2015

MRI as an Adjunct to Conventional Mammography Screening for Cancer in Dense Breast Tissue

Rachel Sunmattie Connett
Walden University

Walden University

College of Health Sciences

This is to certify that the doctoral dissertation by

Rachel Connett

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Robert Hoye, Committee Chairperson, Health Services Faculty
Dr. Marilyn Simon, Committee Member, Health Services Faculty
Dr. Vibha Kumar, University Reviewer, Health Services Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
2015

Abstract

MRI as an Adjunct to Conventional

Mammography Screening for Cancer in Dense Breast Tissue

by

Rachel S. Connett

MS, University of St. Francis, 2006

BS, Emory University, 1998

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Health Services Administration

Walden University

March 2015

Abstract

Diagnostic methods to effectively image dense breast tissue (DBT) can pose challenges for breast cancer screening. While conventional mammography is the gold standard for breast cancer screening, this technique has a low sensitivity to DBT and can miss about 78% of cancers in DBT, but magnetic resonance imaging (MRI) has a high sensitivity for imaging DBT, and produces a smaller number of false positives. The purpose of this study was to determine the extent to which conventional mammograms can miss breast cancer in women with DBT and to determine if an adjunct method of imaging DBT might detect breast cancers that are missed by mammography alone. Quantitative data were collected from a sample of 300 randomly selected participants using surveys. SPSS statistical software was used to analyze the data with the factor analysis method. Qualitative data were collected by telephone interviews from 10 women who were patients of a breast cancer center. NVivo software was used to analyze the data with the thematic analysis method. All analyses were guided by theoretical framework of von Bertalanffy's general systems theory, Miller's living systems theory, and the theory of intelligent medical diagnosis. Key results determined that a significant number of women with DBT had breast cancer that was undetected by mammograms; results also showed that women with DBT can benefit from breast cancer screening by adding an adjunct screening method (e.g., MRI). This study may contribute to social change by making the breast cancer screening community aware of the potential benefit of adding MRI as an adjunct to conventional screening so that more breast cancers are detected in the early stages of the disease.

MRI as an Adjunct to Conventional Mammography Screening for Cancer in Dense Breast Tissue

by

Rachel S. Connett

MS, University of St. Francis, 2006

BS, Emory University, 1998

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Health Services Administration

Walden University

March 2015

Dedication

I dedicate this dissertation to my husband Jim and son Joshua. It would have been impossible to complete this journey without your patience, encouragement, love and support. In addition, this dissertation is dedicated to my mother, late father, mother-in-law and father-in-law.

Finally, I dedicate this dissertation to my seven sisters.

Acknowledgments

This achievement would not have been possible without the support of many. First and foremost, I owe gratitude to my Committee Chair, Dr. Robert Hoye, for his guidance and encouragement, and Committee Member, Dr. Marilyn Simon for her passionate interest in my research topic.

Special thanks to my seven sisters and dear friends who encouraged me through the end of my journey. Thank you all.

Table of Contents

List of Tables

Chapter 1: Introduction to the Study

Introduction

In 2010, the last year for which the Centers for Disease Control and Prevention (CDC) has figures, the leading cause of death in women was heart disease (23.5%), followed closely by all cancers at 22.1% (cdc.gov). The National Cancer Institute (NCI) predicted that in 2013, over 876,000 women would be diagnosed with breast cancer in the United States (2010). Of that number, it was expected that nearly 40,000 would die from the disease. There are risk factors for heart disease, and lifestyle modifications may ameliorate the time of onset or severity of the disease, but estrogen and progesterone in women are the elements that fuel breast cancer, so gender itself is the major risk factor.

Early detection of breast cancer is currently the single most effective way to modify the course of the disease, and treatment may then be made through surgery, radiology, chemotherapy—or a combination (ACS, 2013). . Cancer registries, such as the American Cancer Society (ACS) and the American College of Radiology (ACR), recommend mammography as the diagnostic imaging tool for screening women for breast cancer (ACS, 2013). Conventional mammography will usually detect cancers, but it has a lower sensitivity to dense breast tissue (DBT) and can miss breast cancers in that kind of tissue.

Breast density is measured by a tool called Breast Imaging Reporting and Data System (BI-RADS). When conventional mammographic techniques are used to image breasts with DBT, both fat and glandular tissues are visualized as white areas, making

differentiation between the two difficult (Boyd et al., 2010). Breast cancer can be camouflaged in DBT because dense or glandular tissues have densities that are similar to surrounding tissues. If breast density is high, there is a greater amount of glandular tissues than fatty tissues; if breast density is low, there is a higher amount of fat than glandular tissues. In DBT, conventional mammograms cannot effectively detect cancer in those dense areas of breast tissue (ACR, 2013).

In this study, I explored the effectiveness of ultrasonography and magnetic resonance imaging (MRI) as adjuncts to mammography screening DBT for breast cancer. The sensitivity of these imaging options were compared and contrasted to evaluate whether ultrasonography or MRI should be adjuncts in conventional mammography for breast cancer screening. This investigation was important because the outcome could build upon research that suggests that an additional method is needed to more accurately screen DBT and potentially save lives of women whose breast cancers might otherwise go undetected through conventional imaging (ACR, 2013).

Chapter 1 is a presentation of information about the practice of mammography alone to screen for breast cancer and includes a discussion of the two additional imaging options, ultrasonography and MRI, to determine their efficacy. The chapter also includes the nature of the study, the purpose of the study, the conceptual framework, the hypotheses to support the research statement, the assumptions, scope and delimitations, limitations, and significance of the study.

Background

It was not until prominent women such as Betty Ford and Nancy Reagan went public with their diagnoses and treatment for breast cancer in the 1980s that widespread attention was paid to the disease (Braun, 2003). Nancy Brinker, who established Susan G. Komen for the Cure in 1982 (named for Brinker's sister who died from the disease at the age of 36) helped to bring the subject of breast cancer to the forefront (Harrison, 2013). The wider public became then aware of the disease, its impact, and its complications (Harrison, 2013). The openness about the issue of breast cancer in the 1980s resulted in increased emphasis on early detection through breast self-examinations and scheduling mammograms and having clinical breast examinations (Harrison, 2013).

Although mammography remains the standard of screening for breast cancer, the efficacy and sensitivity of mammographic techniques for imaging DBT are concerns (Drukteinis et al., 2013). In the United States, 40% of all women who had breast screening with mammography had DBT (NCI, 2012). At the New York Cancer Center in 2009, 500 women, aged 40-79 years, who had mammograms were found to have DBT in the following proportions: 74% in their 40s, 54% in their 50s, 42% in their 60s, and 31% in their 70s (Nelson et al., 2009).

