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An Evidence-Based Process Change to Improve Mammography Adherence

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AN EVIDENCE-BASED PROCESS CHANGE TO IMPROVE MAMMOGRAPHY
ADHERENCE

by

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DEDICATION

I dedicate this dissertation to my Lord and Savior Jesus Christ and my family. Jesus Christ, you always answer my prayers, and I stand on your word that says “I can do all things through thee that strengthens me.” A special gratitude to my loving mother Mary J. Smalls for your unrelenting love, support, and prayer; and my dad the late, Nathan “Smiley” Smalls for giving me tenacity and courage to always stand for what I believe in. I am extremely blessed that my siblings, Teresa C. Jennings (Tee) and Corey S. Smalls are my biggest cheerleaders and I am exceedingly grateful for their perpetual love, sacrifice, and support of me. Margo, my sister in marriage, thank you for simply loving me. Morgan, Kory, and Nathan, you all are my inspiration to continuously accomplish more. Finally, I am abounded with thankfulness for the unconditional love and support of my beau Joseph D. Mason and my dearest sister- friends Altonya, Senyene, Asumpter, Twanda, and Kenya.

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ABSTRACT

Breast cancer is a significant disease—affecting 12% of American women in a lifetime. Breast cancer costs \$180 billion annually in healthcare expenditures and productivity. Mammography has been identified as the greatest tool to mitigate morbidity, yet in many organizations, mammography compliance rates are decreasing. This process improvement was conducted to address the barriers to patient follow through with mammography and to recommend strategies to improve the current breast-screening process.

Principles of the Six Sigma DMAIC framework were utilized to analyze the breast-screening clinic process. Chart reviews and organization databases were applied to determine mammography adherence. The opportunities to improve current practices were identified by outlining the current practice flow, chart reviews, data mining of mammography adherence, and obtaining a baseline analysis of a sample of clinic patients who did not follow up with mammography. Informal interviews with providers were conducted as well. The structure of the organization was outlined and internal and external resources were identified.

An extensive review of the literature was conducted to identify best practices and barriers to mammography screening to elicit strategies to improve the breast-screening process. The interventions include assessing barriers to mammography during registration

of clinic visit, alert staff and providers of participants that meet criteria for mammography by flagging or marking the patients' charts, then providing a tailored provider message regarding the importance of mammography and relevance of all steps of the screening process, with an emphasis on financial counseling, and streamlining the current process. The usual care will be compared with the process change. The outcome measure of mammography proportion was calculated using a two-sample proportion test. The mammography proportion for the pre-intervention group was 22% and 51% for the post-intervention group. There was a statistically significant difference ($p = 0.01$) in mammography adherence between the pre-intervention group and the post intervention group. Ultimately, as evidenced by the significant increase in mammography utilization, the breast-screening clinic will positively impact the disease burden of breast cancer through early detection.

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CHAPTER 1

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer in women, and the second most common cause of cancer death (American Cancer Society [ACS], 2015). South Carolina [SC] was ranked 21st in the nation for breast cancer mortality in 2013 (South Carolina Department of Health and Environmental Control [SCDHEC], 2016). Early detection has been identified as crucial to survival. Nationally, when breast cancer is diagnosed in the early stages, the five-year survival rating is above 99% (American Cancer Society, 2015). According to a 2009–2013 surveillance report, about 61% of breast cancers were diagnosed in the early stages (South Carolina Department of Health and Environmental Control, 2016).

Advances in breast cancer treatment and screening initiatives have afforded significant declines in breast cancer mortality over recent years. However, breast cancer continues to be a national priority as every year over 200,000 women will be diagnosed with cancer, and approximately 40,000 will die (American Cancer Society, 2015). Recognizing that the incidence of breast cancer-related deaths remains extremely high, Healthy People 2020 established the goal of decreasing the number of breast cancer mortalities by 10% (Office of Disease Prevention and Health Promotion, 2016).

Effective breast-screening programs have been at the forefront of addressing the demand for early detection and treatment, and subsequently diminishing the death incidence. Mammography is a low-dose radiation X-ray procedure that allows an internal

view to record images of the breast. Mammography is instrumental in early detection as it detects tumors before signs and symptoms manifest. Early detection correlates with survival. The ACS (2015) screening guidelines state that most women aged 40 to 44 years should have a choice to start annual screening mammograms; women 45 to 54 years should get mammograms yearly, and women 55 years and older can have biannual or annual screenings. The American College of Obstetricians and Gynecologists [ACOG] recommends annual screening starting at age 40 years. The United States Preventive Screening Task Force [USPSTF] recommends biannual screening mammography for ages 50–74 years. Though the ACS, ACOG, and USPSTF provide different screening schedule recommendations, there is a consensus that early detection is the best available approach to decrease mortality related to life-threatening breast cancer (American Cancer Society, 2015; Newton, 2016).

Description of Clinical Problem

Mammography is considered the gold standard for early detection of asymptomatic breast cancer and has been linked to up to 39% reduction in mortality from the disease, yet breast cancer screening remains underutilized in many United States [US] populations (Newton, 2016). For more than two decades, mammography rates increased, followed by a period of slight decrease, and then leveled off. In the years 1987, 2000, and 2005–2010 the mammography rates were 39%, 70%, and 67%, respectively (American Cancer Society, 2015). The prevalence of screening mammography is particularly reduced in women that are racial or ethnic minorities, uninsured, have low income, less education, and low health literacy (Alexandraki & Mooradian, 2010; Özmen et al., 2016). In an effort to address the national priority of cancer mortality, it is imperative that

organizations continuously improve the processes by implementing the best practices to facilitate mammography compliance in the populations served. The scope of this quality improvement project is to implement an evidence-based intraorganizational process change that incorporates the best available research to improve screening mammography compliance.

Scope of the Problem

According to the World Health Organization [WHO] (2014), breast cancer is the most common cancer worldwide. Breast cancer is the second leading cause of cancer death for women in the United States (American Cancer Society, 2015). In a five-year surveillance report from 2008 to 2012, breast cancer was the most commonly diagnosed cancer and was the second leading cause of cancer death in the state of South Carolina and locally in Richland County (South Carolina Department of Health and Environmental Control, 2015). In that same report, Richland County ranked among the highest in breast cancer incidence rates, ranking fourth of the 46 counties in South Carolina (South Carolina Department of Health and Environmental Control, 2015). There were a total of 271 new cases during that time frame and 48 deaths (South Carolina Department of Health and Environmental Control, 2015). Data trends suggest that from 2004 to 2014, breast cancer incidence rates across the United States remained stable (American Cancer Society, 2015). However, the 2015 estimation of 235,000 new diagnoses of breast cancer, 43,000 deaths related to breast cancer, and the potential for the United States expenditures for cancer care to reach \$156 billion by 2020 signal that prevention and early detection of breast cancer is a high priority for the U.S. healthcare system (American Cancer Society, 2015; National Cancer Institute [NCI], 2016).

There is a significant need to address the issue of mammography compliance in healthcare practices, as this correlates with improved outcomes related to breast cancer. Breast cancer is a significant health condition, seeing that one in eight women in the United States will develop cancer during their lifetime (American Cancer Society, 2015). Primary diagnoses of breast cancer for inpatient hospitalizations cost more than \$44.0 million in South Carolina during 2014 (South Carolina Department of Health and Environmental Control, 2016). Furthermore, there were 807 inpatient hospitalizations related to breast cancer, with an average length of stay of 2.6 days, and netting an average total cost of stay of \$54,526.80 (South Carolina Department of Health and Environmental Control, 2016). Early detection enables early treatment, which has been shown to correlate with decreased health costs. The average cost for an occurrence of early-stage treatment of breast cancer is \$14,000 per year (Miller, 2012). The average cost of an occurrence of late-stage treatment of breast cancer is more than three times the cost of early-stage treatment, costing approximately \$47,000 per year (Miller, 2012). Mammography compliance correlates with reductions in mortality, morbidity, and cost; thus, it is essential for organizations to assess and recognize opportunities for improvement in their delivery system and key processes of mammography screening.

Research has consistently conveyed that mortality rates decrease with adherence to utilizing mammography screening (Hendrick & Helvie, 2011). In women 40–84 years old, annual mammography screening has proven to be the most advantageous cancer intervention, yielding a significant mortality reduction (Hendrick & Helvie, 2011). Despite the compelling death rate reduction attributed to mammography screening, many women are excluded from the advantage of mammography screening because they do not

comply with their providers' recommendation of screening mammography. The increased incidence of breast cancer among women aged 40 years and older and the prevalence of women not having mammography screenings has incited a concern to providers and healthcare leaders to seek solutions to improve mammography adherence.

Barriers to mammography screening. Women's adherence to breast cancer screening is contingent upon a multitude of factors. Studies have shown that such influences or barriers include confusion related to benefits of mammography and screening guidelines, fear of being diagnosed with cancer, lack of social support, low levels of income and education, and lack of insurance and access to mammography screening service (Jones et al., 2014; Schueler, Chu, & Smith-Bindman, 2008). Distrust of the medical system is another common barrier to mammography, specifically among black non-Hispanic women (Ramirez et al., 1999; Spalter-Roth et al., 2005).

Socioeconomic barriers are complex and tend to require institutional and organizational programs and policies that spur financial contribution. Successful screening programs keep abreast of community resources to eliminate financial access barriers (Schueler, Chu, & Smith-Bindman, 2008). Studies have found that despite socioeconomic status (SES), cognitive and psychological factors can be addressed through initiatives to educate the population on the benefits of screening and early detection and assist individuals with navigation through the healthcare system to achieve recommended preventive services (Ferreira, 2005; Peterson et al., 2016; Wells et al., 2008). Nurse practitioners and physician's assistants provide preventive care services and education in health centers, and thus are in an ideal position to influence women to follow through with mammography screening during clinic visits.

Description and Analysis of the Current Practices

Cancer Health Initiative. The Cancer Health Initiative is one of the programs integrated through the region's largest not-for-profit health system. Since 1998, the health system has pledged to give 10% of their bottom line profits to improving health outcomes of the Midlands communities. Cancer as the second leading cause of death directed the priority of improving cancer outcomes. Screening services and programs attend to the following five cancers, breast, cervical, prostate, colorectal, and lung. ACOG, ACS, American Urological Association, and American College of Gastroenterology (ACG) recommendations guide the screening and prevention education.

One of the goals of the Cancer Health Initiative is to provide quality screening and education to the underserved residents of the surrounding communities (Palmetto Health, 2016). The breast cancer-screening program includes a clinic visit with a nurse practitioner or physician's assistant. During the visit, the provider reviews the patient's history, discusses specific breast-related problems or questions, orders mammography imaging for age-appropriate participants, and refers participants to the Breast Center for abnormalities that may require immediate attention or additional workup. The Breast Center is a subsidiary clinic of the health system that is located onsite at one of the acute health center campuses.

Eligibility for clinic services. Breast cancer screening is a service offered through the Cancer Health Initiative. The breast-screening clinic provides services for uninsured and underinsured (i.e., hospitalization and emergency visit insurance coverage only) patients. Federal eligibility criteria are established by age, income, and residency. The eligibility criteria for screening are women age 21 years or older who are residents of

Richland, Lexington, or Fairfield counties. Participants of the breast-screening clinic have to have an income 200% of the federal poverty line. Mammography screening is available for participants 40 years or older whose income is 100% of the federal poverty line. Federal poverty level calculations are dependent on family size and are readjusted each year. In 2015 the average income at 200% of the poverty line for a household of one and four was \$23,760 and \$60,625, respectively (United States Census Bureau, 2015). The 2016 Poverty Income level thresholds decreased, which likely increased individuals' eligibility to participate in public programs and receive incentive or assistance for health insurance through the federal market exchange. The income for a household of one did not change much in 2016, as it only decreased by \$220. However, for a household of four in 2016 the 200% poverty level income decreased to \$48,600. The percentage of the population for Richland, Lexington, and Sumter with income of less than \$25,000 is 25.4, 26.6, and 28.1, respectively (County Health Rankings, 2015; United States Census Bureau, 2015). The change in poverty level income is a major determinant in the breast clinic participants' access to cancer preventive services. Unfortunately, the mammography, which is the recommended standard of breast cancer screening, has a higher income-qualifying threshold.

Clinic staff and patient clinic visit flow. An all-female direct patient care team staffs the health center. The team includes seven nurse practitioners and one physician's assistant. The other interdisciplinary team members include registered nurses, a licensed practical nurse, patient advocates, laboratory technicians, and a medical social worker. The breast-screening participant's first point of contact is with patient advocates that assist patients with health information paperwork. Eligible participants (having risk

factors, e.g., obesity) transition to the lab for blood glucose screening. Upon completing the health information paperwork and lab screening, a patient advocate or nurse obtains the participant's vital signs and weight. Lastly, the patient is taken to the exam room for breast-screening and/or cervical-screening assessments.

The nurse practitioner or physician's assistant performs the breast and/or cervical screenings and provides patient education. The provider is usually alone with the patient unless a patient advocate is necessary to translate for Spanish-speaking participants. There is only one nurse practitioner provider that is fluent in Spanish. The usual practice is two providers for an average of 16 patients to be seen in a four-hour period.

The provider staff deliver most of the patient education. The AGOG standards for screening and education are utilized. The ACS is also used as a reference for teaching our participants the signs and symptoms. The participants are taught about signs and symptoms of breast cancer. Breast self-awareness is discussed and the techniques of performing a breast self-exam (BSE) are reviewed as an opportunity for breast awareness. Written educational material includes a Breast Exam Shower Card that is given to the patients to take home. Pictures are paired with the verbal education to promote patient understanding. The education includes discussion of breast abnormalities such as lumps, hard knots, swelling, and nipple discharge. In addition, it explains how to feel for changes standing or lying. There is also content regarding examining breasts with implants. The tool does have the organization referenced and there is a number to call to schedule a mammography, however, there is no content explaining how to obtain a mammography screening externally. There is no printed information about breast cancer risk factors or mammography screening. Lastly, the shower card lacks printed education

regarding relative risk associated with having a family history of breast cancer. Providers report delivering verbal education-related screening recommendations adjusted for high risk.

Discussion of clinic outcomes. In 2015, 818 screening participants received 2,505 services, including clinical breast exams, mammography screenings, and ultrasounds (Palmetto Health, 2016). There was one active breast cancer diagnosis in 2015. This clinic's 2015 incidence of breast cancer was 1 positive diagnosis per 818 participants (122 per 100,000). The national incidence in 2008–2012 was 123.1 per 100,000. South Carolina's incidence was 125.3 per 100,000 (National Cancer Institute, 2016), whereas Richland County's breast cancer incidence was 137.9 per 100,000 (Centers for Disease Control and Prevention [CDC], 2015).

The Cancer Health Initiative's participants are uninsured or underinsured. The majority of the population's demographic is unemployed, low-income grade, and minority. This population has limited access to healthcare and preventive services.

Despite race or ethnicity, negative health outcomes are most prevalent in individuals who are uninsured or underinsured, lack access to healthcare, and have low incomes (Davidson, 2014). South Carolina ranks 13th highest for percent of uninsured population, and 48% of the uninsured population are women (SCIMPH, 2014). African Americans/Blacks, Asian Americans, Hispanic/Latinos, American Indians, Alaska Natives, and underserved Whites are more likely than the general population to have higher incidence and death statistics for breast cancer and certain other types of cancer (National Cancer Institute, 2016). Correspondingly, poor health literacy is a gradient to many of the factors that contribute to negative health outcomes. Moreover, the

demographics of the screening participants are compellingly parallel to several of the defining characteristics of individuals with low health literacy, which links the screening participants to higher risks for poorer outcomes related to breast cancer among other diseases.

The author investigated the current practices in the delivery of breast cancer education and reviewed mammography compliance data. The Cancer Health Initiative's mammography compliance was noted to have declined over the past two years.

According to the clinic data, in the fiscal year of 2015, 538 mammograms were ordered, and only 128 were completed, yielding a compliance rate of 23.7%. In 2016 the mammography compliance was 27.8%. These rates are far below the national and state screening rates of mammography, which are 73% and 72%, respectively (South Carolina Department of Health and Environmental Control, 2016). Since the inception of the Affordable Care Act, participants have been required to take an additional step of obtaining financial counseling prior to acquiring a mammography appointment.

Evidence for Need of Change

To identify the barriers and facilitators to mammography screening, the author outlined each step of the mammography screening process. Figure 1.1 outlines the six steps to the breast-screening process: recruiting, scheduling, clinic visit, financial counseling, appointment scheduling, and mammography tracking.



Figure 1.1 Breast-screening Clinic Process Flow

To evaluate further the problem of decreased mammography rates, a data analysis of a sample of patients that did not follow through with mammography was obtained. An Excel spreadsheet was generated by the clinic social worker to log the follow-up contact with patients that did not follow through with mammography. A random selection of the sample of patients was conducted utilizing the Excel spreadsheet random function. Chart reviews and follow-up phone call documentation were examined to create the data in Table 1.1.

Table 1.1 shows the distribution of the sample population N and percentage of selected variables. The sample ($N = 20$) was comprised of randomly selected screening participants who completed a clinic visit in 2016 but did not follow through with mammography. Sixty percent ($n = 12$) of the sample population was in the age bracket 50–59 years; 25% percent ($n = 5$) were aged 40–49 years, and 15% ($n = 3$) were aged 60 years or older. The racial composition was predominantly African-American at 60% ($n = 12$), followed by White at 30% ($n = 6$) and Hispanic at 10% ($n = 2$). One hundred percent of the sample population did not have insurance. Most of the sample had a total income of less than \$10,000 (55%, $n = 11$), whereas 30% ($n = 6$) had total income \$10,000–\$25,000 and 10% ($n = 2$) were in the income bracket of \$25,001–\$50,000. Only 5% ($n = 1$) of the sample had a total income of $>$ \$50,000. Being unable to contact the patients after the initial clinic visit was the most common barrier in the mammography screening process with 45% of the sample not contacted ($n = 11$). Thirty percent ($n = 6$) did not qualify for financial assistance, 20% ($n = 4$) did not submit required financial documentation, and 5% ($n = 1$) had other reasons. Everyone in the sample was uninsured and most reported a total income of $<$ \$10,000, so based on this information they should meet eligibility for some financial assistance. Under the healthcare reform law, states have the option to expand Medicaid coverage to everyone under 138% of the poverty level. The fact that SC did not opt to accept federal funding to expand Medicaid coverage contributes to the number of uninsured. However, it is important to note patients that did not qualify for the organization financial assistance program or the Best Chance Network would not qualify for Medicaid even if it were expanded. The Cancer Health Initiative program qualifications criterion of total family income at or below 150% of the federal

poverty line, whereas the Best Chance Network income criterion is 100% to 200% of the federal poverty line, which increases the threshold for higher family incomes to be eligible for financial assistance.

