceptor. Essentia Health IRB waiver was obtained by the Research Compliance Administrator and the imaging manager at Essentia Health agreed to sponsor the PIP. The sponsor supported the co-investigator with the PIP by providing BD information from the organization and providing feedback with BD notifications. The co-investigator, with the oversight of the primary investigator reviewed each clinic's current BD notification letter. The letter was assessed for health literacy appropriateness, use of evidence-based information, and ease of understanding. The letter was assessed for health literacy using the Flesch-Kincaid Grade, Flesch Reading Ease score, and the CDC Clear Communication Score by the co-investigator. The co-investigator determined that the current BD notification letter template was not written at the recommended literacy level or that the information contained within the letter was not reflective of up-to-date, evidence-based information. Current mammogram result letters with BD notification were evaluated for readability and revised as necessary to a seventh-grade reading level. The co-

investigator prepared a prototype letter with recommended changes to each rural clinic and shared stakeholders of the PIP.

Protection of Human Subjects

North Dakota State University (NDSU) IRB approval was granted for a pilot study for increasing awareness of the role of BD as an independent risk factor for breast cancer (Appendix E). The human subjects involved in the PIP included healthcare providers, nursing staff, and women at two rural Midwestern clinics. Participants, from whom data was collected, received an informed consent form (Appendix G). The coinvestigator was present to answer questions about the informed consent. Additionally, participants received contact information for the investigator and co-investigator, in case the participant had questions or comments in the future. Interview participants received an informed consent letter (Appendix H) prior to the interview. Participants were promised confidentiality of their responses and information. The co-investigator knew the women's names at the interview. Participant names were not recorded or linked to the questionnaire. The participants' names were not included in the questionnaire demographic information. The request demographic information included age range, residing state, and educational level. Only aggregate results were shared in the co-investigator's presentation to providers and staff at the clinics. Additionally, any published or future presentations will include just aggregate results. The responses were placed in a manila envelope that was stored in a locked box. Participants chose either a breast cancer awareness pen or a breast cancer monthly pocket calendar as an appreciation gift for participating in the project. No special precautions were taken to exclude or include minorities. Inclusion criteria for participants was a) females, b) between the ages of 40-80 years of age, c) scheduled for a

mammogram at one of two rural Midwestern clinics presenting to one of two Midwestern clinics for an annual mammogram.

Over the clinic's noon lunch break, the co-investigator delivered an educational presentation on patients' awareness of BD and the risk associated with BD. Providers were given the option to complete an evaluation form at the end of the presentation. Providers were asked not to write identifying information on the evaluation form. After the presentation, the co-investigator was available for feedback and left a contact number for additional question. Clinic providers and other ancillary staff were provided with snack items and the option to choose either a breast cancer awareness pen or a breast cancer monthly pocket calendar gift. A potential barrier on the providers' behalf may have included additional time spent with each patient. Potential risks for the interview participants were the possibility of experiencing some psychological distress about increased risk of breast cancer in the participants with Category C or D. Another potential inconvenience due to potential mammogram results was if the interview participant wanted additional supplemental imaging, as this may have placed a financial stress on the participant, depending upon her insurance coverage.

CHAPTER FIVE. RESULTS

The framework used for the project was the PDSA model. The model is intended to be used cyclically until the desired outcome is achieved. The PIP used only one cycle of the PDSA model.

Results

Women

Data was collected from two rural clinics. The co-investigator worked with the mammography technicians to schedule dates and times to travel to Clinic A. Others included on the team were the mammography technicians and the clinic nurse supervisor. Mammography technicians were informed of the project's aims before the start of the data collection. The clinic nurse supervisor was contacted at Clinic A to set up a provider educational session on BD over the lunch hour. The co-investigator provided her with the BD education PowerPoint (Appendix J) and copies of the provider handout (Appendix K).

The clinic manager at Clinic B was contacted for approval of the project at the facility. The co-investigator worked with the clinic manager, reception staff, and the radiology manager. The clinic manager was informed of the project objectives before the start of data collection. The clinic manager provided the date and time for the mobile mammography truck and census for women scheduled to receive mammograms. The mobile mammography truck is available one day a week, every other week at the Clinic B. The clinic manager suggested a mailing for women before their scheduled mammogram (Appendix H). The reception staff at each site were informed of the project plan and were designated to inform women of the project before their scheduled mammogram. The co-investigator contacted the clinic manager at Clinic B to set up a provider educational session on BD over the lunch hour. The co-investigator provided the

informational technologist with a copy of the BD education PowerPoint and copies of the provider handout.

The co-investigator visited the rural clinics on four different days to collect data from women. Data collection for the breast density questionnaire was completed on December 20, 2018, and January 7, 8, 10, and 11 of 2019. Thirteen women completed the survey from both rural sites. The mammography technician would inform women who were 40 to 80 years of age about the co-investigators project before their scheduled mammogram. Afterward, if the women were open to taking part, they were walked to an office room where the co-investigator obtained consent. After providing consent, the women filled out the questionnaire. The co-investigator was present to help answer questions about the survey. After completion of the questionnaire, the co-investigator reviewed the answers and offered a personalized BD education based off of the women's current understanding of BD. Women were encouraged to take an educational BD handout (Appendix L) and were provided with an appreciation gift option of a women's breast health monthly calendar or breast cancer awareness pen.

Providers

An educational BD presentation was given on January 17th, 2019 to providers and staff at Clinic B. In attendance were the primary investigator, two primary care providers, the clinic manager, and five staff members. The educational BD presentation for Clinic A was given on January 24th, 2019. In attendance were one primary care provider, four staff members, and two medical professional students. In each presentation, the BD PowerPoint was discussed and questionnaire results were disseminated to the audience. Each audience member was provided with a copy of the provider educational BD handout along with the educational BD handout that

was given to the participants. There was no feedback with presentation evaluations. After the presentation, the co-investigator allowed for open-discussion for any questions.

Breast Density Notifications

The rural clinic sites were located in MN and ND. Currently, MN is required by law to notify women of the BD while ND's BD notification law expired in July of 2017. Both dense breast notifications were collected from the two Midwestern clinic (Appendix M and O). Each BD notification was evaluated using the Flesch-Kincaid Reading Ease Score and the Flesch-Kincaid Grade. The Flesch Kincaid Reading Ease scores the text on a scale from 0 to 100. The lower the score, the more difficult the writing is to read, whereas the higher the score, the easier the text is to understand. An eighth-grade level is a score of 60 or greater. The Flesch-Kincaid Grade scores the text to correspond to the U.S. grade level. Microsoft Word has these readability scales incorporated into their software and is accessible to users. The CDC's Clear Communication Index was also used to assess the clarity of the dense breast notifications. The CDC recommends that if the score is higher than a 90 the material presented is easier to understand and use by the public. If the score is less than an 89, the CDC recommends a revision of the material until the index score is higher than 90. The Modified CDC Clear Communication Index Score Sheet was used to assess both BD notifications.

Data Analysis

Objective One Results

Objective One was to assess awareness and knowledge about breast density in women presenting for an annual mammogram at two Midwestern rural clinics. The data collected from each clinic was combined into one data set due to a low census of one participant at one of the

rural sites. The demographic question of “what state do you live in” was eliminated from the results section to protect the anonymity of the participants.

Table 1

Demographics Results

Demographic		N=13	N %
1. What is your age?	40-49	2	15.4%
	50-59	3	23.1%
	60-69	1	7.7%
	70+	7	53.9%
2. What is the highest degree or level of school you have completed?	Less than high school	1	7.7%
	High school degree or equivalent (e.g. GED)	3	23.1%
	College degree or higher	9	69.2%
3. Have you seen the doctor in the last year?	Yes	13	100%
	No	0	0%
4. Do you currently have health insurance?	Yes	12	92.3%
	No	1	7.7%
	Don't Know	0	0.0%
5. Has any member of your family or any friends have or had cancer?	Yes	10	83.3%
	No	1	8.3%
	Don't Know	1	8.3%

Participants were asked about their breast history to help understand their knowledge of preventative breast care and to help guide personalized education on BD. All women (N=13) had a mammogram in the past. The number ranged from 2 to 50 mammograms. The mean age women started having mammograms was 42 with a mode of 40. Only one woman did not continue the questionnaire, due to not having dense breasts.

Table 2

Breast History Results

Breast History		N=13	N%
1. Have you ever had a mammogram?	Yes	13	100%
	No	0	0.0%
2. If yes, how many mammograms?	Number: _____		
3. At what age did you start having mammograms?	Age: _____		
4. When was your most recent mammogram?	Within past 2 years	12	92.3%
	Greater than 2 years ago	1	7.7%
5. Did you ever have to have additional testing after your mammogram such as an ultrasound, MRI, or additional views?	Yes	2	15.3%
	No	10	76.9%
	Unsure	1	7.7%
6. Have you ever had a breast biopsy?	Yes	3	23.0%
	No	10	76.9%
7. Have you ever been on hormone therapy such as estrogen, progesterone, etc.?	Yes	7	53.9%
	No	6	46.1%
8. Do you have a history or a family history of breast cancer?	No	9	69.2%
	Self only	0	0.0%
	Mother, Grandmother, Sister, or Aunt	3	23.1%
	Other Relative	1	7.7%
9. If yes, what age were they diagnosed?	Before age 50	2	50.0%
	After age 50	2	50.0%
10. Have you ever had genetic testing for breast cancer? What were the results?	Yes...If yes, what were the results? _____	0	0.0%
	No	13	100%
11. Do you have dense breasts?	Yes	11	84.6%
	No	1	7.7%
	Unsure	1	7.7%

If you said “no” to question number 11, please stop.

If you said “yes” or “unsure” to question number 11, please continue.

