# IMPLEMENTATION OF HEALTHCARE PROFESSIONAL EDUCATION: BREAST

# DENSITY AS AN INDEPENDENT RISK FACTOR FOR BREAST CANCER

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# Implementation of Healthcare Professional Education: Breast Density as an Independent Risk Factor for Breast Cancer

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# DOCTOR OF NURSING PRACTICE

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# ABSTRACT

A woman living in the United States has a 12.4%, or one in eight lifetime risk of being diagnosed with breast cancer. Breast cancer is the most commonly diagnosed cancer among women in the United States (U.S). The risk factors for developing breast cancer are multifactorial, and dense breast tissue has been found to be an independent risk factor for breast cancer. Women with dense breasts have a four to six times greater risk of developing breast cancer to women with fatty breast tissue. Screening mammography has been the gold standard in breast cancer detection and to measure breast density. Unfortunately, women living in rural areas have lower breast screening rates.

Many women in the United States lack knowledge related to the relationship between density and breast cancer risk. One reason may be related to breast density notification laws. Unfortunately, only 38 states have enacted breast density laws, and the breast density letters do not have uniform verbiage and are written at an average grade level of 10.5, which may cause confusion. Additionally, Rhodes et al. (2019) found less than half of the women in their study had a conversation with their healthcare provider about their breast density. Healthcare providers have also reported feeling uncomfortable discussing breast density with patients due to limited resources and training on this topic.

The goal of this practice improvement project (PIP) was to assess the knowledge and understanding of breast density among women undergoing screening mammography in a rural clinic through implementation of the Mayo Clinic Breast Density Awareness Survey. Healthcare professionals were also educated about survey results and breast density as an independent risk factor for cancer. Assessment of patient knowledge and healthcare professional education on breast density has the potential to improve outcomes and overall patient health.

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# **DEDICATION**

I would like to dedicate my dissertation to my family. To my husband who made sacrifices and has been by my side and offered so much support during my journey. To my greatest blessings,

my children, Brecken and Penelope for growing with me and being so understanding when mommy had homework. I want to be a role model for you and show you hard work, dedication and determination can lead you to success in any of your dreams. Thank you, children, for your patience and teaching me the importance of time management in work, life, and school balance. To my parents and in-laws, I will be forever grateful, thank you for being my go-to people when I needed help, and for helping my children understand the importance of mommy's education. I will be forever grateful for the additional time you gave my children during my years in graduate

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# **CHAPTER ONE. INTRODUCTION**

## **Breast Cancer**

Breast cancer is the most commonly diagnosed cancer among women in the United States (U.S) (DeSantis et. al, 2019; DeSantis, Ma, Goding Sauer, Newman, & Jemal, 2017). Additionally, breast cancer is the second leading cause of cancer death in American women after lung cancer. A woman living in the United States has a 12.4%, or one in eight, lifetime risk of being diagnosed with breast cancer. Although breast cancer is a commonly diagnosed disease among women in the United States, there has been a rapid decline in breast cancer deaths since 1989, which can be attributed to improvements in treatment and early detection using screening mammography. Mammography has been the mainstay gold standard in breast cancer detection. Even with the decline of deaths from breast cancer, approximately 41,760 women in the U.S. were projected to die each year from breast cancer (America Cancer Society, 2019). Early detection through screening is key to surviving breast cancer.

Unfortunately, women living in rural areas have lower breast screening rates and are more likely to be diagnosed in the later stages of breast cancer compared to women living in urban areas (Peppercorn, Horick, Houck, Rabin, & Villagra, 2017). Potential barriers for routine screening mammography among rural women include low socioeconomic status, lack of health insurance, out-of-pocket costs, fear of diagnosis, lack of provider recommendation or referral, and geographical location (Peppercorn, Houck, Bari, Villagra, Wagyu, Lyman, & Wheeler, 2015).

Women living in rural communities commonly must travel long distances to the nearest healthcare facility, which impacts their ability to access healthcare. Additionally, out-of-pocket costs have been found to more commonly affect women compared to men, and one in four

women delay healthcare because of the cost, particularly women of lower socioeconomic status. In fact, Peppercorn et al. (2017) found breast cancer screening rates among rural women significantly increased between 3% and 6% after eliminating the cost of screening. A thorough understanding of breast cancer knowledge and preventative screening practices among rural women may assist healthcare providers in implementing conversations and interventions to enhance screening among this population.

# **Background and Significance**

Various guidelines exist for breast cancer screening in the U.S; however, recommendations may differ from guideline to guideline, such as the recommended starting age and frequency of screening. The Unites States Preventative Centers and Taskforce (USPSTF) and other cancer organizations provide breast cancer screening guidelines that also incorporate risk factors for breast cancer, which are multifactorial. Dense breast tissue is an independent risk factor for breast cancer (Berg & Pushkin, 2017). Women with dense breasts have a four to six times greater risk of developing breast cancer compared to women with fatty breast tissue (Azam et al., 2018). According to the Breast Imaging Reporting and Data System (BI-RADS) categories the term "dense breast" is used when referring to category C and D. Approximately 40-50% of women in the United States have Category C or D density, which is defined as heterogeneously dense or extremely dense breast tissue (Berg & Pushkin, 2017).

Breast density is not determined by how a woman's breast looks or feels. Instead, breast density is assessed via mammogram and interpreted by a radiologist (Berg & Pushkin, 2017). After the radiologist interpretation, healthcare providers discuss results of the mammogram with women. Density appears as a lighter color or white on mammography, and cancerous tissue also appears white. This makes distinguishing dense breasts from cancerous tissue difficult and

reduces mammography sensitivity, as some cancers may be masked by dense breast tissue. There may also be variations in interpretation due to the subjective nature of the breast density reporting system, which may cause discrepancies and confusion when interpreting breast density for healthcare providers and their patients.

Today, 38 states have enacted a breast density notification law (Berg & Pushkin, 2017). The breast density notification laws were enacted to empower and inform women about their individual breast density. The facility that is performing the mammogram is mandated to inform women and healthcare providers regarding women's breast density. There is inconsistent verbiage and information in the letters that vary from state to state, which may cause confusion for patients when reading the letter. In addition to there being no uniform or designated wording for the letters, the readability of the letters is most commonly at a high school level and may be difficult to understand for women with lower health literacy levels (Gunn, Battaglia, Passche-Orlow, West, & Kressin, 2018). Additionally, not all states have enacted breast density notification letters. The state of North Dakota recommends informing and educating women, but breast density notification is not required (Densebreast-info.org, 2018). Since the letters have been enacted, there have also been questions about who is responsible to explain breast density to women (Maimone & McDonough, 2017). Ultimately, subjective mammogram interpretation and variability of the reporting system, along with the lack of a clear and standardized notification process, poses a challenge in ensuring women with dense breast tissue fully understand their mammography results and breast cancer risk.

#### **Statement of the Problem**

Informed women can make educated decisions in their care; however, many women in the United States lack knowledge related to the relationship between density and breast cancer

risk (Santiago-Rivas, Benjamin, Andrews, & Jandorf, 2019). This lack of knowledge interferes with patients' ability to fully participate in informed decision-making about breast cancer screening. Breast notification laws are enacted to empower women in making decisions about breast cancer screening. Unfortunately, variability with state-to-state laws and different verbiage of notification letters has caused confusion among women and their providers. Evidence suggests that the language included in notification letters is vague and difficult to interpret for women who have lower education attainment and health literacy (Fedewa, 2019). Health literacy, or the ability to understand and interpret health information, may influence patients' ability to not only understand letters regarding their health, but also ability to engage as a partner in their healthcare and follow-up with preventative screening recommendations. Unfortunately, women in rural areas have been found to have lower health literacy levels compared to those in urban areas (Temple, 2017). Ultimately, women may misinterpret information or neglect to follow through with breast cancer screenings due to difficulty understanding verbiage in the letters and low health literacy, which may cause anxiety and poor patient outcomes.

In addition to the variation of breast density notification laws from state to state, healthcare providers are finding discussing breast density with patients challenging, and many providers report they lack the training or have limited access to resources to answer their patients' questions (Haas, 2019). One of the most important goals of legislation requiring notification is to encourage women to speak with their providers and make an individually tailored decision about breast cancer screening based on their unique risk factors. Due to the lack of healthcare provider training and appropriate readability of notification letters, women may not fully understand the role of breast density as an independent risk factor for breast cancer.

# **Purpose of the Project**

The purpose of this practice improvement project was to assess the knowledge and understanding of breast density among women undergoing screening mammography in a rural Midwestern community. The project also aimed to educate healthcare professionals about breast density as an independent risk factor for breast cancer, as well as enhance healthcare professionals' awareness of breast density knowledge among women in the rural community they serve. The objectives of the practice improvement project are as follows:

- Assess the understanding and knowledge of breast density among screening age women per the American College of Radiology guideline at a rural Midwestern clinic.
- 2. Increase healthcare professional's knowledge regarding how breast density affects their patients by the end of the educational session.
- 3. Review breast density notification letters utilized by the rural Midwestern clinic and provide suggestions to improve the readability of the notification letters to at least a fifth-grade reading level.

# **CHAPTER TWO. LITERATURE REVIEW**

A systematic literature review was done based on the purpose of the practice improvement project. The databases that were utilized include: Cochrane library, EBSCO, PubMed, DenseBreastinfo, American Cancer Society, U.S. Preventative Services Task Force and the American Academy of Radiology. Keywords utilized in the search include the following: *breast density, knowledge, screening modalities, breast cancer, mammography, legislature, dense breast notification laws, rural women,* and *health literacy.* Inclusion criteria included peerreviewed, full-text articles published within the last 10 years with a focus on breast cancer and density among women. Exclusion criteria included studies involving male participants.

#### **Breast Cancer**

Breast cancer is diagnosed in 200,000 women throughout the United States annually and, approximately 133 out of 1,000 women in North Dakota are diagnosed with breast cancer each year (Kaiser Family Foundation, 2015). Breast cancer is the second leading cause of cancer mortality in women, and mammographic density is considered an independent risk factor for the development of breast cancer (Falcon, Williams, Weinfurtner, & Drukteinis, 2017). Breast density not only contributes to the risk of breast cancer but is also inversely correlated with the accuracy of mammography screening. While mammography is that identifying abnormalities can be difficult among women with breast dense tissue, which demonstrates the importance of understanding each patient's risk for breast cancer. Depending upon risk factors, screening recommendations may be altered and tailored to fit each individual patient's needs.

There is an array of risk factors that may contribute to the risk of developing breast cancer (Centers for Disease Control [CDC], 2018). Aging is one known risk factor, as most

breast cancers are diagnosed after the age of 50. Other risk factors for breast cancer include menarche before age 12, menopause after age 55, first-degree or multiple relatives with breast cancer, personal history of breast cancer, personal history of radiation treatment to the chest, diethylstilbestrol use, and history of maternal diethylstilbestrol during pregnancy. Genetic mutations, such as the BRCA1 and BRCA2, are independent risk factors in the development of cancers. Women who have inherited the BRCA1 and BRCA2 genes have a high risk of developing breast or ovarian cancer. The BRCA1 and BRCA2 gene is the most common cause of hereditary breast cancer (American Cancer Society, 2019) Women who inherit the BRCA1 and BRCA2 gene have up to a 7 in 10 chance of developing breast cancer by the time they are 80.

There are multiple risk calculators or models that are utilized by radiologists and primary care providers to assess a woman's risk for breast cancer (Berg & Pushkin, 2017). Common models that are utilized include, Gail, Claus, BRCAPro, and Tyler-Cuzick. The models are used to assess if a woman is considered high risk for breast cancer and if there may be a BRCA1 and BRCA2 mutation. The Gail model is commonly used by healthcare providers to assess a woman's risk for breast cancer. This model specifically helps providers distinguish if breast cancer risk reducing medications, such as tamoxifen, may be warranted. The seven key risk factors included in the model are age, age of first menses, age at the time of the birth of the first child, family history of breast cancer in first degree relative, number of past biopsies, and race/ethnicity. If a woman's 5-year risk is greater than 1.67% they are classified as "high risk" which may warrant the use of risk reducing medications. Tyler-Cuzick, Penn II, Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA), and BRCAPRO are among the models used to predict the risk of pathogenic mutation. The model that is used to identify women who meet the criteria for high-risk screening MRI is the Claus

model. Using the Claus model, women may begin screening between the ages of 25-30 using MRI if the lifetime risk for breast cancer is 20-25% or more.

An additional independent risk factor for breast cancer is breast density. Dense breast tissue is influenced by many different factors. These factors may include exogenous, and endogenous hormones, lactation, radiation therapy, and chemotherapy (Paterson & Havrda, 2020). There is a correlation between breast density and breast cancer risk, but the level of the correlation is unknown due to the many factors that may affect breast density. Breast density has a significant effect on mammography, which is the gold standard in screening for breast cancer. The sensitivity of mammography is reduced in women with dense breasts due to overlapping and increased fibroglanduar tissue. Overall, the sensitivity of mammography for the detection of breast cancer is 85%; however, in women with dense breast tissue, the sensitivity of mammography is reduced to 47.8–64.4% (Thigpen, Kappler & Brem, 2018).