Table 1.1 Frequency Distribution of Selected Factors of Breast-screening Participants.

Variable	<i>N</i>	(%)
Age		
40–49	5	25
50–59	12	60
60–older	3	15
Race		
African-American	12	60
White	6	30
Hispanic	2	10
Insurance		
No	20	100
Yes	0	–
Total Family Income		
<10,000	11	55
\$10,000–25,000	6	30
\$25,001–50,0000	2	10
>\$50,000	1	5
Financial Counseling		
No	12	60
Yes	5	25
N/A	3	15
Documented Barrier to Mammography		
Did not qualify	6	30
Did not submit financial documentation	4	20
Unable to contact patient	9	45
Other	1	5

The analysis of the mammography process confirms that there is a disconnect between the patient and the organization after the clinic visit. The mammography screening process flow contributes to the aforementioned disconnect. The screening flow is cumbersome, as it requires a total of two visits prior to scheduling the mammography appointment for patients that are U.S. citizens. Based on the patient reported data, most of the patients would qualify for some assistance, but they fail to follow through with counseling. After the initial clinic visit, our program has limited influence on follow through. That being said, interventions should be geared at influencing the patient prior to and during the clinic visit, assessing barriers, and simplifying the process.

The clinic visit was identified as the last point of contact to influence the patient to follow through with mammography. Unfortunately, the current process requires U.S. citizens to attend a financial counseling appointment. The intent is to assist uninsured and low-income patients with applications for health financial resources, which includes healthcare plans afforded by the Affordable Care Act. Though the financial counseling is a patient-centered effort to address barriers to healthcare in terms of finances, many patients did not follow through with this opportunity, and thus did not get a mammography. The clinic social workers have indicated that many patients have expressed a perception of the financial process as in depth and requiring “too much” personal information. Many participants felt uncomfortable providing such information. Emphasis should be placed on ensuring that patients perceive financial counseling as not only a benefit for mammography but more importantly as a means of obtaining funding for comprehensive health services. This lack of knowledge marks a significant opportunity in the area of health literacy.

Moreover, it is significant to note that our noncitizen patients did not qualify for financial provisions of the ACA, and thus did not qualify for the financial counseling services offered by the organization. There was a period of time when the screening clinic was unable to provide mammography to a significant proportion of our patients, specifically Hispanics. This barrier was addressed through collaboration with the Best Chance Network. Best Chance Network served as a funding source for mammography for noncitizen patients. Thus, our noncitizen patients did not have the extra step of financial counseling. Opportunities in the financial component of the process were identified.

Furthermore, in addition to observation of the environment and patient flow, the author conducted informal interviews with providers and other members of the staff regarding educational delivery. Five of the seven providers were asked the following questions:

1. Are you familiar with health literacy?
2. How do you incorporate health literacy principles in practice?
3. Have you had any health literacy training?
4. What breast education do you usually provide?
5. How do you confirm understanding?
6. Is teach-back used always, sometimes, not usually, or never?
7. What barriers do you see in providing breast health education during clinic visits?
8. Do you think health literacy is a concern for the population that we serve?

The intent of the interview questions was to assess current health literacy practices during patient–provider interactions. All the providers indicated that health literacy was a potential issue for the patient population served.

The aforementioned description and analysis of current practice demonstrate that there are significant opportunities for improvement in the current mammography process. In light of the declining mammography rates, it is imperative that the breast-screening clinic investigates and implements evidence-based interventions to improve mammography compliance. Improving mammography compliance will consequently mitigate the negative outcomes of breast cancer for the patient population that the breast-screening clinic serves.

Discussion of Best Practice to Address the Problem

Utilizing practice research methodology, Aspy, Enright, Halstead, and Mold (2008) established best practices for mammography screening programs by evaluating the processes of exemplar practice sites. Exemplar was defined as a practice site having an 80% or higher mammography compliance rate. The best practices were identified as the following,

- Organizations committed to providing mammography screening and adopting a screening protocol such as annual mammography for women age 40 years or over is essential for tracking initiative.
- Use of a clinician reminder system of some sort, for example, a sticker for the charts of women 40 years or over.
- Make the appointment for the patient. Establishing the best day and time for the appointment prior to the patient leaving the clinic visit.

- Use one mammography site and obtain an appointment within two weeks of the clinic visit.
- Track mammography and follow up when appointments are not maintained.

Moreover, the Task Force on Community Preventive Services [The Task Force] (2008, 2012), an independent panel of experts in primary care and prevention, systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services. The Task Force has established several evidence-based strategies to increase breast cancer screening. The Task Force (2008, 2012) has outlined tailored reminders (printed or verbal) that address the individual's risk profile or other relevant characteristics, such as assessing barriers to the client seeking screening or facilitators to encourage the client being screened.

The Task Force (2008, 2012) also recommends one-on-one education and motivational messages with strong evidence of effectiveness. The educational strategy can incorporate media, be tailored to reach a particular target population or untailed for the general population. Health professionals, volunteers, or laypersons can convey information. Studies have found that patient-centered provider recommendations and education correlate with mammography adherence (Task Force, 2012). Recent research found that effective communication correlates with positive patient influences and increases health literacy (Peterson et al., 2016). Communication, the sharing of information between individuals, has a significant association with adherences, and thus is essential to health outcomes (Nouri & Rudd, 2015). For the Cancer Health Initiative, providing information on the importance of mammography is imperative, nonetheless, it is equally critical to ensure that patients obtain and understand the necessary information

to navigate internally and externally through the health system to increase the likelihood of acquiring mammography screening. Communication facilitates adherence, which is the mediating factor between healthcare recommendations and health outcomes (Nouri & Rudd, 2015; Rudd, 2013). Effective provider–patient communication has been shown to have positive effects on patient satisfaction, which correlates with patient adherence to health recommendations (Koo, Horowitz, Radice, Wang, & Kleinman, 2016). Health providers’ clear and patient-centered education of relevance to mammogram and reporting signs and symptoms of breast abnormalities can lead to early detection of breast cancer and improve survival odds if the patient adheres to the advice and follows through with the screening test (Koo et al., 2016).

Furthermore, there is strong evidence that proposes that reducing structural barriers improves mammography compliance (Task Force, 2008, 2012). Structural barriers are hindrances that impact access to screening, such as inconvenient hours and location for screening, complex administrative process, or requiring participants to have multiple clinic visits to obtain a mammography. Strategies to alleviate structural barriers are effective when combined with interventions to provide participant education, information about resources or program availability, or measures to reduce out-of-pocket costs.

Optimal screening rates can be achieved when healthcare organizations tailor strategies to the steps and interfaces in the cancer-screening process that are most critical for their organizations, the providers who work within them, and the patients they serve. The best practices to improve mammography compliance identified through the research will be tailored and applied to improve the breast-screening clinic process. Specific

opportunities will include (a) assessment of barriers to mammography during clinic visits, (b) develop and incorporate a tailored provider message to educate on breast cancer and mammography and the relevance of financial counseling, and (c) investigate procedures to streamline the current process. The best available evidence as discussed will be utilized to develop the process changes.

Statement of Purpose and PICOT

Recognizing that improving mammography rates can prevent breast cancer mortality has established the relevance of improving breast-screening clinics' mammography rates. The purpose of this project is to investigate and identify the barriers to patient follow through with mammography and to identify the best evidence-based strategies to improve the current breast-screening process. The intent is to implement the evidence-based process change and evaluate the effects of the process changes on the mammography rates of clinic participants.

According to Melnyk and Overholt-Fineout (2015), framing questions in the PICOT format assists clinicians in identifying appropriate evidence to answer questions with certainty. The PICOT for the study is: Among breast cancer-screening participants, what are the best practices to improve mammography screening? The population (P) is breast-screening participants aged 40 years and over that have a mammogram order. Intervention (I) is an evidence-based process change, which includes assessing barriers to mammography during registration of clinic visit, alerting staff and providers of participants that meet criteria for mammography by flagging or marking the patients' charts, then providing a tailored provider message regarding the importance of mammography and relevance of financial counseling, and streamlining the current

process. The Intervention is outlined and further discussed in Chapter 3. The comparison intervention (C) is the usual practice. The outcome (O) is mammography proportion. The time frame (T) of the intervention will span from one-month post-process change, wherein the mammography proportion outcome will be evaluated. Table 1.2 outlines the evidence-based inquiry.

Table 1.2. Evidence-based Clinical Question

Population	Intervention	Comparison	Outcome	Timeframe
Breast cancer-screening participants age 40 years and over that have a mammogram order.	Implementation of evidence-based best practices to improve breast-screening process.	Usual practice	Mammography proportion	Mammography proportion one-month post-process change.

PICOT Definitions

1. **Breast-screening** participants for the scope of this project are women aged 40 years or older that have a normal clinical breast exam and do not identify any abnormal breast symptoms, and who obtain a routine screening mammogram order during their clinic visit.
2. **Evidence-based best strategies** are defined as interventions identified through research studies, literature reviews, as having a significant impact on a particular phenomenon. The level of evidence correlates with the validity of study findings (Melnik & Overholt-Fineout, 2015). Advisory agencies such as the USPSTF

define the strength of evidence in terms of effectiveness as strong, sufficient, or insufficient. For the scope of this project, strategies are

- *Assess barriers to mammography* defined as investigating actions or lack of actions that impact mammography screening.
- *Flagging charts* is an action that serves as a means for alerting or reminding the staff that screening participants qualify for mammography.
- *Tailored provider message* is defined as the delivery of health education that promotes breast health literacy. The tailored message takes place in the clinic visit interface of the process. The focus is specific to patient-provider communication. A scripted message that utilizes health literacy principles of clear communication and confirmation of understanding with the use of methods such as teach-back. The message content will explain the importance of mammography, as the intent is to motivate patients to follow the necessary steps to complete mammography. Added emphasis will be placed on financial counseling to provide a comprehensive understanding of breast-screening management.

1. **Health education** is any combination of learning experiences designed to help individuals and communities improve their health, by increasing their knowledge or influencing their attitudes (World Health Organization, 2016, para. 1).
2. **Health literacy** is the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions (Institute of Medicine [IOM], 2004, p. 32).

3. **Breast cancer literacy** is having knowledge of the signs, symptoms, and risk factors of breast cancer and the ability to utilize the information to make decisions to decrease breast cancer risks or seek medical attention appropriately; also includes an awareness of screenings to include mammography, clinical breast exam (CBE), and breast self exam (BSE) or self-awareness (Institute of Medicine, 2004; Williams et al., 2013).
4. **Verbal education** is the use of sounds and words to deliver health information; the use of gestures, diagrams, or pictures (Institute of Medicine, 2004).
5. **Breast-screening process** is the actions that are taken to complete mammography. There are six steps: recruiting, registration, clinic visit, financial counseling, mammography appointment, mammography tracking.
6. **Usual practice process** is defined as the process of mammography screening before the implementation of the process change, as outlined in Figure 1.1.
7. **Provider/Nurse Practitioner** is defined as “an advanced level clinical nurse who through extra education and training is able to practice autonomously, making clinical decisions and instigating treatment decisions based on those decisions, and is fully accountable for his/her own practice” (International Council on Nurses Nurse Practitioner/Advanced Practice Nurses Network, 2016). The nurse practitioner is a provider staff member that will deliver breast cancer education.
8. **Provider/Physician Assistants (PA)** is a nationally certified and state-licensed medical professional. PAs diagnose, treat, and prescribe medications (American Academy of Physician Assistants, 2016). The PA in the context of this QI project

is a provider staff member of the breast-screening clinic who provides breast cancer education.

9. **Clear communication** techniques are defined as the use of plain language, speaking slowly, limiting to two or three messages at a time, and confirming understanding with the teach-back method (Dewalt et al., 2010; Hersh, Salzman, & Snyderman, 2015; Weiss, 2007). Plain language is clear, straightforward communication and avoids complex technical terms and sentences (Dewalt et al., 2010; Hersh, Salzman, & Snyderman, 2015; Weiss, 2007).
10. **Teach-back method** confirms that patients understand health information and best practices for next/subsequent steps by teaching or explaining information back to the provider (Agency for Healthcare Research and Quality, 2012). After explaining breast cancer education the provider will ask the patients to explain the information that was provided. If the patient is unable accurately to explain the information after the provider has reviewed and explained the materials, then the provider will clarify the instructions.
11. **Provider–patient communication** is nonverbal and verbal communication between healthcare professionals and patients (Hersh, Salzman, & Snyderman, 2015; Institute of Medicine, 2004).
12. **Breast cancer education** is education that raises the awareness of breast cancer symptoms and treatment. The knowledge attainment goals are to promote risk reduction behavior and promote earlier detection of breast cancer, which is associated with higher long-term survival rates (Institute of Medicine, 2004; Williams et al., 2013).

13. **Provider perception of understanding** is the process by which a healthcare provider translates sensory impressions into a coherent and unified view; and assessment of information attainment and comprehension (Institute of Medicine, 2004; Kornburger et al., 2013).
14. **Mammography adherence** rate is the time interval within which women are considered compliant with screening guidelines and what constitutes screening rather than a diagnostic mammogram (ACOG, 2016). The mammography compliance rates for the breast-screening participants are determined by the number of women who were referred by providers post-CBE and education visit and received their recommended mammogram within one year of breast-screening clinic visit divided by the total number of screening participants within a set time frame.

Assumptions

The following assumptions are made regarding the project

- The process change variables have a relationship with mammography adherence.
- The providers have the knowledge and skills to deliver the tailored messages utilizing health literacy principles of clear communication strategies and teach-back.
- The participants are capable of learning the subject matter.
- The participants will understand the questions being asked.
- The participants will provide honest expressions of their satisfaction with (or lack thereof) the breast cancer delivery.

Conceptual Framework

The Six Sigma DMAIC methodology is the framework that was selected to guide the development, implementation, and evaluation of improving the process of breast cancer screening. The acronym DMAIC represents Define, Measure, Analyze, Improve, and Control (Taaffe et al., 2012). This process improvement model provides simple, yet structured guidelines that have led to successful organizational process improvements in manufacturing, business, and healthcare. The phases of the DMAIC model facilitate a systematic approach to problem identification. Emphasis is placed on an in-depth analysis of current practices and performance. The analysis is essential as this step is where the underlying causes of flaws within the process are determined. Afterward, planning and recommendations occur to address the process' inefficiencies. Finally, proven practices are implemented to promote sustainable strategies for change. The DMAIC approach to process change is fitting as the steps are aligned with principles of clinical or translational research, utilizing statistics and facts to improve the delivery of care.

The Define component is the first phase of the project. Stakeholders and key team players are established during this phase. The Define actions can be described as “making the case,” where the problem is clearly identified in terms of the magnitude of the problem and consequences if the problem is not resolved (Taaffe et al., 2012). From the beginning, it is essential to establish the need for improvement and identify the possible opportunities and barriers. Clearly defining the problem and setting feasible and measurable goals are crucial to the project outcomes.

The Measure component establishes the metrics for a particular setting. During this phase, relevant baseline data are obtained. Outlining the current process flows

enables the identification of potential opportunities and facilitators within the process (Taaffe et al., 2012). Depicting the current process enables a baseline for comparison with future data. Collecting measurable data provides validation to determine if the improved practices are meeting the intended objectives or goals established as part of the problem (Taaffe et al., 2012). This breast-screening clinic's process was outlined to establish a baseline for comparison of the clinic's current practices with best practices as determined through the best available evidence.

The Analyze phase of the framework begins the task of interconnecting the data that were collected in the Measure phase (Taaffe et al., 2012). The data are utilized to determine the underlying root or causes of the problem. The opportunities that are identified can then be prioritized based on impact relative to the defined problem. Data analysis leads to an enhanced identification of opportunities within the process (Bandyopadhyay & Coppens, 2005).

The Improve component of the framework is when the preparation for improvement takes place. The solutions are determined based on the prioritizing from the Analyze phase, thus solutions that are hypothesized to have the greatest impact on the identified problem should be piloted (Taaffe et al., 2012). Continuous process revisions are essential to maximizing the effects of the process change (Taaffe et al., 2012).

The Control component is the final interface of the framework. During this phase, if the implemented process changes are successful, then ongoing monitoring must occur to ensure sustainability. A continuous process system is instrumental, as it may be necessary to reevaluate the current system and provide further system changes for optimal results (Bandyopadhyay & Coppens, 2005; Taaffe et al., 2012).

The World Health Organization (2009, p. 12) defines quality as the “degree to which health services for individuals and populations increase the probability that the desired outcomes are consistent with current professional knowledge.” The process change intends to eliminate deficits in the breast-screening process in an effort to improve the outcome of mammography compliance. Improving processes correlates with improved quality and health outcomes. Thus, utilizing the DMAIC is an appropriate framework for facilitating the implementation of a breast-screening process change.

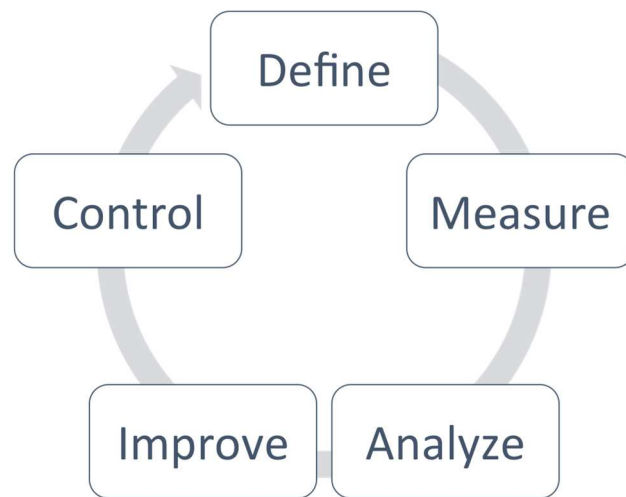


Figure 1.2. Adapted from Six Sigma DMAIC Approach Model (Taaffe et al., 2012).