The following were the results of assessing women’s knowledge of breast density having a masking effect and impact on breast cancer risk. Most women (92.3%, n= 12) knew that dense breasts made it more difficult to see cancers on mammograms; however, about half (46.2%, n=6) knew that dense breast increases risk for breast cancer. One woman did not answer question number 1

Table 3

Knowledge of Breast Density Masking Effect and Impact on Breast Cancer Risk Results

Knowledge of Breast Density Masking Effecting and Impact on Breast Cancer Risk		N=13	N%
1. Dense breasts increase your risk for breast cancer.	Yes	6	46.2%
	No	6	46.2%
	Not Answered	1	0.8%
2. Dense breasts make it more difficult to see cancers on a mammogram.	Yes	12	92.3%
	No	1	7.7%

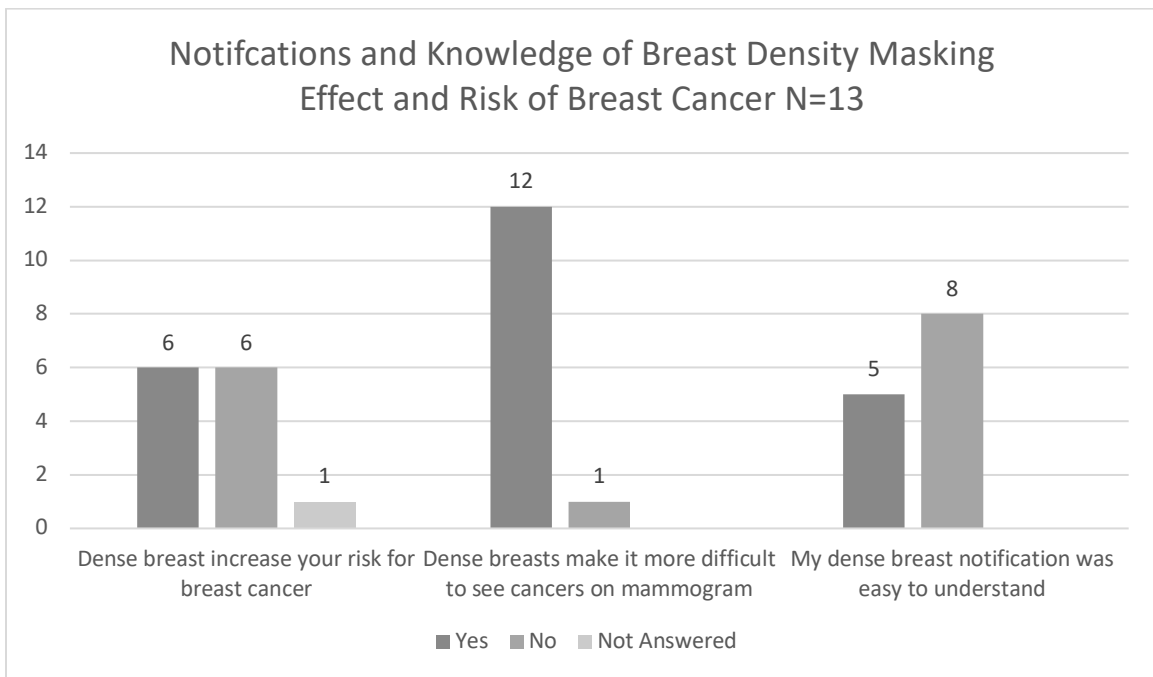


Figure 5. Dense Breast Notification and Knowledge of Breast Density Masking Effect and Risk of Breast Cancer

Table 4

Sources of Dense Breast Information Results

Sources of Dense Breast information		N=13	N%
1. Who told you that you have dense breasts?	My provider	1	7.7%
	A radiologist who read my mammogram report	7	53.9%
	An imaging or x-ray technician	5	38.5%
2. Do you know what type of density you have?	Yes	1	7.7%
	No	11	84.6%
	Unsure	1	7.7%
3. Have you talk about your breast density with your healthcare provider?	Yes	3	23.1%
	No	10	76.9%
4. If yes, what led you to talk about your breast density?	I asked my healthcare provider about my breast density	0	0.0%
	My healthcare provider brought up my breast density	3	75.0%
	Other	1	25.0%
5. Have you heard about breast density from other non-health care provider resources?	Yes	5	38.5%
	No	8	61.5%
6. If yes, where did hear about breast density?	Book/Magazine/Newspapers	2	33.3%
	Radio/Television	0	0.0%
	Internet	0	0.0%
	Family/Friends	3	50.0%
	Other	1	16.7%

The following were the results of the opinions related to BD. None of the women wrote any comments about additional concerns or questions, however many verbalized questions which were answered during their individualized education after completion of the questionnaire.

Table 5

Opinions Related to Breast Density Results

Opinions related to breast density		N=13	N%
1. I feel knowledgeable about my dense breast tissue.	Yes	1	7.7%
	No	12	92.3%
2. My dense breast notification was easy to understand.	Yes	5	38.5%
	No	8	61.5%
3. I feel comfortable making decision about what type of screening to have with my dense breast tissue.	Yes	10	76.9%
	No	3	23.1%
4. My providers asked for additional testing.	Yes	3	23.1%
	No	10	76.9%
5. I asked for additional testing.	Yes	1	7.7%
	No	12	92.3%
6. I wish I had more information on breast density.	Yes	9	75.0%
	No	3	25.0%
7. I think it is important to have more screening with dense breasts as it can be hard to find cancers with mammograms alone.	Yes	8	61.5%
	No	5	38.5%
8. Since my breasts are dense, I would have additional screening done even if it meant more testing and/or having a biopsy done.	Yes	10	76.9%
	No	3	23.1%
9. I get anxious, stressed, or worried about having mammograms.	Yes	2	15.4%
	No	11	84.6%
10. My dense breast tissue has increased my anxiety about getting breast cancer.	Yes	1	7.7%
	No	12	92.3%
11. I think it would be helpful to have reminders about my next mammogram.	Yes	13	100%
	No	0	0.0%
Do you have any additional concerns about dense breast tissue or questions about dense breast tissue?			

Objective Two Results

Objective two was to increase awareness about breast density in women presenting for an annual mammogram at two Midwestern rural clinics. After completion of the questionnaire, women had the option for the co-investigator to provide personalized education based on the woman's risk factors and history found from the questionnaire. Several women who qualified acknowledged the fact they were unaware of their BD prior to meeting with the co-investigator. The majority of the women were older than 70 years of age (n= 7; 53.9%) and most had a college education (n=9; 69.2%). Almost all women acknowledged that having dense breasts does make it more difficult to see breast cancer on a mammogram (n=12; 92.3%); however, only 46.2% (n= 6) recognized BD as a risk factor for breast cancer. Almost all women (n=12; 92.3%) did not feel knowledgeable about their dense breast tissue; however, more than half (n=10; 76.9%) were comfortable about making decisions regarding the type of screening to have with their dense breasts.

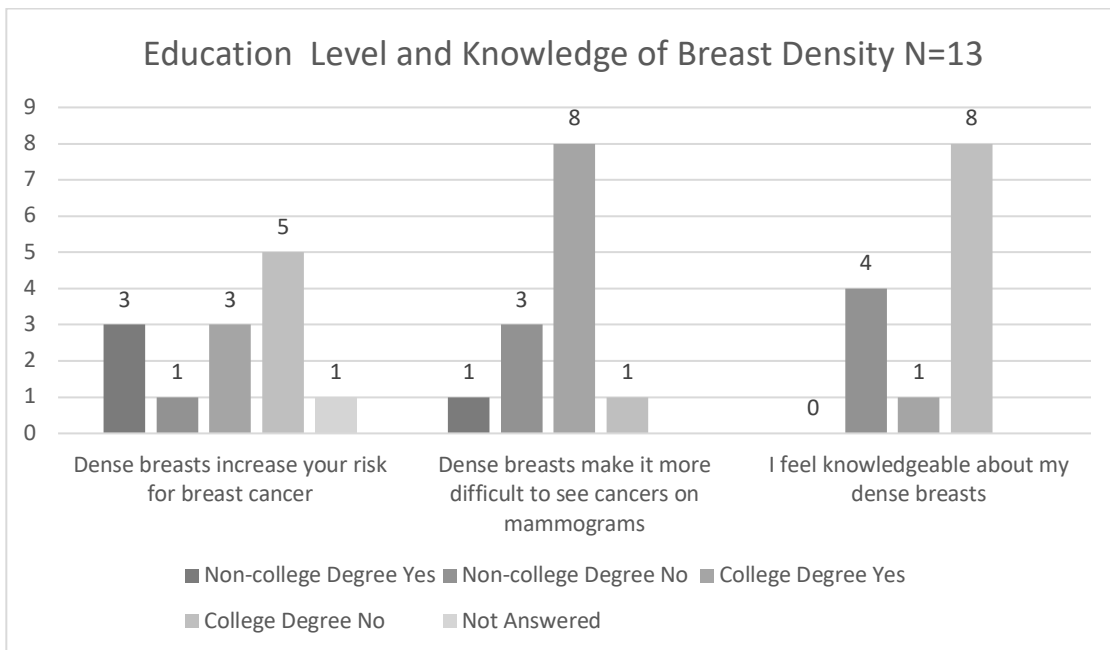


Figure 6. Education Level and Breast Density Knowledge

Women were open to learning more about BD and asked questions regarding how to find out if their breasts were dense, causes of BD, and how to prevent breast cancer. The co-investigator provided education from the two-page handout (Appendix L). Women also shared personal stories of family and friends who were affected by breast cancer.

Objective Three Results

Objective three was to inform providers about BD in women presenting for an annual mammogram at two Midwestern rural clinics and educate providers about breast density risk. Providers were appreciative of the educational BD presentation and sharing the results of the women's questionnaire. Two of the three providers verbalized to the co-investigator they were unaware of the readability levels of the dense breast notifications. One provider had commented, "If our (BD) notification is at a high readability level what other types of notifications aren't being understood by patients?" Another provider had questions about which current organizational guidelines regarding mammograms to follow for women with dense breasts. The co-investigator encouraged the provider to refer to the educational handout (Appendix K). Other discussion included questions related to cost of mammograms, insurance coverage of mammograms, and rural access to mammograms. One staff member shared her personal experience of BD and involvement in a research study.

Objective Four Results

Objective four was to evaluate the readability of BD notification letters at two Midwestern rural clinics. MN and ND do not have specific mandated language in their notification. MN and ND's BD notification letters do include the following: informing the women her breasts are dense, BD has a masking effect, and BD is a risk factor for breast cancer. The BD notifications do not mention BD category, supplemental screening tests, insurance

coverage for supplemental screening, or if a copay and deductible apply for supplemental screening. Each notification letter was transferred into a Microsoft Word document to obtain a readability score. Clinic A’s BD notification’s Flesch Reading Ease Score was 54.1 (fairly difficult to read) and Flesch-Kincaid Grade Level of 10.6. The Clinic B’s BD notification’s Flesch Reading Ease Score was 44.7 (difficult to read) and Flesch-Kincaid Grade Level of 11.8. Each BD notification scored 33.33% on the CDC’s Modified CDC Clear Communication Index Score Sheet with a goal of 90% or more.