#### **Breast Density Classification**

Breast density is classified into four categories defined by breast composition (Berg & Pushkin, 2017). The American College of Radiology (ACR) established the Breast Imaging Reporting and Data System (BI-RADS) in attempt to standardize descriptions and findings in breast tissue (Paterson & Havrda, 2020). According to this system, breast density is grouped into four categories, A-D. Please refer to Figure 1 for mammographic images of each breast density category and to Appendix A for permission to use the images.

# Category A

Category A refers to breasts that appear almost entirely fatty with mammographic screening (Berg & Pushkin, 2017). Approximately 10% of women are classified as having category A density with mammography, and the image field is highly sensitive among these

women. The fatty tissue appears as a darker grey or black color, while small amounts of dense breast tissue or fibroglandualar tissue appears as lighter grey or white markings on imaging.

# **Category B**

Category B refers to scattered areas of fibroglandular density (Berg & Pushkin, 2017). The breast tissue consists of scattered fibroglandular tissue mixed in with fatty tissue, and a malignancy may be undetected if located in an area of denser tissue. Approximately 40% of women in the U.S. are classified as having a category B mammogram.

# **Category C**

Category C is characterized by heterogeneously dense breast tissue (Berg & Pushkin, 2017). A common finding among women in this category is to have primarily fatty areas with other areas of relatively dense tissue. There are also large portions of the breast that may consist of fibroglandular tissue and may mask hidden malignancies. Approximately 40% of women in the United States fall into category C density.

# **Category D**

Category D refers to women who have extremely dense tissue (Berg & Pushkin, 2017). In this category, fibroglandular tissues cover greater than 75% of the breast on imaging, resulting in a "white out" appearance. Identifying calcifications or cancers can be extremely difficult among women with category D mammograms, which is approximately 10% of women.

Even with the BIRADs system in place to standardize reporting, there may be discrepancies due to the radiologist's visualized assessment. The qualitative method of measurement causes variation in reproducibility and reproducibility (Paterson & Havrda, 2020). Therefore, the interpreting radiologist perceptions may differ from another radiologist causing different classifications. The term "dense breast" is used when referring to category C and D

(Densebreast-info.org, 2018). Approximately 50% of women in the United States between the ages 40 to 75 can be classified as having dense breasts (Santiago-Rivas et al., 2019). The sensitivity of mammograms is affected by these categories due to their density, as an increase in breast density alternatively causes a decrease in sensitivity on mammograms (Richman, Asch, Bendavid, Bhattacharya, & Owens, 2017). Given the limitations of mammography with dense breast tissue, supplemental screening tools may be used such as tomographic mammography, ultrasound, or MRI. Due to the lack of evidence on supplemental screening, the USPSTF decided to not make any recommendations for or against supplemental screening for women with dense breasts (U.S. Preventative Services Task Force [USPSTF], 2016).



*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**

Dr. John M. Wolfe was the first researcher to observe and publish studies identifying breast density as an independent risk factor for breast cancer (Wolfe, 1976). Unlike most risk factors for breast cancer, mammographic density is modifiable. Since the original study in 1976, various studies have been published to help identify factors that may contribute to increased breast density among women (Krook, 1978; McCormack & dos Santos Silva, 2006; Threatt, Norbeck, Nelly, Kummer, & Roselle, 1980). Risk factors that may contribute to increase breast density include hormone replacement therapy, race, lifestyle behaviors, age, and genetics. Some of these risk factors may be modifiable.

#### **Hormone Replacement Therapy**

Hormone replacement therapy (HRT) is utilized in women with extreme menopausal symptoms, such as hot flashes, sleep disturbance, muscle joint stiffness, depressive mood, and pain (Azam et al., 2018). Combined HRT with estrogen and progesterone is strongly related to an increase in mammographic density. In fact, Bayne et al. (2017) found that estrogen and progestin combined therapy increased mammographic density among women after one year of use, which increases the risk of breast cancer. Therefore, healthcare providers should initiate a conversation about the risks of utilizing HRT in relation to breast density prior to prescribing the medication.

While the use of HRT increases breast density, tamoxifen has been found to decrease breast density (Azam et al., 2018). Tamoxifen is a selective serotonin estrogen receptor modulator (SERM) and is used to treat breast cancer that express estrogen (ER+). The medication is also prescribed in women who are considered at high risk for breast cancer to reduce the risk of breast cancer occurrence (Densebreast-info.org, 2018).

#### Race

McCarthy et al. (2016) compared breast density in African American and Caucasian women and consistently found that African American women had a higher incidence of breast density. Oppong, Dash, O'Neill, Makambi, Pien, and Campbell (2018) also compared breast density between Hispanic, African American, and Caucasian women and found Hispanic women

had the highest amount of breast density on mammography followed by African American women. While race may be a driving factor in mammographic density, the relationship between race and breast density is not fully understood. Further research regarding race and breast density is needed, as other factors likely also play a role, such as lifestyle, body mass index (BMI), diet, and socioeconomic status.

# **Lifestyle Factors**

Alcohol intake is a known modifiable risk factor in decreasing breast cancer risk. Quandt (2015) found that greater than seven servings of alcohol per week was associated with the risk of increased mammographic density. In the same study, women with a BMI greater than 25kg/m who consumed greater than 7 servings of alcohol per week showed a 17% increase in mammographic density. Conversely, women with BMI greater than 25kg/m who did not consume greater than 7 servings of alcohol per week did not show any significant increase in breast density. BMI is a risk factor for breast cancer. In relation to breast density, BMI is inversely correlated. Patients with BMI >25 are more likely to exhibit predominantly fatty breast tissue and less likely to have extremely dense breast tissue (Hack, et al., 2017). The increase in adiposity tissue results in a higher breast fat content seen on mammography and lower portions of mammographic density (Wanders, Bakker, Veldhuis, Peeters, & van Gils, 2015). An increase in BMI is correlated with finding a later stage of breast cancer. Non-palpable cancers are associated with an increase in women with higher BMI. Even though the effects of BMI on breast density is inversely correlated to breast density, BMI remains an important factor in decreasing breast cancer risk, due to the correlation between BMI and advanced stage of disease at diagnosis.

Age is considered an independent risk factor for mammographic density (Hack, et al., 2017). Women with increased age show a decrease in breast density. Younger women are more likely to have a predominance of fibroglandular tissue, resulting in dense breasts. In older postmenopausal women, breast tissue tends to atrophy, therefore decreasing density (Densebreast-info.org, 2018). Increased age continues to be a risk factor for breast cancer, but like BMI is inversely related to breast density (Hack, et al., 2017). Parity can also influence breast density. Parity and number of births were inversely associated with collagen in the breast tissue (Nazari & Mukherjee, 2018).

#### Heritability

Heritability plays a role when assessing risk for breast density. Comparing monozygotic and dizygotic twins, Nazarri and Mukherjee (2017) found that heredity played a significant role in breast density. In fact, monozygotic twins' density was twice as high when compared to dizygotic twins. The correlation of density in twins is much higher in identical then fraternal twins. Additionally, there is an increased risk for breast density if a woman's mother is known to have dense breast tissue.

#### **Screening Modalities**

Currently, there is no consensus on recommendations to screen for dense breasts and breast cancer, as recommendations differ from various organizations (Berg & Pushkin, 2017). Breast cancer screening recommendations from leading organizations in the United States are illustrated in Figure 2. The variation in screening recommendations has made providing thorough preventative screening education challenging for healthcare professionals.

Age

		ACR/SBI	ACS	ACOG	AMA	NCCN	USPSTF
Age t Mam	to Start nmography <sup>a</sup>	40	45 Option to start at age 40	Offer at 40, not later than 50	40	40	50
Age t Mam	to Stop 1mography	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
Mam Inter	amography rval	Annual	Annual 45-54; Every 1 or 2 years 55 and older	Every 1 or 2 years	Annual	Annual	Every 2 years
View Tom (3D) Mam	v on osynthesis i imography	Improves cancer detection, reduces recall rates	Improvement in detection, lower chance of recall	Not stated	Not stated	Improves cancer detection, reduces recall	Insufficient evidence to support routine use; grade "I"
a 2018	analysis from Har	rvard*. not considered in th	te current guidelines, bla	k, Hispanic, and Asian women h	have peak incidence (	rates	© DenseBreast-infocory Rev. March 2018 40s and should begin screeni
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Figure 2. Screening guidelines comparison by Densebreast-info.org

# Mammograms

Mammography has been the mainstay screening that has proven to be effective in reducing breast cancer mortality (Falcon et al., 2017). Mammography has long been tested and tried for the past 20 years, and digital detection of cancer has been found to be between 81% and 87%. Mammography requires the use of radiation in the form of x-rays (Paterson & Havrda 2020). Mammography utilizes tubes that include molybdenum or rhodium anode target with small focal spots. In order to even out the tissue, compression is applied somewhere between 25 to 45 psi of pressure. The radiation dose required to produce the image is typically between 800mrad to 900mrad. Due to patient variation in thickness of fibroglanduar and fatty tissues, the best way to limit the dose of radiation is accurate positioning to avoid repeat projections.

Mammography has a reduced sensitivity with certain subpopulations, such as women with heterogeneously dense breast tissue. In fact, malignancies may be masked by heterogeneously dense breast tissue approximately 50% of the time on mammography. Therefore, digital breast tomosynthesis mammography, also known as 3D mammography, was developed to improve screening, specifically in women with dense breast tissue. The fatality rate of screening using mammography reduces the breast cancer by about 15- 30% in all women (Paterson & Havrda 2020).

# **Digital Breast Tomosynthesis Mammography**

Sensitivity is improved with 3D mammography, as multiple images are taken and reconstructed to allow radiologists to view thin sections, therefore unmasking the hidden cancers (Falcon et al., 2017). The thin-slice imaging allows clinicians to increase detection of asymmetries, architectural distortions, and masses by minimizing tissue overlap and reconstructing the images to form a 1-mm slice image that can be scrolled through. The addition of 3D mammography has increased cancer detection rates by about 40% and decreased recall rates by approximately 15% (Berg & Pushkin, 2017). Thus, the addition of 3D mammography in women with dense breast tissue has shown to increase sensitivity and specificity (Falcon et al., 2017).

# Ultrasound

Due to the decreased sensitivity of mammography in dense breast tissue, ultrasonography is another option to use in addition to screening mammography for women with dense breasts (Falcon et al., 2017). In September 2012, the Food and Drug Administration (FDA) approved the use of combination ultrasonography and mammography in women who are asymptomatic,

who have normal or benign findings on mammography, have had no prior clinical breast intervention, and have dense breast parenchyma.

Ultrasonography is cost effective and is accurate in finding small masses (Falcon et al., 2017). The procedure is performed by a trained technologist or radiologist and utilizes high frequency sound waves to form a structural image of the breast. The utilization of breast ultrasounds in addition to mammography was found to detect 23 additional breast cancers per 1,000 screens. Tagliafico et al. (2018) compared adjunct screening techniques, such as ultrasound and tomosynthesis, and found that the use of digital mammography and adjunct screening using 3D mammography and ultrasound detected an additional 29 cancers in a sample size of 5300 women. Three cancers were detected by 3D mammography alone, while ultrasonography alone detected 14 additional cancers. Even though ultrasound detected more cancers, there were also significantly higher false-positive recall rates associated with this diagnostic technique.

# **Magnetic Resonance Imaging**

Magnetic Resonance Imaging (MRI) is considered the most sensitive imaging tool available for invasive breast cancer (Falcon et al., 2017). MRI is noninvasive and works by using magnets and pulses of radio waves to manipulate natural magnetic properties in the body. When used in conjunction with gadolinium-based contrast, a breast MRI visualizes structure and blood flow, which is critical in identifying cancerous tumors. Cancerous tumors are very vascular, and abnormal blood flow is visualized on the cross-sectional 3D images produced by an MRI (Densebreast-info.org, 2018). Fibrograndular tissue does not mask cancers on MRI.

Parenchymal tissue does enhance in varying degrees; therefore, there are four categories of parenchymal enhancement, which include the following: minimal, mild, moderate, and

marked. These categories are also included in the BIRADS. In 2007, the American Cancer Society approved the use of MRI in addition to mammography screening for women who are considered high risk and have heterogeneously or extremely dense breasts (Falcon et al., 2017).

Bakker et al. (2019) assessed the effectiveness of supplemental screening using MRI to improve early detection and decrease interval breast cancers in patients with dense breast tissue. Interval breast cancers are cancers that are discovered between regular screening mammograms (NIH, 2011). The study consisted of 40,373 women between the ages of 50-75. The interval cancer rate in women who underwent screening MRI compared to mammography-only was 2.5 and 5.0 per 1,000, respectively. The MRI screening women had significantly fewer interval cancer rates. Even though this study suggests that MRI is effective in reducing interval cancer rates, which in turn reduces mortality and morbidity, the issue of cost plays a factor when assessing the need for supplemental screening. At this time, MRI is considered an adjunct, and the USPSTF does not provide a recommendation for or against adjunct screenings (Baker et. al., 2019). Therefore, lack of insurance coverage may limit access to adjunct screenings.