DBT can mask breast tissue that is cancerous and aggressive, causing these aggressive breast cancers to go undetected before they are treated (Yaghjayn et al., 2011). Adjunct imaging techniques, such as ultrasonography and MRI, are recommended by the ACR, CDC and NCI to image DBT, but MRI is recommended only for women with a

high risk for breast cancer (ACR, 2012). The high-risk group of women with breast cancer is in the group with known BRCA (breast cancer) mutation carriers and first-degree relatives who are carriers of the breast cancer gene (Berg, 2009). Other women who do not fit into this category, such as those with DBT, may not have the option of having an MRI tool as a screening mechanism (Berg, 2009). One of the many advantages of MRI for screening women with DBT is having a more accurate and faster diagnosis and treatment plan if there are cancerous lesions in the DBT (Berg, 2009).

Ultrasonography also complements conventional mammography for dense breast screening, but this imaging modality has several setbacks: It is dependent on the skills of the operator and there is a shortage of operators (ACR, 2014). The technique can also fail to identify small lesions and provides more false positive findings than conventional mammograms (Youk & Kim, 2010). Although ultrasonography and MRI are used for breast imaging, MRI is typically used only for the high-risk population, not for routine breast screening of DBT.

Problem Statement

The use of conventional mammography for breast cancer screening can miss breast cancer in DBT (ACR, 2014; Susan G. Komen, 2013). With the probability of breast cancer occurrence at one in eight women, there is a need for an effective screening process for those with DBT (ACS, 2013; NCI, 2012), since early detection provides the potential for saving more lives. In 2013, Harvard Health Publications published the results of a 2004 study of 171 women in the United States (Harvard Health Publications

(2013). Conventional mammography, ultrasonography, and MRI imaging were all used, and the results showed that MRI was the most accurate at finding breast cancer; biopsies confirmed that MRI found 100% of breast cancer while conventional mammography and ultrasonography found 16% of breast cancer.

Even though mammography alone for breast screening can miss tumors and cancers that are masked by glandular breast tissues—because X-rays have a low sensitivity to glandular tissues—organizations such as the NCI and ACR do not currently recommend MRI to screen for DBT (Berg, 2009). Ultrasonography can detect cancers and tumors in glandular tissues, but studies have shown that its use for imaging DBT has led to detection of small benign tumors and a greater number of false positives—and thus an increased breast biopsy rate—than conventional mammography (Berg, 2009).

MRI has a high sensitivity to glandular breast tissue, and because of its sensitivity to DBT and its specificity, it enables clearer imaging of DBT for breast cancer detection (Karellas and Vedantham, 2008). The way MRI images breast tissue is based on physics. Scientists suggest that normal breast tissues and malignant breast tissues must be separated on acquisition of breast images (Hendricks, 2007). Scientists supported their argument on the longitudinal relaxation times (T1), the transverse relaxation times (T2), and the spin densities of the hydrogen protons that are abundant in water molecules in the human body (Hendricks, 2007). Cancerous tissues were found to have higher T1 and T2 values than normal tissues (Hendricks, 2007). Because MRI can distinguish between normal and cancerous breast tissues, its sensitivity for breast imaging is embraced by the

breast imaging community (Hendricks, 2007). However, MRI alone can lead to false positives. But if it is used with mammography for breast screening in DBT, the gap can be minimized, and women with DBT could have early detection of breast cancer, followed by early treatment.

Purpose of the Study

The purpose of this study was to determine to what extent conventional mammograms can miss breast cancer in women with DBT and to determine if an adjunct method of imaging DBT might detect breast cancers missed by mammography alone. The paradigm was the mixed-methods research model, with the quantitative phase done first to test the theory that conventional mammograms can miss cancers in DBT. The qualitative approach was then used to obtain data provide responses based on the lived experiences of women with DBT. The mixed-method approach was used to broaden understandings of the research topic by integrating the quantitative and qualitative research strands (Creswell, 2009).

Research Questions

The following two research questions guided this study:

Research Question 1 (quantitative): Should MRI be used for screening women with DBT as an adjunct to conventional mammography?

H_0: MRI technique for screening women with DBT should be used as an adjunct to conventional mammography.

H_1: MRI technique for screening women with DBT should not be used as an adjunct to conventional mammography.

Research Question 2 (qqualitative): What are the lived experiences of women with breast cancer in DBT prior to and after the breast cancer diagnosis?

Subquestion 1: What circumstances prompted the need to screen for breast cancer?

Subquestion 2: How were the lives of women with a DBT cancer diagnosis impacted from the initial breast cancer screening to the final breast cancer diagnosis?

Subquestion 3: How does having DBT with a cancer diagnosis affect the lives of women with the disease?

Subquestion 4: How might the addition of an adjunct imaging method, MRI, to the existing method help to bring a deeper understanding and a definite diagnosis of cancer in DBT?

Conceptual Framework

The theoretical framework supporting this study consisted of von Bertalanffy's (1968) general systems theory, Miller's (1978) living systems theory, and the theory of intelligent medical diagnosis (Jones, Lowe, & Harrison 2002). Von Bertalanffy argued that subsystems interrelate and depend on each other for the creation, mutation, process, and survival of the system. In the body, subsystems support each other in order for the body to survive. When these subsystems are not functioning correctly, other subsystems

may fail, causing the body to die. If breast cancer is not diagnosed and treated in the early stages, it can metastasize and spread to other parts of the body, causing other subsystems to fail, resulting in death. When cancer is present, subsystems cannot function holistically.

Subsystems within the human body must work together for the individual to be healthy. If MRI or ultrasonography is used in addition to conventional mammogram, a diagnosis of cancer can be made at the screening phase; intervention and treatment could follow. Treatment could commence immediately, which can bring social change at the individual and community levels.

Miller's (1978) living systems theory presents the supra system of a component and the need for all subsystems within the supra system to be integrated and to adjust within their environments for the survival of the supra system (Miller, 1978). Similarly, all subsystems within the human body are dependent on each other for the survival of the human. When there are untreated diseases in the human supra system, then the supra system will fail. In the case of breast cancer screening in DBT, if the cancer is detected early, it can be treated early? And thus allow subsystems to be integrated and to adjust for human survival.

This study was also informed by the theory of intelligent medical diagnosis (Jones et al., 2002). It permits the use of all knowledge and information that is available from a general and ambiguous perspective in service of an outcome that offers new insights

(Jones et al., 2002). As in this study, early detection of breast cancer in DBT can lead to early treatment for the disease.