Table 6

Breast Density Notification Results

Place	Instrument					
	Flesh-Kincaid Reading Ease Score		Flesh-Kincaid Grade Level		CDC Modified Clear Communication Score	
	Pre	Post	Pre	Post	Pre	Post
Clinic A	54.1	65	10.6	7.1	33%	>90%
Clinic B	44.7	66.3	11.8	6.9	33%	>90%

CHAPTER SIX. DISCUSSION AND RECOMMENDATIONS

Interpretation of the results was limited by the small sample size, thus, inhibiting possible further data analysis or relations within the data obtained. The PDSA model provided the framework to achieve the PIP. The pilot study opened areas for improvement with education for women with BD, education for providers, and communication improvement for dense breast notifications.

Objective One Interpretation

The first objective was to assess awareness and knowledge about BD in women presenting for an annual mammogram at two Midwestern rural clinics. Per questionnaire responses, the objective was partially met. The findings correlated with Rhodes (2018) survey suggesting that BD “awareness” does not translate to knowledge about BD as an independent risk for breast cancer. Knowledge about the masking effect of BD and increased risk for cancer varied between women with a college degree and without a college degree (Figure 5).

Objective Two Interpretation

The second objective was to increase awareness about BD in women presenting for an annual mammogram at two Midwestern rural clinics. Per individualized education provided to women, the objective was met. An increase awareness of BD was completed by providing individualized education to women after completion of the dense breast questionnaire and by providing a dense breast fact sheets for women to the clinics for distribution. About 75% (n=9) of women “wished” they had more information on BD. All women who had BD (N=13) were individually educated after completion of the questionnaire. A few of the verbal comments after education included “I didn’t know I had dense breasts until today,” “How do I know if I have dense breasts?” and “This was helpful to learn about, thank-you.” All women (N=13) were given

an educational handout on BD. Women were encouraged to share the knowledge they learned that day with other women in their community and to talk with their providers about their BD.

Objective Three Interpretation

The third objective was to inform providers about BD in women presenting for an annual mammogram at two Midwestern rural clinics and educate providers about BD risk. Per the educational session and through provider feedback the objective was met. The co-investigator increased providers' awareness of rural women's knowledge through the PowerPoint presentation on dense breast tissue, dissemination of the results of the questionnaire, and provision of a dense breast fact sheet. More than half of the women (n=10; 76.9%) surveyed did not talk to their healthcare providers about their dense breast tissue. Most healthcare providers, according to the women surveyed (n=3; 75%), brought up the topic of BD. However, 61.5% (n=8) of the women surveyed reported hearing about BD from other non-healthcare provider resources, specifically from a family/friend (n=3; 50%) or books/magazines/newspapers (n=2; 33.3%). The results suggest that providers are often the first to address BD with women, solidifying the need for educating healthcare providers on BD. Providers who attended the presentation appeared interested and thanked the co-investigator for the information. Providers who were unable to attend received a dense breast fact sheet for their future reference. Both clinic managers were given a hard copy of the provider and patient BD fact sheet for reproduction as needed.

Objective Four Interpretation

Objective four was to increase readability of breast density letters by providing feedback of dense breast notification result letters at two rural Midwestern clinic sites. Notification letter revisions were suggested by the co-investigator and therefore the objective was met. Several

researchers have suggested that notifying women about their BD increases their anxiety, resulting in inappropriate screening decisions (Steven & Jones, 2014; Yeh et al., 2015). However, most women (n=11; 84.6%) with known BD denied feelings of anxiety, stress, or worry about their mammogram. Almost all women (n=12; 92.3%) with marked dense breast tissue denied increased concern about their risk for breast cancer. About 61.5% (n=8) of women indicated that BD was not easy to understand and 84.6% (n=11) of women were unaware of their BD type.

The co-investigator revised the BD notification letters. The language in the letter was not taken from a specific guideline; rather a blended approach was used that incorporated the major recommendations of several of the guidelines. Since women who received the BD notification letter had completed a mammogram, they were encouraged to discuss the recommendations for future breast cancer screening with their provider. The co-investigator shared the original and the revised dense breast notification to providers at each clinic to garner feedback. A concern shared by a provider that if the BD notification was written at a 12th-grade level, should the clinic take an in-depth look at the readability of all patient letters? Providers approved the revised notification letter. The revised notification letter at Clinic A had a calculated Flesh Reading Ease score of 65 and a Flesch-Kincaid Grade level of 7.1 (Appendix N). The revised letter at Clinic B had a Flesh Reading Ease score of 66.3 and a Flesch-Kincaid Grade level of 6.9 (Appendix P). Both of the letters had a CDC Modified Clear Communication Index Score of greater than 90 (greater than 90 is considered excellent). The administration and staff at each clinic will review and independently decide whether to employ the revised BD notification letters

Project Limitations

The major limitations of the project were the low number of participants and scheduling difficulties at one clinic location. Originally, ten women were scheduled for an annual mammogram. One week prior to the scheduled mammogram, two women cancelled their appointment. By the scheduled date, only four women remained on the mammogram schedule. Only one of the 4 women scheduled for a mammogram showed-up, likely due to unfavorable weather conditions. The other clinic has mammography screening on site, which allowed for multiple data collection days. However, some women rescheduled their annual mammogram due to weather conditions and others missed their appointment for unknown reasons.

Another limitation was the process of recruiting women to participate in the project. The staff was informed of the PIP; however, there was no prepared script to tell women about the project. At Clinic A, the mammogram technician introduced the PIP to the patient just prior to their annual mammogram. The technician informed the woman that she would qualify for participation due to breast density. More than one participant verbalized to the co-investigator that she was unaware of her BD until the mammogram technician informed her and that she qualified for the PIP questionnaire. Informing women about their BD prior to completing the questionnaire could have skewed the responses to question number 11 under the breast history section, “Do you have dense breasts?”

Attendance for the provider education session at Clinic A was poor with only one provider attending the educational meeting. While other healthcare providers were on site, they were unable to participate in the session for a variety of reasons. Other core staff attended educational sessions. Clinic A had 5 additional staff members and Clinic B had 7 additional staff members. The clinic manager distributed copies of the PowerPoint at one rural clinic for

providers who were unable to attend. Attendance could have been improved by blocking out time on the provider's schedule, having multiple sessions at different times, or by providing email reminders for the educational session.

Recommendations

A recommendation to repeat the PDSA cycle or advance the pilot study to full implementation is strongly encouraged to strengthen the PIP. Knowing the average number of mammograms done each month at the rural health clinics could help to obtain a more accurate representation of the rural women. Another suggestion would be to implement the project during October, which is Breast Cancer Awareness Month. Each rural clinic had mammogram events during October to encourage women to participate in preventative mammography. Implementation during October has the opportunity to increase the number of participants and healthcare providers.

Another recommendation is to have women complete the BD questionnaire before their scheduled mammogram, therefore, eliminating knowledge of density status prior to completing the questionnaire and then having the individualized educational session for women to be completed after their appointment. Repeating the PDSA will continue to increase awareness of BD and the risk of breast cancer among rural women.

Due to ongoing research on breast density screening and management on BD, if this PIP is repeated there is the potential that a more defined guideline and algorithm will be developed to present to providers. A recommendation would be to set a date for the provider education session at least a month in advance, so providers can plan this in their schedule. The educational session should be offered on more than one date to allow other healthcare providers to participate

which could also increase the healthcare provider attendance. Offering a continuing education credit could be an incentive for healthcare providers to attend the education session.

The PIP can be applied to a variety of different preventative health services. The setting can be changed to an urban or underserved population. A recommendation would be to review the health literacy and readability level of other patient notifications and educational materials.

Implications for Practice

The findings of the PIP supported the need for increased awareness and knowledge among rural women and healthcare professionals about dense breast tissue and the risk of breast cancer. The PIP also supported a need for an increase in readability with dense breast notifications. Empowering women with knowledge of their dense breast tissue can lead to increased conversations with their healthcare providers and promote them to seek out appropriate screening options. Increasing awareness of BD through education may be the difference between the diagnosis of an early stage breast cancer with a high survival rate versus a late-stage breast cancer with a high mortality rate. Having a BD notification letter that is readable and provides information on BD will encourage women to discuss BD with their provider and to seek out education on BD, thus, increasing their knowledge on BD. Printed copies of the BD educational information should be available at the clinic waiting area or enclosed with the BD notification. Having this information readily available will increase women's awareness and knowledge regarding BD.

Dissemination

Dissemination of the PIP findings is essential to share knowledge learned and provide the ability to improve practice. The results from the BD questionnaire were disseminated to each rural facility where the PIP was conducted during the educational PowerPoint presentation for

healthcare providers. The PIP was also presented at NDSU College of Health Professions Poster Presentation in April 2019. The co-investigator provided the two clinics with results of the PIP. The co-investigator plans to submit for publication in a peer reviewed nurse practitioner journal in the summer of 2019.

Implications for Future Research

Future PIPs on BD could involve how best to notify women of their mammogram results after their mammogram. Another PIP could be what are the best ways to inform women of their breast cancer risk? Due to new research on modalities to screen for breast density, a study could be completed on discovering the best supplemental imaging for women with dense breasts. A PIP could assess if providers are assessing risks for breast cancer and choosing the correct screening intervals for risk level. Further education on BD and the risk for breast cancer for providers or women is needed. Only one participant from the PIP indicated feeling knowledgeable about BD, which validates the need for more education for women. Providers acknowledge that the educational PowerPoint was helpful, and previous studies have found that providers do want more information on BD (Maimone et al, 2017). Many providers were unaware of the readability of BD notifications. Increasing awareness about BD for providers has the possibility for improved management and early diagnosis of breast cancer in women with BD.