#### **Dense Breast Notification and Healthcare Provider Knowledge**

Breast density notification laws have been enacted in 38 states, and only seven states mandate insurance to cover additional supplemental screening, which poses an issue for women in the remaining states with out-of-pocket costs (Fedewa, 2019). In the 38 states that have breast density notification laws, healthcare providers are mandated to supply a letter to women whose mammograms indicate heterogeneously or extremely dense breasts. The verbiage in the notification letters differs in each state. In 2017, the FDA made it mandatory to include in the notification letters that breast density does relate to breast cancer risk (DenseBreastinfo.org, 2018). The Breast Density and Mammography Reports Act of 2017 states that mammography facilities are to provide up-to-date information in written form regarding the patient's mammography results and breast density (Congress.gov, 2017). The summary must contain the effects of masking the presence of breast cancer on mammogram and that individuals with dense breast should speak with their healthcare providers regarding additional testing. As previously discussed, there are many different recommendations for breast cancer screening. The purpose of this law is to entice a conversation and open communication for providers and patients to make informed decisions about breast cancer screening options on an individual basis.

Women in states that have enacted breast density notification laws, have shown to have an increase in knowledge about their density (Rhodes et. al., 2019). Women in the states where laws are already enacted have better communication with their providers about breast density and are more likely to discuss supplemental screening recommendations than women who do not live in a state with breast density legislature. Although, the women in the states with breast density legislature enacted are more likely to have knowledge about breast density there is still a lack of knowledge about breast density and the masking of breast cancer.

There are concerns about providers' knowledge on dense breast tissue due to the variability of notifications and follow-up care. Notification letters may result in more patient questions and use of additional screening tests, such as MRI and ultrasound for high-risk women (Haas, 2018). Additionally, even though 38 states mandate notification letters for breast density, Rhodes, Jenkins, Hruska, Vachon, and Breikopf (2019) found less than half of the women in their study had a conversation with their healthcare provider about their breast density, demonstrating that patient education about breast density during clinical visits is lacking.

Maimone and McDonough (2017) asked healthcare providers about their understanding of their role during discussions with patients regarding breast density and how confident they felt

about their knowledge. Only 2% percent of the healthcare providers reported feeling very confident in their knowledge of breast density, while 35% were moderately confident, and 63% were not confident in their knowledge about breast density. The lack of consensus on screening and lack of provider knowledge may cause confusion regarding preventative screening among patients. Additionally, variability in notification letters may also contribute to this confusion; however, the letters do provide the breast imaging community a threshold to proactively lead individualized screening.

### Women's Knowledge on Breast Density

Rhodes et al. (2019) performed a three- and five-year survey of women regarding their breast density knowledge. In the second survey that was distributed in 2017, 65.8% of women reported that they have heard about breast density, compared to 57.5% in 2012. More women were found to be aware of breast density after the FDA mandate, but still less than half were aware that density masks breast cancer. Rhodes et al. (2019) also analyzed who the women spoke with first about breast density and found 57.1% of women reported being told about breast density by the provider ordering the mammogram, illustrating the importance of provider education and knowledge about breast density. Another study conducted by Santiago-Rivas, Benjamin, Andres, and Jandorf (2017) found that 69.2% of women reported hearing about breast density after the Breast Density and Mammography Reports Act of 2017 had passed, but only one-third of the women knew their own density. While dense breast notifications letters are aimed to inform and educate women, many questions remain regarding women's knowledge and ability to interpret these letters.

A study done by Santiago et. al (2019) found that the main factor influencing women's intentions to complete supplemental screening is the cost. Women with lower salaries or lower

socioeconomic status are at risk of not completing recommended supplemental imaging due to the lack of insurance coverage. Santiago et al. (2019) also discussed that less than half of women that initiated screening mammograms have spoken with their healthcare providers about the risks and benefits of screening. This demonstrates how lack of provider communication can influence a woman's ability to make an informed decision regarding tailored breast cancer screening.

Another barrier in women's knowledge is the lack of consensus in verbiage of breast density notification letters (Berg & Pushkin, 2017). Due to the unregulated information contained in the letters, women may have different interpretations regarding density and screening. In fact, Santiago et al. (2019) found that only 55% of women reported their breast density notification letter mentioned supplemental screening, and the other 45% reported the letter only indicated their density on mammogram. The evidence suggests women are not being adequately educated on dense breast tissue and the associated risk of breast cancer.

## Health Literacy

Approximately one-third of Americans have basic or below basic health literacy (Imoisili, Levinsohn, Pan, Howel, Streiter, & Rosenbaum, 2017). Patient education materials are commonly written at a grade five to grade eight level with a level four and below being considered "easy to read." A study done by Imoisili et al. (2017) assessed patients' health literacy levels at a primary practice clinic. After assessing the average level of health literacy, the patient education materials for the five most common diagnoses in the clinic were reviewed, and most were written at a level greater than ninth grade. Therefore, the clinic did not meet the requirements from Joint Commission, which recommended all health information materials should be available at a fifth-grade reading level (Stossel, Segar, Gilatto, Fallar, & Karani, 2012).

Ensuring patient education materials are delivered in a suitable health literacy level has the potential to improve patient-provider communication, patient satisfaction, and health outcomes.

Gunn, Battaglia, Passche-Orlow, West, and Kressinm (2018) found that the readability of breast density notification letters differs from state to state. The range included readability of 7-19.4, with a mean grade of 10.5 readability. This infers that most of these letters have a readability at a high school level or above. Health information written above a grade level eight leads to misinterpretation and uncertainty in making well-informed decisions. The high readability of the dense breast notification letters may cause women anxiety and confusion and reduce follow-up care. In fact, Gunn et al. (2018) found that 81% of women recall receiving a breast density letter, but very few could remember the content and describe important elements.

Health literacy plays a factor in women's knowledge regarding dense breast tissue, and breast density knowledge is associated with intentions to complete breast cancer screening (Santiago-Rivas et al., 2019). Women with higher health literacy may be more inclined to understand their breast density category and follow with breast screening guidelines. Women in rural areas have been found to have lower levels of health literacy and less inclined to seek preventative services compared to urban women (Peppercorn et al., 2017). Improving the delivery of correct and understandable information throughout healthcare provider discussions and notifications letters has the potential to facilitate good breast cancer behaviors and adherence with screening recommendations and supplemental imaging.

#### **Health Promotion Model**

The Health Promotion Model (HPM) was developed by Nola Pender in 1982 and was revised in 1996 (Pender, 2011). The HPM is built to examine the multidimensional nature of a person as they interact in their environment to pursue their health. The HPM was based on two other theoretical frameworks. The theoretical roots for HPM include the expectancy value theory and social cognitive behavior theory. The HPM focuses on three specific components, which include individual characteristics and experiences, behavior specific cognition and affect, and behavioral outcomes. The philosophical roots for the HPM are based upon addressing humans as a whole and modifying environments to attain individualized needs and goals. The central focus of the model is based on eight core beliefs. The HPM recognizes the past successes and failures of an individual and identifies interpersonal relationships and situational influences that will positively impact the overall goal of optimal wellbeing, valuable living, and personal fulfillment (Pender, 2011). Please refer to Appendix B for the HPM diagram and Appendix C for permission to use the HPM.

The eight core beliefs included in the HPM are; prior related behaviors, personal factors, perceived benefit if action, perceived barriers of action, perceived self-efficacy, activity related affect, interpersonal influences, situational influences, and commitment to plan of action. Using the eight core beliefs to guide this practice improvement project, the survey addressed most of the eight core beliefs. For example, prior related behaviors were assessed through breast history questions. Additionally, personal, and social factors were assessed through family and history questions. The perceived barriers were assessed by asking the "opinion" questions, for example, "I feel comfortable making decisions about what type of preventative screening to have with my dense breast tissue." The survey was be utilized to assess the interpersonal relationships and knowledge acquired about breast density from providers or other various sources. The survey given out to the women in the target population utilized the HPM model to guide the questions.

Educating healthcare professionals and promoting knowledge about breast density has the potential to impact the screening outcomes among women. Increasing women's knowledge about

breast density may increase the incidence of individualized screening methods and promote patients' overall health. The HPM is utilized in assessing rural women's knowledge about dense breast tissue via survey. Using the knowledge obtained from the survey the HPM can be utilized to discover the barriers and deficits the rural women are experiencing and convey this knowledge back to the healthcare team.

# **Project Framework**

The Plan-Do-Study-Act (PDSA) is a scientific method utilized in action-orientated change (Institute of Healthcare Improvement, 2018). The PDSA is a shorthand model to test and assess change and was developed to determine whether a change leads to improvement. The PDSA is a 4-step cyclic model that can be repeated until the desired outcome is achieved, and the model moves in a continuous forward motion (Donnelly & Kirk, 2015).

According to the Institute of Healthcare Improvement (2018), the PDSA is made up of three fundamental questions that can be addressed in any order: "what are we trying to accomplish," "how will we know that change is an improvement," and "what change can we make that will result in improvement?" The first step in the PDSA is *Plan*, and during this step, it is critical to organize and build a specific team to suit the needs of the project. The aim of the project should be time-specific and measurable, along with a specific target population. The second step is *Do*, and in this phase, the project is carried out. The *Study* phase comes after the successful implementation of a project and is when the data is analyzed and recorded to assess the efficacy of the project. The *Act* phase happens after observations are made about the project and necessary modifications are implemented based on observations to acquire the desired outcome, in order to repeat the process over again.

# **PDSA Steps**

The first step is to *Plan* the project (Institute of Healthcare Improvement, 2018). Project planning included developing a team and committee, locating the setting, and receiving Institutional Review Board (IRB) approval. The Plan phase included clarifying objectives and identifying potential barriers to the project and performing an intensive literature review. The survey was developed using literature to guide the development. During the Do step, the project plan was be set into motion. The project was completed in a rural health care clinic, Coal Country Community Clinic in Center, ND. At this clinic, the patient survey was administered to identify women's knowledge regarding breast density, and the breast density notification letter was analyzed. The next step is step 3, Study. The study phase was utilized to analyze the collected data from the project. In this step, the summarization of the data and observations were reflected upon, including what was learned and the effectiveness of the project. The fourth step is Act. This stage of the project requires time to assess the project outcome and if modifications should be made to the project. After reviewing data from the patient surveys, the PDSA cycle was started over again with planning an educational session to educate healthcare professionals regarding the patient survey results in order to make necessary changes to continue to implement the intervention.

# Conclusion

The practice improvement project is based on an extensive literature review. Research suggests that even though there have been attempts to inform women about breast density, women are often unaware of the correlation between breast density and the masking of breast cancer, which is likely related to several factors (Rhodes et al., 2019). For example, the guidelines for screening mammography differ in among organizations, including

recommendations on when to start or stop having a mammogram. Additionally, even though the Breast Density Act of 2017 was enacted, the notification letters that are being distributed to women in different states contain different verbiage and have an average grade level readability of 10.5 (Gunn et al., 2018). Therefore, women may not fully understand their breast density and related breast cancer risk, which may result in poor patient outcomes.
### **CHAPTER THREE. METHODS**

This practice improvement project aimed to evaluate women's knowledge about breast density and educate healthcare professionals about breast density and breast cancer knowledge among women in their community. Specific objectives for the project included 1) assess the understanding and knowledge of breast density among screening age women per the American College of Radiology guideline at a rural Midwestern clinic, 2) educate healthcare professionals at the clinic about breast density risk and the knowledge of breast density among women in their respective rural community, and 3) review breast density notification letters utilized by the clinic and provide suggestions to improve the readability of the notification letters to at least a fifthgrade reading level.

Women between the ages of 40 and 75 who presented to the chosen rural, Midwestern clinic during the project implementation period and agreed to participate were surveyed about their knowledge and awareness of breast density. Additionally, the clinic's breast density letter template was analyzed to determine the grade level and readability using the Flesch-Kincaid tool in Microsoft Word. Dissemination of the patient survey results occurred through an education session at a rural Midwestern clinic to enhance healthcare professionals' knowledge about breast density, as well as provide them with information regarding the patient survey results. Suggestions regarding changes for improvement to the breast density letter to enhance readability were made during this educational session.

### **Project Design**

### Setting

The physical setting for the practice improvement project was a Midwestern clinic in rural North Dakota. Coal Country Clinic is located in Center, ND. Center is a rural community in Oliver County, and the population is approximately 573 people (Centernd.net, n.d.). One-third of the population in Center report to have children under the age of 18, and there are 196 families that reside in Center.

Coal Country Clinic is family-oriented primary care clinic. The clinic provides health services to the rural community of Center and surrounding communities. The clinic is equipped with two exam rooms, one treatment room, a pharmacy, and laboratory services. The clinic offers preventative care, chronic disease management, rehabilitation, diagnostic imaging, and laboratory services to individuals residing in Center and the surrounding communities.

## Sample

The participants for this practice improvement project included both female patients and healthcare professionals. Female patients included women between the ages of 40 and 75 who presented to the clinic for any appointment during the implementation period. The implementation period was two months from June 2020 through August 2020. After verbal consent was obtained from the participants, the clinic nurse provided them with a survey to complete on breast density. Please see Appendix D for informed consent to participate in the project, and please see Appendix E for the breast density survey questions.

Healthcare professionals working at the rural Midwestern clinic were also included in the practice improvement project. Participants from Coal Country Clinic included one nurse practitioner and three additional healthcare professionals working in radiology/laboratory, nursing, and pharmacy. The healthcare professionals were interviewed and asked a series of five open-ended questions. Prior to the interview, the healthcare professionals were given an informed consent sheet to review by the coinvestigator (Appendix F). Additionally, an e-mailed invitation to participate in a thirty-minute educational session over the noon hour was sent out to

the healthcare team one-month prior to education session date. A reminder e-mail was sent out two weeks prior to the educational session date. Please see Appendix G for the sample e-mail invitation. Participation was voluntary, and attendance in the educational session demonstrated the healthcare professionals' consent to participate.