General systems theory and living systems theory have a direct relationship to the study. All systems within the human facilitate the proper function of the body, but when breast cancer is not detected, this can cause disruption in the harmonious flow and integration of subsystems, which will cause the holistic supra system to fail. In the life process, life can end if breast cancer is undetected or if it is detected too late. If breast cancer is not detected in DBT, then subsystems cannot adjust to compensate for malfunction, a fractured system results, which can lead to a breakdown and nonregeneration of the holistic system (Miller, 1978; von Bertalanffy, 1968). In addition, the theory of intelligent medical diagnosis has a direct relationship with the study, as it allows for vague evidence, when analyzed, contributing to an understanding of the topic.

Nature of the Study

This study used mixed methods with a sequential explanatory strategy (Creswell, 2009). I chose this methodology because health care issues are complex, and neither the quantitative nor the qualitative approach alone has the scope to explore, synthesize, analyze, or provide support to the research hypothesis that MRI can be used as an adjunct to conventional mammography to screen DBT for breast cancer (Creswell, 2009).

The quantitative method was used in the first phase to guide the study, to explore, test, explain, and make predictions about the research phenomenon (Simon & Goes, 2013). The qualitative strand was used in the second phase and built on the quantitative

data to amplify the topic (Creswell, 2009). The results of both paradigms were integrated to present the findings (Creswell, 2009; Simon & Goes, 2013).

Quantitative data were used to test the hypothesis and to learn whether an adjunct imaging method was needed for DBT because conventional mammography has a low sensitivity to glandular tissues and can miss cancer in glandular breast tissue. Statistical techniques were used to determine if the hypothesis was accepted or rejected. This research method also includes a narrow angle to show the effectiveness of conventional mammography, sonograms, and MRI to image DBT. Sonograms and MRI techniques were reviewed to show which imaging technique is effective or has a high sensitivity to DBT. Data for the quantitative portion were collected from national registries, such as the CDC, NCI, and ACR. Data were analyzed to determine if the statistical connection showed a need for an adjunct imaging method to image DBT for this specific population of women.

In Phase 2, I asked 20 women with DBT who had conventional mammograms, sonograms, and MRI for breast cancer screening to respond to a questionnaire. An e-mail explained the purpose of the study and the intended use of the results, including providing them to participants as an incentive to participate. The women surveyed for the study were selected from a small suburb in California. I will discuss the details of data collection in Chapter 3; synthesis and analysis appear in Chapter 4.

Definitions of Terms

The following terms are defined for the purpose of this study:

BRCA: Term used to describe breast cancer susceptibility genes. A BRCA gene test can be done by a blood test to determine if one is a carrier of the inherited BRCA gene (Mayo Clinic, 2013).

BI-RADS: Term used to quantitatively express densities of breast tissue (ACR, 2013).

Conventional mammography: A diagnostic examination that used radiation to image breast tissue and to screen for breast cancer (Radiologyinfo.org, 2013).

Dense breast tissue: Glandular breast tissue (Susan G. Komen, 2013).

False positive: General findings that are positive for a broad spectrum of a specific disease that cannot be determined as malignant or benign without further investigation (Elmore et al., 2013).

MRI: Magnetic resonance imaging is a diagnostic imaging method that does not use ionizing radiation, but uses a magnetic field, hydrogen protons in the body, radiofrequency pulses, and a powerful computer to produce cross sectional images of the body (WebMD, 2013).

Ultrasonography: A process that uses sound waves to reveal images of bodily tissue (WebMD, 2013).

Assumptions

This study was based on several assumptions:

1. MRI can be used to image breast tissue, but usually only for high-risk patients. It also increases breast-screening costs.

2. Some health care insurance providers oppose MRI for screening for DBT because of the cost of the test.
3. MRI is not used to image DBT for breast cancer screening because of cost.
4. Not all states require radiologists and physicians to notify women if there is a finding of DBT.
5. Some physicians believe that MRI produces false positive results and might cause patients with DBT to experience increased anxiety.
6. An MRI can be uncomfortable because of claustrophobia or discomfort during the long testing procedure.
7. Only physicians from California, Connecticut, New York, Texas, and Virginia are mandated to notify patients of the results of conventional mammography for DBT results (Advance for Imaging & Radiation Oncology, 2013).

Scope and Delimitations

The scope of the study was to learn the specificity of ultrasonography and MRI in relation to the recommended method of conventional mammography. I collected data from cancer registries at the ACS, ACR, and CDC and analyzed them to determine if there is a gap in imaging modalities when imaging DBT in breast cancer screening. SurveyMonkey was used to collect data from an e-mailed Internet interview (Creswell, 2009). SurveyMonkey is a web-based data collection tool that has been used since 1999, has been field tested, and has proven to be effective. To establish validity of SurveyMonkey, I assessed the tool for four criteria: credibility, transferability,

dependability, and conformability (Creswell, 2009, p. 149; Simon & Goes, 2013, p. 1; Trochim & Donnelly, 2007). I checked reliability for the qualitative data collection using SurveyMonkey using member checking (Simon & Goes, 2013). Data provided information about the timeline of the dense breast diagnosis and other imaging options that were provided. The diagnosis for each imaging modality for DBT was analyzed, compared, and contrasted.

Qualitative data were collected over 2 weeks from women in a specific region who had been diagnosed with DBT and who responded to open-ended questions to gain a detailed response to their experiences with alternative methods of screening. They were asked to describe (a) the imaging method used for breast screening, (b) cancer diagnosis or not, (c) whether additional imaging techniques were used to further test if the result of breast cancer screening was abnormal or inconclusive because of DBT, and (d) when treatment commenced after a cancer diagnosis or prognosis of the disease.

Limitations

The following were considerations relative to the outcomes:

1. The study might have been hindered by time and cost constraints, as both numeric and text data were collected. Since the study is complete, would you know the answer to this?
2. Weight of the methodology paradigm might determine if the research would depend more on quantitative or qualitative data. Since the study is complete, does this issue remain?

3. What would be the right point in data collection to mix results of collection, analysis, or interpretation? (Creswell, 2009). It is not clear how this would be a weakness.
4. The number of women with DBT in the region did not provide enough participants for the study.
5. Some women with DBT choose not have an MRI and have a sonogram instead. This decision may yield a smaller sample, which might not be generalizable or applicable to a larger population.
6. MRI can produce false positive results, a diagnosis that could lead to anxiety.