Application to the Nurse Practitioner Role

With over 1.06 billion annual visits to nurse practitioners (NPs), NPs can make a difference in healthcare and in the health of their patients. According to the American Association of Nurse Practitioners (AANP), NPs are unique, as their emphasis is focused on the

health and well-being of the whole person, with an emphasis on health promotion, disease prevention, and education (AANP, 2019).

As a profession, NPs wholeheartedly invest in their patients' lives and strive to empower them with knowledge to improve their health. Nurse Practitioners are also advocates for patients, and, as such, should take an active role in supporting BD notification laws. All women have the right to know about their personal breast density. When the risks are known, the patient and NP can make an individualized and informed plan for breast cancer screening.

Conclusion

Breast cancer is the number one new cancer diagnosis in the U.S. and the second leading cause of cancer death in the U.S. (CDC, 2018). Dense breast tissue can reduce the sensitivity of a mammogram, increase risk of breast cancer, and delay breast cancer diagnosis, (Berg et al, 2017). Increasing awareness and knowledge about BD and the associated risk for breast cancer can empower women and providers to collaboratively make educated choices about breast health and breast cancer screening. Early detection saves lives.

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APPENDIX A. BREAST DENSITY INTERVIEW QUESTIONS

Questions Demographic	Response Choices
What is your age?	40-49 50-59 60-69 70+
What is your race/ethnicity?	White/Caucasian Black/African American Hispanic/Latino/Spanish American Indian/Alaskan Native Asian Native Hawaiian or Pacific Islander Other
What is your marital status?	Single (never married) Married, or in a domestic partnership Widowed Separated Divorced
What is the highest degree or level of school you have completed?	Less than high school High school degree or equivalent (e.g. GED) College degree or higher
What state do you live in?	MN ND Other
Have you seen the doctor in the last 12 months?	Yes No
Do you currently have health insurance?	Yes No Don't know
Has any member of your family or any friends have or had cancer?	Yes No Don't know
Breast History	Response Choice
Ever had a mammogram?	Yes No
If yes, how many mammograms?	Number:
At what age did you start having mammograms?	Age:
When was your most recent mammogram?	Within past 2 years Greater than 2 years ago
Did you ever have to have additional screening tests after your mammogram such as an ultrasounds, additional views, or MRI?	Yes No
Ever had a breast biopsy?	Yes No

Have you ever been on hormone therapy such as estrogen, progesterone, etc.?	Yes No
Do you have history or family history of breast cancer?	No Self only Mother, Grandmother, or Aunt Other relative
Have you ever had any genetic testing for breast cancer? What were results?	Yes ___ If yes, what were the results? No
If you said “no” to question number 11, please stop. If you said “yes” or “unsure” to question number 11, please continue.	
Knowledge of BD Masking Effect and Impact on BC Risk	Response Choices
Impact of dense breast on ability of mammogram to detect breast cancer. Which do you agree with?	Dense breasts make it easier to see cancer on mammogram. Dense breasts do not affect ability to see cancer on mammogram. Dense breasts make it more difficult to see cancer on mammogram. Unsure
Having dense breast that are heterogeneously dense or extremely dense on mammogram:	Does not put you at increased risk for breast cancer. Does put you at an increased risk for breast cancer
Sources of Dense Breast Information	Response Choices
Do you have dense breasts?	Yes No
If yes, who told you that you have dense breast?	Healthcare provider who ordered my mammogram. Radiologist who read my mammogram/mammogram report. Imaging or x-ray technician.
Do you know what type of density you have?	Yes No Unsure
Have you discussed your breast density with your healthcare provider	Yes No
If yes, what led to your discussion about breast density?	I asked my healthcare provider about my breast density. My healthcare provider brought up the topic of breast density. Other
Have you heard about breast density from non-health care provider sources?	Yes No
If yes, from what other sources have you heard about breast density?	Book/magazine/newspapers Radio/television Internet Family/Friend Other
Opinions Related to Breast Density	Response Choices
“I feel knowledgeable about my dense breast tissue”	Yes No
“My dense breast notification was easy to understand”	Yes No

“I feel comfortable making decisions about what type of preventative screening to have with my dense breast tissue”	Yes No Unsure
“My providers asked for additional breast testing”	Yes No
“I asked for additional breast testing”	Yes No
“I wish I had more information on breast density”	Yes No
“It is important to have more screening with dense breasts because it can find breast cancers that may not be found with mammography alone”	Yes No
“Since my breast are dense and require additional screening, I would still have additional screening done even if it meant I may need more testing and/or biopsy.”	Yes No
“Having mammograms make me anxious, stressed, or worried”	Yes No
“Knowing that I have dense breast tissue has increased my anxiety about getting breast cancer”	Yes No
“It would be helpful to have reminders about my next mammogram”	Yes No

APPENDIX B. PERMISSION TO USE DENSEBREAST-INFO.ORG IMAGES



JoAnn Pushkin <jpushkin@dense-info.org>

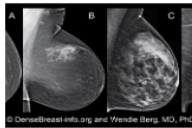
Mon 9/17, 10:02 AM
Motis, Kari



Reply | v

Dissertation

You replied on 9/17/2018 1:03 PM.



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Thank you, Kari, for the specific details.

Yes, you have DB-I's and Dr. Berg's permission to use the attached image for inclusion in your dissertation as long as it is used *as is* without any edits or crops. The copyright information must be featured exactly as provided. Any additional use of the image does require a reach-out for our permission.

Good luck with the dissertation!

Best,



JoAnn Pushkin
Executive Director
DenseBreast-info, Inc.
JPushkin@Dense-info.org

A 501(c)(3) non-profit
PO Box 997 | Deer Park | NY | 11729
516.721.4270



JoAnn Pushkin <jpushkin@dense-info.org>

Mon 9/17, 1:49 PM
Motis, Kari



Reply | v

Dissertation

Hi Kari,

For use *only in your dissertation*, that is fine as well as long as all footnotes are included, and both table revision date and copyright are clearly indicated.

Best,



JoAnn Pushkin
Executive Director
DenseBreast-info, Inc.
JPushkin@Dense-info.org

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516.721.4270

APPENDIX C. PERMISSION TO USE NOLA PENDER'S HPM MODEL



Nola Pender <npender@umich.edu>

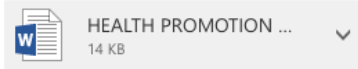
Tue 9/18, 12:57 PM

Motis, Kari ✕



↩ Reply | ▾

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Dear Kari:

You have permission to use the Health Promotion Model in your dissertation.

Wishing you good health,

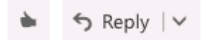
Nola Pender

**APPENDIX D. PERMISSION TO USE MAYO CLINIC BREAST DENSITY
AWARENESS AND KNOWLEDGE SURVEY**

RE: Request to reuse Survey Questions from Journal doi: 10.1200.JCO.2014.57.0325



Rhodes, Deborah J., M.D. <Rhodes.Deborah@mayo.edu>
Thu 9/20, 3:00 PM
Motis, Kari ✕



Dissertation

Hi, Kari. Thank you for feedback on our survey. We would welcome you to include our survey in your dissertation. Please refer to it as the Mayo Clinic Breast Density Awareness and Knowledge Survey. FYI, we're about to publish a 5-year update on the survey results. Good luck on your dissertation!

APPENDIX E. NDSU IRB APPROVAL LETTER



December 10, 2018

Dr. Tina Lundeen
School of Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #PH19115, "Increasing Awareness of the Role of Breast Density as an Independent Risk Factor for Breast Cancer"

Co-investigator(s) and research team: Kari Motis
Date of Exempt Determination: 12/10/2018 Expiration Date: 12/9/2021
Study site(s): Larimore, ND and Fosston, MN
Sponsor: n/a

The above referenced human subjects research project has been determined exempt (category #2b) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the original protocol submission (received 11/29/2018).

Please also note the following:

- If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
- The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
- Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.
Sincerely,

A handwritten signature in purple ink that reads "Kristy Shirley".

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult http://www.ndsu.edu/research/integrity_compliance/irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD

NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

NDSU is an EO/AA university.

APPENDIX F. ESSENTIA HEALTH IRB WAIVER



Essentia Health

November 15, 2018

To whom it may concern,

Re: Awareness of Breast Density in Two Rural Clinics

Thank you for submitting the Human Subject Research Determination Form and information for the project listed above. Based on a review of the documentation you provided, this project does not meet the definition of research with human subjects, according to the Office of Human Research Protections (OHRP) [guidance](#): “*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” or “*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or identifiable private information.”

Because the project does not meet the federal definition of human subjects research, it will not require further review by the Essentia Health Institutional Review Board or a scientific review committee. If during the process of data collection or analysis it becomes clear that findings could be generalizable or benefit others, please submit your project for IRB review at that time.

If you have any questions concerning this letter, please contact me at 218-576-0489.

I wish you success with your project.

Sincerely,



Deneice Kramer, MBA, MA, CCRP
Manager, Human Research Protection Program

APPENDIX G. PATIENT CONSENT TO PARTICIPATE IN INTERVIEW

North Dakota State University

Department of Nursing
1919 N University Drive
NDSU Dept. 2670
PO Box 6050
Fargo, ND 58108-6050
701.231.7395

Increasing Awareness of the Role of Breast Density as an Independent Risk Factor for Breast Cancer

Dear Participant,

My name is Kari Motis. I am a graduate in School of Nursing at North Dakota State University (NDSU), and I am doing a practice improvement project to increase awareness and knowledge about dense breast tissue and breast cancer risk. The objective of this research is to understand the awareness that rural women have about breast density and the risk for breast cancer.

Because you are a female who is 40 to 80 years of age and are scheduled for a mammogram, you are invited to take part in this research. You will be asked to complete a survey and attend an educational session with the researcher at your convenience before or after your mammogram appointment. The total expected time commitment for participation is 30 minutes.

Participation in the research is voluntary. You will not incur cost nor will you be reimbursed for participation. If you feel uncomfortable in any way while filling out the survey, you have the right to decline to answer any question(s), and stop taking the survey without consequence. You may also choose not to participate or to leave the educational session at any time without consequence. This survey is anonymous. If you choose to participate, do not write your name or other identifying information on the survey. The responses you give on the survey will not influence the care that you receive at the clinic. The survey responses you give will aid in evaluating rural women's knowledge on dense breast tissue.