#### **Project Implementation**

The project design utilized the PDSA steps (Institute of Healthcare Improvement, 2018). The *Plan* step included identifying stakeholders, which included committee members, the target patient population, and the healthcare team in the rural Midwestern clinic. The target population included healthcare professionals at the clinic and women between the ages of 40 and 75, as this is the recommended ages for initiation and completion of routine mammography based on the American College of Radiology guideline (Monticello et al., 2017). The *Plan* step included obtaining approval from the North Dakota State University dissertation committee and the IRB (Institute of Healthcare Improvement, 2018). Additionally, identifying survey tools that were utilized to evaluate rural women's knowledge of breast density took place during the *Plan* stage.

The *Do* step of the project included assessment of women's knowledge regarding breast density at the rural healthcare clinic in North Dakota, which was accomplished through utilization of the Mayo Clinic Breast Density Awareness and Knowledge Survey (Rhodes et al., 2019). Please refer to Appendix G for permission to use the survey and Appendix H for the survey questions. The survey was the first nationally representative survey that assessed breast density knowledge and awareness. The survey was first conducted in 2012 when only one state, Connecticut, had enacted a breast density reporting law for greater than one year (Rhodes et al., 2015). The second study was conducted in 2017 and utilized the same survey from 2012 to

assess the change in knowledge about breast density over a five-year period (Rhodes et. al., 2019).

The Mayo Clinic Breast Density Awareness Survey was utilized in 2012 and the reliability and validity were therefore tested and tried and utilized in the same study in 2017. The survey was conducted using a web panel, KnoledgePanel, that has been used broadly in past medical literature. The validity of the Panel methodology has been tested and tried. The Panel members are recruited using addresses. Any recruited households who did not have access to internet to complete the survey were given complimentary tablets and internet access for survey participation (Rhodes et. al., 2019).

Survey questions were taken from Mayo Clinic Breast Density Survey and modified by the co-investigator with permission from the author to use and modify (Rhodes et al., 2019). The questions utilized in the survey focused on breast density knowledge, awareness, and opinions. Additionally, there were six demographic questions included in the survey. Questions from the original survey were chosen based on the project objective, which was to assess women's knowledge about breast density and awareness. The questions from the original survey regarding legislation were omitted due to North Dakota's status of not mandating breast density notification letters.

During the *Do* step, the survey questions were taken from the Mayo Clinic Breast Density Awareness and Knowledge Survey and distributed to all women between the ages of 40 and 75 who agreed to participate and presented to the rural healthcare clinic for any appointment during the two-month duration. Informed consent was obtained from women meeting the inclusion criteria by the nurse prior to completing the survey. Informed consent and survey were given to the women by the nurse during the rooming process in the exam room. The survey was

completed by the women in the exam rooms than returned to the nurse prior to leaving the clinic. After completion of the survey, the nurse collected the surveys and kept them in a folder for the coinvestigator. The folder was kept in a locked drawer at the nurse's station. The coinvestigator made a site visit monthly to collect the surveys and was also available via email, phone, or inperson to answer any questions that arose. The surveys were distributed to the participants in paper format by the nurse who acted as the liaison between the women and the coinvestigator. The coinvestigator had no direct patient interaction.

The third step of the PDSA framework is *Study* (Institute of Healthcare Improvement, 2018). After distributing the survey, the coinvestigator analyzed the data to evaluate the knowledge of breast density among participants in the rural clinic. Additionally, the breast density letter from the rural clinic was evaluated using the Flesh-Kincaid tool in Microsoft Word to assess the readability and grade level. The last step of the PDSA framework is *Act*, and survey results from the women were evaluated, and the breast density letter was modified during this step (Institute of Healthcare Improvement, 2018).

The PDSA is cyclic, and the cycle started over with the next planning phase (Institute of Healthcare Improvement, 2018). The coinvestigator then gathered all the data collected from surveys and breast density letters, which was utilized in the planning of an educational session for healthcare providers. The data guided the development of a PowerPoint presentation for the healthcare team at the rural healthcare clinic. The PowerPoint included information related to the rural participants' knowledge of breast density, as well as general information about breast density and breast density as an independent risk factor for breast cancer. Please see Appendix I for the PowerPoint presentation utilized at the educational session for healthcare professionals.

The *Do* step included implementation of the educational session to the healthcare team, which took place at the clinic over the lunch hour. The educational session was held on October  $6^{th}$ , 2020 and was approximately 30 minutes long, as well as 15 minutes allotted for questions. Healthcare professionals at the clinic were asked to complete a pretest (Appendix J) and posttest (Appendix K), prior to and after the educational session, respectively. The healthcare professionals included a nurse, nurse practitioner, lab technician/radiology technologist, and pharmacy technician. During the *Study* step, the coinvestigator analyzed the pre- and posttests to assess if the educational session was effective in enhancing healthcare professionals' knowledge about breast density. During the *Act* step, the coinvestigator assessed if the clinic planned to continue to utilize recommended changes to the language and verbiage of the breast density notification letters.

# Evaluation

The PDSA model was utilize das a framework not only in the planning and implementing phases of the project, but also in evaluating the project outcomes. Evaluation of the practice improvement project was based on the three project objectives.

### **Objective One**

Objective one was to assess the understanding and knowledge of breast density among women with known dense breast tissue between the ages of 40 and 75 who presented to the clinic for any appointment during the implementation period. This objective was evaluated by implementing the Mayo Clinic Breast Density Awareness and Knowledge Survey at the rural Midwestern clinic. The survey was given out over a duration of a two-month period between June and August 2020. Permission was granted from the authors to use questions from the Mayo Clinic Breast Density Awareness and Knowledge Survey developed by Rhodes et. al. (2015)

(Appendix H). The survey was modified by the co-investigator with permission from authors. The survey consisted of 8 demographic questions, 9 questions related to breast history, 2 questions on breast density, 7 questions related to sources of breast density information, and 11 questions on participants opinions related to breast density (Appendix E). Participating women were asked to complete the 37-question survey. Descriptive statistics were utilized to analyze the results, which can be found in chapters four and five.

# **Objective** Two

Objective two was to educate and enhance knowledge among health professionals in a rural Midwestern clinic regarding breast density. The Healthcare professionals at the clinic were interviewed by the co-investigator and asked a series of five open-ended questions regarding their thoughts and beliefs about breast density resources, barriers for women in their community, and resources available regarding breast cancer screening recommendations and breast density.

The five open-ended questions were as follows:

- 1. What are the barriers to breast cancer screening and follow-up for women in your community?
- 2. How comfortable are you talking with women about breast cancer screening results and screening recommendations?
- 3. What are the challenges in educating women about breast density?
- 4. What communication strategies have you found helpful when discussing breast density and recommending breast cancer screening/follow-up for patients?
- 5. What resources are available at your clinic pertaining to breast cancer screening and how do you feel about these resources?

Prior to the interview session, the healthcare professionals were given a consent form and were made aware that the co-investigator would record the interview for later documentation purposes. The recorded interview would not be shared with anyone and deleted after the co-investigator was able to perform the documentation. A 30-minute PowerPoint presentation was given over the noon hour to the healthcare professionals on October 6, 2020 in the rural Midwestern clinic. The presentation included information about dense breast tissue, screening guidelines and modalities, breast density legislation, and survey results regarding women's knowledge of breast density in the community. Feedback was also provided on the readability of the clinic's breast density notification letter. Lunch was provided to all staff who attended. The healthcare professionals were sent an invitation to participate in the educational session one month prior to and one week prior to the 30-minute session. Evaluation of the PowerPoint educational session was achieved and measured through pretest and posttest (Appendix J & K).

The pretest and posttest questions were utilized to identify healthcare professionals' knowledge regarding breast density knowledge, as well as if the patient survey results will impact their practice. The pretest was used to assess the knowledge of healthcare professionals immediately prior to the educational session, and the posttest was given to the participants to complete immediately after the educational session. The pretest and posttest were given to the participants in paper form and completed immediately before and after the educational session. The pretest and posttest were completed based on the learning objectives in the educational session (Appendix I). The first objective in the educational session was to provide education on breast density classification and enhance knowledge regarding breast density. Questions three, four, and five in the pre- and post-tests were utilized to address this objective. Question three was a true or false question that stated, "Breast density is an independent risk factor for breast

cancer?" Question four was, "Which BIRADS category(s) are considered to be "dense breasts?" with the response options as follows: a) Category A, b) Category B, c) Category C, d) Category D, e) Category C & D. Questions number five also addressed the first objective in the PowerPoint. The question was, "What percentage of women are categorized as "dense breast: or category C & D? The responses included, a) 10%, b) 20%, c) 30%, d) 40%.

The second objective for the educational session was to identify the screening recommendation guidelines and modalities. The pre- and posttest questions that addressed this educational session objective included questions six and seven. Question six was a true or false question; "there are two or more screening recommendation guidelines?" Question seven was, "What is the screening recommendation modality for women with dense breast tissue?" with the following responses: a) Standard 2D mammography, b) Tomographic mammography, c) Ultrasound. Four posttests were collected. After the PowerPoint presentation, the co-investigator allowed time for open discussion and questions.

#### **Objective Three**

North Dakota does not currently have a breast density notification law in place. The third objective of the practice improvement project was to review the breast density notification letter utilized by the clinic. This objective was evaluated by the coinvestigator utilizing the Flesh-Kincaid Grade Level tool to assess readability of the breast density notification letter from the clinic. The letter obtained by the co-investigator from the rural clinic was put into Microsoft Word. Using the Flesh-Kincaid reading ease tool and Flesch-Kincaid grade in Microsoft Word, the readability and health literacy appropriateness were assessed.

The Flesch-Kincaid Grade is scored by the following levels, 0, 2, 4, 6, 8, 10, 12, 14, 16, 18. The higher the score, the more difficult the material is to read. For example, a score of 8

would conclude that the material is at an 8<sup>th</sup> grade level of reading (Flesch Kincaid Grade Level Readability, 2020). The average reader has reading skills equivalent to an 8<sup>th</sup> grade reading level. The Flesch-Kincaid reading score was also utilized to evaluate the materials contents and ease of reading for the recipient of the letter. The Flesch-Kincaid reading ease is scored from 0 to 100. A score of 100 would indicate that the material is straightforward, and easy to read, however a score of 0 would be considered very confusing and hard to read. A score of 60-70 is considered "standard" and is largely accepted for patient materials. A higher Flesch-Kincaid reading ease score is the goal, inversely a lower Felsch-Kincaid grade is desired to promote the best results for readability and understanding in patient materials.

The current letter being utilized by the clinic was evaluated and revised as necessary to reflect more understandable, and readable healthcare material. Recommended changes to the letter were distributed during the educational session.

#### **Protection of Human Subjects**

The practice improvement project was reviewed by the North Dakota State University IRB. The IRB was completed in June 2020 and considered "exempt" (Appendix L). The human participants involved in this project included women ages 40-75 who agreed to participate in the survey and healthcare professionals working in the healthcare clinic where the educational session was held. The survey poses minimal risks to participants throughout the project. The practice improvement project involved no children, and the coinvestigator had no direct patient contact. Demographic data, pretest, posttest, and survey data were confidential and anonymous. The patient surveys were stored safely in the nurse's station at the clinic in a folder marked as confidential.

# Resources

Information from Densebreast-ino.org (2018) was obtained with permission to use images for the educational PowerPoint (Appendix A). The author utilized Microsoft Word to assess the readability and grade level of the breast density letter. Clinic staff were important in distribution of the survey, especially the clinic nurse. The author utilized a budget of 150 dollars to provide lunch during the educational session. The committee chair member and other committee members were essential in providing feedback and guidance in this practice improvement project.

# Timeline

The timeline for this project was as follows:

- May 2020 Completion of proposal and IRB approval.
- June 2020 to August 2020 Distribution of surveys to female patients meeting sample criteria. Evaluation of breast density notification letter.
- September 2020 Analyzation of data and development of PowerPoint for healthcare professional education session.
- October 2020 Dissemination of survey results and education to healthcare professionals.
- October 2020- February 2021- Analyzation of educational session results and completion of implications and recommendations for practice. Completion of final defense.

## **CHAPTER FOUR. RESULTS**

# **Data Analysis**

Sixteen women from the rural clinic participated in the practice improvement project over the two-month implementation period. All participants (n=16) resided in North Dakota (ND). Only 6.3% (n=1) of the participants did not have health insurance. All of the participants (n=16) had seen a healthcare provider in the last year. It is unknown how many women declined to participate in the breast density survey. Approximately 62.5% (n=10) of participants had a college degree or higher, and 31.3% (n=5) of participants had a high school degree or something equivalent, such as a GED. Only 6.3% (n=1) had an education that was less than high school. Please refer to Table 1 for additional information on participant demographics.