Summary

The complexity of today’s healthcare system makes it difficult for many individuals to understand and navigate available information and services. It is estimated that only 12 percent of Americans have proficient health literacy (Joint Commission, 2012). The combined effects of convoluted breast-screening processes and low health literacy suggest that organizations are challenged to address the incongruence of individuals’ capabilities and requirements of the healthcare system to facilitate health recommendations such as mammography. The inability to understand information

impacts accessibility to services and the capacity to make informed decisions, which can lead to subsequent poor health outcomes.

Health processes that are multifaceted and require numerous actions correlate with declines in patient participation in health services such as mammography. The cancer-screening process requires a series of steps that entails collaboration of patient, organization, and providers. These steps include recruitment, patient attending health visit, and performance of the screening (Anhang Price, Zapka, Edwards, Taplin, et al., 2010). The coordination of care is described as “interfaces” or the communication and transfer of responsibilities among the organization and patient, organization and providers, and patient and provider (Anhang Price et al., 2010).

Patient education, provider referral, and appointment setting are integral components of the process; subsequently, failures in any aspects of these steps can adversely impact follow through with mammography (Anhang Price et al., 2010; Zapka & Lemon, 2004). Women’s participation in mammography screening is largely determined by their ability to both access and navigate through health organizations that provide the services. Research has validated the importance of evaluating and streamlining the mammography process to increase mammography adherence (Anhang Price et al. 2010; Goins et al., 2003; Zapka & Lemon, 2004). Thus, the goal of this DNP project is to implement an evidence-based process change to identify barriers and implement best strategies to improve the breast-screening process, ultimately to improve mammography adherence.

CHAPTER 2

REVIEW OF THE LITERATURE

Description of Search Strategy

Conducting a systematic review of the literature is a key component to extrapolating relevant scientific evidence that yields support to particular clinical questions (Melnyk & Overholt-Fineout, 2015). The purpose of this DNP project is to improve mammography compliance by identifying barriers to mammography, investigating effective strategies to improve mammography acquisition, and implementing the proven strategies into the mammography screening process. Reduced mammography compliance contributes to negative breast cancer outcomes, and consequently continues to be a significant health issue in the US, with detrimental health and financial consequences (American Cancer Society, 2015; Hendrick & Helvie, 2011; National Cancer Institute, 2016).

PUBMED, CINAHL, PsycINFO, Google Scholar, and Cochrane databases were accessed to obtain substantial evidence to address the clinical question, “Among breast cancer-screening participants, what are the best practices to improve mammography screening?” In addition, consultations with medical reference librarians at the University of South Carolina (USC) and Kaiser Permanente Hospital-Oakland contributed to the literature that was assessed for relevance for the evidence-based project. For each of the databases, the search mode was set for Boolean/phrases, peer-reviewed (scholarly) journals, English language, and all publication types. Additional search limitations

included setting the publication time frame to five years, sorting by relevance, and the inclusion of all article types (clinical trials, systematic reviews, etc.) with full-text availability. The key terms included health education, breast cancer, prevention, early detection, education, breast education, health literacy, breast cancer pamphlets, mammography, compliance, adherence, patient compliance, barriers, prevention, screening, organizational structure, and best practices. The key terms were utilized in different combinations, applying connectors AND, OR, and NOT to retrieve relevant content.

An inclusion criterion was established to facilitate obtaining applicable evidence. The author included studies that referenced healthy women aged 40 years or over, interventions specific to promoting cancer screening, and mammography screening or cancer screening. Both clinical and community settings were considered. The exclusion criteria included articles that were not specific to an intervention that improved mammography or cancer-screening adherence, did not address a targeted population of women, or did not have an outcome measure specific to mammography compliance. The titles and abstracts of the literature found were examined based on these criteria. Examining bibliographies of articles obtained through initial searches retrieved additional related studies. This review of the literature yielded 25 relevant studies.

Analysis of Evidence to Support Implementation of Best Practices

Critical appraisal of evidence is a vigilant and systematic process of evaluation of research, which determines the trustworthiness and relevance of an article or study to a particular context (Melnik & Overholt-Fineout, 2015). The author utilized Johns Hopkins Evidence and Quality Guide (Appendix B) as a reference for appraising the

literature (Dearholt & Dang, 2012). The evidence is ranked from Level I (highest level) to Level V (lowest level) based on set criteria, and quality is ranked on a scale of A (highest quality) to C (lowest quality). Appendix A details the standards for ranking the level and quality of evidence. Appendix C outlines the literature that was retrieved to address the derived PICOT.

Barriers and Strategies

Socioeconomic Factors. Even though numerous local, state, and national healthcare programs have been developed to improve access to preventive services and breast cancer survival rates, disparities still exist among some populations of women. In a recent review of the literature, researchers established that women with low SES, lower education levels, a lack of insurance, and lack of regular access to a primary healthcare provider are among the population of women who have low mammography compliance (Alexandraki & Mooradian, 2010; Todd & Stuijbergen, 2011). The authors further discussed that these barriers directly impact the compliance of mammography screenings (Alexandraki & Mooradian, 2010). Poverty and economic status were found to be the most influential impediments to mammography compliance (Alexandraki & Mooradian, 2010).

According to the ACS (2016), outreach programs and services should target women who fall within the parameters of poverty, as this population compared with more affluent populations tends to have lower rates for screening mammography. A crucial contributing factor is that low SES is correlated with low educational levels (Todd & Stuijbergen, 2011). Low education levels influence knowledge levels and impact one's ability to access, navigate, and comply with health services and recommendations. This

predisposes this population of women to less than optimal overall healthcare outcomes (Alexandraki & Mooradian, 2010; Todd & Stuijbergen, 2011).

In 1990, Congress responded to an overwhelming body of research indicating that mammographic and cervical screenings were associated with the reduction of death rates of the aforementioned cancers by approximately two years by authorizing the National Breast and Cervical Cancer Early Detection Program [NBCCEDP]. The NBCCEDP is channeled through the CDC, which enables the operation of federally funded programs by the individual states, territories, and other national partners (Centers for Disease Control and Prevention, 2016).

The provisions of the NBCCEDP provide preventive healthcare services to women who fall within subgroups that include low income, uninsured, underinsured, and those who lack access to timely screening and diagnostic services. These women would now have access to preventive healthcare services (Centers for Disease Control and Prevention, 2016). Comprehensive breast health services such as breast exams and mammograms are provided to diminish adverse breast outcomes (Centers for Disease Control and Prevention, 2016). Referral and treatment services were additional services that emerged when the program was enhanced with the Breast and Cervical Cancer Prevention and Treatment Act in 2000, which authorized Medicaid services for women who were diagnosed with cancer through NBCCEDP screenings. Research has supported that in an effort to decrease the rates of cancer occurrences and cancer-related deaths, information and screenings must be readily available for all women irrespective of their SES, race, or educational background. National policy and programs have reacted to the

evidence and accelerated early detection by eliminating SES barriers and providing financial resources for breast-screening programs.

Socioeconomic Strategy (Identified Resource): Best Chance Network

The Best Chance Network (BCN), one of the first funded programs through NBCCEDP, was established in SC in 1991. The program provides health resources and services to all 46 counties in SC. Screening services offered through the BCN include mammograms, clinical breast exams, pap tests, pelvic exams, and human papillomavirus tests. Other services include diagnostic testing for women with abnormal screening results, support services with patient navigation, referral for treatment, and community education on breast and cervical cancer. Since the BCN's inception, the program has provided breast and cervical cancer screenings to more than 11,755 women and 178,162 mammograms (South Carolina Department of Health and Environmental Control, 2016). In addition, the BCN program has diagnosed more than 1,800 breast cancers and 3,400 cervical cancers since 1991 (South Carolina Department of Health and Environmental Control, 2017). The appropriation of additional funding from the SC State Legislature in years 2015 and 2016 has enabled BCN to increase services and expand eligibility criteria, which allows more women to be screened (South Carolina Department of Health and Environmental Control, 2017). Best Chance is a resonant resource that moderates the financial barrier to early detection and partners with organizations to extend assistance to address low-income populations.

Health Literacy. The IOM (2004) describes health literacy as a mediator between individuals' awareness (knowledge) of disease and risk factors and their actions of disease prevention (behavior), and subsequent outcomes. There is a growing body of

research that supports the association of health literacy, knowledge, behavior, and outcomes (Halverson et al., 2015; Institute of Medicine, 2004; Komenaka et al., 2015; Smith et al., 2013). Halverson et al. (2015) conducted a cross-sectional study of cancer patients to evaluate health literacy with health-related quality of life outcomes. The study concluded that low levels of health literacy at the patient level had a significant relationship with poor health-related quality of life among breast, lung, prostate, and colorectal cancer patients (Halverson et al., 2015). Komenaka et al.'s (2015) study revealed that health literacy had the strongest relationship to the use of screening mammography compared with all the sociodemographic variables examined. In a Level I/Quality B experimental study, Smith et al. (2013) conceptualized the dynamic components of literacy as those components related to knowledge attainment. The investigation provided evidence that ability, motivation, and heuristic message cues impacted knowledge scores for individuals receiving messages written for different literacy levels (Smith et al., 2013). The aforementioned research findings highlight that an individual's ability to gain knowledge or comprehend knowledge is a necessary outcome of health-related information.

Unfortunately, consistent and accurate uses of such principles by primary care providers and clinic organizations are lacking (Hersh et al., 2015). Significant barriers to evidence-based practice adoption include lack of knowledge or skills, negative attitudes, limited time for the patient encounter, and lack of organizational support. Healthcare providers often do not address health literacy in routine patient care, overestimate patients' health literacy, and incorrectly assume that health information and instructions have been understood (Dewalt et al., 2010; Kripalani & Weiss, 2006; Weiss, 2007).

Health literacy correlates with an individual's ability to make informed decisions and choices related to care (Halverson et al., 2015; Institute of Medicine, 2004). Prompt reporting of new breast symptoms and routine mammography screenings are key components to early detection of breast cancer (American Cancer Society, 2015). Moreover, one has to be able to identify risk factors and understand steps to accessing services before actions to promote risk reduction can be considered. Thus, to address breast health literacy among breast-screening participants, it is important to provide patient-centered education via effective patient-provider communication while ensuring that learning has occurred (Pigone, Dewalt, Sheridan, Berkman, & Lohr, 2005).

Health Literacy Strategies

The growing realization that it is imperative to meet the demand of facilitating patients' understanding and the likelihood of acting on health recommendations has integrated health literacy as an essential aspect in improving healthcare. Several evidence-based health literacy toolkits have been developed to assist health providers and organizations to improve patient-provider communication, which has a direct impact on information understanding and thus indirectly influences health outcomes.

The Agency for Quality Health Research Health Literacy Toolkits provide straightforward methods to improve patient-provider communication. Some of the techniques include the use of plain or nonmedical language, listening to the words that patients use to describe their illness, and then using the common words in conversation (Agency for Quality Health Research, 2012). Prioritizing conversation and limiting content to three to five key points have also proven to improve patient understanding (Agency for Quality Health Research, 2012). Another key strategy to improving patient-

provider communication is the use of the teach-back method. The teach-back method confirms that patients understand health information and know what to do as a result, by having patients teach or explain information back to the provider.

Confirmation of understanding has been found to be an essential component of effective patient education, as patients rarely disclose their lack of understanding of the information provided (Hersh et al., 2015). Several studies have validated that teach-back is an effective educational strategy for health professionals to incorporate in healthcare for improving health behaviors and subsequent outcomes (Dinh et al. 2013; Ferreira, 2005; Schillinger et al., 2003). A study that evaluated 74 diabetic patient encounters by 38 physicians by audiovisual means found that patients whose physicians had assessed comprehension and recall had significantly lower levels of hemoglobin A1C levels than patients whose physicians did not (Schillinger et al., 2003). A multiple regression analysis confirmed that the interactive communication was the variable most associated with improved glycemic control (Schillinger et al., 2003). Likewise, a quasi-random control trial of 2,046 veterans due for a colonoscopy screening established that colorectal cancer-screening rates improved when healthcare professionals incorporated health literacy communication strategies (Ferreira, 2005). Furthermore, a recent systematic review of the effectiveness of health education using the teach-back method established that teach-back is an effective strategy for improving management of chronic disease, knowledge of informed consent, and reduction in readmission rates (Dinh et al., 2013). The teach-back method has been used in diverse populations, including health professionals, low-income women, and people with low health literacy and chronic

disease, and it is associated with improved patient knowledge and self-efficacy (Dinh et al., 2013).

Breast Health Education. Health education is a strategy that has been emphasized in the U.S. healthcare system in disease prevention and early detection of diseases such as breast cancer. The literature review resulted in one Level I and Quality B experimental study, five Level II/Quality B quasi-experimental studies, one Level III/Quality A meta-analysis, and one Level III/Quality B mixed experimental/qualitative study that explored the impact of health education (Alkahlili et al., 2015; Burgess et al., 2009 Dieng et al., 2014). Seven, Akyüz, and Robertson (2015) explored three methods of education—individual, individual with an educational brochure for spouses, and group—on participation in breast cancer screening and found that group education was an effective method of increasing breast cancer knowledge and screening awareness. The study was derived from an extensive literature review, utilizing block randomization with a sample size sufficient to achieve statistical significance ($N = 327$), suggesting that study findings have significant credibility and generalizability.

Bushatsky et al.'s (2015) quasi-experimental study reinforced that the health knowledge among a convenience sample of 84 women notably improved after a health education intervention. The educational content was comprised of breast cancer symptoms, performance of a BSE, and modifiable risk reductions through dialogue and visualization (Bushatsky et al., 2015). While the results of the study are relevant, the study's design impedes the overall strength and generalizability of the findings. Content-specific education delivered in a manner to address improving participants' general

education knowledge about disease and risk factors was found to have statistically significant effects (Bushatsky et al., 2015).

A similar study conducted with a small group of Korean women demonstrated that a tailored education based on the individual's pretest data information had a positive correlation with breast cancer awareness, self-efficacy for BSE, and intent to participate in screenings (Park et al., 2013). The information incorporated risk factors, knowledge, screening behaviors of breast cancer, and breast cancer prevention behaviors (Park et al., 2013). The generalizability is limited and related to the small and homogeneous sample population. Although a criterion was established for study participants, the assignment of treatment was nonrandom, which impacts the study's internal validity. These findings provide worthy proposal support for the use of family health education intervention in improving breast health literacy.

Güçlü and Tabak (2013) and Burgess et al. (2009) similarly determined that health education activities conjoined with health screenings increased women's overall knowledge of breast cancer. In addition, Burgess et al. (2009) investigated the sustainability of the knowledge by conducting one-month post-intervention assessments and found that the mean knowledge of breast symptoms increased and maintained at six months. The findings established that printed education only and combined printed education and interview are effective interventions to improve sustained knowledge attainment. In contrast, Maxwell et al. (2008) found that the use of printed educational material did not result in statistically significant increases in mammography screenings and suggested the exploration of combined education strategies to increase education and subsequent behaviors. A mixed experimental and qualitative study design reiterated that a

diverse community-based education intervention had a positive effect on increasing knowledge of breast cancer (Zeinomar & Moslehi, 2013).

Community Preventive Task Force [Task Force] (2012) has also corroborated that one-on-one health education and group education are effective tools to increase breast-screening uptake. However, tailored education was found to have an increased effect on mammography uptake compared with untailored education strategies (Task Force, 2012). The Task Force endorses one-on-one health education based on strong evidence, while group education is proposed on the basis of sufficient evidence (Task Force, 2012).

Organizational. Research has conveyed that organizational processes impact mammography adherence (Anhang Price et al., 2010; Stone et al., 2002; Weingart et al., 2009). The mammography screening process requires a series of steps by the triad of organization, patient, and health providers. Failures or breakdowns in the process can delay mammography screening, thus negatively affecting breast health outcomes (Weingart et al., 2009). Investigators have examined both screening process failures and strategies that can be utilized to address the demand for continuous improvement of screening programs, which are necessary to facilitate early detection and treatment of breast cancer (Anhang Price et al., 2010; Stone et al., 2002; Weingart et al., 2009).

There are a number of studies that evaluated the effects of attributes of the breast-screening process on mammography adherence (Anhang Price et al., 2010; Stone et al., 2002; Weingart et al., 2009). In a systematic review, 49 of 79 studies evaluated the association of organizational factors and mammography adherence (Anhang Price et al., 2010). Eight studies assessed scheduling appointments and discovered that enabling patients to schedule their appointments via telephone calls was associated with increases

in mammography use (Anhang Price et al., 2010). Tailored mailings and telephone counseling based on patient barriers to screening (cognitive, logistical, affective), previous screening history, intention to be screened or not, and/or other pertinent chart data had mixed results in terms of having a significant impact on screening rates. Nonetheless, tailored telephone counseling consistently had substantial effects on the promotion of mammography (Anhang Price et al., 2010). In addition, provider recommendation was found to be significantly associated with patient's mammography adherence. Prompting providers through electronic or paper chart reminders had positive associations in several studies (Anhang Price et al., 2010).

Although the studies' outcomes quantified the provider rate of referral or ordering of mammography, investigators linked physician-provider interaction, knowledge, and attitudes as influences on screening behaviors, suggesting that such variables should be further evaluated in future research studies (Anhang Price et al., 2010). The systematic review identified two studies that validated that crosscutting processes had a positive effect on mammography screening (Anhang Price et al., 2010). One study process reduced steps and eliminated the requirement for interorganizational navigation by providing onsite mammography (Anhang Price et al., 2010). In the study, providing onsite mammography showed the most significant change; nonetheless, studies validated that reducing steps and simplifying the breast-screening navigation process in any measure has the potential to influence subsequent steps and positively impact mammography use.