Your information will be kept confidential and you will not be identifiable in the survey results. Individual respondent's information will be combined with the information gathered from other people taking part and reported in aggregate form only. The results will be part of the researcher's Doctor of Nursing Practice dissertation at NDSU and may be published in a professional journal; however, we will keep your name and other identifying information private.

It is not possible to identify all potential risks in research procedures, but we have taken reasonable safeguards to minimize any known risks.

If you have any questions about completing the survey or participating in the educational session, please contact me at 701.226.9215 or at kari.motis@ndsu.edu contact my advisor at Dr. Tina Lundeen at 701.231.7747 or tina.lundeen@ndsu.edu. You have rights as a research participant. If you have questions about your rights or complaints about this research, you may talk to the researcher or contact the NDSU Human Research Protection Program at 701.231.8995, toll-free at 1-855-800-6717, by email at ndsu.irb@ndsu.edu, or by mail at NDSU HRPP Office, NDSU Dept. 4000, and P.O. Box 6050, Fargo, ND 58108-6050.

Thank you for your taking part in this research.
Sincerely,
Kari Motis RN BSN CCRN
NDSU Doctor of Nursing Practice Student



APPENDIX H. DENSE BREAST PRACTICE IMPROVEMENT PROJECT MAILING

North Dakota State University

Department of Nursing
1919 N University Drive
NDSU Dept. 2670
PO Box 6050
Fargo, ND 58108-6050
701.231.7395

NDSU DOCTOR OF NURSING PRACTICE STUDENT IMPROVEMENT PROJECT

Increasing Awareness of the Role of Breast Density as an Independent Risk Factor for Breast Cancer

To Whom It May Concern:

My name is Kari Motis. I am a graduate student in the Department of Nursing at North Dakota State University, and I am conducting a practice improvement project to increase awareness and knowledge about dense breast tissue. It is our hope, that with this project, we will learn more about rural women and dense breast tissue.

Because you are a female who is 40 to 80 years of age and are scheduled for an upcoming mammogram, you are invited to take part in this practice improvement project. Your participation is voluntary, and you may change your mind or quit participating at any time, with no penalty to you.

It is not possible to identify all potential risks in research procedures, but we have taken reasonable safeguards to minimize any known risks. By taking part in this research, you may benefit by gaining a better understanding of dense breast tissue. However, you may not get any benefit from being in this study.

A survey regarding breast density will be given in a paper format with a pen or pencil. It should take about 5 minutes to complete the questionnaire. Your identity will not be linked to your survey responses. Your information will be combined with information from other people taking part in the study, we will write about the combined information that we have gathered. You will not be identified in these written materials. We may publish the results of the study; however, we will keep your name and other identifying information private. You may also choose to meet with me for a brief educational session about breast density and breast cancer risk.

If you have any questions about this project, please contact me at 701.226.9215 or email at kari.motis@ndsu.edu.

Thank you and I look forward to meeting you.
Sincerely,



Kari Motis RN BSN CCRN
NDSU Doctor of Nursing Practice Student

APPENDIX I. DENSE BREAST QUESTIONNAIRE DATA

Demographic		N=13	N%
1. What is your age?	40-49	2	15.4%
	50-59	3	23.1%
	60-69	1	7.7%
	70+	7	53.9%
2. What is the highest degree or level of school you have completed?	Less than high school	1	7.7%
	High school degree or equivalent (e.g. GED)	3	23.1%
	College degree or higher	9	69.2%
3. Have you seen the doctor in the last year?	Yes	13	100%
	No	0	0%
4. Do you currently have health insurance?	Yes	12	92.3%
	No	1	7.7%
	Don't Know	0	0.0%
5. Has any member of your family or any friends have or had cancer?	Yes	10	83.3%
	No	1	8.3%
	Don't Know	1	8.3%
Breast History			
1. Have you ever had a mammogram?	Yes	13	100%
	No	0	0.0%
2. If yes, how many mammograms?	Number: _____		
3. At what age did you start having mammograms?	Age: _____		
4. When was your most recent mammogram?	Within past 2 years	12	92.3%
	Greater than 2 years ago	1	7.7%
5. Did you ever have to have additional testing after your mammogram such as an ultrasound, MRI, or additional views?	Yes	2	15.3%
	No	10	76.9%
	Unsure	1	7.7%
6. Have you ever had a breast biopsy?	Yes	3	23.0%
	No	10	76.9%
7. Have you ever been on hormone therapy such as estrogen, progesterone, etc.?	Yes	7	53.9%
	No	6	46.1%
8. Do you have a history or a family history of breast cancer?	No	9	69.2%
	Self only	0	0.0%
	Mother, Grandmother, Sister, or Aunt	3	23.1%
	Other Relative	1	7.7%
9. If yes, what age were they diagnosed?	Before age 50	2	50.0%
	After age 50	2	50.0%
10. Have you ever had genetic testing for breast cancer? What were the results?	Yes...If yes, what were the results? _____	0	0.0%
	No	13	100%

11. Do you have dense breasts?	Yes	11	84.6%
	No	1	7.7%
	Unsure	1	7.7%

If you said “no” to question number 11, please stop.

If you said “yes” or “unsure” to question number 11, please continue.

Knowledge of Breast Density Masking Effecting and Impact on Breast Cancer Risk

1. Dense breasts increase your risk for breast cancer.	Yes	6	46.2%
	No	6	46.2%
	Not Answered	1	0.8%
2. Dense breasts make it more difficult to see cancers on a mammogram.	Yes	12	92.3%
	No	1	7.7%

Sources of Dense Breast information

1. Who told you that you have dense breasts?	My provider	1	7.7%
	A radiologist who read my mammogram report	7	53.9%
	An imaging or x-ray technician	5	38.5%
2. Do you know what type of density you have?	Yes	1	7.7%
	No	11	84.6%
	Unsure	1	7.7%
3. Have you talk about your breast density with your healthcare provider?	Yes	3	23.1%
	No	10	76.9%
4. If yes, what led you to talk about your breast density?	I asked my healthcare provider about my breast density	0	0.0%
	My healthcare provider brought up my breast density	3	75.0%
	Other	1	25.0%
5. Have you heard about breast density from other non-health care provider resources?	Yes	5	38.5%
	No	8	61.5%
6. If yes, where did hear about breast density?	Book/Magazine/Newspapers	2	33.3%
	Radio/Television	0	0.0%
	Internet	0	0.0%
	Family/Friends	3	50.0%
	Other	1	16.7%

Opinions related to breast density			
1. I feel knowledgeable about my dense breast tissue.	Yes	1	7.7%
	No	12	92.3%
2. My dense breast notification was easy to understand.	Yes	5	38.5%
	No	8	61.5%
3. I feel comfortable making decision about what type of screening to have with my dense breast tissue.	Yes	10	76.9%
	No	3	23.1%
4. My providers asked for additional testing.	Yes	3	23.1%
	No	10	76.9%
5. I asked for additional testing.	Yes	1	7.7%
	No	12	92.3%
6. I wish I had more information on breast density.	Yes	9	75.0%
	No	3	25.0%
7. I think it is important to have more screening with dense breasts as it can be hard to find cancers with mammograms alone.	Yes	8	61.5%
	No	5	38.5%
8. Since my breasts are dense, I would have additional screening done even if it meant more testing and/or having a biopsy done.	Yes	10	76.9%
	No	3	23.1%
9. I get anxious, stressed, or worried about having mammograms.	Yes	2	15.4%
	No	11	84.6%
10. My dense breast tissue has increased my anxiety about getting breast cancer.	Yes	1	7.7%
	No	12	92.3%
11. I think it would be helpful to have reminders about my next mammogram.	Yes	13	100%
	No	0	0.0%

Do you have any additional concerns about dense breast tissue or questions about dense breast tissue?

APPENDIX J. EDUCATIONAL POWERPOINT FOR PROVIDERS

Breast Density What is it and what you need to know.

KARI MOTIS

Objectives

- ▶ Modifiable/Non-modifiable risk for breast cancer
- ▶ Breast Density Definitions
- ▶ What affect breast density
- ▶ Screening guidelines and modalities
- ▶ Dense breast legislation

Breast Cancer

- ▶ Most common cause of cancer, no matter the race or ethnicity (CDC, 2018).
- ▶ 1 in 8 women will get breast cancer
- ▶ According to the CDC (2015)
 - ▶ ND
 - ▶ #1 Cause of new cancer diagnosis
 - ▶ #2 Cause of cancer deaths
 - ▶ MN
 - ▶ #1 Cause of new cancer diagnosis
 - ▶ #3 Cause of cancer deaths

Breast Cancer Risks: Non-modifiable

- ▶ Age
- ▶ Genetic Mutations
- ▶ Reproductive History
- ▶ Having dense breasts
- ▶ Personal history of breast cancer or certain non-cancerous breast diseases
- ▶ Family history of breast cancer
- ▶ Previous treatment using radiation therapy
- ▶ Women who took the drug DES

Breast Cancer Risks: Modifiable

- ▶ Not being physically active
- ▶ Being overweight or obese after menopause
- ▶ Taking hormones
- ▶ Reproductive history
- ▶ Drinking alcohol

Age and being female are the two biggest risk factors for breast cancer.

Table 2. Age-specific Probability of Developing Invasive Breast Cancer for US Women

Current age	10-year probability:	or 1 in:
20	0.1%	1,567
30	0.5%	220
40	1.5%	68
50	2.3%	43
60	3.4%	29
70	3.9%	25
Lifetime risk	12.4%	8

Note: Probability is among those free of cancer at beginning of age interval. Based on cases diagnosed 2012-2014. Percentages and "1 in" numbers may not be numerically equivalent due to rounding.