Table 1

Demographics		N=16	N%
1.What is your age?	40-49	6	37.5%
	50-59	5	31.3%
	60-69	3	18.8%
	70+	2	12.5%
2. What is the highest level of school you have completed?	Less than high school	1	6.3%
	High school degree or equivalent (i.g.GED)	5	31.3%
	College degree or higher	10	62.5%
3. What state do you live in?	ND	16	100.0%
	Other	0	0.0%
4. Have you seen the doctor in the last year?	Yes	16	100.0%
	No	0	0.0%
5. Do you currently have health insurance?	Yes	15	93.8%
	No	1	6.3%
	Don't Know	0	0.0%
6. Has any member of your family or friends	Yes	14	87.5%
have or had cancer?	No	2	12.5%
	Don't Know	0	0.0%

Demographic Results

# **Objective One Results**

Objective one was to assess the understanding and knowledge of breast density among screening age women between 40 and 75 years old per the American College of Radiology guidelines at a rural, Midwestern clinic. Participants were asked a series of breast history questions to better understand their knowledge of preventative breast care. All women (n=16) reported having a mammogram in the past. The number of mammograms women reported having in their lifetime ranged between one and 35 mammograms. The mean reported age the women began screening mammograms was 42, and the mode was 40. One participant answered with a question mark on the question that addressed at what age women started having a mammogram within the last two years, whereas 12.5% of the participants (n=13) reported their last mammogram being greater than two years ago. All women (n=16) completed the questionnaire in its entirety, and no one stopped due to not having dense breasts. Eleven of the women (68.8%) reported having dense breasts, while five women (31.2%) were unsure if they have dense breasts. Please see Table 2 for additional information on participants' breast history survey results.

# Breast History

Breast History			
1.Have you had your mammogram?	Yes	16	100%
	No	0	0.0%
2. If yes, how many mammograms"			See Text
3. At what age did you start having			See Text
mammograms?			
4. When was your most recent mammogram?	Within the past 2 years	14	87.5%
	Greater than 2 years ago	2	12.5%
5. Did you ever have to have additional	Yes	8	50%
testing after your mammogram such as an	No	8	50%
ultrasound, MRI, or additional views?	Unsure	0	0.0%
6. Have you ever had a breast biopsy?	Yes	4	25.0%
	No	12	75.0%
7. Have you ever been on hormone therapy	Yes	4	25.0%
such as estrogen, progesterone, etc?	No	12	75.0%
8. Do you have a history or a family history	No	6	37.5%
of breast cancer?	Self only	0	0.0%
	Mother, Grandmother,	9	56.3%
	Sister, or Aunt		
	Other relative	1	6.3%
9. If yes, what age were they diagnosed?	Before age 50	5	31.3%
	After age 50	5	31.3%
10. Have you ever had genetic testing for	YesIf yes, what were the	0	0.0%
breast cancer? What were the results?	results?		
	No	16	100%
11. Do you have dense breasts?	Yes	11	68.8%
	No	0	0.0%
	Unsure	5	31.3%

The survey also included questions regarding participants' knowledge and attitudes of breast density and the impact on breast cancer risk. All the participants (n=16) agreed that dense breast tissue made it more difficult to see cancers on a mammogram. Only 56.3% (n= 9) of the women attributed dense breast tissue as a risk factor for breast cancer. Please see Table 3 for additional information.

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

Knowledge of Breast Density Masking Effecting and Impact on Breast Cancer Risk			
1. Dense breasts increase your risk for cancer.	Yes	9	56.3%
	No	7	43.8%
2. Dense breasts make it more difficult to see cancers on a mammogram.	Yes	16	100%
	No	0	0.0%

Participants were also asked an array of questions about the sources of information from which they learn about breast density. Fifty percent of the women (n=8) reported they were told by their healthcare provider that they have dense breasts; however, only 12.5% of the women (n=2) reported knowing what type of breast density they had. Additionally, 63.8% of the participants (n=11) reported they have not talked about their breast density with their healthcare provider. On the other hand, 31.3% of the participants (n=5) reported that they have talked with their healthcare provider about breast density. One of the five participants reported she initiated a conversation about breast density with her healthcare provider, whereas the other four participants reported their healthcare provider initiated the conversation about breast density. Please see Table 4 for additional information.

Sources	of I	Dense	Bı	reast	Infor	mation	Results
	./				./		

Sources of Dense breast Information			
1. Who told you that you have dense breasts?	My provider	8	50.0%
	A radiologist who read my mammogram report	6	37.5%
	An imaging or x-ray		
	technician	1	6.3%
2. Do you know what type of density you	Yes	2	12.5%
have?	No	8	50.0%
	Unsure	6	37.5%
3. Have you talked about your breast density	Yes	5	31.3%
with your healthcare provider?	No	11	68.8%
4. If yes, what led you to talk about your breast density?	I asked my healthcare provider about my breast density.	1	6.3%
	My healthcare provider brought up my breast density.	4	25.0%
	Other		
5. Have you heard about breast density from	Yes	4	25.0%
other non-health care provider resources?	No	12	75.0%
6. If yes, where did hear about breast density?	Book/Magazine/Newspapers	2	12.5%
	Radio/Television	0	0.0%
	Internet	1	6.3%
	Family/Friends	1	6.3%
	Other	0	0.0%

The survey also included questions related to the participants' opinions of breast density. Only 56.3% (n=9) of the participants reported that they felt knowledgeable about their dense breast tissue. Additionally, 62.5% of the participants (n=10) felt the breast density notification letter was easy to understand. Question 12 was an open-ended question that addressed any additional concerns or comments the participants would like to make. Two participants put, "no,"

and the only other comment made was one participant stated, "don't understand why all

mammograms didn't switch to 3D." Please see Table 5 for additional information.

# Table 5

# **Opinions Related to Breast Density**

Opinions related to breast density			
1.I feel knowledgeable about my dense breast tissue.	Yes	9	56.3%
	No	7	43.8%
2. My dense breast notification was easy to understand.	Yes	10	62.5%
	No	6	37.5%
3. I feel comfortable making decisions about what type of screening			
to have with my dense breast tissue.	Yes	10	62.5%
	No	6	37.5%
4. My providers asked for additional testing.	Yes	6	37.5%
	No	10	62.5%
5. I asked for additional testing.	Yes	1	6.3%
-	No	15	93.8%
6. I wish I had more information on breast density.	Yes	6	37.5%
	No	10	62.5%
7. I think it is important to have more screening with dense breasts		12	75.0%
as it can be hard to find cancers with mammograms alone.	Yes		
	No	4	25.0%
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	12	75.0%
	No	4	25.0%
9. I get anxious stressed, or worried about having mammograms.	Yes	5	31.3%
	No	11	68.8%
10. My dense breast tissue has increased my anxiety about getting		3	18.8%
breast cancer.	Yes		
	N.	13	81.3%
	No		
11. I think it would be helpful to have reminders about my next	Yes	9	56.3%
mammogram.	No	7	43.8%
12. Do you have any additional concerns about dense breast tissue or questions about dense breast tissue? Comments:			See Text

# **Objective Two Results**

Objective two was to educate healthcare professionals in a rural, Midwestern clinic regarding breast density knowledge among women in their rural community and improve professionals' knowledge regarding breast density. Four health professionals participated in the educational session. The healthcare professional participants had many years in healthcare with three participants whom had 10 to 20 years, and one whom had greater than 20 years.

# Table 6

Question	Response to pretest ( <i>N</i> =4)		
How many years have you been in			
healthcare?			
1-5	0	0.0%	
5-10	0	0.0%	
10-20	3	75.0%	
20+	1	25.0%	
Before today how many times have you,			
discussed breast density with patients?			
Always	0	0.0%	
Routinely	1	25.0%	
Rarely ever	2	50.0%	
Never	1	25.0%	

## Healthcare Professional Demographics

The participating healthcare professionals were asked how often they discuss breast density with patients. One of the healthcare professionals reported that they routinely discuss breast density with patients whereas two of the health professionals reported that they rarely discuss breast density with patients, and one health care professionals reported never discussing breast density with patients. None of the participants answered that they always discuss breast density with women.

The pretest consisted of five questions regarding the healthcare participants' knowledge about breast density and screening recommendations. On the pretest, three of the participants knew that breast density was an independent risk factor for breast. The only questions that all participants scored 100% on in the pretest was question six, a true or false question regarding screening recommendation and guidelines. The posttest revealed that the participants scored 100% correct on all five of the breast density knowledge and screening questions. Please see table 7 for more details.

# Table 7

Question	Response	Percentage	Response to	Percentage
	to pretest	(%)	posttest (N=4)	(%)
	( <i>N</i> =4)			
True or False. Breast density is an				
independent risk factor for breast				
cancer?				
True	3	75%	4	100%
False	1	25%	0	0.0%
Which BIRADS category(s) are				
considered to be "dense breasts?"				
Category A	0	0.0%	0	0.0%
Category B	0	0.0%	0	0.0%
Category C	1	25%	0	0.0%
Category D	0	0.0%	0	0.0%
Category C & D	3	75%	4	100%
What percentage of women are				
categorized as "dense breasts" or				
category C & D?				
About 10%	0	0.0%	0	0.0%
About 20%	0	0.0%	0	0.0%
About 30%	1	25%	0	0.0%
About 40%	3	75%	4	100%
True or False. There are two or more				
screening recommendation				
guidelines?	4	100%	4	100%
True	0	0.0%	0	0.0%
False				
What is the screening				
recommendation modality for				
women with dense breast tissue?				
Standard 2D mammography	0	0.0%	0	0.0%
Tomographic mammography	3	75%	4	100%
Ultrasound	1	25%	0	0.0%

# Pretest and Posttest Questions and Responses

The pretest and posttest survey were utilized to assess the healthcare participants' comfort level when discussing breast density and screening recommendations had increased after the PowerPoint educational session. Two questions were measured on a Likert scale with 1= Not at all, 2= Slightly, 3= Moderately, 4= Very, 5= Completely. Question 8 stated, "I feel comfortable discussing breast density with women." Figure 3 illustrates participations responses on the pretest compared to the posttest. Two healthcare professionals responded they felt "very comfortable" talking with women prior to and after the educational session. One responded they felt "moderately" comfortable after the educational session. Prior to the educational session, two participants felt slightly comfortable discussing breast density with women, and this number decreased to one participant after the educational session. Figure 3 demonstrates the levels of reported comfort when discussing breast density before and after the educational session. Additionally, the second question measured on a Likert scale stated, "I feel comfortable discussing recommended supplemental screening with women?" Table 8 demonstrates an increased comfort when discussing supplemental screening by increasing the magnitude of shift from 3.75 to 4.



*Figure 3.* Pretest and posttest responses about comfort level when discussing breast density with women.

Table 8 also demonstrates the healthcare professionals' increase in confidence and knowledge after the educational session. The magnitude of shift was calculated using the two questions as previously discussed. The posttest results reveal a magnitude of shift towards the participants feeling more comfortable in discussing breast density and supplemental screening with women. Additionally, the healthcare professionals were asked on the posttest, as a result of the educational activity if their practice would be modified. Half of the participants (n=2) answered that they will seek more information before modifying their practice, and the other half of the participants (n=2) reported they will modify their practice.

Magnitude of Shift for Self-Confidence When Discussing Breast Density and Supplemental Screening

Question	Pretest	Posttest
I feel comfortable discussing	3	3.25
breast density with women		
I feel comfortable discussing	3.75	4
additional supplemental		
screening with women		

The last question on the posttest was an open-ended question and asked healthcare professionals how the survey results from the women in the community regarding breast density may change their practice. Common answers included initiating more conversations about breast density with women and offering a clearer explanation of breast density, as well as options for supplemental screening. One healthcare professional participant felt that the survey responses would not affect their practice. Improving healthcare professionals' knowledge about breast density enhanced confidence in answering women's questions about breast density and has the potential to better assist women in their decision-making process regarding preventative screening in the future. After the educational session, the coinvestigator provided resources on breast density that can be used, but it is unknown if the clinic planned to utilize them.

## **Qualitative Data**

Five open-ended questions were asked to the four participating healthcare professionals. The participants reported barriers to breast cancer screening and follow-up for women in the community. Lack of resources available to women at the clinic was identified as the most common barrier, as the clinic does not offer screening mammography on site. Therefore, women who wish to complete their screening mammogram must drive to the neighboring towns for screening. The healthcare professional participants infer that this is a barrier particularly to women of lower socioeconomic status and elderly women with whom which transportation may be a challenge.

Participants were also asked if they felt comfortable talking with women about breast cancer screening results and screening recommendations. Two of the participants felt comfortable discussing mammogram recommendation and results with women, while the other two participants reported that they did not have to directly discuss mammogram results with women due to the workflow in place at the clinic. Additionally, only one participant felt confident in her knowledge of breast density.

Challenges to educating women about breast density were also assessed. One participant felt that her competency and education was sufficient and did not find any challenges when educating women. The other participants felt that they did not ever discuss breast density with women and that the facilities that perform the mammograms take care of the education. Therefore, the participants felt that they did not educate women due to resources and lack of knowledge regarding breast density. The participants felt that being in a rural county and lack of resources for their patients was a strong barrier for their clinic.

The healthcare professionals were also asked to identify communication strategies they have found helpful when discussing breast density and recommending breast cancer screening or follow-up for patients. The overwhelming response was that they directed the women to the facility that performed the mammogram. The healthcare professionals felt that the facilities that performed the mammograms were better equipped to answer patients' questions.