Significance of the Study

One in eight women in the United States will die from breast cancer (NCI, 2012). Although the United States has the best equipment for diagnosis, highly qualified radiologists, physicians, hospitals, and medical clinics, breast cancer can be missed in DBT with the use of only conventional mammography for breast cancer screening (Boyd et al., 2007). However, MRI is a newer imaging modality for breast cancer diagnosis, and many physicians do not trust the results of this advanced technique because of the number of false positive findings. MRI, however, has a higher sensitivity for breast cancer detection in DBT, and the use of this technique can complement conventional mammography for breast cancer evaluation.

The literature reveals that conventional mammography remains the only method for breast cancer screening, and conventional mammograms have a low sensitivity to

glandular tissue and can miss cancer in DBT (Boyd et al., 2007/2010). There is a need for an adjunct imaging method that has a higher sensitivity to glandular tissues (Berg, 2009). Ultrasonography has been used to image DBT, but the false positives remain very high (Berg, et al. 2008; Padilla et al. 2013). False positive results from DBT using ultrasonography have resulted in a higher number of breast biopsies that were benign (Berg, et al, 2008; Padilla et al. 2013). MRI has produced accurate results for dense breast imaging but currently has been used only for high-risk breast cancer patients.

The current trend in breast screening is conventional mammograms, and this technique is used nationally to screen women for breast cancer. (ACS, 2013). In California, Connecticut, New York, Texas, and Virginia, radiologists and physicians are required to inform patients if they have DBT (ADVANCE for Imaging & Radiation Oncology, 2013). DBT is measured using the six-category system initiated by the ACR called BIRADS. There are six levels of breast density measurements: 0, <10%, 10-25%, 26-50%, 51-75%, and >75% (Yaffe, 2008). Findings of DBT must be disclosed to the patient. Usually, the physician recommends that additional imaging is needed to see inside the DBT. At this stage, though, it is the patient's decision to explore additional options for dense breast imaging. If the patient is not familiar with options for dense breast imaging and physicians believe that a sonogram is a better choice because of the cost factor, then the patient may follow that recommendation. MRI, however, has produced extremely stable results for dense breast imaging, and when used with

conventional mammogram, it can produce accurate results for breast cancer diagnosis in DBT (Berg, 2009).

Summary

Mammography is the standard tool used for breast cancer screening, and although it is effective for routine mammography, it has a low sensitivity for DBT and can miss some cancers (Giuliano & Giuliano, 2012). Ultrasonography is used as an adjunct to conventional mammography, but this method yields more false positives for breast cancer anomalies than conventional mammography. Imaging of DBT utilizing MRI has yielded accurate findings for breast cancer among the group of women with DBT and produces a lower number of false positive cases. MRI has a higher sensitivity for imaging DBT because its unique characteristics enable it to reveal the matter inside dense tissue. Added to conventional mammography, MRI will result in more accurate diagnoses of breast cancer.

Chapter 2 is a review of professional and peer-reviewed literature on breast cancer screening, including comparisons among conventional mammography, ultrasonography, MRI, and their application and results. In Chapter 3 the methodology that was used to conduct the study is covered. Chapter 4 presented the results of the study and Chapter 5 presented an interpretation of the study, limiting factors, recommendations for future research and how the results of this study might effect social change social.

Chapter 2: Literature Review

Introduction

The purpose of this study was to determine to what extent conventional mammograms can miss breast cancer in women with DBT and to determine if an adjunct method of imaging DBT might detect breast cancers missed by mammography alone. The purpose of this chapter was to learn what research has shown about the sensitivity of MRI and ultrasonography to cancer in DBT. Although conventional mammography is effective for routine breast cancer screening, it has a low sensitivity to DBT and can therefore miss cancers in these tissues (ACR, 2012); in the United States, the figure is about 20%.

The literature review consists of four sections:

1. Section 1presents peer-reviewed material on an historical overview of options for dense breast tissue imaging.
2. Section 2 is a discussion of the theoretical foundation of the study: general systems theory, living systems theories, and the theory of intelligent medical diagnosis. It draws a parallel to the hypothesis that an adjunct imaging option can be of benefit in imaging dense breast tissue.
3. Section 3 includes arguments that agree or disagree with the premise of the study.

4. Section 4 explores peer-reviewed material on the sensitivity or lack of sensitivity of conventional mammography, ultrasonography, and MRI imaging methods for cancer detection in glandular breast tissues.

Literature Search Strategy

Most sources in this chapter are from the American College of Radiology (ACR), the American Cancer Society (ACS), the National Cancer Institute (NCI), and the Susan G. Komen Foundation. Additional sources were obtained through the following databases: EBSCO, MEDLINE, CINAHL, PubMed, Science Direct,Cochrane Database of Systemic Reviews, and ProQuest Dissertations & Theses. The following keywords used to search the literature: *DBT, imaging options, MRI as a screening tool, uultrasonography as a glandular tissue screening tool, adjunct imaging screening tools, sensitivity of conventional mammography to screen for DBT, sensitivity of ultrasonography to screen for DBT, dense breast measurement, BI-RADS, general systems theory*, and *living systems theory.*

Theoretical Foundation

System theory asserts that elements within an entire system are dependent upon each other for the system to function properly (von Bertalanffy, 1968). When a subsystem within the general system cannot function or fails, this can cause the holistic system to stop its functionality (Miller, 1974; von Bertalanffy, 1968). Thus, since the failure of one system in the human body can cause the organism to fail, this theory has application to the study. The living systems theory (LST) explains the concept of the

living organism and the integration of its parts for sustainability, while general systems theory (GST) explains adaptation of networks within a complex system. These theories are relevant to this study because DBT is part of the holistic human body, and if cancer is found and treated, then the human body can achieve sustainability. Cancer researchers apply GST and LST to their work because these theories can explain that if a disease is detected early, it can be treated early and prevent systemic morbidity (Rosenfeld & Kaptanovic, 2008). Additionally, this study is guided by the theory of intelligent medical diagnosis (Jones et al., 2002). The theory of intelligent medical diagnosis is to understand the disrupted homeostasis of all aspects of a particular phenomenon and combine a variety of options for a robust solution (Jones et al., 2002; Koutsojannis & Hatzilygeroudis, 2006). The theory of intelligent medical diagnosis is relevant to the study because cancer in DBT can interrupt the normal function of the human body, and if not found in the early stages, can disrupt the normal function of the body.