©2017, American Cancer Society, Inc., Surveillance Research

Sex, Age, and Risk of Breast Cancer

Relative Risk and Breast Cancer

Relative Risk	Factor
>4.0	Age (65+ vs <65)
	Biopsy-confirmed atypical hyperplasia
	BRCA1 and/or BRCA2
	DCIS
	LCIS
	Mammographically dense breasts (compared to least dense)
	Personal history of early-onset(<40)
	Two or more first degree relatives with breast cancer diagnosed at an early age

Relative Risk and Breast Cancer

Relative Risk	Factors
2.1 – 4.0	Personal history of breast cancer (40+)
	High endogenous estrogen or testosterone levels (postmenopausal)
	High-dose radiation to chest
	One first-degree relative with breast cancer

Relative Risk and Breast Cancer

Relative Risk	Factors	
1.1 – 2.0	Alcohol consumption	Late menopause (>55yrs)
	Ashkenazi Jewish heritage	Never breastfed a child
	DES exposure	No full-term pregnancy
	Early menarche (<12 yrs)	Obesity (postmenopausal)/adult weight gain
	Height	Personal history of endometrium or ovarian CA
	High socioeconomic status	Proliferative breast disease without atypia
	Late age at 1st full term pregnancy (>30 yrs)	Recent and long-term use of menopausal hormone therapy containing estrogen and progestin
		Recent oral contraceptive use

Relative Risk and Breast Cancer

Relative Risk	
BRCA1 or BRCA2	15x
Prior DCIS	10x
Extremely Dense breast tissue	4x
Prior atypical ductal hyperplasia	5x
Heterogeneously Dense breast tissue	2x
First-degree relative diagnosed with breast cancer by age 50	2x
Combined estrogen and progesterone therapy after menopause	1.5x

Why is Breast Density Important?

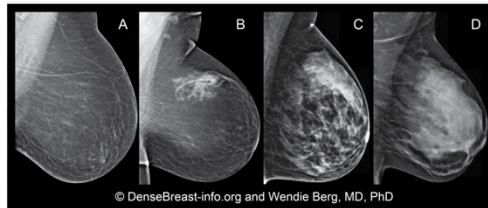
- ▶ Sensitivity of mammography is **reduced** with **increased** breast tissue density.
- ▶ Dense breast tissue can mask breast cancer **delaying** finding of breast cancer and treatment.
- ▶ Dense breast tissue is an **independent** risk factor for breast cancer.
 - ▶ Women with dense breasts have a 1.2 to 2 times greater chance of developing breast cancer.

What is Breast Density?

- ▶ The breast is composed of adipose tissue and fibroglandular tissue, the higher the amount of fibroglandular tissue the "denser" the breast.
- ▶ Reflected on *mammogram*:
 - ▶ fibroglandular tissue will appear radiodense or white
 - ▶ adipose tissue is radiolucent or black
- ▶ A BIRADS scale is used to describe density
- ▶ BD varies from woman to woman **without** correlation to breast size, breast texture, or fibrocystic changes
- ▶ Density **cannot** be determined by physical and visual exam.

BIRADS Scale

- ▶ **Category A:** Fatty
 - ▶ 10% of women
- ▶ **Category B:** Scattered Fibroglandular Density
 - ▶ 40% of women
- ▶ **Category C:** Heterogeneously Dense
 - ▶ 40% of women
- ▶ **Category D:** Extremely Dense
 - ▶ 10% of women



- Dense breasts refer to Category C and D
- BD is normal and common
 - about 40% of women have BD
- Density decreases with age and menopause

Cancer Risk and Dense Breasts

Breast Density is an independent risk factor for breast cancer

Studies often compare different categories of density

- ▶ Category D Extremely Dense to Category A Fatty
 - ▶ 4x as likely to develop breast cancer
- ▶ Category C Heterogeneously Dense to Category B Scattered Fibroglandular Density
 - ▶ 1.5x as likely to develop breast cancer
- ▶ Category D Extremely Dense to Category B Scattered Fibroglandular Density
 - ▶ 2x as likely to develop breast cancer

What affects breast density?

Race/Ethnicity

- ▶ 40-50% of American women have Category C or D breasts
- ▶ Asian women typically have denser breasts
- ▶ Conflicting evidence on African-American women

Age

- ▶ Dense breast lessens with age
 - More than half of women under age 50 have dense breasts
 - About 40% of women in their 50's have dense breasts
 - About 25% of women 60+ have dense breasts

What affects breast density?

Family

- ▶ Having a mother or twin sister with dense breasts increased a woman's likelihood of dense breast tissue

Size

- ▶ Smaller breasts tend to be denser than larger

Pregnancy/Breastfeeding

- ▶ Women who given birth < 20 yrs of age had predominately fatty breasts vs women who bore children later in life had higher rates of BD
- ▶ During pregnancy/breastfeeding glandular tissue grows and breasts become denser and larger.

What affects breast density?

Weight, Diet, Exercise

- ▶ BMI is an independent risk factor separate from breast density
- ▶ Women with higher BMI's may have fattier breast tissue however; it does not change the percentage of fibroglandular tissue in the breast
- ▶ Women with lower a BMI were more likely to have denser breast tissue than those with higher a BMI
- ▶ Women consumed > 7 alcohol servings per week and a BMI < 25 had 17% higher BD than non-drinkers.

What affects breast density?

Hormone Replacement Therapy

- ▶ The Women's Health Initiative Trial found women had a 1% increase in BD one year after discontinuing HRT .

Tamoxifen (SERM)

- ▶ Shown to decrease density by 10% and a 63% reduction in risk of the redevelopment of breast cancer.

Screening Dense Breast Tissue

- ▶ Mammography is the *only* proven modality to reduce breast cancer related mortality with an average sensitivity rate of 85% in detection of breast cancer.
- ▶ Mammography is the first step to screening women, including women with dense breasts.
- ▶ In the U.S., major guideline organizations differ regarding the method of breast cancer screening in women with dense breast tissue.

Breast Cancer Screening Guidelines - Comparison

	ACR/SBI	ACS	ACOG	AMA	NCCN	USPSTF
Age to Start Mammography*	40	45 Option to start at age 40	Offer at 40, not later than 50	40	40	50
Age to Stop Mammography	No age limit; tailor to individual health status	When life expectancy is < 10 years	Age 75, then shared decision	Not stated	Not stated	74 years
Mammography Interval	Annual	Annual 45-54; Every 1 or 2 years 55 and older	Every 1 or 2 years	Annual	Annual	Every 2 years
View on Tomosynthesis (3D) Mammography	Improves cancer detection, reduces recall rates	Improvement in detection, lower chance of recall	Not stated	Not stated	Improves cancer detection, reduces recall rates	Insufficient evidence to support routine use; grade "I"

* In a 2018 analysis from Harvard*, not considered in the current guidelines, black, Hispanic, and Asian women have peak incidence of breast cancer in their 40s and should begin screening at least by age 40. *Stapleton SM, Osei TO, Babalokov YJ, Hang T, Chang DC. Race/Ethnicity and Age Distribution of Breast Cancer Diagnosis in the United States. *JAMA Surg*. Published online March 07, 2018. doi:10.1093/jamasurg.2018.0035

Resources

- ACR/SBI** Breast Cancer Screening for Average-Risk Women. Recommendations From the ACR Commission on Breast Imaging. 2017
See also: Breast Cancer Screening in Women at Higher-Than-Average Risk. Recommendations From the ACR. 2018
- ACS** Offitger KC, Fontham ET, Etzioni R, et al. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. *JAMA*. 2015;314(15):1999-2014. <https://www.acs.org/press-releases/2015/05/05/20150505-acs-breast-cancer-screening>
- ACOG** <https://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins/Gynecology/Breast-Cancer-Risk-Assessment-and-Screening-in-Average-Risk-Women>
- AMA** Action of the AMA House of Delegates 2012 Annual Meeting: Revisions to AMA policy H-525.993 "Mammography Screening in Asymptomatic Women Forty Years and Older". Adopted 06-19-2012. Available at: <https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/council/council%20reports/council-on-science-public-health/015-council-screening-mammography.pdf>
- NCCN** NCCN Guidelines Breast Cancer Screening and Diagnosis Guidance PDF v.2.187. 6/2/17
- USPSTF** Siu AL, on behalf of the U.S. Preventive Services Task Force. Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2016;164(2):279-296. doi:10.7326/M15-2886

Modalities used to screen Dense Breasts

- ▶ **Standard 2D Mammogram**
 - ▶ film (analog) or digital (full field digital)
- ▶ **3-D mammography**
 - ▶ Digital breast tomosynthesis (DBT)
- ▶ **Whole Breast Ultrasound (WBUS)**
 - ▶ Hand-held ultrasound, Automated breast ultrasound (ABUS), or semi-automated
- ▶ **MRI**
 - ▶ Molecular Breast Imaging and breast specific gamma imaging
- ▶ Breast PET Exam
- ▶ Contrast-enhanced digital mammogram

2D Mammogram and Dense Breasts

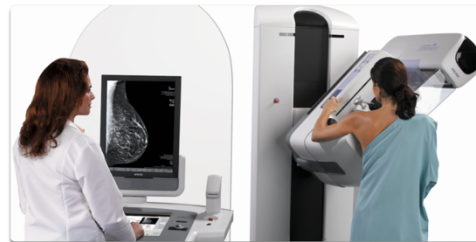
- ▶ 2D mammogram only proven modalities to reduce breast cancer deaths
- ▶ 2D Digital mammography can obscure 12-22% of breast cancers and the percent rises to 50% in women with extremely dense breast tissue.
- ▶ Detect two to seven breast cancers per 1000 women screened using ionizing radiation.



Please make sure women are getting a digital film over a film mammogram. (sensitivity 70% vs 55%)

3D Mammograms and Dense Breasts

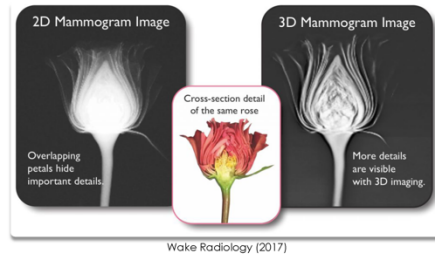
- ▶ 3D was approved by the FDA in February of 2011 as an *adjunct* breast cancer screening tool .
- ▶ 3D compresses the breast like 2D and arcs over the breast to capture multiple images of the breast tissue in thin 1-mm slices.