The participants were also asked about available resources at the clinic pertaining to breast cancer screening. One participant reported that she felt they had adequate resources to address patients' needs or questions. The other participants echoed each other and identified a

barrier in that mammograms are not offered at the clinic. Even though the participants reported distance and travel to the closest mammography facility as a barrier, they state that they feel there is no barrier in communication between the clinic and neighboring facilities when attempting to facilitate appointments for mammograms.

## **Objective Three Results**

Objective three was to review breast density notification letters utilized by the rural, Midwestern clinic and provide suggestions to improve readability of the notification letters to at least a fifth-grade reading level. North Dakota does not have specific verbiage and language that is utilized in breast density letters. The Breast Density Notification Act 2017 was enacted nationally to require the notification letters to include the following information: informing women breast density is a factor for breast cancer, breast density has a masking effect, and individual breast density results. The notification letter was input into Microsoft Word, which has the capability and function to obtain a Flesh-Kincaid Ease readability and grade. The Flesh Reading Ease score was 48.1, and Flesh-Kincaid Grade Level of the letter was 10.7, which is categorized as difficult to read. The co-investigator, with the help from the project investigator, modified the breast density letter. Results can be seen in Table 9. The modified breast density letter had a Flesh-Kincaid Ease Score 65.9, and Flesch-Kincaid Grade of 7.2. The modified score of 7.2 is considered "easy to read" according to the Flesch-Kincaid grade levels.

#### Table 9

Breast Density Notification Results

	Pre-modification	Post-modification
Flesch Reading Ease Score	48.1	65.9
Flesch-Kincaid Grade level	10.7	7.2

Feedback from the healthcare professionals was positive. The participants all agreed that the modified letter would be useful in decreasing confusion and increasing the understandability of their breast density letter. The healthcare professionals had no outstanding questions regarding changes made to the breast density letter.

#### **CHAPTER FIVE DISCUSSION AND RECOMMENDATIONS**

#### Summary

Objective one was to assess the understanding and knowledge of breast density among screening age women in a rural, Midwestern clinic, and this objective was met. Survey results revealed knowledge deficits exist among women in this rural community related to breast density. For example, 68.8% of women who participated in the survey reported knowing that they had dense breasts; however, only 12.5% of the women knew what category or type of breast density they have. Even though women are becoming more aware of the term "dense breasts," there are still knowledge deficits regarding the type of density and the link between breast density and breast cancer (Guterblock et. al., 2016).

Objective two was to increase healthcare professional's knowledge regarding how breast density affects their patient by the end of the educational session, which was met. Prior to the educational session, 50% of the health professional participants reported "never" discussing breast density with patients. The lack of conversation between healthcare professionals and women regarding breast density is consistent with literature findings. Santiago et al. (2019) found that only 50% of women who initiated screening mammograms reported having a discussion with their healthcare provider about screening recommendations, risks, and benefits (Santiago et, al., 2019). After the educational session was completed, the participants report higher scores on the Likert scale, which were questions that assessed if the participants felt comfortable discussing breast density and supplemental screening as evidence by the magnitude of shift for both questions. Although the objective was met, a larger sample size is needed in order to correlate findings to the broader Midwest or national regions.

Objective three was to review the clinic's breast density notification letter and provide suggestions to improve readability to at least fifth-grade reading level. This objective was partially met. The co-investigator and primary investigator were able to increase the readability by increasing the Flesch-Kincaid ease score to a 65.9 after modification. The increase of the reading ease score placed the breast density letter into the "standard" category for readability versus the previous reading ease score, which is considered "difficult" to read. The readability score was reduced from 10.7 to 7.2; however, the goal to decrease the readability score to at least fifth-grade level was not met. Due to the complex material that must be included to inform women of their breast density, a fifth-grade level may not be possible to achieve. The goal to meet a fifth-grade reading level may not be feasible due to the medical terminology such as "mammogram," that increases the Flesch-Kincaid grade. Medical terminology in the letter is necessary and women have already discussed the term mammogram and what it entails prior to the healthcare provider ordering the screening. Therefore, patients may be familiar with the terminology being used in the breast density notification letter.

Literature does suggest that health information written above a grade level eight leads to misinterpretation and ultimately lead to misinformed decisions (Gunn et al., 2018). However, the letter was able to be modified to a seventh-grade reading level. The co-investigator shared the modified breast density letter with the clinic. The clinic healthcare professional's expressed appreciation in improving the readability and will plan to implement the new modified letter when informing women of mammogram results.

#### Discussion

The survey results highlight that knowledge deficits exist related to the link between dense breasts and breast cancer among women in this rural community, as approximately 43.7%

of the participants did not know that increased breast density increases the risk for breast cancer. These findings did correlate with previous literature suggesting that women's knowledge of breast density does not correlate with the knowledge that breast density is an independent risk factor for breast cancer (Rhodes et al., 2019). Existing knowledge deficits demonstrate the importance of patient education regarding breast density. Schifferdecker et., al. (2020) found that very few woman report receiving information about breast density during healthcare visits beyond screnning. Additionally, the study found that women were aware of breast density but did not correlate breast density with breast cancer.

Many of the patients who participated in the project were highly educated. Because the average education level throughout this rural community is not known, it is uncertain whether the community has higher education levels or if this represents a sampling bias, resulting in a higher-than-average education level of participants. If the education level of participants is representative of the average education level of the community, the modified breast density letter at a Flesch-Kincaid grade level of 7.2 would be at a sufficient reading level for the population to understand. Additionally, if the community has higher education levels, the original letter potentially may not have needed to be modified to improve readability. Another key finding included the fact that only 68.8% (n=11) participants reported that they have not spoken with their healthcare provider about breast density. The lack of provider and patient communication correlates with the Rhodes et al. (2019) study in which less than half the women in the study had a conversation with their healthcare provider about breast density. The conversation about breast density is most often initiated by the healthcare provider, which again reinforces the importance of provider education regarding breast density to improve patient understanding and decision making. Almost half (*n*=7) of the women did not feel knowledgeable about dense breast tissue.

Women who have a clear understanding of breast density are more likely to initiate a conversation with their healthcare provider about supplemental screening and make a tailored and informed decision about their breast health (Paterson & Havrda, 2020).

The practice improvement project also identified knowledge deficits among healthcare professionals related to breast density; however, after a short educational session, all participants scored 100% on the five posttest questions addressing breast density and screening recommendations. This indicates that the educational session for healthcare professionals was effective in increasing their knowledge about breast density categories, screening guidelines, and breast density as an independent risk factor for breast cancer. In fact, 50% of the participants reported they will modify their practice post educational session. Continuing education on breast density for health professionals is imperative to improve patients' understanding of their mammogram results and implications of dense breast tissue. Mirghani, S., Goldberg, J., Jaspan, D., Copit, D., Scaven C. (2017) found that only 32% of providers understand the clinical significance of increased breast density. Additionally, only 21% of healthcare providers discuss supplemental screening. After education on the Breast Density Notification Act 2017 was provided, 47% of providers reported that they would now change their management of women with dense breasts. Simple interventions such as clinician education can increase providers confidence when discussing breast density with women and improve compliance with dense breast notification laws. Increasing education about breast density necessitates new conversations between healthcare professionals and patients (Berg & Pushkin, 2017). The lack of comfort level when talking about breast density may interfere with relaying education to women about breast density (Maimone & McDonough, 2017).

The practice improvement project also identified barriers to breast cancer screening, particularly for women living in rural settings, which include lack of on-site mammography, elderly population, low socioeconomic status, travel, and distance to the nearest screening mammography site. The barriers identified by the healthcare professionals are consistent with those found in the literature (Santiago et al., 2019). Improving access to care, including having an on-site mammography mobile truck, would benefit women in a rural community by improving the screening rates and increasing cancer detection (Vang, et al., 2018). Additionally, Vang, Margolies, and Vandorf (2018) found that mobile mammography trucks who visited sites regularly improved access to care for underserved women

Results from the breast density notification letter also reveal that certain patient education materials are written at a readability level that patients may not understand. Saraiya, Baird, and Lourenco (2019) found that online patient education materials about breast cancer screening and breast density had a Flesch-Kincaid reading ease score of 45, and Flesch-Kincaid mean grade level between 6 and 11.3, with the highest at 19.4. Both scores identified the need to increase the readability of breast screening and breast density information to match the national average grade level of 6 for patient education materials. Additionally, Metcalfe-claw et. al. (2017) found that only 18% of women were aware of the breast density notification laws.

The PDSA provided the framework for the practice improvement project (Institute of Healthcare Improvement, 2018). This practice improvement project has facilitated an opportunity for enhancement of knowledge and future open discussion about breast density between healthcare professionals and women. Additionally, the practice improvement project has provided the clinic with a more comprehensible and understandable breast density notification letter, which in turn will ultimately result in less confusion and misunderstanding in women

about their breast health. The generalizability of the practice improvement project results were limited by the small sample size, which is discussed in the following limitations section.

#### **Project Limitations**

The major limitation of the practice improvement project was the small sample size of healthcare professional participants. The clinic is in a rural setting that is limited to only one healthcare provider and nurse practicing on each shift, due to population and demand. There are four healthcare professionals at the clinic, and while all four did participate in the educational session, only one was a healthcare provider. Additionally, some of the health professional participants may not talk directly with women about results or have it in their scope of practice. This PIP was initially intended for providers and nurses but due to the COVID-19 pandemic, time frame, and inability to implement at nearby clinics, the coinvestigator was unable to have more providers and nurses in the study. Some of the professions included in the project may not directly discuss breast density with patients in their current roles. A larger clinic or the implementation of the project at two rural sites would have given the co-investigator more data on the assessment of increasing healthcare professional knowledge about breast density.

Another limitation was the two-month duration of the survey implementation. More participants may have been captured if the survey was implemented for an extended amount of time versus two months. The small sample size of women was also a limitation. Due to the COVID-19 pandemic, the clinic reduced the number of available appointments, which may have resulted in a lower number of women who were able to participate in the project. Additionally, it is unknown how many women refused to participate in the survey during the two-month implementation period. The increase in the duration of survey implementation may have given

more comprehensive data regarding women's knowledge and attitudes about breast density in the community.

The coinvestigator was not available at the site after women participated in the survey, which may be another limitation. Because the coinvestigator was not on site, no additional education was provided to patients. Having the coinvestigator available at the clinic for any questions from the women may have increased participation and addressed concerns from the women at the site. Due to the coinvestigator not having direct contact with the women participants, it is unknown if there were any outstanding questions or concerns.

#### Recommendations

Due to the positive results in enhancing healthcare professional's knowledge, it is reasonable to recommend repeating the practice improvement project by following the framework of the PDSA cycle that has been established (Institute of Healthcare Improvement, 2018). Another recommendation is to repeat the practice improvement project on a larger sample size of healthcare professionals or if this is not possible due to the rural community sizes, to apply the practice improvement project at multiple sites to gather more data. This practice improvement project can be applied to not only rural clinics, but also in urban settings. Women with less education, lower incomes, and non-white race/ethnicity have been found to be less likely to have heard of breast density (Kressin, 2019). Therefore, implementing the project in both rural and urban settings may have the potential to reduce barriers in healthcare and improve breast density education to all women. Additionally, after completion of the survey of the women participants, it is recommended in the future to supply breast density educational handouts to the women who completed the survey to reduce knowledge deficits and improve understanding of breast density as an independent risk factor for breast cancer.

Feedback regarding the PowerPoint educational session was positive. Multiple participants felt that the topic of breast density is not often discussed enough with patients and reported their resources are limited. The rural clinic that participated in the practice improvement project does not have the capability to perform mammograms on site, which was a barrier identified by the staff at the clinic. A recommendation would be to discuss with the healthcare organization the possibility of providing a mobile mammogram truck to serve the population in this rural community. As previously discussed, the improvement of screening rates is reliant on women's access to care. Mobile mammography trucks increase the access to care in rural and underserved areas, therefore increasing screening rates and cancer detection (Vang et al., 2018). Furthermore, healthcare professionals at the rural clinic referred patients back to where they had their mammogram when patients had questions or concerns due to lack of knowledge and resources. Further education for healthcare professionals has the potential to increase their ability to provide education to patients, while reducing barriers. Improved breast density notification and education materials about breast density gives the healthcare providers opportunity to discuss evidence and screening options based on individual patient's risk stratification and shared decision making. (Schifferdecker et. al., 2020).

# Dissemination

Dissemination of the practice improvement project results and findings are fundamental to improving practice. The knowledge obtained from the project must be shared in order to facilitate practice change. The results from the survey of women's knowledge and attitudes about breast density and readability results of the breast density letter was disseminated to the rural clinic through the educational presentation. Additionally, this practice improvement project was presented at the North Dakota Nurse Practitioner's Association Twelfth Annual Pharmacology

Conference in September 2020 and to the committee during the final defense, poster session in 2021 as well as through a three-minute video published on the NDSU library database. The coinvestigator also has intent to publish.