The ACS promotes screening for early detection of breast cancer by advising those who are at a high risk for breast cancer to seek MRI breast screening, as conventional mammography has limitations for detecting cancer in DBT (2013). If there is early detection of the disease, early treatment options can be pursued. As suggested by the social change theories of von Bertalanffy and Miller, holistic systems are comprised of multiple subsystems that integrate to form the whole system and that the system may die if one subsystem fails (von Bertalanffy, 1968). Similarly, the human body may die if breast cancer is undetected and spreads to other organs. Additionally, Miller (1978) stated

that if a subsystem within the general systems fails, but is repaired, then the general system could continue to function.

GST application in nursing practice (Glennister, 2011) showed the importance of sub disciplines within the holistic nursing practice and its position in the community. Glennister, (2011), and stated that because nursing covers a multitude of subsystems for its functionality, a failure of one subsystem can cause the holistic system to cease to function. The application of GST is well demonstrated in system thinkers such as Henning (2011), who argued that for human beings to achieve their goals, a human network support must be available. However, if there is a failed mental health subsystem in the support network, the goal will not be achieved and the whole system will fail.

LST application to combat models for the army (Crawford & Naval Post Graduate School, 1981), articulated the need to integrate more organization into the existing framework. The author stated that the combat model is dependent on the existence and integration of all levels of personnel, peer and subsystems, for a robust combat model. Riss (2012) connected LST with migration and stated that migration occurs because of the malfunction of the status quo from which interconnectivity arises. Riss (2012) also stated that migration causes reproducibility, which can create a new living system in a different environment. Similarly, GST and LST are frameworks that helped to guide and build this study.

Dense Breast Tissue Imaging Options

The ACR (2012) reported that about 80% of women have DBT. Conventional mammography has been the sole method to screen women for breast cancer; however, this method can miss cancers are in DBT (Berg, 2009). Imaging methods such as ultrasound and MRI have proven to detect cancers in DBT, but these methods are not used for routine screening for the dense breast population (ACS, 2012; ACR, 2012; Berg, 2011).

Conventional Mammography

Although breast X-ray examinations were done prior to 1969, it was not until 1969 that that dedicated machines were developed for breast cancer screening (ACS, 2012). Seven years later, mammography became the customary method to screen for breast cancer (ACS, 2012). In addition, the Mammography Quality Standards Act (MQSA) was passed by Congress in 1992, an act that mandated that operators of mammography machines be well trained to operate the equipment, the machines regularly updated, and results of tests communicated to patients (FDA, 2012). Mammography has been the standard for breast cancer screening since 1969 (ACS, 2012). If anomalies were seen on breast screening radiographs, diagnostic mammograms were then done on concentrated areas of the breast, (ACS, 2012).

There was one major setback for diagnostic mammograms with a breast cancer diagnosis. Although the FDA required minimizing the radiation dose, an additional mammogram was sometimes necessary, increasing the dose to the patient (ACS, 2012).

Other setbacks for mammograms and diagnostic mammograms were accuracy of imaging equipment, expertise of the interpretation radiologist, and the expertise of the technologist. However, mammography was the sole imaging method for breast cancer screening despite an increased radiation dose to the patient, and any abnormal breast finding would result in a repeat mammogram (Breast Cancer.Org, 2012). The ACS reported that in 1969 when breast screening began, abnormal mammograms were not attributed to DBT, and abnormal breast tissue findings were followed by additional mammograms (2012). This practice increased the radiation load and still could not provide accurate images in DBT.

The ACS recognizes that DBT is not an abnormal finding for breast screening, especially in asymptomatic women, younger women, and older women, but there is no consensus on what other imaging examinations should be used in addition to a conventional mammogram (2012). DBT is problematic because mammography has a low sensitivity to dense tissues and can miss cancers in them (Berg, 2011). Cancers can hide and grow in DBT, and if this anomaly is not found using other imaging techniques with higher sensitivity to DBT, there is a high probability that breast cancer can be missed, remain untreated, metastasize, and spread to other parts of the body (Berg, 2011).

The ACR recommends that women should have a mammogram beginning at age 40 for breast cancer detection, but does not have recommendations for screening for DBT (2012), even though in the United States, 40% of women who had mammograms have DBT (Senatorsimitian, 2012). In the general population, 10% of women have DBT while

80% have a mixture of fatty and DBT (ACR, 2012). The Mayo Clinic (2013) reported in a recent study that 75% of breast cancers in DBT are undetected by mammographic screening. Dense breast tissues are very bright in mammograms, and abnormalities in DBT appear bright as well, which makes diagnosis difficult. Many women have DBT: those who are younger, who have low hormone levels, who have borne children, are in menopause, or who are pregnant (ACS, 2012). Although a radiologist may tell women they have DBT, often there is no recommendation for what the women should do next.

The CDC recommends screening for breast cancer in three ways: a mammogram, a clinical breast exam (CBE), and a breast self-exam (2012). However, the CDC says these screening methods must be discussed with a physician and does not recommend other imaging options. The CDC (2012) reported that each year 350,000 people will have a cancer diagnosis, and 100,000 will die from the cancer. Healthy People 2020 observed that although the target rate for breast cancer screening is 81%, breast cancer screening is only 72.4%. Women are not being screened for breast cancer at recommended rates, which makes it difficult to know about the population with DBT.

Ultrasonography for Imaging Dense Breast Tissue

When ultrasound techniques were introduced for breast imaging in 1951, it was embraced by the medical community because the technique does not use radiation for imaging. Rather it differentiates between cysts and masses for surgical invasive breast procedures (Medscape, 2012). In ultrasound imaging, a transducer sends out high frequency sound waves and listens for returning echoes that are sprung back from

internal organs such as blood vessels, fluids, and tissues. These echoes are measured by a specialized computer for a real-time image.

While ultrasound techniques evaluate obvious anomalies such as lumps, breast pain, postsurgical breast tissue, and breasts that have had an abnormal mammogram finding, ultrasonic techniques are limited for breast cancer screening. Factors such as operator expertise and quality of equipment used for using ultrasound to scan breasts for breast cancer screening are major considerations. Sabih (2013) stated that using hand-held transducers for breast cancer screening and even basic breast screening is inadequate for breast imaging. The American College of Radiology Imaging Network (ACRIN) reported that breast screening can only be accurately done if ultrasound machines are automated; since automated ultrasound machines have higher resolution that produces more accurate findings because of its inherent near-field resolution (Sabih, 2013).