Breastlink.com (2018)

3D Mammogram and Dense Breasts

- ▶ The slices are then reconstructed into a 3-D images allowing for better discrimination of breast tissues structures and possible lesions



3D Mammograms and Dense Breasts

- ▶ Multiple studies show the *increased* sensitivity of 2D mammography in combination with 3D mammogram screening in women with dense breast tissue
 - ▶ Oslo Tomosynthesis Screening Trial
 - ▶ STORM-2 Trial
 - ▶ Malmö Trial
 - ▶ TOMMY Trial
 - ▶ Meta Analysis by Lei et al. (2014) Diagnostic accuracy of digital breast tomosynthesis versus digital mammography for benign and malignant lesions in breasts: a meta-analysis. *European Society of Radiology*
- ▶ 2-D plus 3D found 3-9 breast cancers per 1000 women with a call back number of 70 (reduction of 40-60% of women)

Ultrasound and Dense Breasts

- ▶ WBUS is an widely available, reproducible, and cost-effective without the use of radiation.
- ▶ ABUS was approved by the FDA in Sept 2012 as an adjunct with mammography.
- ▶ ASTOUND trial evaluated WBUS after negative findings on 2-D in women with dense breast and found an additional 23 breast cancers per 1000 women.

Ultrasound and Dense Breasts

- ▶ WBUS remains limited due to operator variability, shortages of trained personnel, and reduction in radiologist efficiency for image acquisition
- ▶ 2-D mammogram plus WBUS found four to eleven breast cancers per 1000 women using sounds wave with a call back of 170 to 230



MRI and Dense Breasts

- ▶ The most sensitive imaging modality for dense breast tissue
- ▶ MRI is an expensive screening which requires IV contrast.
- ▶ Mostly reserved for women at high risk for breast cancer (20% risk).
- ▶ Many studies have shown a benefit from MRI in high-risk women with a >20% lifetime risk for breast cancer.



Breastlink (2018)

How to guide patient's with dense breasts

- ▶ Assess each woman (40 yrs +) based on her risks factors for breast cancer and what risk factors she can modify.
- ▶ Assess **genetic risks** that would be her at a high risk:
 - ▶ Known mutation in a cancer susceptibility gene within the family
 - ▶ 2 or more breast cancer primaries in a 1st, 2nd, or 3rd degree relative
 - ▶ Ovarian cancer primary
 - ▶ 1st or 2nd degree relative with breast cancer ≤ 45
- ▶ Personal and/or family history of 3 or more of the following: pancreatic cancer, prostate cancer, sarcoma, adrenocortical cancer, brain tumors, endometrial cancer, thyroid cancer, kidney cancer, dermatologic manifestations
- ▶ Received chest radiation between the ages 10-30 years old
- ▶ History of atypia (ADH, LCIS, ALH, SEA)

How to guide patient's with dense breasts

- ▶ Use a breast cancer screening tool to assess risk.
- ▶ Risk models vary, therefore use more than 1
 - **Gail Model**
 - <http://www.cancer.gov/bcrisktool/>
 - **Tyrer-Cuzick** * includes breast density*
 - <http://www.ems-trials.org/riskevaluator/>
 - **Penn II**
 - <http://www.afcri.upenn.edu/itacc/penn2/>
 - **Claus**
 - <http://www.ncbi.nlm.nih.gov/pubmed/8299086>
 - **Breast Cancer Surveillance Consortium** *includes breast density*
 - <https://tools.bcscc.org/BC5yearRisk/calculator.htm>

How to guide patient's with dense breasts

- ▶ If the woman is at an intermediate or high risk >15% and/or has genetic factors
 - ▶ Continue to advise the patient to maintain annual mammogram and clinical breast exams
 - ▶ Refer to a high risk breast clinic for a personalized assessment and additional recommendations
 - ▶ WBUS, or MRI's

How to guide patient's with dense breasts

- ▶ If woman is not at an intermediate or high risk <15% or no genetic factors
 - ▶ Reassure her that up to 50% of women have dense breasts
 - ▶ Explain the dense breast tissue and the risk of breast cancer
 - ▶ **Category C: Heterogeneously Dense**
 - ▶ 40% of the population
 - ▶ Relative Risk of 1.2
 - ▶ Decreases mammogram sensitivity by 10-20%
 - ▶ **Category D: Extremely Dense**
 - ▶ 10% of the population
 - ▶ Relative Risk of 2.0
 - ▶ Decreases mammogram sensitivity 10-20%

How to guide patient's with dense breasts

- ▶ Inform the woman about a 3D mammogram for the next annual screening
- ▶ Encourage breast self-awareness and to report any changes promptly.
- ▶ Encourage modifiable risk factors:
 - ▶ Exercise and maintain healthy weight
 - ▶ Limit ETOH to 1 drink per day
 - ▶ Make educated choices on postmenopausal hormone therapy

Dense Breast Notification Legislation

- ▶ In 2009, Connecticut was the first state to pass the *Breast Density Notification Law*.
- ▶ Currently there are 36 state density reporting laws
- ▶ MN passed their law on July 1, 2014.
- ▶ ND's law was passed on April 9, 2015 however expired on July 31, 2017
- ▶ If a woman has either Category C or D breasts, a state-mandated notification letter will be sent to the woman with the principal message that increase breast density can obscure signs of malignancy on a mammogram. Notification content varies from state to state



Breast Density Awareness and Knowledge

- ▶ Women need to be aware of their breast density, so they are better able to make decisions about their screening options.
- ▶ Empower women with knowledge about breast density can make a difference between an early stage breast cancer with a high survival rate versus a late stage breast cancer with a high mortality rate.

Any Questions??



References

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- ▶ Center for Disease Control (2018) Breast Cancer. Retrieved from <https://www.cdc.gov/cancer/breast/index.htm>
- ▶ The Institute for Clinical and Economic Review (2014) An action guide for supplemental cancer screening for women with dense breasts: next steps for patients, clinicians, and insurers. Retrieved from <https://icer-review.org>

APPENDIX K. DENSE BREAST TISSUE FACTS FOR PROVIDERS

DENSE BREAST TISSUE



WHAT IS BREAST DENSITY?

The breast is composed of fat, glands, ducts, and fibrous connect tissue. The more fibroglandular (glands + fibrous) tissue the denser the breast. Breast density is determined by the proportion of fibroglandular tissue (dense) and fat.

WHY DOES BREAST DENSITY MATTER?

EARLY DETECTION AND TREATMENT OF BREAST CANCER IS IMPORTANT TO SAVE LIVES. The earlier breast cancer can be found, the better chance of survival.

Dense breast tissue can *mask or hide* breast cancer delaying finding of breast cancer and early treatment. On mammography, dense fibroglandular tissue blocks x-rays and appears white. Cancerous tissue also appears white making it difficult to see on mammography.

Dense breast tissue is an *independent* risk factor for breast cancer. Women with dense breasts have a 1.2 to 2 times greater chance of developing breast cancer.

HOW IS BREAST DENSITY DETERMINED?

Breast density is determined by a woman's mammogram. Radiologists will subjectively evaluate a woman's density using the BI-RADS scale. Breast density is **NOT** determined by the breast size, shape, look, or feel. A woman's breast tissue is categorized into one of four BI-RADS categories.

There are 4 categories of breast density:

- Category A: Almost entirely fatty
- Category B: Scattered fibroglandular density
- Category C: Heterogeneously dense**
- Category D: Extremely dense**

Category C: Heterogeneously dense and Category D: Extremely Dense are considered dense breast tissue. Category C has a relative risk of 1.2 and Category D has a relative risk of 2.0 for breast cancer.

WHAT CAN I DO AS A PROVIDER?

- Recommend digital mammography* over film mammography when using 2D mammograms.
- Have a **CONSISTENT** and **CLEAR** dialogue for explaining dense breast tissue to woman and the impact on the risk for breast cancer.
- Know what supplemental screening options are available to your patients
 - Ultrasound
 - Digital Breast Tomosynthesis (3D mammogram)
 - MRI
- Use assessment tools to help assess a woman's overall breast cancer risk. ****include breast density****
 - ****Tyreer-Cuzick:** <http://www.ems-trials.org/riskevaluator/>
 - ****Breast Cancer Surveillance Consortium:** <https://tools.bccsc-scc.org/BC5yearRisk/calculator.htm>
 - Gail Model: <http://www.cancer.gov/bcrisktool/>
 - Penn II: <http://www.afcri.upenn.edu/itacc/penn2/>
 - Claus: <http://www.ncbi.nlm.nih.gov/pubmed/8299086>
- Use a shared decision-making process to decide about options for supplemental screening.
 - Talk with your patient ☺

APPENDIX L. DENSE BREAST TISSUE FACTS FOR WOMEN

DENSE BREAST TISSUE FACTS



WHAT IS DENSE BREAST TISSUE?

Breasts contain glands, fibrous tissue, and fat. *Dense tissue* is made up of glands and fibrous tissue, called fibroglandular tissue. Each woman's breast is different on how much fat and fibroglandular tissue is in the breast. Some women have more fatty tissue while some have more fibroglandular tissue.

The more fibroglandular tissue you have the denser your breasts will be.

HOW DO I KNOW IF I HAVE DENSE BREASTS?

Breast density is **NOT** determined by the breast size, shape, look, or feel. After your mammogram a doctor who reads mammograms, known as radiologists will examine your mammogram and determine your breast density.

There are 4 categories of breast density:

- Category A: Almost entirely fatty
- Category B: Scattered fibroglandular density
- Category C: Heterogeneously dense**
- Category D: Extremely dense**

***Category C: Heterogeneously dense and Category D: Extremely Dense are called dense breast tissue.*

WHY DOES BREAST DENSITY MATTER?

EARLY DETECTION AND TREATMENT OF BREAST CANCER IS IMPORTANT TO SAVE LIVES. The earlier breast cancer can be found, the better chance of survival. Dense breast tissue can *mask or hide* breast cancer delaying finding of breast cancer and early treatment.

Dense breast tissue is a risk factor for breast cancer. Women with dense breasts have a 1.2 to 2 times greater chance of developing breast cancer.

ARE DENSE BREAST COMMON?

Yes! Dense breast tissue is common. It is not unusual to have dense breast tissue.

- More than 50% of women less than 50 years of age have dense breast tissue
- About 40% of women aged 50 to 60 have dense breast tissue
- About 25% of women 60 and older have dense breast tissue

DENSE BREAST RESOURCES

- Susan G. Komen: <https://ww5.komen.org/BreastCancer/HighBreastDensityonMammogram.html>
- Densebreast-info.org: <https://densebreast-info.org>
- Centers for Disease Control and Prevention: <https://www.cdc.gov/cancer/breast/index.htm>
- American Cancer Society: <https://www.cancer.org/cancer/breast-cancer.html>

WHAT CAN YOU DO?