## **Application to the Nurse Practitioner Role**

Nurse practitioners are the cornerstone of practicing health care providers in America. As healthcare is ever changing and progressing, it is important recognize the beneficial role nurse practitioners play in patients' lives. As of today, nurse practitioners provide a full range of primary, acute, and specialty healthcare services. Nurse practitioners use a unique approach and place an emphasis on health and well-being of the whole person. Health promotion and disease prevention are the specialty of the nurse practitioner and are core values of the nurse practitioners learning and training. Promoting breast health and women's healthcare consistent with current practice standards is essential for all nurse practitioners working in primary care or women's health. Up-to-date guidelines and continuing education are necessary to stay current with the changing guidelines of the breast health (American Association of Nurse Practitioners, 2019). Existing literature and this practice improvement project reinforce that proper education on breast density is prudent in keeping patients informed and improving outcomes (Patterson & Havrda, 2020).

## Conclusion

Mammography sensitivity continues to be lower in women who present with dense breast tissue (American Cancer Society, 2019). Dense breast tissue can not only reduce the sensitivity of mammograms, but in turn can mask breast cancer and lead to diagnosis at a later stage. Women have the right to know and understand the risks that are attributed to breast density and breast cancer. The FDA is currently developing and proposing guidelines for language in breast

density letters nationwide (Kressin, 2019). Increasing awareness among healthcare professionals and women will lead to an open communication forum, where women can be a part of their breast cancer screening options and make individualized decisions based on their risk factors. Breast cancer screening and improved understanding of breast density as a risk factor for breast cancer has the potential to improve patient outcomes and save lives.

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### APPENDIX A. PERMISSION TO USE DENSEBREAST-INFO.ORG IMAGES

### Image Use

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JoAnn Pushkin <jpushkin@dense-info.org> Tue 1/28/2020 5:45 AM Berger, Molly ⊗



3 attachments (7 MB) Download all Save all to OneDrive - North Dakota University System

### Hi Molly,

For your dissertation use *only* (any other use requires our written approval and images cannot be published), please find attached images which can be used. Please note the images must be used *as is* without any edit, photoshopping, cropping or changes; the copyright information must be featured as shown.

We applaud your valuable research, the entire mission of DenseBreast-info.org is provide medically-sourced education on the topic to patients and providers. In the event you are not aware, among many other components, for patients we feature a downloadable <u>Patient Brochure</u> and video series, <u>Let's Talk About</u> <u>Dense Breasts</u> – and for health providers there is a comprehensive CME/CE opportunity (2 AMA credits) <u>Breast</u> <u>Density: Why it Matters</u>.





### **APPENDIX B. HEALTH PROMOTION MODEL**

### APPENDIX C. APPROVAL TO USE NOLA PENDER'S HPM MODEL



Nola Pender <npender@umich.edu> Mon 11/18/2019 2:30 PM Berger, Molly ⊗



HEALTH PROMOTION MODE... 14 KB

Dear Molly:

You have my permission to use the graphic of the Health Promotion Model in your dissertation. Please see DeepBlue site in attachment for other information related to the Model. Good luck with your dissertation.

Wishing you good health, Nola Pender

....

### APPENDIX D. INFORMED CONSENT FOR WOMEN

### North Dakota State University

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

### Implementation of Healthcare Professional Education: Breast Density as an Independent Risk Factor for Breast Cancer

Dear Participant,

My name is Molly Berger, I am a graduate student in School of Nursing of North Dakota State University (NDSU), and I am doing a practice improvement project to increase awareness and knowledge about dense breast tissue and its relation to 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 75 years of age, you are invited to take part in this research. You will be asked to complete a survey prior to your appointment with your primary care provider. The total expected time commitment is 15 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. The survey is anonymous. If you choose to participate you 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 a 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 identifying information private.

It is not possible to identify 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, please contact me at 701-425-4708 or molly.berger@ndsu.edu or contact my advisor Dr. Allison Peltier at 701-224-3820 or Allison.peltier@ndsu.edu. You have the 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 e-mail at ndsu.irb@ndsu.org by mail at NDSU HRPP office, NDSU dept 4000, and P.O. Box 6050, Fargo, ND 58108-6050.

Thank you for taking part in this research. Sincerely, Molly Berger, RN, BSN, NDSU School of Nursing Practice Student

### APPENDIX E. BREAST DENSITY SURVEY QUESTIONS

Demographic
1. What is your age?         □       40-49         □       50-59         □       60-69         □       70+
<ul> <li>2. What is the highest degree or level of school you have completed?</li> <li>Less than high school</li> <li>High school degree or equivalent (e.g., GED)</li> <li>College degree or higher</li> </ul>
3. What state do you live in? D ND Other
<ul> <li>4. Have you seen the doctor in the last year?</li> <li>Yes</li> <li>No</li> </ul>
<ul> <li>Jo you currently have health insurance?</li> <li>Yes</li> <li>No</li> <li>Don't Know</li> </ul>
<ul> <li>6. Has any member of your family or any friends have or had cancer?</li> <li>Yes</li> <li>No</li> <li>Don't Know</li> </ul>
Breast History
<ol> <li>Have you ever had a mammogram?</li> <li>☐ Yes</li> <li>☐ No</li> </ol>
2. If yes, how many mammograms? □ Number:
3. At what age did you start having mammograms? □ Age:
<ul> <li>4. When was your most recent mammogram?</li> <li>□ Within past 2 years</li> <li>□ Greater than 2 years ago</li> </ul>

5. Did you ever have to have additional testing after your mammogram such as an ultracound MBL or additional views?
$\Box  I \in S$
6. Have you ever had a breast biopsy?
$\Box$ Yes
7. Have you ever been on hormone therapy such as estrogen, progesterone, etc.?
$\Box$ Yes
8. Do you have a history or a family history of breast cancer?
□ Self only
Mother, Grandmother, Sister, or Aunt
□ Other Relative
9. If yes, what age were they diagnosed?
□ Before age 50
□ After age 50
10. Have you ever had genetic testing for breast cancer? What were the results?
YesIf yes, what were the results?
11. Do you have dense breasts?
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.
$\Box$ Yes
2. Dense breasts make it more difficult to see cancers on a mammogram.
$\Box$ Yes
Sources of Dense Breast information
1. Who told you that you have dense breasts?
□ My provider
A radiologist who read my mammogram report
□ An imaging or x-ray technician
2. Do you know what type of density you have?
□ Yes
3. Have you talk about your breast density with your healthcare provider?
4. If yes, what led you to talk about your breast density?
□ I asked my healthcare provider about my breast density.
My healthcare provider brought up my breast density.
□ Other
5. Have you heard about breast density from other non-health care provider
resources?
6. If yes, where did hear about breast density?
□ Book/Magazine/Newspapers
□ Radio/Television
□ Internet
□ Family/Friends
□ Other

Opinions related to breast density
1. I feel knowledgeable about my dense breast tissue.
2. My dense breast notification was easy to understand.
3. I feel comfortable making decision about what type of screening to have with my
dense breast tissue.
$\Box$ Yes
4. My providers asked for additional testing.
$\Box Yes$
I asked for additional testing
J. T asked for additional testing. $\Box$ Ves
$\square$ No
6. I wish I had more information on breast density.
7. I think it is important to have more screening with dense breasts as it can be hard
to find cancers with mammograms alone.
$\square$ Yes
No Since my breasts are dance. I would have additional sevening danc even if it
<ol> <li>Since my breasts are dense, I would have additional screening done even if it meant more testing and/or having a bionsy done</li> </ol>
□ Yes
9. I get anxious, stressed, or worried about having mammograms.
10. My dense breast tissue has increased my anxiety about getting breast cancer.
11. I think it would be helpful to have reminders about my next mammogram.
$\Box$ Yes
12. Do you have any additional concerns about dense breast tissue or questions about
uense preast ussue?

### APPENDIX F. INFORMED CONSENT HEALTHCARE PROFESSIONALS

### North Dakota State University

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

### Implementation of Healthcare Professional Education: Breast Density as an Independent Risk Factor for Breast Cancer

Dear Participant,

My name is Molly Berger, I am a graduate student in School of Nursing of North Dakota State University (NDSU), and I am doing a practice improvement project to increase awareness and knowledge about dense breast tissue and its relation to 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 healthcare professional working at Coal Country Clinic in Center, ND, you are invited to take part in this research. You will be interviewed and asked a total of five open-ended questions about breast density knowledge and barriers that women may experience in the community. The total expected time commitment is 15 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 during the interview, you have the right to decline to answer any question (s) and stop the interview without consequence. The interview is anonymous. If you choose to participate your name will not be written on the questionnaire or any other identifying information. Interview responses you give will aid in evaluating rural women's knowledge on dense breast tissue and resources available to women.

Your information will be kept confidential and you will not be identifiable in the 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 a 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 identifying information private.

It is not possible to identify 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, please contact me at 701-425-4708 or molly.berger@ndsu.edu or contact my advisor Dr. Allison Peltier at 701-224-3820 or Allison.peltier@ndsu.edu. You have the 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 e-mail at ndsu.irb@ndsu.org by mail at NDSU HRPP office, NDSU dept 4000, and P.O. Box 6050, Fargo, ND 58108-6050.

Thank you for taking part in this research. Sincerely, Molly Berger, RN, BSN,

### APPENDIX G. INVITATION TO PARTICIPATE

Dear healthcare professionals,

My name is Molly Berger, I am a current North Dakota State University Student in the Doctor of Nursing Practice Program. Today, I am working on my clinical dissertation and would like to invite you to participate in a 30-minute educational session focusing on the topic of breast density as an independent risk factor for breast cancer. Prior to the educational session I will hand out a paper survey to assess the knowledge of each individual healthcare professional regarding the topic presented. After the educational session I will then handout a paper survey to assess the knowledge obtained from the 30-minute educational session. The survey will take approximately 10 minutes to complete. Your identity will not be linked to your survey responses. Your information will be combined with other people taking part in the study, we will write about the combined information 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.

Your participation in this project is strictly voluntary.

If you have any questions about this project, please contact me at 701.425.4708 or email at molly.berger@ndsu.edu

Thank you for participating in this important practice improvement project.

Sincerely,

Molly Berger DNP-S, BSN, RN

### APPENDIX H. APPROVAL TO USE MAYO CLINIC BREAST DENSITY AWARENESS

### SURVEY

Re-us	e survey questions from journal doi/full/10.1200/JCO.2014.57.032	25		<b>≬</b> 1∨	+
R	Rhodes, Deborah J., M.D. <rhodes.deborah@mayo.ed u&gt; Wed 2/5/2020 3:46 PM Berger, Molly ⊗</rhodes.deborah@mayo.ed 	ᡌ	5	≪ →	
	pdf     Breast Density Awareness, Kn       Image: 432 KB				
	Thank you for your interest, Molly. We have had several similar requests and we a the questions in your dissertation. Good luck!!	sk that	you cit	te the source	≀ of

### **APPENDIX I. EDUCATIONAL PRESENTATION POWERPOINT**



Category D compared to Category B > 2X as likely to develop breast cancer

#### Breast Density and Breast Cancer Risk

- Increase in breast density reduces the sensitivity of mammography
- Dense breast tissue masks breast cancer delaying finding breast cancer and treatment
- 4 to 6X more likely to develop breast cancer

### Breast Density Risk Factors

Hormone replacement therapies
 Combined HRT estrogen and progesterone therapy is strongly related to an increase irongly related to an increase irongly

# Lifestyle factors Increased alcohol consumption BMI- inversely related Age- increase in age shows a decrease in density

Hispanic women have the highest preast density followed by African American women

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### Screening Recommendations

In the U.S. various screening guidelines in organizations differ regarding screening for breast cancer

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-					-	

### Screening Dense Breast Tissue

- Mammography is the first step to screening women with dense breast tissue > Standard 2D mammography > Full field digital > 3D mammography > Digital breast tomosynthesis > Ultracound

2D Mammogram

# Detect two to seven breast cancers per 1000 women screened using ionizing radiation Cancer may be missed due to breast density

Overse Brease Even a large carice is difficult to detect





### 3D Mammogram

- In 2011 3D mammogram was approved by the FDA to use in adjunct in screening dense breast tissue
- 3D compresses the breast similarly to the 2D but the 3D images take more pictures in thin slices and show more detail





### Magnetic Resonance Imaging (MRI)

- Most sensitive tool in breast imaging Expensive (lack of insurance coverage) Approved by American Cancer Society to use in 2007 to use in adjunct to screening mammorgraphy



#### How to guide women with dense breasts

- Assess each women 40+ as an individual case, based on modifiable and non-modifiable risk factors
- If a women is at an intermediate to high risk >15%
   >Advise annual screening mammograms, clinic breast exams, follow-up ever 6 months with WBU or MRI
   > Refer to high risk breast clinic

### How to guide women with dense breasts

- If a woman is NOT at intermediate or high risk and <15%
   Reassurance that 50% of women have dense breast tissue
   Explain breast density and the increase risk of breast cancer
   Inform women about 3D manmography benefits
   Encourage self breast awareness
   Encourage modifiable risk factors
   Smoking cessation
   Etimit alcohol to 1 drink/day
   Maintain healthy diet and exercise
   Make educated choices on postmenopausal hormone therapy

#### Breast Density Notification and Legislation

- In 2017 the FDA made it mandatory to include in the notification letters that breast density does relate to breast cancer risk
- Breast density notification laws have been enacted in 38 states
- Only 7 states mandate insurance coverage for supplemental screening

#### **Breast Density and Notification Letters**

- Readability and verbiage from breast density vary from state to state
- Range includes 7-19.4
- Any healthcare information with a readability score of greater than 8 leads to misinterpretation

#### Survey Results From Women

- 68% of the women report they have not talked with their healthcare provider about breast density
   Only 50% of women report that dense breast increase risk for breast cancer
   Only 50% of women report that dense breast increase risk for breast cancer

Women's Knowledge About Dense Breasts

Women need to be aware of their breast density sot hey can make educated and informed decisions about their breast health

Empower women with the knowledge about breast density, this can make a difference between an early detection of cancer vs a later detection. Early detection can increase the survival rate.