Although there is a growing development of recent studies that explore the impact of interventions and organizational processes on preventive care services, no recent meta-

analysis was found. Thus, the best available meta-analysis, which was the underpinning of recent research, was included in this review of the literature. Stone et al. (2002) evaluated the effectiveness of a variety of approaches to promote preventive care services, such as cancer screenings. The meta-analysis of 108 randomized controlled clinical trials concluded that the most effective interventions entailed organizational changes (Stone et al., 2002). The interventions included the use of designated clinics for particular prevention screening, planned preventive care visits that included patient education, and utilization of nonphysician staff to facilitate prevention activities (Stone et al., 2002). The studies substantiated that targeted changes that address deficits in work processes can increase patient use of preventive services.

In addition, health authorities have established some evidence-based recommendations in the realm of organizational processes that increase mammography adherence (Task Force, 2012). The Task Force (2012) has determined that reducing out-of-pocket costs has a positive effect on mammography acquisition. Measures identified to minimize or reduce economic barriers included the use of vouchers, adjustments in federal and state insurance coverage, and funding through programs (Task Force, 2012). The interventions were combined with patient education and information about program availability and necessary patient actions to alleviate structural barriers (Task Force, 2012). The Task Force (2012) found the strategies to reduce the out-of-pocket cost to be sufficient for recommendation.

The Task Force (2012) found substantial evidence that removal of structural barriers is an effective strategy to improve mammography uptake. The studies established significant positive correlations with mammography uptake and the

following, establishing patient-centered service delivery relative to time and distance of the targeted population and services delivered in nontraditional settings such as in residential communities and via mobile mammography. Several of the studies that provided support for the recommendation of the removal of structural barriers entailed intraorganizational process changes. Organization changes such as reducing or eliminating administrative steps, limiting clinic visits, use of patient navigators, and providing and simplifying scheduling were the combination of interventions that were mediating factors to increasing breast-screening mammography use (Task Force, 2012). The Task Force identified a total of eight studies to assess the relationship between removal of structural barriers and mammography screening rates, finding that each study had a 17.6% average increase in mammography screening. The Task Force, therefore, recommends this strategy on the basis of strong evidence (Task Force, 2012).

Synthesis of the Literature

This literature review guides the process improvement of implementation of evidence-based strategies to improve mammography adherence in a breast-screening clinic. There is a significant need to address mammography adherence, as it is a necessary element to early detection and reducing breast cancer morbidity and mortality. The literature review has revealed that patients continue to exhibit significant barriers to mammography, and organizations that continuously seek to identify and develop strategies to improve mammography uptake could greatly improve their population's health outcomes.

There were similar findings among patients included in the studies that researched the barriers to screening mammography. These included socioeconomic factors, lack of

insurance, underinsurance, racial factors, lack of knowledge or limited health literacy in terms of mammography, and how to navigate through the complex organizational processes (Anhang Price et al., 2010; Davis et al., 2002; Halverson et al., 2015; Komenaka et al., 2015; Smith et al., 2013; Task Force, 2012; Todd & Stuijbergen, 2011). There was an aggregate of interventions or strategies identified in the literature that can be considered for the proposed process improvement to mammography in a breast-screening clinic. Effective strategies to improve mammography adherence include many components discovered in this literature review. The examination of evidence established that interventions should include all team members and be tailored to meet the specific needs of the screening clinic.

Potential Barriers or Supports to Implementation

The feasibility analysis of a potential process improvement project requires one to forecast the strengths and weaknesses of the proposed project. The investigator must consider whether there are the time and number of participants necessary to complete the study (Melnik & Overholt-Fineout, 2015). In addition, the study design will have to consider ethical and legal barriers (Melnik & Overholt-Fineout, 2015). Economic feasibility has to be evaluated as well. The investigator has to determine what resources are available for the project implementation and prepare accordingly (Melnik & Overholt-Fineout, 2015).

Strengths. There are several facilitators that contribute to the feasibility of the evidence-based project (EBP). The most notable strengths are that the organization is receptive to the idea of assessing and identifying strategies to improving mammography adherence, and this crucial opportunity currently exists. The leadership and providers

particularly are cooperative and eager to support actions that will lead to improved patient outcomes. Another strength is this EBP aligns with the Cancer Health Initiative's existing goals, providing health education and delivering quality preventive services to the most vulnerable patients in our community. Moreover, there will be some support in terms of resources, such as the production of patient education materials, which are necessary materials needed to prompt changes in workflow. The interventions are practical and can be incorporated in usual employee paid time for work. Staff education and training regarding the process changes can be facilitated through existing scheduled monthly meetings, provided online, and reinforced through e-mail and onsite reminders, thus alleviating the need to budget for additional staff training. Additional assets to the EBP are that project population will be retrieved from the usual patient population, and the intervention is in the realm of quality improvement. All patients will receive the benefits of the enhanced process, and thus, ethical limitations of risk versus benefits are eliminated from this project. The crucial opportunity to improve mammography adherence has the potential to save healthcare dollars and increase health, yielding a suggestive return on investment of quality improvement.

Limitations. Potential weaknesses in the process improvement exist. This EBP is implemented to improve the practice and outcomes of one screening clinic site; thus, unlike research, the results are not generalizable. The interventions can be duplicated, but they were tailored specifically to the aspects of the screening clinic. Second, most of the medical record system is paper-based and later uploaded to a computer database. There is a data team that provides data tracking via retrieval of manual data and analyzes the data through the use of Excel spreadsheets. Manual stratification of data increases the risk of

inaccuracy by omission or miscalculation. The author has developed a working relationship with the data manager and members of the data team. The author has obtained access from information technology to view applicable system data and has the ability to compare the data reports with scanned medical records and social work tracking to safeguard accuracy. In addition, the data team has a continuous monitoring process to confirm accuracy.

Second, the inability to calculate precisely the cost of the current practices is a limiting factor. A short-term advantage is that improving the process to mammography will expand clinic services, which is a significant quality indicator for the breast-screening clinic's vitality. The increase in mammography uptake will suggest a demand for the organization to continue these services, while a decrease in mammography reflects ineffective utilization and productivity of programs and services and can signal a need to eliminate or change the direction of the program services. The long-term benefit is that improved mammography rates facilitate early detection and treatment, which has the potential to reduce breast cancer morbidity and mortality as well as healthcare expenditures.

The routinely collected data were utilized to investigate the underlying problem within the focus population. Similar to convenience sampling, collecting information on a proportion of the population enabled a swift and cost-efficient route to data analysis and extrapolation of theories, however, this method of population inquiry has limitations. A significant drawback to making generalizations from the proportion of the population analyzed is that the population analyzed may not be reflective of the trends of the total population (Melnik & Overholt-Fineout, 2015). This project will measure the

effectiveness of the evidence-based process change by comparing pre-intervention process proportion of mammograms to the post-intervention proportion of mammograms during a designated time interval of one month. Therefore, a significant limitation of this project is that the data analysis will be based on the outcome metric of a small sample of the breast-screening participants. To evaluate the maximum effectiveness of the process improvement it will be essential to continue to monitor the outcome metric at set intervals beyond the scope of this project. Statistical data analysis tests will be integrated to describe accurately the pre-intervention and post-intervention outcome metrics.

Summary

The interventions appraised through this literature review focus on overcoming the barriers to effective mammography screening. The declining mammography rates in the breast-screening clinic led to the investigation and identification of the barriers that exist in the current breast-screening clinic process. The emphasis of this project is incorporating effective interventions to address declining mammography rates in a breast-screening clinic. The goal is to identify the barriers to mammography and address the issues. Patient-centered care was a motivating factor of the process improvement, as all women desiring to have mammography screening should be screened and offered optimal, evidence-based delivery of care throughout the process.

Promoting effective strategies that improve mammography rates is essential to accomplish the “Triple Aim: better care, better health, less cost” (Institute for Healthcare Improvement, 2014). Breast cancer is a leading cause of death in the United States and aggressive measures to combat the disease must continue. Screening clinics’ vigilance in

continuous process improvement to expand mammography screenings has positive outcomes for all constituents—organization, team members, and patients

CHAPTER 3

METHODOLOGY

Introduction

This chapter outlines the methodology utilized for the evidence-based process improvement project to improve mammography adherence in a breast-screening clinic. The DMAIC methodology is described in the context of the implementation of the project at the breast-screening clinic site. The significance of improving mammography adherence and the evidence-based strategies to facilitate mammography screening have been outlined in previous chapters; the application of the evidence will be discussed in this chapter.

Setting

The breast-screening clinic is an affiliate of a large not-for-profit healthcare organization located in the midlands region of South Carolina, in the Southeastern United States. The team includes seven nurse practitioners and one physician assistant. The other interdisciplinary team members include registered nurses, a licensed practical nurse, patient advocates, laboratory technicians, and a medical social worker. The breast-screening clinic is located in Richland County, which is a small metropolitan area surrounded by rural areas. The county has a total population of 393,830 and a median household income of \$47,603. Black or African Americans are 44.9% of the population, 44.6% are Caucasian, and 5% Hispanic (United States Census Bureau, 2015).

Approximately 6% of the population is foreign born and 2.9% are not proficient in English (United States Census Bureau, 2015).

This breast-screening clinic is an outreach program that seeks to address the needs of the vulnerable individuals in its communities. Cancer-screening services and education are provided to the uninsured, underinsured, and individuals with family household incomes 100–200% of the federal poverty line. The primary stakeholders of this clinic are the providers and team members, participants of the screening clinic, the organization, and local communities.

Sample

The population sample for this project will include the breast-screening participants who qualify for screening mammography. Exclusions include participants that have had a screening or diagnostic mammography performed within the previous year or have current abnormal breast symptoms that require additional evaluation. The majority of this population is low income, uninsured, and minority—demographics that often correlate with low health literacy skills. The sample size will be contingent on the number of screenings ordered postimplementation, during the designated timeframe. On average, 25 mammography screenings are ordered monthly. One month after the change implementation, mammography utilization will be evaluated for all participants who had a mammogram offered during their clinic visit.

Design

The DMAIC framework provided structure for this quality improvement project. The intervention is a process change. The outcome measure is mammography proportion. The outcome will be evaluated prior to the process change and after the process change.

Each component of the DMAIC framework is discussed as it applies to the process improvement project.

Define

Breast cancer continues to be the second leading cause of mortality in the US, making the disease a national health priority (American Cancer Society, 2015; Office of Disease Prevention and Health Promotion, 2016). The literature has indicated that late detection and diagnosis exponentially correlate with increased mortality and healthcare costs (Miller, 2012; South Carolina Department of Health and Environmental Control, 2016). Although research has yet to discover a primary prevention for breast cancer, it is conclusive that the risk of death from breast cancer can be reduced by regular mammography screening (American Cancer Society, 2015; Newton, 2016; Office of Disease Prevention and Health Promotion, 2016). Breast cancer screening improves earlier detection of the disease when it is more likely to be localized and responsive to treatment. Mammography screening has been identified as the key factor in minimizing the detrimental effects of breast cancer, but women with risk factors such as low sociodemographic status and health literacy are less likely to complete mammography screening (Alexandraki & Mooradian, 2010; Newton, 2016; Özmen et al., 2016).

One of the goals of this project is to provide support through the screening process by enabling all participants of the breast-screening clinic who have the following characteristics to achieve the goal of mammography: women aged 40 years or older who meet the criteria for screening mammography and desire to have a mammography. Women who have any active breast problems—lumps, masses, pain, significant discharge—are excluded from the screening mammograms. Effective screening programs

are pivotal to achieving mammography and reducing breast cancer mortality among all women. Sociodemographics, health literacy, and complex processes have been found to have great influence on mammography adherence (Alexandraki & Mooradian, 2010; Anhang Price et al., 2010; Halverson et al., 2015; Institute of Medicine, 2004; Komenaka et al., 2015; Smith et al., 2013; Stone et al., 2002; Weingart et al., 2009). Addressing the barriers to screening mammography has been consistently found to increase mammography use (Anhang Price et al., 2010; Davis et al., 2002; Task Force, 2012). The focus of this project is implementing evidence-based strategies to improve the breast-screening process.

Measure

The measure phase of the project included an evaluation of the current breast-screening process. Data collection included clinical data from the clinic's database, tracking documentation used by the clinic's social worker, interviews with the staff, and observation of the clinical setting.

The following parameters were assessed:

- Prevalence of patients that had screening mammography ordered but did not complete.
- Outcomes of the current process for the breast-screening mammography.
- Barriers and facilitators of the current breast-screening process.
- Resources to address the identified barriers to the current screening process.

Outcome measure. The intervention is a process change. The outcome measure is clinic mammography proportion. The metric will be determined by calculating the number of mammograms ordered after the onset of the process change intervention

(numerator) divided by the number of mammograms completed (denominator) at the designated interval post-intervention to yield mammography proportions at one-month, two-month, and three-month intervals. The one-month postimplementation results will be discussed in the results section of this project write-up, while subsequent intervals will be a part of the continuous process improvement measures at the facility.

Analyze

The analysis component consists of outlining and assessing the breast-screening process. The process and structure of the breast-screening clinic were examined to identify particular patterns to establish common barriers to mammography screening. The process flow map provided awareness of the process deficits, whereas the convenience sample of patients that did not follow through with mammography provided insight about both structural and process deficits. Similarly, the practice observations and provider informal interviews revealed opportunities for improvement related to structure (provider skills knowledge related to health literacy) and process.

Data Analysis. Statistical Analysis System (SAS 9.4) was utilized to analyze the data for this process improvement project. Quantitative data for the quality improvement project were collected utilizing the organization's Access database and Cerner software system. The Access database enables simultaneous data entry. Users can create tables, queries, forms, and reports and connect them (Microsoft, 2017). Power users (members of the data team) have extended user capabilities such as advanced automation, data validation error trapping, and multiuser support (Microsoft, 2017).

The Cerner system is utilized once a patient is registered for a mammogram appointment. This system, unlike the Access database, is a more integrative system, as

fields are populated through a predefined categories list to ensure valid data entry (Cerner, 2017). The software system supports the validated data entry of mammogram orders, patient demographics, and mammogram completion status (Cerner, 2017). The system enables a full range of clinical and demographic information to be retrievable into accurate and printable summary reports (Cerner, 2017). The data generated from the Cerner database is uploaded to the Access database to achieve a comprehensive database for the breast-screening clinic.

The breast-screening clinic's data mining capabilities were an integral component to the development of the process improvement project. In the pre-intervention phase, descriptive statistics of the following variables were utilized to categorize patterns of potential facilitators and barriers to mammography, age, race, insurance coverage, total family income, participation in financial counseling, and documented barriers to mammography screenings. Qualitative data were obtained from the informal interviews and observations. The data collected during the pre-intervention process were used to develop the strategies for the process change aimed to improve mammography uptake. Two proportion tests will be done to examine the difference between the proportion of mammograms completed pre-intervention and post-intervention.

Improve

The Define, Measure, and Analyze phases of the process established the underpinning for the improve phase of the project. The process improvement interventions specific to the breast-screening clinic were not recognized prior to the completion of the initial steps of the process. After defining the problem and determining the outcome measure, the evidence was comprehensively reviewed for the best available

strategies and interventions to improve the mammography screening process. The analysis of the current process and synthesis of the evidence yielded the process improvement.

Control

The control phase of the improvement process outlines how to maintain the improvements without reverting back to the former procedure. During this process, the improvement to the practice has been made and sustainability is contingent upon a standard operating practice. The success of the improvement implementation relies upon a standardized practice that can be consistently replicated to improve sustainable outcomes. A standard operating process of the improvement might require future revision; therefore, a control plan must be put in place to monitor ongoing progress and performance outcomes of the implemented change in the operating practices of the process.

For the purpose of this project, the control phase will entail monitoring and maintaining the successful interventions that are implemented as a part of the clinic's process change to improve mammography adherence. This process improvement outcome metric was screening mammography proportion, and as a result interval monitoring of mammography proportion will continue. In addition, it will be necessary to continually identify and address opportunities for improvement of the breast-screening process. An effective breast-screening program reflects continuous process evaluation and improvement (Bandyopadhyay & Coppens, 2005).

Description of the Intervention

The intervention for this DNP project is a process improvement. The Agency for Healthcare Quality and Research (2012) recommends that one of the first tasks of a quality improvement initiative is to select a limited number of improvement areas. The organization's structure should be considered during the process of selecting opportunities for improvement. In particular, the selection of interventions should be a reflection of the patients' needs or concerns, staff's concerns, and leadership priorities (Health Resources and Services Administration [HRSA], 2011).

The analysis of the current process and synthesis of the evidence revealed the following opportunities for enhancing the breast-screening clinic process:

- Assess patient barriers to appointments/confirm contact phone numbers.
- Alert the staff/provider that the patient is scheduled for mammography; provide one-on-one patient education with a tailored message.
- Streamline the current process.

The interventions selected for the process improvement were substantiated by the literature to have positive outcomes on screening mammography (Anhang Price et al., 2010; Davis et al., 2002; Halverson et al., 2015; Komenaka et al., 2015; Smith et al., 2013; Task Force, 2012; Todd & Stuijbergen, 2011). In addition, the methods were feasible to implement in terms of organizational constructs. Figure 3.1 represents the evidence-based breast-screening process flow.