WHAT TYPE OF SCREENING SHOULD I DO?

Continue to receive regular mammograms based on your provider's recommendation.

Talk to your provider if supplemental screening is an option for your next annual mammogram. Supplemental screening can include an ultrasound or 3D mammograms.

KNOW YOUR RISKS FOR BREAST CANCER

It is important to know your *overall* risk for breast cancer. Breast density is a risk factor for breast cancer. Remember, there are many risk factors that affect breast cancer.

Risk Factors include:

- Age
- History of breast cancer in a first-degree relative
- Inherited gene mutations such as BRCA1 and BRCA2
- Personal history of breast cancer
- Early periods
- Late menopause
- First pregnancy after age 30 or never having been pregnant
- Lifestyle choices: alcohol use, physical inactivity, and obesity/overweight

KNOW YOUR BREASTS

We encourage you to have breast self-awareness. *Know what is normal for you.* Talk to your doctor if you experience any of these changes.

- Lump, hard knot or thickening inside the breast or underarm area
- Swelling, warmth, redness, or darkening of the breast
- Change in the size or shape of breast
- Dimpling or puckering of the skin
- Itchy, scaly sore or rash on the nipple
- Pulling in of your nipple or other parts of the breasts
- Nipple discharge that starts suddenly
- New pain in one spot that doesn't go away.

MAINTAIN HEALTHY LIFESTYLE CHOICES

Make healthy lifestyle choices.

- Maintain a healthy weight
- Regular exercise into your daily routine
- Limit alcohol intake
- Limit menopausal hormone use
- Breastfeed, if you are able

APPENDIX M. ESSENTIA HEALTH DENSE BREAST NOTIFICATION ORIGINAL



Essentia Health

**1027 WASHINGTON AVENUE
Detroit Lakes, MN 56501-3905**

June 10, 2015

Optime Zzztest
456 Test Rd
Duluth MN 55811

Dear Optime:

We are pleased to inform you that your recent breast imaging examination done on 6/10/15 showed no suspicious findings for breast cancer.

Negative breast imaging does not exclude the possibility of breast disease. You should never ignore a breast lump or any other change in your breasts, even when the breast imaging is normal. If you find a lump or other change, talk to your health care provider about it as soon as possible. Please keep in mind that good breast care involves a combination of three important steps: monthly breast self-examination, an annual examination by a health care professional, and periodic mammograms. Current American Cancer Society Guidelines recommend screening mammograms every year beginning at the age of 40.

Your mammogram shows that your breast tissue is dense. Dense breast tissue is relatively common and is found in more than 40% of women. However, dense breast tissue may make it more difficult to identify precancerous lesions or cancer through a mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your own awareness and to help inform your conversations with your treating clinician who has received a report of your mammogram results. Together you can decide which screening options are right for you based on your mammogram results, individual risk factors, or physical examination.

A report of your breast imaging result was sent to [REDACTED], MD

Your breast imaging examination will become part of your Essentia Health medical record for at least 10 years. You are responsible for informing any new health care provider or breast imaging facility of the date and location of this examination.

An American College of Radiology Board-Certified physician has interpreted your

APPENDIX N. ESSENTIA HEALTH DENSE BREAST NOTIFICATION REVISED

DENSE BREAST NOTIFICATION

Essentia Health
1027 Washington Avenue
Detroit Lakes, MN 56501-3905

June 10th, 2015

Optime Zzztest
456 Test Rd
Duluth MN 55811

Dear Optime:

Your mammogram that was done on *(date)* showed **NO** findings of breast cancer.

Your mammogram did show that your breast tissue is dense. You have Category *(Insert)*.

- Dense breast tissue is common. More than 40% of women have dense breasts.
- Dense breast tissue makes it harder to see cancers on a mammogram.
- Dense breast tissue is linked to an increase risk of breast cancer.

Please, talk with your healthcare provider about your dense breasts. Your healthcare provider did receive a copy of your mammogram results. Together, you can choose what screening options are right for you based on your mammogram results and personal health history.

A negative mammogram does not lower the chance of breast cancer. Please continue to practice self-breast awareness. Self-breast awareness is knowing what is and isn't normal for your breasts. Never ignore a breast lump or any other changes in your breasts even when your mammogram is negative. If you do find a lump or other change talk to your health care provider about it as soon as possible.

Please talk to your healthcare provider about how often mammogram screening is right for you. Early detection of breast cancer saves lives and we value yours. Please see us at your next scheduled mammogram on *(Date)*.

Thank you for choosing Essentia Health.

Sincerely,

Breast Imaging Center
(701) 364-8000

****Mobile Breast Imaging Services is provided by DMS Imaging, INC. An American College of Radiology Board-Certified physician has read your mammogram. A report of your mammogram result will be sent to (blank) MD. Your mammogram will become part of your Essentia Health medical record for at least 10 years. You are responsible for telling a new healthcare provider or breast imaging facility of the date and location of this mammogram.****

APPENDIX O. NDHC DENSE BREAST NOTIFCATION ORIGINAL

Northwood Deaconess Health Center

and

DMS Imaging

Hello,

Your mammogram that was performed at Northwood deaconess Health Center by DMS imaging, an FDA certified mammography provider, was negative for cancer, which means no cancer was found.

Your mammogram does show that your breast tissue is dense. For most women, breast density decreased with age, but in some women, there is little change over time. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to find cancer on a mammogram and may also be associated with an increased risk of breast cancer. North Dakota law requires that we inform you of dense breast tissue to raise awareness and to promote discussion with your healthcare provider about you own risk for breast cancer. Together with your health care provider, you can determine whether additional breast imaging tests would be beneficial based on your risk factors and physical examination. A report of your results was sent to your health care Provider.

Remember that you should never ignore a breast lump, even if your mammogram is normal. If you find a lump or any other change in your breast, talk to your healthcare provider about it as soon as possible. Your mammogram will become a part of your medical file here at Northwood Deaconess Health Center for at least 10 years. You are responsible for informing any new health care provider or mammography facility of the date and location of this examination.

Sincerely,

Radiology Staff

Northwood Deaconess Health Center Radiology Department

(701) 587-5889

APPENDIX P. NDHC DENSE BREAST NOTIFICATION REVISED

DENSE BREAST NOTIFICATION

Northwood Deaconess Health Center
4 S Park St.
Northwood, ND 58267

February 1st, 2019

Jane Smith
123 4th St
Northwood, ND 58267

Dear Ms. Smith

Your mammogram that was done on *(date)* showed **NO** findings of breast cancer.

Your mammogram did show that your breast tissue is dense. You have Category *(Insert)*.

- Dense breast tissue is common. More than 40% of women have dense breasts.
- Dense breast tissue makes it harder to see cancers on a mammogram.
- Dense breast tissue is linked to an increase risk of breast cancer.

Please, talk with your healthcare provider about your dense breasts. Your healthcare provider did receive a copy of your mammogram results. Together, you can choose what screening options are right for you based on your mammogram results and personal health history.

A negative mammogram does not lower the chance of breast cancer. Please continue to practice self-breast awareness. Self-breast awareness is knowing what is and isn't normal for your breasts. Never ignore a breast lump or any other changes in your breasts even when your mammogram is negative. If you do find a lump or other change talk to your health care provider about it as soon as possible.

You can start screening for breast cancer as early as age 40. Please talk to your healthcare provider about what age is right for you. Early detection of breast cancer saves lives and we value yours. Please see us at your next scheduled mammogram on *(Date)*.

Sincerely,

Radiology Staff
Northwood Deaconess Health Center Radiology Department
(701) 587-5889

****Mobile Breast Imaging Services is provided by DMS Imaging, INC. An American College of Radiology Board-Certified physician has read your mammogram. A report of your mammogram result will be sent to *(your provider)*. Your mammogram will become part of your Northwood Deaconess Health Center medical record for at least 10 years. You are responsible for telling a new healthcare provider or breast imaging facility of the date and location of this mammogram. ****

APPENDIX Q. EXECUTIVE SUMMARY

April 2019

Executive Summary

Increasing Awareness of Dense Breast Tissue as an Independent Risk Factor for Breast Cancer: A Pilot Study

Breast cancer is the most common cause of cancer in the United States no matter race or ethnicity. It is the number one cause of cancer diagnosis and the second cause of cancer death in the U.S. In fact, 1 in 8 women will get breast cancer. Early detection and prevention is vital to reduce the mortality associated with breast cancer. Notification of breast density legislation has increased awareness about breast density and the risk for breast cancer. Current breast-screening guidelines vary from leading U.S. preventative organizations, making prevention education difficult for providers and patients to understand. The purpose of the project was to increase awareness of dense breast tissue as an independent risk factor for breast cancer, assess current understanding of BD among rural women with known dense breast tissue, and to increase awareness of BD among healthcare professionals in rural healthcare.

In the Fall of 2018, the project was implemented at two rural Midwestern primary care clinics using the Plan-Do-Study-Act and Nola Pender's Health Promotion model as a framework. A total of 13 women participate in the project. A questionnaire was used to assess rural women's knowledge and awareness of dense breast tissue. All participants (N=13) received personalized education on BD and risk for breast cancer. Almost all women acknowledged that having dense breasts does make it more difficult to see breast cancer on a mammogram (n=12; 92.3%), however only 46.2% (n= 6) recognize BD as a risk factor for breast cancer. Almost all women (n=12; 92.3%) did not feel knowledgeable about their dense breast tissue, however more than half (n=10; 76.9%) were comfortable about making decisions regarding the type of screening to have with their dense breasts. Results were aggregated and disseminated to providers. Providers had an increased awareness of dense breast tissue and the risk for breast cancer. Also, BD notifications were revised to reflect a seventh-grade reading level.

The findings of the project supported the need for increased awareness and knowledge among rural women and healthcare professionals about dense breast tissue and the risk of breast cancer. The project also supported a need for an increase in readability with dense breast notifications. Empowering women with knowledge of their dense breast tissue can lead to more increased conversations with their healthcare providers and allow them to seek out appropriate screening options. Increasing awareness of breast density through education may be the difference between an early stage breast cancer with a high survival rate versus a late-stage breast cancer with a high mortality rate.

Early detection saves lives.