In a 2013 publication by the ACRIN, Berg stated that using sonography for DBT provided results that showed small non palpable tumors in DBT that were not seen on conventional mammograms. Berg further stated the benefit of sonography use to detect anomalies in DBT was not 100% clear. Finding small non palpable tumors during mammogram might create bias in the sonography findings. A larger study provided results from data published by Kelly et al. (2010) in which 4,419 women were scanned using the automated whole breast ultrasound (AWBU). Results from this study showed that using the AWBU yielded significant cancer detection in DBT when this technique was used in conjunction with mammography, but it did not clearly define if AWBU can

be used solely for DBT screening. Berg (2008) had a similar view that ultrasound to image DBT has setbacks, including inconsistent proficiency of the operators and lack of standardized protocols.

The ACR implemented a standardized process called Breast Imaging Reporting and Data Systems (BI-RADS), a classification used as evaluation criteria (Nothacker, 2009). The BI-RADS standard process yielded occult tumors and increased the number of unnecessary biopsies. Berg (2008) stated that when ultrasound was added for dense breast screening with mammography, cancer identification increased to 1.1 to 7.2 per 1,000 high risk women, but Berg concluded that ultrasound use increases the number of false positives. The ACS (2012) recommends that high-risk women have additional imaging for breast cancer but does not recommend ultrasound for women with DBT. However, the ACS reported that in addition to conventional mammography, ultrasound techniques can produce benefits if there is a DBT finding on a screening mammogram. They concluded, however, that the quality of an ultrasound of DBT depends on the skill of the operator.

The NCI (2012) stated that ultrasound can detect breast cancer in 3.7 cases per 1,000 women who are screened after the second and third annual breast screen. However, the NCI suggested that there are a high number of false positive and false negative findings using this technique and does not recommend it be used to screen for breast cancer (NCI, 2012). The Susan G. Komen foundation reported in 2013 that physicians do not normally use breast density as a measure of whether a woman is at risk for breast

cancer but that ultrasound techniques were being studied to use with conventional mammogram.

The U.S. Food and Drug Administration approved the first ultrasound machine to image DBT in September 2012 (FDA, 2012). Because 226,870 women would be diagnosed with breast cancer in 2012, and 38,510 would die from the disease, the agency recognized the need for another imaging option for DBT (FDA, 2012). The FDA approved the first Automated Breast Ultrasound System (ABUS) to image DBT using a technique that was faster, more efficient, and surpassed the images produced by other ultrasound machines. This technique was approved for use in patients with DBT who had had negative conventional mammograms. However, the ABUS system has a specific exclusion criterion for its application: It does not include women who had prior clinical breast interventions such as surgeries, were pregnant, or were breast feeding, because these factors can alter the appearance of breast tissue (FDA, 2012). In addition, the use of the ABUS system must follow the ACS's BI-RADS categories for density and composition as shown below:

1. BI-RADS 1: The breast is almost entirely fat (<25% glandular).
2. BI-RADS 2: There are scattered fibro glandular densities (approximately 25-50% glandular).
3. BI-RADS 3: The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular).

4. BI-RADS 4: The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular. (ACR, 2012, p. 5; FDA, 2012)

In an analysis of 100,000 women with DBT, there were many false positive results, and some patients were referred for additional imaging or for unnecessary workups (FDA, 2012; Kloten et al., 2013). MRI has a high sensitivity for breast cancer detection, but it is currently used for high risk patients and not for DBT screening (Berg, 2011; van Goethem et al., 2009).

MRI Use for Dense Breast Tissue

MRI uses a "strong magnetic field, hydrogen protons in the water of the body, radio waves, surface coil, and a specialized computer to image soft tissues and organs inside the human body" (Frank, 2011, p. 330). The physics of this technique allows to clearly see inside dense breast tissue where anomalies can remain hidden and metastasize if they are cancerous and remain undetected (RSNA, 2013). This technique can also produce 3-dimensional, high resolution images which can be reformatted to any orthogonal plane where the breast anatomy and anomaly can be best visualized (RSNA, 2013). Additionally, this technique does not use ionizing radiation, which can place the patient at risk of dangerous radiation exposure if additional imaging is needed (WebMD, 2013). MRI imaging is noninvasive, but an MRI examination of the breast may be less tolerable to the patient, as it may take up to 30 minutes. Additionally, certain metal in the body automatically excludes MRI examination due to heating, torque, and potential malfunctioning of the implanted metal (Shellock, 2012).

MRI was introduced for clinical use in late 1970, but it was not until 1991 that it was approved by the FDA for breast imaging (Imaginis, 2013). In the 1980s, researchers further studied breast imaging and discovered MRI techniques could differentiate between normal and abnormal breast tissue (Hendrick, 2008). This MRI technique was a breakthrough for imaging breast cancer, and the added incentive was that the technique was noninvasive. MRI of the breast can be used to detect anomalies in unilateral or bilateral breasts, the chest wall, axillary regions and surrounding areas of the chest (ACR, 2013). In addition, MRI can evaluate questionable anomalies identified on mammograms and ultrasound exams (Radiologyinfo, 2013). The approval of MRI was embraced by the breast cancer community due to its sensitivity to breast anomalies detected in a mammographic examination. Although the use of breast imaging techniques such as mammograms and ultrasound are still recommended, renowned cancer registries such as the ACS (2012) and ACR (2013) stated that MRI excels at imaging dense breast tissue because this technique has a very high sensitivity to dense breast tissue.

MRI is also useful to image younger women that are not predisposed to breast cancer, but have dense breast tissue (Berg, 2009). This group is asymptomatic and not predisposed to breast cancer, that is, no family history of breast cancer, and therefore cancer can be undiagnosed. This group falls under the 40 year old group, which is the age that agencies and organizations such the ACS, ACR and CDC recommended that women should be screened for breast cancer (ACR, 2013; ACS, 2012; CDC 2012). Also women that are in the menopausal status and take hormone therapy medication are at risk for

dense breast tissue (ACS, 2013). Cancers in DBT for this group that can be missed by mammogram screening for breast cancer, but MRI provides very clear images of anomalies that can see inside dense breast tissues (Hendrick, 2008). In addition to breast imaging, MRI is widely used to image women with augmented breasts, surgery planning, both implants and post-surgery (Berg, 2009). However, MRI examinations also led to false positive findings (Elmore et al., 2013; Imaginis, 2013), and as a result, ACS does not recommend an MRI for breast screening, as it may lead to unnecessary invasive breast procedures. But when MRI is compared to conventional mammogram and ultrasonography for breast cancer screening, false positive findings are fewer. Therefore, the literature showed that there is a significant benefit to use MRI for breast imaging. However, breast cancer agencies and organizations do not provide guidelines that MRI can be used to screen asymptomatic women with DBT.