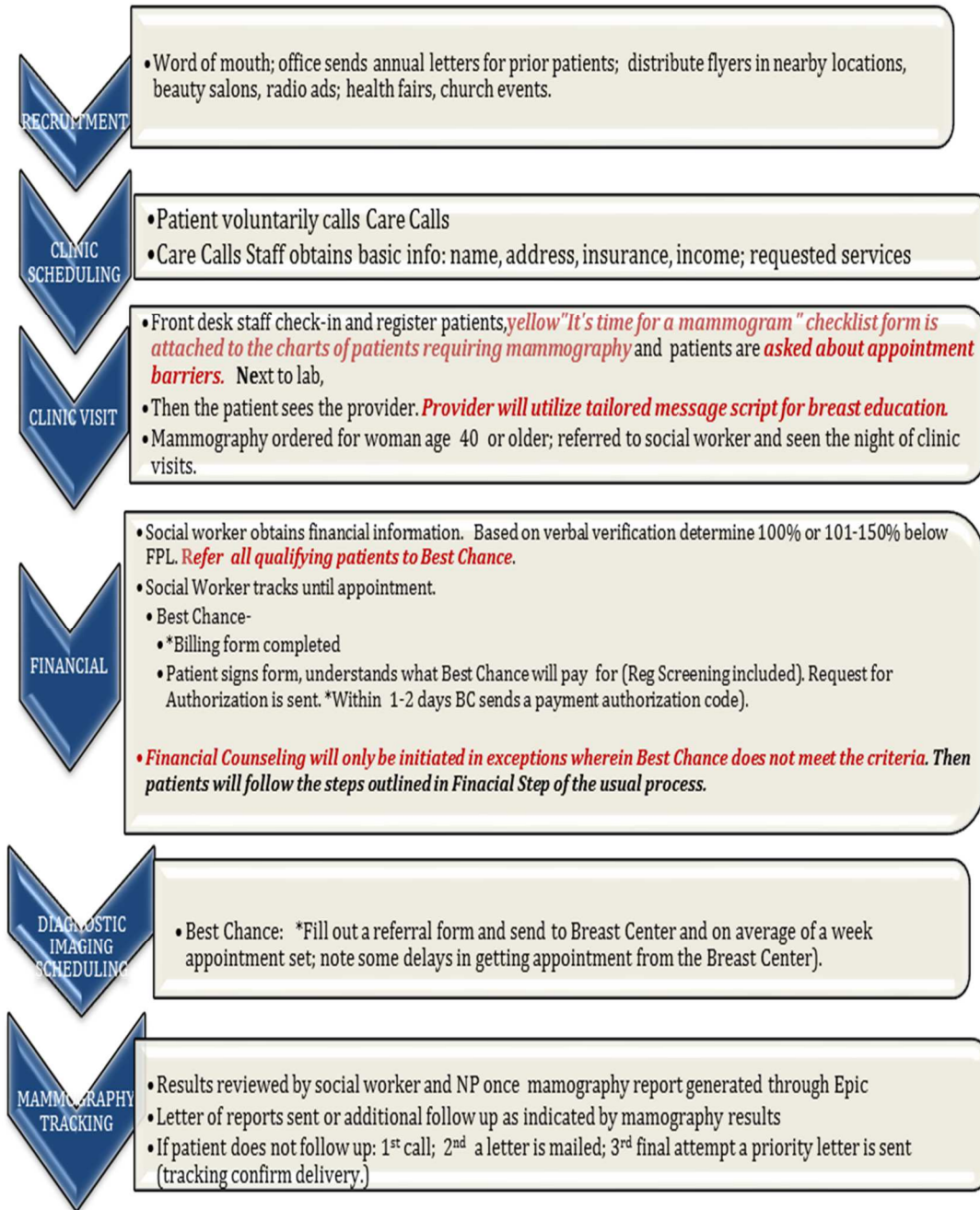


Figure 3.1 The Evidence-based Breast-screening Process Flow *Changes denoted in red.*

Procedure

A process change to improve the outcomes of screening mammography involves systematic activities that are organized and implemented by team members (Health Resources and Services Administration, 2011). Prior to the initiation of the DNP project, a Quality Improvement team was established. The Quality Improvement team members are comprised of the clinic nurse practitioner (team leader, the author of this project), the director of the breast-screening clinic, the clinic manager who is a Registered Nurse, the lead social worker, and the manager of the data team. Establishing a plan and detailing the activities of the actions of each team member are essential for successful implementation of organization process changes (Health Resources and Services Administration, 2011).

The quality team leader collaborated in several face-to-face meetings with the clinic leaders and other quality team members from January 2017 to April 2017. Telephone and e-mail communication were also utilized. During the February 2017 monthly provider meeting, the providers were introduced to the tentative process improvement. The providers were given an overview of the problem with mammography adherence. In addition, the current process flow was shared, and their input was garnered regarding strategies to improve the current process. The evidence-based breast-screening process change was based on the comprehensive assessment of the clinic process, patient and staff needs, and appraisal of the literature.

The assessment of barriers, which is usually discussed with only the social worker at the end of the clinic visit, will be addressed during the registration phase of the clinic visit. The ideal method is to discuss barriers prior to the clinic appointment; however, the

leadership team indicated that the Care Calls team was responsible for all screenings and organizational scheduling, and they felt that the assessment of barriers should first be piloted in the clinic. A yellow “It’s time for a mammogram” checklist form will be attached to the patients’ charts and identify the patients that need a mammogram. This yellow checklist will have a designated area to document patient barriers and the provider message will be printed on the back of the form. For the scope of this project, barriers will be assessed in the registration phase by the patient advocate asking the participants “What problems or concerns do you have attending your scheduled appointments?” (for example, do not have a ride, time or scheduling is hard because you work, have to care for children or other family members, or concerns for payment of service). Barriers will be denoted on the chart and further discussed with the social worker. In this registration phase, the patients’ phone contacts will also be verbally confirmed.

The scripted provider education/message was created utilizing key concepts of health literacy principles (i.e., the use of plain language and teach-back). The scripted message was printed on the back of the yellow “It’s time for a mammogram” checklist form that served to alert the staff of patients that were due for a screening mammography. Providers were also given a laminated copy of the scripted education. The one-on-one patient education with a tailored message highlighted the importance of mammography screening and follow through with all components of the process, including financial counseling if required.

Streamlining the current process is another strategy that was implemented. Analysis of the process identified that a current resource (BCN) had the potential to alleviate several required actions of the financial step of the breast-screening process.

Financial counseling is an effort by the organization to assist patients with healthcare financial resources. This includes assistance with establishing healthcare through the health exchange rendered through the Affordable Care Act, Medicaid, Medicare, or organizational financial programs. Though the organization required financial counseling prior to qualification of funding for mammograms, the 2015–2016 data indicate that greater than 90% of the patients that did not complete mammography screening did not complete financial counseling. The Hispanic noncitizen patients could not proceed to the financial counseling step because the financial counseling program was available only to U.S. citizens. The Hispanic noncitizen patients could be seen because the breast-screening program collaborated with the BCN. The BCN became the sole funding source for our noncitizen patients. The patients navigated through the process as they had previously, and the social worker handled the necessary paperwork to bridge the payer source for mammography, thus eliminating additional steps for the patients. After exploring the BCN resource, it was recognized that the funding option could be offered to all qualified screening participants and not just noncitizens. This streamlining strategy will be implemented for all qualifying patients, eliminating steps in the screening process, which is strongly associated with mammography uptake.

Staff education will be provided during the April 12th staff development meeting for all breast-screening team members. A PowerPoint presentation will be developed and e-mailed to all team members to ensure that team members who did not attend the meeting were aware of the goals of the process change and their roles and responsibilities in completing the actions. Furthermore, the quality team leader or member of the quality team was available onsite during the implementation of the process improvement to

provide support and ensure that all staff working the evening of the clinic were abreast of process changes.

The process change will be initiated on April 25, 2017. After the implementation of the process improvement, a post-intervention measurement of mammography proportion will be obtained one-month postimplementation. The quantitative data from the pre-intervention and post-intervention assessments will be analyzed to determine if the evidence-based process change had a positive impact on screening mammography.

Table 3.1. Timeline for Evidence-based Process Change

Timeline	Objective/Action	Connect to DMAIC framework
August 23 – October 9, 2016	Clinic observation; informal surveys, literature review.	Defining the underlining problems is the first step to address deficits effectively in an organization, system, or process.
October 19, 2016	Retrieved mammography data to determine compliance rates for 2015 and 2016.	Defining the underlying problem; Measure component: establishing a metric to quantify clinic problems.
October 19 – 26, 2016	Met with organization’s Quality Manager.	Define Phase: Continue to investigate the problem. Collaborating with the organization’s quality manager to obtain resources and information regarding DNP project.

November 1 – 10, 2016	<p>Outlined current process flow.</p> <p>Data analysis of a proportion of patients that did not follow through with mammography.</p> <p>Telephone conference with financial counselors.</p> <p>Continued the review of the literature.</p>	<p>Continue to define the problem. The data confirmed the declining mammography rates. These actions further investigated the why, leading into the Analyze phase.</p>
Jan – Feb 2017	<p>E-mailed reports to established team outlining deficits in the clinic process flow and review of literature (Director, Clinic Manager, Key Social Worker, and Data Manager).</p>	<p>Developing a team of key supporters is essential to identifying the problems and developing and implementing strategies to make improvements. These actions are key components of the Define phase.</p>
March 3, 2017	<p>Meeting with quality team members. Met extensively with lead social worker outlined process change.</p>	<p>Analyze Phase: Preparing for implementation. Establishing components to the change based on organizational feasibility.</p>
April 3 – 11, 2017	<p>The study was submitted to the organization IRB, and a collaboration was established with the USC.</p>	<p>Analyze Phase: Prior to implementation, the project materials were evaluated to determine if local/federal human research compliance was applicable. The study application was confirmed to be not human subject research.</p>

April 12th	Collect Pre-process data and input into Excel. Pre-process data analysis via SAS.	Measure Phase: Establish outcome metric data collection and metrics have to be determined at baseline for postimplementation comparison.
April 2017 – June 2017	Staff education was provided during the staff development for all breast-screening team members. A PowerPoint presentation was developed and reviewed during the meeting. In addition, it was e-mailed to all team members to ensure that team members who did not attend the meeting were aware of the goals of the process change and their roles and responsibilities in completing the actions.	Improve phase: Staff education prior to the implementation of process change.
April 25 thru May 2017	<p>Implementation of Project</p> <p>Communication: Feedback regarding barriers and successes.</p> <p>Provided onsite staff support.</p> <p>Quality team meetings weekly to monitor progress.</p>	<p>Improve Phase:</p> <p>Monitor progress and make changes as needed to facilitate.</p>

June – July 2017	Post-intervention Measure and Data Analysis.	Control Phase: Utilizing data is necessary to make recommendations to sustain successful process change.
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Strategies to Reduce Barriers and Increase Support

The potential for resistance is inevitable in any process change (Agency for Healthcare Research and Quality, 2012). Thus, throughout the preparation of the process improvement phase, and more explicitly in the analysis phase, the team was included in the planning and their input was considered as the process changes were developed. The team was vested in improving mammography adherence and receptive to changes that did not bombard the current workload. Thus, careful deliberation was given to select evidence-based interventions that were simple and easily integrated with workflow. Adaptable tools to support the integration of the best strategies in the workflow were selected for use. A simple and cost-efficient color checklist form was developed to be used to alert the staff/provider of patients requiring mammography screenings. This form will also serve as an area for the registration staff to document barriers earlier in the process. In addition, providers will be able to reference the printed patient message printed on the back of the form. The use of these forms involved an insignificant increase in time and effort to the current workload.

Provider cards were created for each provider to assist with the tailored education message. The providers were active participants in the development of the cards. In addition, providers were encouraged to incorporate their personalities and own style of education delivery in breast education, but the key was to implement the health literacy

principles of plain language and teach-back. The potential for providers spending more time educating patients is expected. During the first two weeks of the process change, the author will be available to assist staff. Continuous communication will be the key component to reducing barriers and increasing support. Communication, particularly for addressing successes and opportunities, will be established through informal interviews and shared with the staff to support the successful implementation of the process change.

Summary

Methods for process improvement have been described utilizing the DMAIC framework. The process improvement was supported by the evidence presented in the Literature Review. The pre-process change and post-process change data analysis will provide insight into the effectiveness of the evidence-based process change and will be detailed in Chapter 4.

CHAPTER 4

RESULTS

The purpose of this project was to develop and implement an evidence-based process improvement to increase a breast-screening clinic's declining mammography rates. The DMAIC (Define-Measure-Analyze-Improve-Control) framework guided this project. The framework provided a construct to analyze concisely the root causes associated with participants' lack of mammography adherence. During the pre-intervention phase, staff education and training of the evidence-based process training was provided. The staff education was rendered during a staff meeting, and an audio power point presentation of the process changes and a list of training resources were provided by e-mail to all clinic staff. In addition, onsite education was available to staff 1 week prior to process change implementation. During the pre-intervention phase, the author collected pre-intervention mammography proportion. The intervention is an evidence-based process change, which comprises assessing barriers to mammography during registration of clinic visit, alerting staff and providers of participants that meet criteria for mammography by flagging or marking the patients' charts, providing a tailored provider message regarding the importance of mammography and relevance of financial counseling, and streamlining the current process. During the post-intervention phase, a mammography proportion was calculated 1-month post implementation of evidence-based process change.

The author implemented the intervention over a course of 4 weeks after the initial evaluation. Results of the pre-intervention data analysis and a comprehensive review of literature of the best practices to improve mammography usage were utilized to tailor the specific evidence-based changes to the breast-screening clinic process. As recommended by the DMAIC framework, a methodical analysis of the underlying problems within the organization will lead to viable solutions. The analysis of the pre-intervention data and process flow suggested that there were opportunities to thoroughly assess barriers to mammography as evidenced by the declining mammography rates in 2015 and 2016, and the pre-intervention mammogram proportion rate of 22%. The observation and interviews with the staff implied opportunities to utilize the patient-provider relationship to facilitate optimal mammography education. The literature consistently emphasized that the use of health literacy principles such as use of plain language and teach-back are associated with effective communication, improved health literacy, and subsequently positively influenced patient behavior. Thus, a component of the intervention included providers delivering a tailored breast education message during the patient clinic visit. The providers were given resources to aid in the delivery of a message utilizing health literacy principles to emphasize the importance of screening mammography and follow through with all steps of the screening process.

The organizational and process flow analysis revealed that the financial counseling step was a barrier to patients following through with mammography. As discussed in Chapter 1, 60% of a sample of patients that did not follow through with mammography did not adhere to the financial counseling. This steered the structural improvement of the process. The collaboration with the Best Chance Network enabled

funding for screening mammography, wherein administrative financial screening process occurred during the clinic visit. The Best Chance Network provided a two-fold improvement by eliminating patients out of pocket costs, while reducing the steps to screening mammography.

Description of Sample

The pre-intervention mammogram sample population were breast-screening participants that had clinic visits during the month of May 2016 ($n = 27$). The post-intervention sample population included breast-screening participants during the month of May 2017 ($n = 25$). The participants were women age 40 or over, who had a screening mammography order. The author identified the following variables for the pre-intervention and post-intervention samples in the data: age, race, status of total income, insurance, smoking, and obesity.

Pre-intervention Data

The breast-screening clinic's total population is predominately minority, low income, and uninsured women. The pre-intervention population sample characteristics aligned with those of the total population. Table 4.1 outlines the frequency of selected variables of the pre-intervention sample.

Table 4.1 Summary of Variables of the Pre-intervention Population

Variables	<i>N</i>	%
Race		
African American	16	40.74
White	6	22.22
Hispanic	10	37.04
Age		
40-59 years	15	55.56
50-59 years	9	33.33
60 or older	3	11.11
Income		
<\$10,000	22	81.48
\$10,001-\$25,000	5	18.52
Insurance		
Yes	0	0
No	27	100

The entire sample was uninsured. African Americans ($n = 11$) and Hispanics ($n = 10$) collectively were 78% of the total pre-intervention sample population, and whites ($n = 6$) were 22% of the sample. The participants were categorized in three age groups. The majority of the patients in the intervention sample were in the age group 40-49 years ($n = 15$), followed by the age group 50-59 years ($n = 9$). The age group 60 or older ($n = 3$) was the least representative in the pre-intervention sample. Income status was outlined in four categories: < 10,000, \$10,001-25,000, 25,001 to 50,000, and > 50,000. The sample of the pre-intervention population income levels were < \$25,000. Specifically, total income levels less than 10,000 and 10,001 to 25,000 represented 82% and 22% of the sample respectively.

Post Intervention Data Analysis

The post-intervention population ($n = 25$) was smaller than the pre-intervention population ($n = 27$). Eight-four percent of the post intervention population was comprised of Hispanic and African American participants. Most of the participants were African American ($n = 16$), followed by Hispanic ($n = 5$), and then White ($n = 4$). Similar, to the pre-intervention population the post-intervention group was predominantly minority, low income, and uninsured. The 50-59-age span had the greatest number of participants ($n = 12$), followed by the age span 40-49. Comparable to the pre-intervention group, the post-intervention age span 60 and over ($n = 5$) had the least number of participants. Ninety-two percent of the participants had an income \$25,000 or less. The percentage of participants with the income of \$10,000, \$10,001-\$25,000, and \$25,001-\$50,000 were 60%, 32%, and 8%, respectively. Eighty-four percent ($n = 21$) of the patients denied barriers to screening mammography. Twelve percent, ($n = 3$) reported language barriers, and 4% ($n = 1$) indicated that finances were a barrier. Only 4% ($n = 1$) of the participants did not qualify to have the organization or Best Chance Network cover the mammogram. The Best Chance Network covered 93% of the participants ($n = 23$) and 4% ($n = 1$) were covered with the organization's financial assistance program. Table 4.2 summarizes the post-intervention population by race, age group, income, insurance; patient reported barriers, and financial payment source for mammography.

Table 4.2 Post-intervention Group Frequencies of Selected Variables

Variables	<i>N</i>	%
Race		
African American	16	64
White	4	16
Hispanic	5	20
Age		
40-59 years	8	32
50-59 years	12	48
60 or older	5	20
Income		
<\$10,000	15	60
\$10,001-\$25,000	8	32
\$25,001-\$50,000	2	8
Insurance		
Yes	0	0
No	25	100
Patient Reported Barriers		
Language	3	12
Finances	1	4
None	21	84
Mammography Payment Source		
PH organization	1	4
Best Chance	23	92
Other (did not qualify)	1	4

Analysis of PICOT Question

Mammography proportion was the established metric of effectiveness to address the project question quantitatively. The post-intervention measure was assessed 1-month

post-intervention implementation and compared to the pre-intervention mammography proportion. The author analyzed the pre-intervention and post-intervention mammography proportions and other data, applying the appropriate statistical tools to include descriptive statistics and inferential statistics.

The PICOT for the study was the following: Among breast cancer screening participants, what are the best practices to improve mammography screening? A comprehensive literature review preceded the development of an evidence-based process change to improve mammography adherence. The post-intervention measure was assessed 1-month post-intervention implementation and compared to the pre-intervention mammography proportion. The evaluation of the effects of the process improvement on mammography adherence was based on the following hypotheses:

- H0: There is not a significant increase in screening mammography proportion between screening participants who navigated through the evidence-based process change (intervention group) and the participants who navigated through the usual process (pre-intervention group).
- H1: There is a significant increase in screening mammography proportion between breast-screening participants who navigated through the evidence-based process change (intervention group) and the participants who navigated through the usual process (pre-intervention group).