### APPENDIX J. PRETEST SURVEY FOR HEALTHCARE PROFESSIONALS

- 1. How many years have you been in healthcare?
  - a. 1-5
  - b. 5-10
  - c. 10-20
  - d. 20+
- 2. Before today how many times have you, discussed breast density with patients?
  - a. Always
  - b. Routinely
  - c. Rarely ever
  - d. Never
- 3. True or False. Breast density is an independent risk factor for breast cancer?
  - a. True
  - b. False
- 4. Which BIRADS category(s) are considered to be "dense breasts?"
  - a. Category A
  - b. Category B
  - c. Category C
  - d. Category D
  - e. Category C & D
- 5. What percentage of women are categorized as "dense breast" or category C & D?
  - a. About 10%
  - b. About 20%
  - c. About 30%
  - d. About 40%
- 6. True or False, there are two or more screening recommendation guidelines?
  - a. True
  - b. False
- 7. What is the screening recommendation modality for women with dense breast tissue?
  - a. Standard 2D mammography
  - b. Tomographic mammography
  - c. Ultrasound

Circle the best number that fits your evaluation.

5=Completely 4=Very 3=Moderately 2=Slightly 1=Not at all

- I feel comfortable discussing breast density with women.
   5 4 3 2 1
- 9. I feel comfortable discussing additional supplemental screening with women.

5 4 3 2 1

### APPENDIX K. POSTTEST SURVEY FOR HEALTHCARE PROFESSIONALS

- 1. Before today how many times have you, discussed breast density with patients?
  - a. Always
  - b. Routinely
  - c. Rarely ever
  - d. Never
- 2. True or False. Breast density is an independent risk factor for breast cancer?
  - a. True
  - b. False
- 3. Which BIRADS category(s) are considered to be "dense breasts?"
  - a. Category A
  - b. Category B
  - c. Category C
  - d. Category D
  - e. Category C & D
- 4. What percentage of women are categorized as "dense breast" or category C & D?
  - a. About 10%
  - b. About 20%
  - c. About 30%
  - d. About 40%
- 5. True or False, there are two or more screening recommendation guidelines?
  - a. True
  - b. False
- 6. As a result of this activity how often will you discuss breast density with women?
  - a. Always
  - b. Routinely
  - c. Rarely ever
  - d. Never

Circle the best number that fits your evaluation.

- After this educational session I feel comfortable discussing breast density with women.
   4 3 2 1
- 8. After this educational session I feel comfortable discussing additional supplemental screening with women.
  - 5 4 3 2 1

- 9. As a result of this educational activity:
  - a. I will modify practice.
  - b. I will seek more information before modifying practice.
  - c. I see no need to modify practice.
- 10. How will the survey results from the women in the community regarding breast density change your practice?

### **APPENDIX L. IRB APPROVAL**

### NDSU NORTH DAKOTA STATE UNIVERSITY

June 4, 2020

Dr. Allison Peltier School of Nursing

Re: IRB Determination of Exempt Human Subjects Research: Protocol #PH20275, "Implementation of Health Professional Education: Breast Density as an Independent Risk Factor for Breast Cancer"

NDSU Co-investigator(s) and research team: Molly Berger Date of Exempt Determination: 6/4/2020 Expiration Date: 6/3/2023 Study site(s): Coal Country Heath Care Center, Beulah, ND Funding Agency: n/a The above referenced human subjects research project has been determined exempt (category 1, 2(i)) 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 received 5/31/2020 with updated provider letter received 6/4/2020.

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,

Kristy Sincerg

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult https://www.ndsu.edu/research/for\_researchers/research\_integrity\_and\_compliance/institutional\_review\_board\_i rb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

Demographics		N=16	N%
1.What is your age?	40-49	6	37.5%
	50-59	5	31.3%
	60-69	3	18.8%
	70+	2	12.5%
2.What is the highest level of school you have completed?	Less than high school	1	6.3%
-	High school degree or equivalent (i.g.GED)	5	31.3%
	College degree or higher	10	62.5%
3. What state do you live in?	ND	16	100%
	Other	0	0%
4. Have you seen the doctor in the last year?	Yes	16	100%
	No	0	0%
5. Do you currently have health insurance?	Yes	15	93.8%
	No	1	6.3%
	Don't Know	0	0%
6. Has any member of your family or friends	Yes	14	87.5%
have or had cancer?	No	2	12.5%
	Don't Know	0	0%
Breast History			
1.Have you had your mammogram?	Yes	16	100%
	No	0	0%
2. If yes, how many mammograms"			
3. At what age did you start having mammograms?			
4. When was your most recent mammogram?	Within the past 2 years Greater than 2 years ago	13 2	81.3% 12.5%
5. Did you ever have to have additional	Yes	8	50%
testing after your mammogram such as an	No	8	50%
ultrasound, MRI, or additional views?	Unsure	0	0%
6. Have you ever had a breast biopsy?	Yes	4	25%
	No	12	75%
7. Have you ever been on hormone therapy	Yes	4	25%
such as estrogen, progesterone, etc?	No	12	75%

### APPENDIX M. DENSE BREAST QUESTIONNAIRE DATA

Demographics		N=16	N%
8. Do you have a history or a family history	No	6	37.5%
of breast cancer?	Self only	0	0%
	Mother, Grandmother, Sister, or Aunt	9	56.3%
	Other relative	1	6.3%
9. If yes, what age were they diagnosed?	Before age 50	5	31.3%
	After age 50	5	31.3%
10. Have you ever had genetic testing for breast cancer? What were the results?	YesIf yes, what were the results?	0	0%
	No	16	100%
11. Do you have dense breasts?	Yes	11	68.8%
	No	0	0%
	Unsure	5	31.3%
Knowledge of Breast Density Masking Effecting and Impact on Breast Cancer Risk			
1. Dense breasts increase your risk for cancer.	Yes	9	56.3%
	No	7	43.8%
2. Dense breasts make it more difficult to see	Yes	16	100%
cancers on a mammogram.	No	0	0%
Sources of Dense breast Information			
1. Who told you that you have dense breasts?	My provider	8	50%
	A radiologist who read my mammogram report	6	37.5%
	An imaging or x-ray		
	technician	1	6.3%
2. Do you know what type of density you	Yes	2	12.5%
have?	No	8	50%
	Unsure	6	37.5%
3. Have you talked about your breast density	Yes	5	31.3%
with your healthcare provider?	No	11	68.8%
4. If yes, what led you to talk about your breast density?	I asked my healthcare provider about my breast density.	1	6.3%
	My healthcare provider brought up my breast density.	4	25%
	Other		

Demographics		N=16	N%
5. Have you heard about breast density from	Yes	4	25%
other non-health care provider resources?	No	12	75%
6. If yes, where did hear about breast density?	Book/Magazine/Newspapers	2	12.5%
	Radio/Television	0	0%
	Internet	1	6.3%
	Family/Friends	1	6.3%
	Other	0	0%
Opinions related to breast density			
1.I feel knowledgeable about my dense breast	Yes	9	56.3%
tissue.	No	7	43.8%
2. My dense breast notification was easy to	Yes	10	62.5%
understand.	No	6	37.5%
3. I feel comfortable making decisions about what type of screening to have with my dense breast tissue.	Yes	10	62.5%
	No	6	37.5%
4. My providers asked for additional testing.	Yes	6	37.5%
	No	10	62.5%
5. I asked for additional testing.	Yes	1	6.3%
-	No	15	93.8%
6. I wish I had more information on breast	Yes	6	6.3%
density.	No	10	62.5%
7. I think it is important to have more		12	75%
screening with dense breasts as it can be hard to find cancers with mammograms alone.	Yes		
	No	4	25%
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	12	75%
more testing and or naving a stopsy doner	No	4	25%
9. I get anxious stressed, or worried about	Yes	5	31.3%
having mammograms.	No	11	68.8%
10. My dense breast tissue has increased my	Vac	3	18.8%
anxiety about getting breast cancer.	1 08	13	81.3%
	No		01.070
11. I think it would be helpful to have	Yes	9	56.3%
reminders about my next mammogram.	No	7	43.8%

Demographics	N=16	N%
12. Do you have any additional concerns		
about dense breast tissue or questions about		
dense breast tissue?		
Comments:		

# APPENDIX N. COAL COUNTRY CLINIC DENSE BREAST NOTIFICATION LETTER

### ORIGINAL

July 22, 2020

Dear :

I am pleased to inform you that the results of your recent mammogram did not show any evidence of malignancy and was interrpreted as being normal. Your mammogram indicates that the density of your breast tissue is {almost entirely fatty (least dense), scattered fibroglandular density, heterogeneously dense, extremely dense (most dense)}.

Breast density is graded by radiologists as one of four levels.

- 1. Almost entirely fatty (least dense).
- 2. Scattered fibroglandular density.
- 3. Heterogeneously dense.
- 4. Extremely dense (most dense).

For most women, breast density decreases with age, but in some women, there is little change over time. Dense breast tissue is relatively common and may make it more difficult to detect small abnormalities in the breast and may increase your risk of breast cancer. If you ever feel a lump in your breast or have other reasons for concern, you need to come in and let us know.

The American Cancer Society Guidelines recommend annual mammography for ages 40-74 (for women of average risk) and annual physical exams. I encourage you to continue to stay current with your mammograms and to be seen at the clinic for annual exams and for any other concerns you may have.

If you have any questions or concerns, please do not hesitate to contact me at the clinic number listed below.

Sincerely,

### APPENDIX O. COAL COUNTRY CLINIC DENSE BREAST NOTIFICATION LETTER REVISED

(Date)

Dear patient:

Your mammogram that was done (date) showed NO findings of breast cancer. Your mammogram shows breast density. Your category of breast density is (insert category).

- Dense breast tissue is common. 40% of women have dense breasts
- Dense breast tissue makes it harder to find cancers on mammogram.
- Dense breast tissue is linked to increased risk of breast cancer.

Please talk to your provider about your breast density. Together you can decide which screening options are right for you based on your mammogram results and personal health history.

A negative mammogram does not lower your risk for breast cancer. I encourage you to continue to stay current with your mammograms and to be seen at the clinic for annual exams. Please continue to practice self-breast awareness and recognize what is and isn't normal for your breasts. Never ignore a breast lump, if you find a lump or notice a change talk to your healthcare provider as soon as possible.

If you have any questions or concerns, please call the clinic number listed below.

Sincerely,

### **Executive Summary**

### Implementation of Healthcare Professional Education: Breast Density as An Independent Risk Factor for Breast Cancer

### Introduction

Breast cancer is the most diagnosed cancer among women in the United States (U.S). A woman living in the United States has a 12.4%, or 1 in 8, lifetime risk of being diagnosed with breast cancer. Approximately 40-50% of women in the United States have Category C or D density, which is defined as heterogeneously dense or extremely dense breast tissue. Dense breast tissue is a known independent risk factor in the development of breast cancer. Today, 38 states have enacted a breast density notification law, unfortunately, the verbiage and information in letters sent to women are inconsistent and hard to understand with a median readability of 10.5.

### Purpose

The purpose of this practice improvement project is to assess the understanding of rural women's knowledge of breast density as an independent risk factor and educated healthcare professionals about breast density and the women's knowledge in the community. Additionally, review the breast density letter sent by the clinic to assess the readability and health literacy in the letter. Education about breast density to healthcare providers is provided with intentions to empower healthcare professionals to feel confident and comfortable in their knowledge about breast density and open lines of communication with their patients to ultimately improving patient outcomes.

### **Project Design and Implementation**

The educational curriculum was developed through literature reviews and expert consultations from a multidisciplinary team. Providers in urban Midwestern primary care clinics provided feedback on the content and preferred methods of education delivery.

- A survey distribution for 2 months was performed and utilized to assess the knowledge of women in the rural community education.
- The breast density letter utilized by the clinic was analyzed for readability and health literacy levels using the Flesch-Kincaid tool in Microsoft Word.
- A 30- minute education session was presented to the healthcare professionals at the rural Midwestern clinic. The PowerPoint educational session discussed breast density knowledge, screening options for women, and the results of the survey from women in the community as well as a modified breast density letter with an increase in readability. The educational session was developed through literature reviews and expert consultations. Knowledge on the topic was assessed by a pretest and posttest.

### **Results and Conclusion**

There appeared to be an overall approved understanding in breast density knowledge by providers, exhibited in the pre and posttest results. There was a significant increase in readability and reading ease of the breast density letter that was modified for the clinic to utilize. Overall,

the healthcare professionals made comments that the educational session was "useful." This practice improvement project was consistent with literature stating that clear concise language in breast density letters will improve health literacy and knowledge about breast density empower providers and women to communicate and discuss a known risk factor for breast cancer.

### **Recommendations for Future studies**

• Increase sample size of healthcare professionals to obtain a more accurate picture of knowledge and improvement knowledge. This project may continue to be implemented at rural clinics, but two sites may be more beneficial than one.