Scholarly Literature

In a 2012 report, the ACR recommended and applauded the use of conventional mammography for breast cancer screening and suggested that women who are predisposed to breast cancer because they carried the BRCA gene or whose close relatives have a breast cancer history should seek supplemental breast imaging (ACR, 2012; ITN, 2013). However, the ACR did not provide recommendations for screening of DBT and offered the same recommendation in 2013. The ACR (2012) stated that although MRI can detect cancers in dense tissue that cannot be seen on a mammogram, some of these findings are not cancers which can result in unnecessary biopsies. Yet, the

ACR (2012) suggested that if breast cancer is detected early, treatment can be done at the early stages after cancer detection, but the ACR does not provide recommendation for asymptomatic women with DBT.

Likewise, the CDC has not provided a recommendation that a diagnostic imaging technique should be used to screen women with DBT (CDC, 2011). What the CDC recommended is that DBT can be screened using scintimammography (2011), an imaging technique where a radioactive tracer is injected intravenously and images of the breast taken to show if the tracer attaches itself to the cancer cells in the breast tissue (ACS, 2013). This technique is used to image DBT for high risk patients, but it is not recommended for screening the dense breast population (CDC, 2011). Like the ACR and ACS, the CDC does not recommend a screening method for DBT. Although the ACR, the ACS, and the CDC are advocates for early breast cancer screening that can lead to early treatment of the disease, they do not recommend imaging protocols for DBT.

The ACS recommended that women 40 years and older should have a screening mammogram every year, and women between 20 – 30 years of age should a clinical breast exam every three years (ACS, 2014). In addition, the ACS recommended against using MRI as a screening tool to screen women for breast cancer whose lifetime risk of breast cancer is less than 15% (ACS, 2014).

Similarly, the NCI reported that other imaging technologies are being developed to detect tumors, but did not have recommendations for imaging DBT for screening (NCI, 2012). The NCI stated that a patient with a high mammographic breast density,

which is a marker to develop breast cancer, does not indicate increase mortality rates for breast cancer. The NCI stated that more research is needed to recommend MRI as a screening tool for asymptomatic women with DBT (NCI, 2012).

The FDA has recommended diagnostic imaging options including ultrasonography, scintimammography, thermography, and digital breast tomosynthesis, but the FDA has not recommended a screening tool for DBT (NCI, 2011, p. 22). Although the FDA a regulatory amendment that women in all states should be informed if there is a DBT finding, they do not provide a recommendation for additional screening for asymptomatic women with DBT (FDA, 2013).

Some state government officials have declared that physicians must inform their patients if they find DBT during a screening mammogram. Senator Joe Simitian of California, Senator Jeremy Ring of Florida, Governor Rick Perry of Texas, and government officials from Alabama, California, Connecticut, Hawaii, Indiana, Maryland, New York, North Carolina, Nevada, Oregon, Tennessee, Texas and Virginia have advocated that physicians must inform their patients if there is a dense breast finding (ACR, 2013; Simitian, 2012; Florida Senator, 2013; Henda's Law, 2012; Diagnostic Imaging, 2012). In states such as Utah, Maine, and Illinois, it is optional for physicians to inform their patients if they find DBT during a screening mammogram (ACR, 2013). Massachusetts, Michigan, New Jersey, Michigan, New Jersey, Ohio and Pennsylvania are states that have pending legislation to inform patients if there was a DBT finding during a screening mammogram (ACR, 2013).

In a 2012 article, the NCI reported that 2,800 women with DBT were screened for breast cancer. Data obtained from 612 women showed an increase in cancer detection using ultrasonography, but this finding led to breast biopsies that yielded a small number of positive breast cancer findings (NCI, 2012). The same group of 2800 women with DBT was screened using MRI. Although MRI yielded a higher number of positive breast cancer cases more than mammography and ultrasonography, the NCI stated that breast density does not influence breast cancer mortality (NCI, 2013).

The Cochrane Collaboration provides health information to evaluate the possibility of a risk or advantages of a specific condition. The Cochrane Database of Systemic Reviews reported that screening mammograms can lead to 30% over diagnosis and overtreatment, and it remains unclear if screening mammograms benefit or harm women (Cochrane Summaries, 2011). The Cochrane Collaboration has also not issued recommendations for DBT screening. The United States Preventive Services Task Force (USPSTF), an independent organization that studies and recommends screening practices to health systems, suggested that women should be screened for breast cancer biannually from ages 50 to 74 years of age but not routinely screened from 40 to 49 because there is not enough research data to warrant the need for screening (2009). Further, the USPSTF suggested that it should be the choice of women to decide when routine screening for breast cancer should begin, but the organization has not made recommendations for DBT screening.

The following states have laws that require physicians to inform patients of DBT findings: Alabama, California, Connecticut, Hawaii, Indiana, Maryland, New York, North Carolina, Nevada, Oregon, Tennessee, Texas and Virginia. However, they but do not mandate a referral for this population for additional imaging, such as an MRI or ultrasound, only that other imaging options be available (ACR, 2013; Brower, 2013). Other imaging options are available for women at high risk for breast cancer, but not for asymptomatic, women with DBT (Wood et al., 2013).

Gap in the Literature

Further breast cancer screening for DBT stops after there is a DBT finding, according to the Susan G. Komen Foundation (2013). A strong advocate for breast cancer prevention and treatment, Komen states that there is not an imaging method to screen the dense breast population and that physicians do not normally use breast density numbers to make a breast cancer diagnosis. However, since 2009, the Breast Density Inform law in the United States has required that physicians inform women of their breast density numbers. Subsequently, 11 states require physicians to inform women of their breast densities (Pushkin, 2013). Although this is a positive step for women with DBT, there is not a follow-up after the finding. The ACR, ACS, and the NCI have also reported the need for an adjunct imaging method to complement conventional mammography for DBT, but MRI is used only for women in the high-risk population, those with a history of breast cancer, a strong family history of breast cancer, atypical hyperplasia, and DBT (Saslow et al., 2009).

MRI and Sonogram for Dense Breast Tissue Imaging

Ultrasound methods can detect 30% more cancer than mammograms (AuntMinnie, 2010) and is useful for identifying breast anomalies such as protuberance, swelling, nipple discharge, fluid-filled cysts, and for differentiating between solid and fluid-filled masses (RSNA, 2013). Ultrasound imaging for DBT can be used with conventional mammograms as an adjunct for breast screening, but both ultrasound imaging and conventional imaging can miss 22% of cancers in DBT, but MRI has shown a high sensitivity to image DBT (Radiologyinformation.org, 2013). Currently, MRI is not used for breast cancer screening except for high-risk cases, although it has yielded more breast cancer findings.