The mammography proportion for the pre-intervention group was 22% and 51% for the post intervention group. Group sample sizes of 25 in Group 1 and 27 in Group 2 achieved 76.389% power to detect a difference between the group proportions of -0.3000. The proportion in Group 1 (the post intervention group) was assumed to be 0.5200 under

the null hypothesis and 0.2200 under the alternative hypothesis. The proportion in Group 2 (the control group) was 0.5200. The test statistic used was the one-sided Z-Test with unpooled variance. The significance level of the test was 0.0500. There was a statistically significant difference ($p = 0.01$) in mammography adherence between the pre-intervention group and the post intervention group. This large effect post intervention supports prior studies and answers the PICOT that best practices to improve mammography uptake include the implementation of the following evidence-based interventions in screening processes:

- assess and address patient barriers to appointments,
- alert the staff/provider that the patient is scheduled for mammography,
- provide one on one patient education with tailored message, and
- streamline the current process.

Additional analyses

Researchers have linked smoking to a higher risk of breast cancer in younger, premenopausal women (ACS, 2015). Furthermore, researchers have found smoking to increase complications in breast cancer treatment. The author collected data on the pre-intervention and post-intervention breast-screening participants smoking status to determine if there were opportunities to improve the delivery of care by including smoking education and resources for smoking cessation. The data indicated that smoking prevalence was particularly reduced among the breast-screening participant, 74.07% ($n = 20$) of the pre-intervention and 92% ($n = 23$) of the post-intervention group were nonsmokers.

Similarly, a positive association has been found between obesity and breast cancer in postmenopausal women, and literature has consistently linked obesity and poor prognosis of breast cancer in both pre- and postmenopausal women (Carmichael & Bates, 2004). The author identified and defined obesity by body mass index > 30 in the breast-screening participants pre-intervention and post-intervention. Table 4.3 outlines the frequency of smoking and obesity of breast-screening participants pre-intervention and post intervention. The result of the chi square test did not reveal a significant association between smoking (p value = 0.088) and obesity (p value=0.586) by the pre and post interventions.

Table 4.3 Smoking and Obesity Frequency of Pre and Post Intervention Participants

	Pre-intervention Group		Post Intervention Group	
	<i>N</i>	%	<i>N</i>	%
Smoking				
Yes	7	25.93	2	8
No	20	74.07	23	92
Obesity				
Yes	12	44.44	13	52
No	15	55.56	12	48

Limitations

There were some limitations related to a process improvement project design. One disadvantage was that the evaluation data analysis was conducted on participants during a 1-month time-frame pre-process change and 1-month post process change; subsequently both samples were relatively small. The post power analysis indicates that the sample size

achieved 76% power to detect a difference between the proportion between pre and post intervention. The significant level of test was 0.05.

An additional limitation was related to the assessment of barriers. The author asked patients about barriers, and specific training that was not rendered to the front desk staff to obtain this information. In retrospect, a structured assessment of barriers should have been utilized to include a list of the most prevalent barriers outlined in the current evidence, such as language, finances, transportation, fear of being diagnosed with breast cancer, and lack of perceived risk. The method of delivery of the assessment possibly influenced the participants' responses.

The time frame it takes for breast-screening participants to obtain a mammography appointment was another identified limitation. Breast-screening participants that did not obtain their mammography screening within 1-month post process improvement implementation were captured as non-adherent. This factor can negatively affect the post-intervention mammography proportion rate.

Summary of Findings

Mammography proportion outcome was obtained from breast-screening participants in Richland County. The evaluation population included a total of 52 women, comprised of 27 participants navigated through the usual breast-screening process (pre-intervention group) and 25 participants navigated through the evidence-based breast-screening process change (post-intervention group). The total sample population ($n = 52$) was uninsured and majority was in the age range 40-59 (85%; $n = 44$). Ninety-six percent ($n = 24$) of the post-intervention participants qualified to have mammogram covered

through the organization or Best Chance Network, and 84% ($n = 21$) did not report any barriers to mammography, yet 48% ($n = 12$) did not follow-through with mammography.

Adherence to Mammography

Nineteen participants, six in the pre-intervention group and 13 in the post intervention group, adhered to mammography screening. Thirty-three of total participants (63%) did not receive their mammography screening. In the pre-intervention group, the adherence determined by mammography proportion was 22%; the mammography proportion for the post intervention group was 52%. Ninety-six percent ($n = 24$) of the post-intervention participants qualified to have mammogram cost funded through the organization or Best Chance Network, and 84% ($n = 21$) did not report any barriers to mammography, yet 48% ($n = 12$) did not follow-through with mammography.

The post intervention group rate of 52% is close to the reported annual mammography screening rate in the entire United States and South Carolina of 58 % and 54 %, respectively. Screening rates of mammography acquired every 2 years were higher in both the United States and South Carolina. The biennial reported mammography screening rates for the United States and South Carolina were 73% and 71% respectively.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

This chapter includes a summary of the project findings and implications for practice, education and research, as well as recommendations for further research.

Summary of the Project

The purpose of this process improvement was to identify barriers to screening mammography and implement best practices to improve the clinics screening mammography rates. The DMAIC framework was the underpinning to the development and implementation of the process improvement project. The project was designed to evaluate the efficacy of an evidence-based process change and to potentially add to the knowledge base regarding best practices to improving breast-screening mammography. The results of this project help validate past research about organizations that optimize screening processes specifically through communication with a health literacy focus, assessing and addressing barriers, increases participants' likelihood of participating in screening mammography. This project is a basis for further study that involves the influence of nurse practitioners in organization changes and patient outcomes, such as mammography screenings.

Recommendations

Implications for Nursing Education

The Institute of Medicine asserts that to meet the needs of the ever-evolving healthcare system, health professionals should achieve higher levels of education and

training (Institute of Medicine [IOM], 2003). When considered in the scope of nursing, this suggests that as the demands of the United States healthcare system continue to evolve in complexity, there will be an increased need for the education and training of nurses to evolve in order to ensure quality healthcare. In addition to research and leadership skills, it is essential that advanced nursing programs incorporate and assess competency of health literacy principles and practices in the curriculum of advanced health professionals. The complexity of the healthcare system makes health literacy provider training crucial to empowering patients to navigate effectively the healthcare system. The Doctor of Nursing Practice (DNP) graduate is an individual who has obtained advanced skills and education to meet the evolving challenges of healthcare. Upon degree completion, the DNP is adept at applying advanced science and evidence-based data to care for individuals and families across all settings.

This project summarizes the education and skill set of the DNP to improve breast cancer outcomes through mammography. Breast cancer mortality continues to be a significant health concern in the United States. Mammography has been clearly recognized as the course to early detection and treatment, and subsequent abating breast cancer related deaths. Effective breast-screening programs are required connectors to mammography, thus are essential components to addressing the persistent increase in breast cancer mortality. Doctoral prepared nurse practitioners are in a unique position to synthesize their clinical expertise and the application of scientific underpinning to bring resolutions to specific problems, deficiencies, and complexities of screening processes. It is imperative that DNP's utilize their knowledge of the promotion of health and disease prevention for the prevention of breast cancer.

Implications for Practice

This project was a successful implementation of an evidence-based breast-screening process change. In a 1-month time frame, there was significant improvement of mammography uptake in the breast-screening clinic practice site. Thus, it is essential that the practice site retain the implemented evidence-based interventions, while simultaneously monitoring for additional opportunities for improvement. Secondly, mammography adherence data should be collected at set time intervals to monitor continuously the effects of the process. Frequent monitoring and report of data is an essential component to process mapping and enhances the ability to identify process problems early on. In addition, mammography data should be shared with all staff to promote team awareness of patient outcomes and team accountability of the role they have in quality improvement initiatives that affect patient outcomes.

According to the Health Resource and Services Administration (2011), organizations that experienced successful improvements found that data shared with staff and patients outside the core of the improvement team correlated with sustainability of improvement strategies. Finally, the breast-screening clinic should utilize benchmarking to gauge the quality of the screening mammography program. Benchmarking will enable the breast-screening clinic to continuously measure and compare its processes with those of organizations that are exemplars in breast-screening mammography practices.

Implications for Policy

Since the inception of the discipline of nursing, nurses have been in the forefront of advocacy. Florence Nightingale began the patient and nursing advocacy by vocalizing the need for clean environments to promote wellness. In addition, in the 1800s when

medical doctors were the only perceived authority of patient care delivery. Nightingale was active in publicizing the significant effect of nursing to the delivery of patient care. Today, nurses continue to advocate ensuring quality healthcare, promoting safety, and protecting patient rights. The DNP graduate curriculum prepares the students to answer to the charge of healthcare policy and advocacy. The doctoral prepared nurse practitioner has the leadership ability, research knowledge, and direct practice experience to significantly influence policy (Chism, 2013).

The central focus of this DNP project was to increase screening mammography to women age 40 and older. Research has identified cost as a significant barrier to patient lack of adherence to screening mammography (Jones et al., 2014; Schueler et al., 2008). Extensive scientific research shows a 39% reduction of breast cancer deaths with regular mammographic screening, and that the greatest mortality reduction, the most lives saved, and the most life years gained occur with yearly mammography starting at age 40 (Coldman et al., 2014; Newton & Harris, 2016). It is the responsibility of the DNP to educate the public and elected officials of the aforementioned scientific facts regarding mammography. Thereafter, it is imperative that DNP nurse practitioners advocate for legislation that provide care for woman; such as the Affordable Care Act (ACA) that propels screening mammography. Insurance plans governed by ACA guarantee that all health insurers, including the Centers for Medicare and Medicaid Services (CMS), cover women ages 40 and older for annual mammograms as a preventive service, without additional cost sharing or co-payments. The DNP must advocate for policy and legislature that improves access to healthcare for all Americans, and refute legislation that will leave millions of Americans uninsured. Increases in uninsured patients would

widen the gaps of health disparities and health outcomes of the United States most vulnerable populations. In this current volatile political climate, it is critical for DNPs to emerge from the confines of practice or organizational walls and facilitate change by having a voice at the political roundtable.

Implications for Research

The IOM (2003) has identified that a major barrier to delivery of the safest and highest quality of care is related to the inability of healthcare members to effectively collaborate and translate research into practice. The DNP prepared nurse has been discussed as the clinician delegate who can bridge the research and practice gap, and thus lead the transformation of the U.S. healthcare system (IOM, 2003). Accordingly, nursing organizations convened to revamp the DNP and advanced practice nurses (APN) curricula to further prepare nurses for this role. The DNP curriculum emphasizes the integration of research into practice and provides a foundation of theory, research, and scholarship. Theory, research, and scholarship are interrelated concepts that a DNP will learn about through matriculation of the doctoral program. The American Association of College of Nursing (AACN) captures the definition of scholarship in the nursing discipline as those activities that systematically advance the teaching, research, and practice of nursing through rigorous inquiry that (a) is significant to the profession, (b) is creative, (c) can be documented, (d) can be replicated or elaborated, and (e) can be peer reviewed through various methods. The definition of scholarship reflects how DNP nurses can implement evidence-based research into practice (American Association of College of Nurses [AACN], 1997). This evidence-based process improvement to improve mammography adherence integrated the foundational elements of the DNP education in

all phases of the project, and upon dissemination, this research will be an important scholarly contribution to translational research.

Further Research Recommendations

The author strongly recommends that future projects similar to this one continue for at least a 6-month time frame. The extended time frame would engage a larger sample of the breast-screening clinic's population, and the effects of the evidence-based interventions would have more generalizability. The author implemented this evidence-based process in Richland County, South Carolina, and the data provided trends for uninsured and low income women participants in the Richland County, South Carolina. The organization services Sumter, Fairfield, and Lexington Counties, and geographical variations related to barriers to screening mammography and the breast-screening process may exist. Thus, expanding the interventions throughout the screening program would provide insight and possible opportunities for improvement across the program.

In light of the data that 96% of the post-intervention participants qualified for a free mammography through the organization or Best Change Network, only 48% of the population did not adhere to mammography, suggesting that additional investigation as to why the screening participants did not adhere to screening mammography is necessary. In future process improvements, it will be important to obtain both qualitative and quantitative data to assess barriers and beliefs of the screening participants through a structured evidence-based tool.

Summary

Ongoing practice investigation is essential to elicit evidence-based interventions that improve mammography adherence. The results of this project identified that there

was as a significant increase ($p = 0.02$) of mammography proportions of the pre-intervention and post intervention groups. This study validates that improving the screening process, has a positive correlation with screening mammography adherence; however, it is imperative to continue the clinic's investigation and identify other factors that influence women's decisions to adhere to mammography screening.

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APPENDIX A. EVIDENCE AND QUALITY GUIDE

Evidence Levels	Quality Guides
Level I Experimental study, randomized controlled trial (RCT) Systematic review of RCTs, with or without meta-analysis	A High quality: Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence B Good quality: Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence C Low quality or major flaws: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn
Level II Quasi-experimental study Systematic review of a combination of RCTs and quasi-experimental, or quasi-experimental studies only, with or without meta-analysis	
Level III Non-experimental study Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only, with or without meta-analysis Qualitative study or systematic review with or without a meta-synthesis	
Level IV Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence Includes: <ul style="list-style-type: none"> • Clinical practice guidelines • Consensus panels 	A High quality: Material officially sponsored by a professional, public, private organization, or government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years B Good quality: Material officially sponsored by a professional, public, private organization, or government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years C Low quality or major flaws: Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the last 5 years

<p>Level V Based on experiential and non-research evidence</p> <p>Includes:</p> <ul style="list-style-type: none"> • Literature reviews • Quality improvement, program or financial evaluation • Case reports • Opinion of nationally recognized experts(s) based on experiential evidence 	<p>Organizational Experience:</p> <p>A High quality: Clear aims and objectives; consistent results across multiple settings; formal quality improvement, financial or program evaluation methods used; definitive conclusions; consistent recommendations with thorough reference to scientific evidence</p> <p>B Good quality: Clear aims and objectives; consistent results in a single setting; formal quality improvement or financial or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence</p> <p>C Low quality or major flaws: Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial or program evaluation methods; recommendations cannot be made</p> <p>Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference:</p> <p>A High quality: Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field</p> <p>B Good quality: Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions</p> <p>C Low quality or major flaws: Expertise is not discernable or is dubious; conclusions cannot be drawn</p>
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Dearholt, S. L. and Dang, D. Johns Hopkins Nursing Evidence-Based Practice: Models and Guidelines (2). Indianapolis, US: Sigma Theta Tau International, 2014. ProQuest ebrary. Web. 19 April 2016. Copyright © 2014. Sigma Theta Tau International.

APPENDIX B. EVIDENCE TABLE

Brief Reference, Type of study, Quality rating	Methods	Threats to validity/ reliability	Findings	Conclusions
Barriers				
<p>Article 1</p> <p>Alexandraki, I., & Mooradian, A. D. (2010). Barriers related to mammography use for breast cancer screening among minority women. <i>Journal of the National Medical Association, 102</i>(3), 206–218.</p> <p>Literature Review</p> <p>Level V/Grade B</p>	<p><i>N</i> = 17 studies 13 cross-sectional 4 prospective</p> <p>Patient characteristics, outcomes regarding knowledge, attitudes, beliefs; social norms; accessibility; and cultural competence regarding breast cancer screening were abstracted. Studies were rated using a methodological quality score</p>	<p>Limited to full-text articles; some relevant studies may not have been captured.</p> <p>All ethnic minority groups were not included.</p>	<p>Most frequent barriers included pain, embarrassment, low income, lack of health insurance, poor knowledge about breast cancer screening, lack of physician recommendation, lack of trust in hospitals and doctors, language barriers, and lack of transportation.</p>	<p>Assessing and addressing barriers are associated with improving utilization of screening mammography among minority women.</p>
<p>Article 2</p> <p>Todd, A., & Stuijbergen, A. (2011). Barriers and facilitators related to breast cancer screening. <i>International Journal of MS Care, 13</i>(2), 49–56. https://doi.org/10.7224/1537-2073-13.2.49</p> <p>Qualitative Descriptive Design</p> <p>Level III/Grade B</p>	<p>Qualitative descriptive design of perceived barriers and facilitators related to breast cancer screening.</p> <p>Women participating in a longitudinal study of health promotion and health quality were recruited to participate in semi-structured audio-taped interviews, 10–45 minutes long</p>	<p>Subsample of participants from larger study, suggesting participants likely had higher health-promoting behaviors. Samples were well educated. These factors impact generalizability.</p>	<p>80% of women not screened had mobility limitations.</p> <p>Environmental and intrapersonal barriers were prevalent (i.e., transportation, healthcare-provider attitudes, not remembering and experiencing fear and discomfort).</p>	<p>Barriers were environmental, healthcare-provider relationship, difficulty with positioning, and transportation. Intrapersonal barriers were fear, lack of knowledge, lack of self-efficacy, and lack of perceived susceptibility.</p>

Health Literacy				
<p>Article 3</p> <p>Mazor, K. M., Rubin, D. L., Roblin, D. W., Williams, A. E., Han, P. K. J., Gaglio, B., ... Wagner, J. L. (2015). Health literacy–listening skill and patient questions following cancer prevention and screening discussions. <i>Health Expectations</i>, n/a–n/a. http://doi.org/10.1111/hex.12387</p> <p>Quasi-experimental study design (intervention within-group, no control, nonrandom)</p> <p>Level II/Grade B</p>	<p>Sample population $N = 433$ adults listened to simulated physician–patient interactions discussing (i) prophylactic tamoxifen for breast cancer prevention, (ii) PSA test for prostate cancer, and (iii) colorectal cancer screening, and identified questions they would have. Health literacy–listening was assessed using the Cancer Message Literacy Test–Listening (CMLT–Listening). Two authors developed a coding scheme, which was applied to all questions. Analyses examined whether participants scoring above or below the median on the CMLT–Listening asked a similar variety of questions.</p> <p>Results Questions were coded into six major function categories.</p> <p>A stratified random sample of health plan participants aged 40–70 years.</p>	<p>Intervention was a simulated versus actual conversation with participants. Possibly this environment can inhibit or influence question asking.</p> <p>There is not information regarding the stability of CMLT–Listening scores over time.</p> <p>Many study participants were college educated, suggesting that the sample was more educated than the general population.</p>	<p>Participants that scored higher on the CMLT–Listening asked a greater variety of risks/benefits questions.</p> <p>Participants who scored lower asked a greater variety of questions seeking to personalize the information.</p>	<p>Patient’s health literacy is associated with distinctive patterns of question utilization following cancer screening and prevention counseling.</p>

<p>Article 4</p> <p>Halverson et al. (2015). Health literacy and health-related quality of life among a population-based sample of cancer patients. <i>Journal of Health Communication</i>, 20(11), 1320–1329. http://dx.doi.org/10.1080/10810730.2015.1018638</p> <p>Non-experimental study design</p> <p>Level III/Grade B</p>	<p>Eligible participants were Wisconsin residents. N=2,582</p> <p>Ages 18–79 years old, newly diagnosed with lung, prostate, breast, or colorectal cancer in 2004; had reported to the Wisconsin Cancer Reporting System with valid addresses and alive at first contact per the Social Security Death Index or study telephone call. Eligibility for lung cancer cases also required a publicly available telephone number. In 2006, a random sample ($N = 2,582$) of non-Hispanic White breast, colorectal, and prostate cancer cases was drawn from the Wisconsin Cancer Reporting System. In addition, all non-White and/or Hispanic cases ($n = 269$) were selected for participation. In all, the total initial sample was 3,265 patients. Of these, 2,431 subjects meeting the eligibility criteria, who were living, and had valid</p>	<p>The data are cross-sectional; therefore, a causal association between health literacy and HRQOL cannot be inferred. There is a potential for survival bias. Responses to questions of health literacy, HRQOL, and socioeconomic factors are based on self-report and could be subject to social desirability, nonresponse, and other sources of bias. The quality of life instrument used for this study was designed to require relatively low literacy levels (i.e., it was written at approximately seventh-grade level). Hahn and colleagues (2007) tested literacy bias among participants (high vs. low literacy) completing the FACT-G using a Talking Touchscreen and found that scores were not subject to</p>	<p>Unadjusted regression models indicated that health literacy was positively and significantly related to HRQOL scores ($p < .0001$). In addition, age ($p < 0.001$) and being non-Hispanic White ($p < .01$) were associated with greater HRQOL scores.</p> <p>Compared with their referent groups, HRQOL scores were significantly lower among cancer patients with 1–3 years of college ($p < .0003$), a high school degree or equivalent ($p < .0001$), less than 12 years of schooling ($p < .0001$); annual incomes of \$15,000–29,000 ($p < .0001$), or less than \$15,000 ($p < .0001$); living in urban ($p < .0004$) and rural ($p < .01$) counties; colorectal ($p < .007$) and lung ($p < .0001$) cancer patients, and cancer patients with distant systemic cancer at diagnosis ($p < .0001$).</p> <p>Health literacy remained associated with HRQOL scores (p</p>	<p>Low health literacy at the patient level may be a determinant of poor HRQOL among breast, lung, prostate, and colorectal cancer patients. Given that patient understanding is affected by individual health literacy skills and the health literacy demands of the healthcare system, these findings highlight the need for system-level adoption of health literacy best practices.</p>
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	<p>addresses, were mailed a packet including a self-administered survey, cover letter, a study information sheet, return envelope, and a book of U.S. postage stamps that served as an incentive.</p> <p>One week following the initial mailing, a postcard reminder was sent to all subjects. At three weeks, a cover letter, a second (identical) questionnaire, and study information sheet were sent to non-respondents and, at five weeks, telephone calls were made to the remaining potential study participants.</p> <p>The ACCESS survey was conducted from 2006–2007 and gathered data on cancer care, patient satisfaction, comorbid conditions, and HRQOL among a population-based sample of Wisconsin cancer patients.</p>	systematic literacy bias.	<p>< .0001) after inclusion of the covariates into the model. Breast cancer, colorectal cancer, and education were not significantly associated with HRQOL scores after adjusting for health literacy and other study covariates.</p> <p>Health literacy was also positively and significantly ($p < .0001$) related to each HRQOL scale.</p>	
<p>Article 5</p> <p>Komenaka et al. (2015). Association of health literacy with adherence to screening mammography</p>	<p>All patients seen at a breast clinic underwent prospective assessment of health literacy</p>	<p>Whether patients underwent screening mammography was determined</p>	<p>After adjustment for all of the aforementioned variables in a logistic regression analysis, this study</p>	<p>Of all the sociodemographic variables examined, health literacy had the strongest relationship with the use of</p>

<p>guidelines. <i>Obstetrics & Gynecology</i>, 125(4), 852–859. http://dx.doi.org/10.1097/AOG.0000000000000708</p> <p>Non-experimental Study Design</p> <p>Level III/Grade B</p>	<p>from January 2010 to April 2013. All women at least 40 years of age were included. Men and women diagnosed with breast cancer before age 40 years were excluded.</p> <p>Routine health literacy assessment was performed using the Newest Vital Sign.</p> <p>Demographic data were also collected. Medical records were reviewed to determine if patients had undergone screening mammography: women aged 40–49 years were considered to have undergone screening if they had another mammogram within two years. Women 50 years or older were considered to have undergone screening mammography if they had another mammogram within one year.</p> <p>A total of 1,664 consecutive patients aged 40 years or older were seen. No patient declined the health literacy assessment.</p>	<p>by a review of documentation in the medical record. Although it is possible that some patients may have had mammograms at different facilities but were unable to recall the date or location, ascertainment of mammography screening from medical records is likely more accurate than patient self-reporting.</p> <p>When patients received mammograms outside our system, the reports were checked for availability of comparison films, which is routinely documented on mammogram reports (Strengthen internal validity—ensuring complete and accurate data collection). Largely represented of total patient population</p> <p>The population was from a breast clinic rather than a primary care clinic and this may</p>	<p>found that four factors were associated with not undergoing screening mammography: low health literacy (odds ratio (OR) 0.27, 95% confidence interval (CI) 0.19–0.37; $p < .001$), smoking (OR 0.64, 95% CI 0.47–0.85; $p < .002$), older age (OR 0.86, 95% CI 0.79–0.94; $p < .001$), and being uninsured (OR 0.66, 95% CI 0.51–0.85; $p < .001$).</p>	<p>screening mammography.</p>
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		<p>inadvertently select for patients more or less likely to have undergone screening compared with a primary care population.</p> <p>The study involved a significant proportion of Hispanic and Spanish-speaking patients. Ascertain generalizable to other populations by analysis of race/ethnicity, language, income, and other commonly assessed socio-demographic variables were not significant predictors of screening mammography when health literacy status was considered in the analysis, suggesting that this is not a concern.</p>		
<p>Article 6</p> <p>Smith, S. W., Hitt, R., Nazione, S., Russell, J., Silk, K., & Atkin, C. K. (2013). The effects of heuristic cues, motivation, and ability on systematic processing of information about breast cancer environmental factors. <i>Journal of Health</i></p>	<p>Population: 4,155 women recruited through the Love/Avon Army of Women, a volunteer participant pool.</p> <p>Age Range 19–54</p>	<p>The sample was largely White and quite well educated.</p> <p>Limited knowledge for women with lower literacy; thus, information on</p>	<p>The results demonstrated that perceptions of heuristic cues did not directly predict knowledge gain scores across the three message topics.</p> <p>Results were</p>	<p>With over three topics on possible environmental risks for breast cancer, the message that was translated to a lower literacy level increased knowledge gains substantially.</p> <p>The HSM proved to be</p>

<p><i>Communication, 18(7), 845–865.</i> http://dx.doi.org/doi:10.1080/10810730.2013.768722</p> <p>Experimental (Interventional) Study Design</p> <p>Level I/Grade B</p>	<p>years</p> <p>95% Caucasian</p> <p>Most participants had a college degree (36.4%) or graduate training (36%).</p> <p>Approximately 23% had some college or technical training, and 5% had a high school degree. Less than 1% had less than a high school education or did not want to report the highest level of education.</p> <p>Randomly assigned to one of the six interventions: (a) genetic higher literacy message, (b) genetic lower literacy message, (c) PFOA higher literacy message, (d) PFOA lower literacy message, (e) progesterone higher literacy message, and (f) progesterone lower literacy message.</p> <p>An online survey conducted via e-mail. Participants were randomly assigned to one of the six interventions upon clicking on survey e-mail.</p>	<p>how lower literacy women would process the lower literacy messages was not tested in this study.</p> <p>Self-assessment of confidence in scientific ability may have been perceived rather than actual scientific literacy.</p>	<p>largely consistent with ability, measured by education level and number of science courses taken, predicting knowledge gain.</p> <p>Confidence in scientific ability was a significant predictor for two of the three topics.</p> <p>Lower literacy messages worked very well across topics with average gains over the scientific messages for the genetic, PFOA, and progesterone messages.</p>	<p>a relevant theory to apply to the issue of knowledge gain about possible environmental influences on breast cancer.</p>
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Communication				
<p>Article 7</p> <p>Charlton, C. R., Dearing, K. S., Berry, J. A., & Johnson, M. J. (2008). Nurse practitioners' communication styles and their impact on patient outcomes: An integrated literature review. <i>Journal of the American Academy of Nurse Practitioners</i>, 20(7), 382–388. https://doi.org/10.1111/j.1745-7599.2008.00336.x</p> <p>Systematic Review (non-experimental studies)</p> <p>Level III/Grade B</p>	<p><i>N</i> = 7</p> <p>Examined the published research from 1999 to 2005 describing nurse practitioner (NP)–patient interactions to determine the best practice to enhance patient outcomes.</p>	<p>A limited number of studies; Measure of communication style varied among studies.</p>	<p>The studies analyzed demonstrated that biopsychosocial (patient-centered) communication style positively influences patient outcomes as evidenced by (a) improved patient satisfaction, (b) increased adherence to treatment plans, and (c) improved patient health.</p>	<p>The results of this integrated literature review suggest that patient-centered communication incorporated into NPs' practice is associated with improving patient outcomes.</p>
<p>Article 8</p> <p>Nouri, S. S., & Rudd, R. E. (2015). Health literacy in the “oral exchange”: An important element of patient-provider communication. <i>Patient Education & Counseling</i>, 98(5), 565–571. https://doi.org/10.1016/j.pec.2014.12.002</p> <p>Systematic Review</p> <p>Level III/Grade B</p>	<p><i>N</i> = 12</p> <p>The search yielded 999 articles—12 of which were included in this review. Intervention (communication).</p>	<p>A significant number of relevant papers did not surface and had to be searched for separately. Search terms, research methods, and outcome measures varied; standardization enables cross-comparison.</p>	<p>Low patient oral and aural literacy are associated with poor health outcomes. Use of plain language and teach-back had a positive association with reducing literacy demands.</p>	<p>Universal use of plain language and teach-back by providers, as well as incorporation of awareness of oral and aural literacy into community programs.</p>
<p>Article 9</p> <p>Peterson, E. B., Ostroff, J. S., DuHamel, K. N., D'Agostino, T. A., Hernandez, M., Canzona, M. R., & Bylund, C. L. (2016). Impact of provider-patient communication on cancer screening adherence: A systematic review. <i>Preventive Medicine</i>, 93, 96–105.</p>	<p><i>N</i> = 35 studies</p> <p>Breast-screening studies <i>n</i> = 5</p> <p>Utilized Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for this</p>	<p>Patient self-report of adherence outcome measures may provide inaccurate information. The interventions varied in each study. There</p>	<p>Provider recommendation was associated with receipt of a mammogram. A lack of doctor recommendation was significantly associated with lower odds of screening among Latinas</p>	<p>Provider recommendation had a significant impact on mammography adherence. Other provider communication factors that correlated with positive screening adherence were addressing patient barriers and clearly and thoroughly explaining</p>

<p>https://doi.org/10.1016/j.yjmed.2016.09.034</p> <p>Systematic Review</p> <p>Level III/Grade A</p>	<p>review.</p> <p>Assessed provider recommendation alone; included studies that explored the quality and content of provider–patient discussions about screening, and interventions designed to improve provider–patient communication about screening and subsequent screening behaviors.</p>	<p>were not consistent or missing operationalization measures.</p>	<p>(OR = 0.01, 95% CI = 0.002–0.12) and Arab women (OR = 0.25, 95% CI = 0.10–0.61) but not significant for Black women.</p>	<p>screening procedures.</p>
<p>Teach-back</p>				
<p>Article 10</p> <p>Baker, H., Uus, K., Bamford, J., & Marteau T. M. (2004). Increasing knowledge about a screening test: preliminary evaluation of a structured, chart-based, screener presentation. <i>Patient Education Counseling</i>, 52, 55–59.</p> <p>Quality Improvement</p> <p>Level V/Grade B</p>	<p>Randomized group of usual care participants received a printed leaflet and short verbal information. The intervention group received usual care, in addition to illustrated information, followed by an assessment of understanding; and additional information as indicated by patients' lack of understanding.</p> <p>$N = 40$</p>	<p>Small sample size</p>	<p>Overall knowledge was high for total population; for women with lower levels of education, the structured presentation resulted in significantly higher levels of knowledge than the standard presentation only.</p>	<p>Participants with lower levels of education had significantly higher knowledge scores than those receiving the standard presentation only (means 5.00 and 3.38, MWU $p < 0.05$).</p>
<p>Article 11</p> <p>D. A. DeWalt, R. M. Malone, M. E. Bryant, M. C. Kosnar, K. E. Corr, R. L.</p>	<p>12-month randomized control trial</p>	<p>Small sample size</p> <p>Uneven distribution of</p>	<p>There was not a significant difference in terms of major outcomes:</p>	<p>There is some benefit to self-management programs that include education that may be generalizable to</p>

<p>Rothman, C. A. Sueta, M. P. Pignone (2006). A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial. <i>BMC Health Services Research</i>, 6, 30.</p> <p>Quality Improvement</p> <p>Level V/Grade B</p>	<p>$N = 123$</p> <p>Intervention patients received education on self-care emphasizing daily weight measurement, diuretic dose self-adjustment, and symptom recognition and response. Picture-based educational materials, a digital scale, and scheduled telephone follow up were provided to reinforce adherence (patient understanding was assessed). Control patients received a generic heart failure brochure and usual care.</p>	<p>baseline variables among the groups ($n = 65$, Control; $n = 62$, Intervention)</p>	<p>hospitalizations or death, cardiac hospitalizations, and heart failure quality of life.</p> <p>The intervention group had fewer hospitalizations or deaths and less cardiac hospitalizations compared with the control.</p>	<p>vulnerable populations to include low literacy populations.</p> <p>A significant difference in terms of knowledge intervention group than in the control group. Mean difference in score improvement was 12 percentage points (95% CI 6–18; $p < 0.001$).</p> <p>Heart failure self-efficacy improved more in the intervention group than in the control group. Mean difference in score improvement was 2 points (95% CI 0.7–3.1; $p = 0.0026$).</p> <p>In terms of self-care behaviors, more patients in the intervention group than in the control group reported daily weight measurement at 12 months (79% vs. 29%, $p < 0.001$).</p>
<p>Article 12</p> <p>Ferreira M. R. (2005), Colorectal cancer screening, USA</p> <p>Level II/Grade A</p>	<p>Quasi randomized control trials (RCT) (cluster), Patients: $N = 2046$ (I = 1049, C = 997); HPs: $N = 113$ (I = 60, C = 53)</p> <p>Veterans aged 50+ years.</p> <p>Literacy/numeracy: mixed, assessed for a subsample ($n = 382$) using REALM.</p> <p>Health care providers attend a</p>	<p>Subsample of veteran population</p>	<p>Health literacy communication has positive effects on screening uptake.</p> <p>Videos, simplified language has a positive correlation with screening knowledge, though HC professional interaction/communication has a stronger correlation.</p>	<p>Colorectal cancer screening improved with health literacy communication strategies utilized; 41.3% vs. 32.4% ($p = 0.003$).</p> <p>Results suggest generalizability to other screenings.</p>

	<p>workshop on colorectal screening and communicating with patients with limited literacy, and four group sessions comprising feedback on clinic's and own screening recommendation and completion rates, discussion of barriers, role play, and lecture on communicating with patients with limited literacy. Patients receive a brochure with simplified language and graphics, video on overcoming barriers to screening, and simplified instructions with a screening test.</p> <p>For professionals, five contacts over 24 months; for patients, one contact, follow up at 6–18 months.</p>			
<p>Article 13</p> <p>Schillinger, D., Piette, J., Grumbach, K., Wang, F., Wilson, C., Daher, C., Leong-Grotz, K., Castro, C., Bindman, A. B. (2003). Closing the loop: Physician communication with diabetic patients who have low health literacy. <i>Arch Intern Med.</i> 163(1), 83–90. 10.1001/archinte.163.1.83.</p>	<p>74 audiovisual encounters were reviewed to evaluate patient–provider communication; 38 physicians encounter one to five patients (average 1.9).</p> <p>Stratified $n = 10$ physicians who assessed understanding.</p>	<p>Small sample size limits generalizability</p> <p>Multiple Regression Analysis to evaluate intended outcome measure</p>	<p>Interactive communication was associated with improved glycemic control is consistent with prior research in physician–patient communication.</p>	<p>92% of patients whose physicians assessed their recall or comprehension at least once had a HbA_{1c} value of 8.6% or less compared with 55% of patients whose physicians did not assess recall or comprehension (odds ratio, 8.96, 95% confidence interval, 1.1–74.9; $p = .02$).</p>

Quality Study Level V/Grade B	$n = 28$ physicians who did not ever assess.			
Health Education				
Article 14 Seven, M., Akyüz, M., & Robertson, L. B. (2015). Interventional education methods for increasing women's participation in breast cancer screening program. <i>Journal of Cancer Education: The Official Journal of The American Association For Cancer Education</i> , 30(2), 244–252. http://dx.doi.org/10.1007/s13187-014-0709-8 Experimental (Interventional) Study Design Level I/Grade B	Three methods of education— individual, individual with an educational brochure for spouses, and group-on participation on breast cancer screening in Turkey. A total of 550 home visits were made and 446 women were interviewed to accrue 327 women for the study, of whom 26.7% reported receiving a screening mammogram within the past two years. Participants were divided into one of three educational groups using block randomization and following the educational session; they were invited to attend a breast cancer-screening program. The results indicated that the decision to have a screening mammogram was influenced by the method of education and the knowledge score. Women who were educated, within a	The study design did not ensure that spouse brochure was actually received, read, or fully understood by the spouse. Therefore, the similarity of the results in both groups cannot be completely determined.	The results indicated that the decision to have a screening mammogram was influenced by the method of education and the knowledge score. Women who were educated within a group scored the highest.	These results demonstrate that group education is an effective method of increasing breast cancer knowledge and screening awareness. Further studies involving spouses are needed to determine the effect of spousal support on women's decisions to be screened for breast cancer.

	<p>group, scored the highest. These results demonstrate that group education is an effective method of increasing breast cancer knowledge and screening awareness.</p> <p>Discussion of extensive literature review.</p>			
<p>Article 15</p> <p>Burgess, C., Linsell, L., Kapari, M., Omar, L., Michell, M., Whelehan, P., ... Ramirez, A. (2009). Promoting early presentation of breast cancer by older women: A preliminary evaluation of a one-to-one health professional-delivered intervention. <i>Journal of Psychosomatic Research</i>, 67(5), 377–387. http://dx.doi.org/10.1016/j.jpsychores.2009.01.005</p> <p>Quasi-experimental (comparative) Study Design</p> <p>Level II/Grade B</p>	<p>Women attending their final routine appointment in the English NHS Breast-screening programme received a booklet or a booklet supplemented by a brief interview, in addition to usual care.</p> <p>The trial was a within-group before-and-after evaluation, in which women were allocated to one of the two versions of the intervention, in addition to the usual care provided by the Breast-screening program.</p> <p>$N = 292$ core intervention ($n = 176$) and boosted intervention ($n = 116$).</p> <p>The primary outcome was a change in the knowledge of</p>	<p>This was a within-group evaluation-randomized control necessary to provide evidence that outcomes are related to interventions (lack of internal or external validity).</p> <p>Patient population limited to older women.</p>	<p>At one-month post-intervention, the mean number of breast cancer symptoms identified increased significantly ($p < .001$) and ($p < .001$) in the booklet-plus-interview group ($p < .001$).</p> <p>Improvements were sustained at six months. Positive improvements were made in the knowledge of the risk of developing breast cancer and the confidence to detect a breast change in both groups.</p>	<p>Both interventions had positive effects on knowledge of cancer symptoms, risk of developing breast cancer, and confidence to detect breast cancer.</p>

	breast cancer symptoms from baseline to one-month post-intervention. Secondary outcomes were knowledge of the risk of developing breast cancer, confidence to detect a breast change, and the likelihood of disclosure to someone close. Levels of cancer worry and any adverse effects caused by the intervention were also monitored.			
Article 16 Bushatsky, M. et al. (2015). Health education: A strategy for action against breast cancer. <i>Ciencia, Cuidado E Saude</i> , 14(1), 870–878. http://dx.doi.org/doi:10.4025/cienccuidsaude.v14i1.23259 Quasi-experimental study Level II/Grade B	The objective was to evaluate the effectiveness of the educational intervention on breast cancer with users of the Family Health Strategy (FHS), through pre- and posttest comparisons. Study population: 84 women from 18 years old that resided in the Family Health Units of the municipality of Sirinhaém–Pernambuco. The timeframe was from May to September in 2013. The study design had three phases: The study participants were subject to a	Though the findings are relevant, this study has limitations in the absence of a control group, women of different age groups. Convenience sample obtained from a group of FHS users. However, the investigation was performed with the proposed objective through practice, low cost, and simple technique. Nevertheless, the survey can be used as a proposal to be easily performed by the public health system	The intervention was significant, as the study observed the understanding of women regarding breast cancer to be a curable disease and means of prevention, as well as the association of women who are over 50 years old, as a risk factor for neoplasm; in both variables, a value of $p < 0.001$ was obtained through the comparison of pre- and posttest. Thus, the strategy employed served as the foundation for the acquisition of knowledge by the participants.	The educational intervention was effective as evidenced by the comparison of the pre- and posttests. There was significant evidence of learning noted by response patterns related to breast cancer being a genetic disease, breast cancer association with ages 50 years and above, and breast cancer having some means of prevention. In addition, learning about the main risk factors and therapeutic modalities were engaged.

	preassessment, pretest, and then they were exposed to an intervention and posttest.	(duplicable).		
<p>Article 17</p> <p>Güçlü, S., & Tabak, R. S. (2013). Impact of health education on improving women's knowledge and awareness of breast cancer and breast cancer self examination. <i>Journal of Breast Health</i>, 9(1), 18–22.</p> <p>Quasi-experimental Study Design with Pre/Posttest</p> <p>Level II/Grade B–C</p>	<p>Study population: The study group consisted of 33 literate women in 15–49 year age groups attending courses in the Public Training Center of a primary school in Kütahya Province (Turkey). A questionnaire developed by the researcher was answered by the participants three days before the interventional health education activities, represented the pretest, and five days after the intervention was the posttest. The data were processed using SPSS 14.0.</p> <p>Descriptive methods were used.</p>	<p>Study design—subjects' exposure to pretest can influence the outcome.</p> <p>(There was no discussion on how covariance was controlled.)</p> <p>Relatively small sample size.</p> <p>Potential sample of convenience (women taking courses in the Public Training Center).</p>	<p>Results: Married women were found to have significantly higher knowledge levels in breast self-examination ($p < 0.001$).</p> <p>After the educational intervention in breast cancer and breast self-examination, there was a significant increase in women's knowledge levels ($p < 0.001$).</p>	<p>After the educational activity, significant progress was defined on women's knowledge levels. Healthcare professionals should perform training and screening programs together with educational societies to increase women's awareness on examination methods for early diagnosis of breast cancer.</p>
<p>Article 18</p> <p>Maxwell, A. E., Jo, A. M., Chin, S., Lee, K., & Bastani, R. (2008). Impact of a print intervention to increase annual mammography screening among Korean American women enrolled in the National Breast and Cervical Cancer Early Detection Program. <i>Cancer Detection and Prevention</i>, 32(3), 229–235. doi:10.1016/j.cdp.2008.04.0</p>	<p>During the three-month intervention period (July–September 2005), clinic staff mailed the print intervention together with the routine reminder postcard to 360 women who were due to return for their annual mammogram,</p>	<p>Only authorized to receive screening data on the group level, not on individual women. Lack of a randomly assigned control group, which was not feasible within the funding timeframe and available</p>	<p>Almost all women (90%) were encouraged to have regular mammograms and appreciated the information. About one-third of the women discussed the brochure with somebody and 78% stated that they would recommend it to a</p>	<p>The effect that was achieved with the print intervention was encouraging but not statistically significant.</p> <p>Involving Korean American women in intervention development resulted in print materials that were well accepted by their peers.</p>

<p>03</p> <p>Quasi-experimental design</p> <p>Level II/Grade B</p>	<p>using address information from the NBCCEDP database.</p> <p>Population: Women were 40 years of age or older, had no health insurance, and a self-reported income of less than 200% poverty level.</p> <p>Identified as Korean based on the last name.</p> <p>Used the RE-AIM framework to evaluate comprehensively the impact of the print intervention on repeat screening rates because it emphasizes factors at both the individual level (reach and effectiveness) and the setting level (adoption, implementation, and maintenance) that are important for translating research into practice.</p> <p>Debriefed telephone surveys with 59 women who were mailed the print intervention three months after the mailings, between October and December 2005, to assess reach and acceptability of the print</p>	<p>budgetary resources.</p>	<p>friend. During the debriefing interview, several of the women described in detail the messages and the pictures of the print intervention. Only one-third of the respondents remembered receipt of the brochure.</p> <p>The repeat screening rate was 6 percentage points higher in the intervention period than in the control period, representing a relative increase of 18%.</p>	
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	<p>intervention.</p> <p>A quasi-experimental design was used. Repeat screening rates among women who were mailed the print intervention in 2005 were compared with the rates achieved with the reminder postcard only during the same three months in 2004 using a chi-square test.</p>			
<p>Article 19</p> <p>Park et al. (2013). Effects of tailored message education about breast cancer risk appraisal for obese Korean women. <i>Oncology Nursing Forum</i>, 40(6), E382-E392. http://dx.doi.org/doi:10.1188/13-ONF.E382-E392</p> <p>Quasi-experimental study</p> <p>Level II/Grade B to C</p>	<p>Population: Study participants included 64 women who were obese in a rural community in South Korea.</p> <p>Pre/posttest comparing two treatments. Based on the Health Belief Model, a tailored message education involved a one-session individual approach addressing cognitive, emotional, and behavioral domains.</p> <p>The comparison group received a one-time standard education group session. Data on breast cancer risk factors and mammography findings were</p>	<p>Nonrandom treatment assignment</p> <p>The generalizability of the findings is limited because of the small sample size and nonrandom treatment assignment. Most of the tailored message education was individualized; diet and exercise content was limited to general guidelines.</p>	<p>Compared with standard education, the tailored message education showed significantly higher score changes on awareness of personal risk ($F = 5.21, p < 0.05$), self-efficacy for BSE ($F = 5.16, p < 0.001$), intent to perform BSE ($F = 6.24, p < 0.05$), intent to have mammography ($F = 5.45, p < 0.05$), and intent to prevent breast cancer with eating habits ($F = 7.28, p < 0.05$) and exercising ($F = 12.51, p < 0.001$).</p>	<p>Individually tailored education effectively enhanced awareness of the personal risk for breast cancer, self-efficacy for BSE, and intent to screen and prevent breast cancer.</p> <p>The tailored message education in this study did not fully address cultural factors related to obesity, which also need to be more fully considered in future interventions.</p>

	recorded.			
<p>Article 20</p> <p>Dieng, M., Watts, C. G., Kasparian, N. A., Morton, R. L., Mann, G. J., & Cust, A. E. (2014). Improving subjective perception of personal cancer risk: Systematic review and meta-analysis of educational interventions for people with cancer or at high risk of cancer. <i>Psycho-Oncology</i>, 23(6), 613–625. http://doi.org/10.1002/pon.3476</p> <p>Systematic Review/Meta-Analysis</p> <p>Level III/Grade A</p>	<p>A systematic review of RCT and prospective observational studies. Evaluated the effect of genetic counseling (education) on personal perceived risk.</p> <p>$N = 40$</p>	<p>Most of the studies were conducted on breast cancer patients ($n = 29$).</p>	<p>RCT ($n = 12$) showed that short-term or long-term educational interventions did not have a significant effect on risk perception level ($p < .001$).</p> <p>One study showed a short-term difference in risk rating ($p = .01$).</p> <p>Of the prospective observational studies ($n = 28$), many reflected a change in perception of risk and accuracy of risk rating in short-term and long-term education groups.</p>	<p>Further development and investigation of education interventions using good quality RCT are necessary.</p>
<p>Article 21</p> <p>Zeinomar, N., & Moslehi, R. (2013). The effectiveness of a community-based breast cancer education intervention in the New York State Capital Region. <i>Journal of Cancer Education: The Official Journal of The American Association for Cancer Education</i>, 28(3), 466–473. doi:10.1007/s13187-013-0488-7.</p> <p>Mixed Experimental Qualitative Design</p> <p>Level III/Grade B</p>	<p>Population: $N = 417$ students recruited from five colleges/universities and 67 women from four community group organizations.</p> <p>Method: Baseline and posteducation knowledge were assessed via self-administered mostly multiple-choice questionnaires. There was one open-ended question soliciting opinions about public health prevention strategies against breast cancer</p>	<p>There was not a control group. There was a possibility of self-selection bias and lack of information on the long-term impact of the education intervention.</p> <p>The study design does not enable information on long-term benefit of education.</p>	<p>The mean percentage of correct answers among college students increased from preeducation to posteducation correct answers for both the college group and community group. There was a statistically significant difference between pre- and posttest means ($p < 0.0001$).</p> <p>Qualitative analysis of students' answers to the open-ended question revealed two common</p>	<p>Education intervention was effective in increasing knowledge about breast cancer among demographically diverse populations with low baseline knowledge in the NYS Capital Region.</p> <p>Low levels of baseline knowledge among subpopulations in the NYS Capital Region, particularly with respect to certain important aspects of breast cancer such as disease biology and associated risk factors.</p> <p>There was a significant improvement in knowledge following</p>

	<p>included on college/university students' questionnaires.</p> <p>The effectiveness of education intervention was measured through a paired <i>t</i>-test.</p>		<p>themes of screening and primary prevention (which included awareness and avoidance of risk factors at both the individual and societal levels).</p>	<p>the education intervention among these subpopulations.</p> <p>Findings identified specific areas of knowledge gaps as well as specific subgroups of the population who could benefit the most from future targeted public health efforts.</p>
Organizational Process Articles				
<p>Article 22</p> <p>Anhang Price, R., Zapka, J., Edwards, H., & Taplin, S. H. (2010). Organizational factors and the cancer screening process. <i>JNCI Monographs</i>, 40, 38–57. https://doi.org/10.1093/jnci-monographs/lgq008.</p> <p>Systematic Review</p> <p>Level II/Grade A</p>	<p><i>N</i> = 79 studies</p> <p>49 measured the association between organizational factors and breast cancer screening, 21 measured associations with cervical cancer screening, and 20 measured associations with colorectal cancer screening.</p>		<p>Enabling appointment scheduling through telephone calls was associated with increases in mammography use in all eight studies that assessed this approach.</p> <p>Tailored message paired with telephone scheduling improved mammography adherence.</p>	
<p>Article 23</p> <p>Stone, E. G., Morton, S. C., Hulscher, M. E., Maglione, M. A., Roth, E. A., Grimshaw, J. M., ... Shekelle, P. G. (2002). Interventions that increase use of adult immunization and cancer screening services: a meta-analysis. <i>Annals of Internal Medicine</i>, 136(9), 641–651.</p> <p>Meta-Analysis</p>	<p><i>N</i> = 108 (95 randomized clinical trials; 13 control clinical trials)</p> <p>Two reviewers independently extracted data on characteristics and outcomes from unmasked articles. Intervention components to increase use of services were</p>	<p>Evaluated interventions empirically designed with components that are evaluated as a unit, making it difficult to identify what caused the intervention as a whole to succeed or fail.</p> <p>Robust multiregression</p>	<p>The extensive literature on methods for changing provider behavior in general and on improving prevention rates, in particular, provides many insights; the authors did not find specific evidence about how best to improve indicated</p>	<p>Rates of cancer screening (and immunization) increased when healthcare organization makes provisions for screenings through organizational changes in staffing and clinical procedures.</p> <p>Financial incentives and patient reminders also had a positive</p>

Level I/Grade A	classified as reminder, feedback, education, financial incentive, legislative action, organizational change, or mass media campaign. Meta-regression models were developed for immunizations and each cancer screening service using 81 studies with a usual care or control group.	models to minimize threat.	prevention uptake actions.	correlation with screening uptake.
Article 24 Weingart, S. N., Saadeh, M. G., Simchowitz, B., Gandhi, T. K., Nekhlyudov, L., Studdert, D. M., ... Shulman, L. N. (2009). Process of care failures in breast cancer diagnosis. <i>Journal of General Internal Medicine</i> , 24(6), 702–709. https://doi.org/10.1007/s11606-009-0982-	Retrospective chart review Cohort of patients referred to two Boston cancer centers with new breast cancer diagnoses between January 1, 1999 and December 31, 2004. N = 103 Tabulated the number and types of the process of care failures and examined risk factors using bivariate analyses and multivariable Poisson regression.	Retrospective chart review of 103; many excluded for insufficient provider records and may not represent the population of patients who suffer medical errors or injuries.	Twenty-six of 102 patients encountered ≥ 1 process of care failure; 19 experienced two or more process failures.	Patients and clinicians/organizations contribute to process break downs in screening and diagnostic processes.
Level V/Grade B				
Article 25 The Community Prevention Screening Task Force [Task Force] (2012). Updated recommendations for client- and provider-oriented	The number of studies varied per intervention that was recommended. Experimental,	The generalizability of the findings is limited because some studies had a small size and	Evidence-based strategies are available to improve prevention screenings.	Recommendations One-on-one and group education (Strong Evidence and Good Evidence, respectively)

<p>interventions to increase breast, cervical, and colorectal cancer screening. <i>American Journal of Preventive Medicine</i>, 43(1), 92–96.</p> <p>Expert Panel/Government Authority Recommendations based on Systematic Review of Evidence</p> <p>Level V/Grade A</p>	<p>Intervention, and Retrospective studies utilized.</p> <p>Randomized and Nonrandomized samples.</p>	<p>nonrandom treatment assignments.</p> <p>Some studies had positive correlations but did not have statistically significant results.</p> <p>The author had to investigate to retrieve additional information about the studies explored in the systematic review.</p>		<p>Provide funding opportunities for screenings (Good)</p> <p>Reduce structural barriers and streamline complex processes (Strong)</p> <p>Recommendations should be analyzed according to the specific needs of clinic settings and populations served prior to integrating into practice.</p>
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APPENDIX C. INSTITUTION REVIEW BOARD LETTER



Institutional Review Board

Not Human Subject Research Determination

April 11, 2017

Tara Smalls
Tara98rn@yahoo.com

Dear Ms. Smalls:

On April 11, 2017 the following was reviewed:

Type of Review:	Initial
Title:	An evidence-based process improvement to improve mammography adherence
IRB ID:	Pro00065931
Funding:	None
IND, IDE, HDE:	None
Documents Reviewed:	AN EVIDENCED-BASED PROCESS CHANGE TO IMPROVE MAMMOGRAPHY ADHERENCE Last modified 4/3/17

The proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

IRB review and approval by Palmetto Health is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request to the IRB for a determination.

Sincerely,

Sarah Newman-Norlund[†]
IRB Administrator

[†]**Electronic Signature:** This document has been electronically signed through the HSSC eIRB Submission System.