Literature Related to Research Methods

A mixed methods design was used for this investigation of whether there is a need for an additional method to image women with DBT. The quantitative approach was also used to test the hypothesis, using statistics from the CDC, ACR, and ACS. Secondary data was collected from those cancer registries to determine whether a method is needed as an adjunct to conventional mammography. This quantitative data was analyzed to inform the qualitative phase of the study (Creswell, 2009).

The second phase was a qualitative approach that builds upon the first. Descriptive statistics were collected from answers women give about the methods used to image their DBT (Simon & Goes, 2013). Answers provided richer data about the accuracy of the method used for screening mammograms.

Summary

In this chapter, I presented a review of literature published within the past 5 years that asserts that conventional mammography can miss cancer in DBT because this imaging method has a low sensitivity to DBT. Ultrasonography to image DBT was also reviewed as was the sensitivity of MRI for breast cancer screening. The purpose of the literature review was to highlight the sensitivity of ultrasonography and MRI techniques as screening methods for DBT.

Chapter 3 describes the method I followed to collect secondary data from cancer registries such as the CDC, ACS, ACR, and NCI to support whether an adjunct imaging tool is needed in conjunction with conventional mammography to image DBT. In addition, it describes how I collected qualitative data from a small group of women in San Jose, California, who responded to survey about their experiences with breast screening options used for their mammograms.

Chapter 3: Research Method

Introduction

The purpose of this study was to determine to what extent conventional mammograms can miss breast cancer in women with DBT and to determine if an adjunct method of imaging DBT might detect breast cancers missed by mammography alone.

Although the ACS, ACR, and CDC advocate early detection and treatment of breast cancer, they do not mandate imaging options for breast cancer screening for women with DBT by. (ACR, 2013; ACS, 2012; CDC, 2013). Because conventional mammograms detect less than half of cancers in DBT, many breast cancers are missed (Are You Dense? 2013). As a result, there was a need to determine if there is an additional method for screening women in the DBT population.

Most of the literature in Chapter 2 concluded that mammography should still be used, but that an adjunct method with a high sensitivity to detect cancer in glandular tissue is needed (Berg, 2009; Susan G. Komen, 2012; Zonderland et al., 2013). For those reasons, I explored whether there was a need for ultrasonography and MRI—two standard alternatives--following a determination of DBT (Creswell, 2012). A mixed-methods design was determined to be best suited for this study because they provide complementary approaches to learning more about a topic that has both physical and emotional aspects. Greene, Caracelli, and Graham (1989) asserted that research is enriched using mixed methods (as cited in Simon & Goes, 2013).

Before I collected any data, I submitted a proposal to the Walden University Institutional Review Board for approval and was given Approval No. 10-07-14-0078441. The first results are from the quantitative strand, which tested whether an adjunct method of screening is needed for the 40% of women with DBT. In the second strand, responses from women with DBT (which included the imaging methods used for their breast cancer diagnosis), illustrated the qualitative or personal effects of their experiences. Creswell (2009) emphasized that using both quantitative and qualitative strands of inquiry can provide broader insight into a question. Campbell and Fiske (1959), Jick (1959), and Plano Clark (2007) also supported the use of the mixed methods design and noted that this approach allows for integration of data, which can produce stronger results.

Quantitative data are important in a mixed-methods explanatory design because the data can explain a phenomenon using objective data and analysis. Quantitative analysis began with a random, yet systematic sampling of secondary data about breast cancer from the following cancer registry databases: ACR, ACS, CDC, the California Department of Public Health (CDPH), and the NCI. From that information, I selected every 20^{th} person until I had 500 names using G*Power, a power analysis tool used to calculate the appropriate number of participants (Faul, Erdfelder, Lang, & Buchner, 2007). The process also followed recommendations by Creswell and Plano (2011) and Rudestam and Newton (2007).

An introductory e-mail was sent to the selected sample to explain the rationale for the study and request their responses. I secured permission from each person, obtained an

electronically signed consent from those willing to participate, explained online access, and told them the closing date for participation (Creswell & Plano, 2011; Rudestam & Newton, 2007). Systematic random sampling can eliminate bias by ensuring everyone in the sample population has an equal opportunity to participate and to ensure the results of the survey are representative of the population (Creswell & Plano, 2011; Teddlie & Tashakkori, 2009). Data collected were synthesized, analyzed, and tested by inferential data analysis using ANOVA (Hoare & Hoe, 2013; Norkett, 2013). Results from the quantitative strand led to the qualitative strand.

The qualitative strand was guided by the phenomenological inquiry approach of Moustakas (1994), who stated that the goal of phenomenological inquiry is to bring to light the lived experiences of persons who have experienced a phenomenon. This investigation highlights the lived experiences of women with DBT and the time it took to determine if cancer was present when conventional mammography and MRI were used. Based on phenomenological philosophers such as Husserl, Kierkegaard, Heidegger, and Sartre, I chose a phenomenological approach because the inductive method can gather data through interviews to explain lived experiences of participants (Simon & Goes, 2013). These data bring a deeper explanation of a phenomenon because it comes from women who have experienced it (Moustakas, 1994).

Although the qualitative method could have been the sole research method, I also used quantitative data to add objectivity (Creswell & Plano, 2011; Teddlie & Tashakkori, 2009). Additionally, intertwining the strands can create a more robust study because

together they contribute different avenues of information to the investigation (Rudestam & Newton, 2007). The qualitative strand can provide richer data to build upon the quantitative strand to help the researcher understand and put findings from the quantitative strand into perspective (Creswell & Plano, 2011; Rudestam & Newton, 2007; Teddlie & Tashakkori, 2009). Qualitative data include the subjective responses of participants that provided their lived experiences (Houghton, Casey, Shaw, & Murphy, 2013). Frels and Onwuegbuzie (2013) suggested that the researcher has more flexibility in the qualitative approach because of the natural environment where data are collected, the explicit process, and the open-ended nature of questions for data collection. In addition, responses to open-ended questions can yield detailed responses that may lead to a deeper understanding of the premise of the research (Frels & Onwuegbuzie, 2013).

Chapter 3 describes the research design as suggested by Creswell (2009), Plano Clark (2007), and Campbell and Fiske (1959) and includes the research design, the role of the researcher, the methodology, description of the research instruments to include validity and reliability, the data analysis plan, and ethical procedures.

Research Setting

The time and place (some natural setting) for the qualitative strand were controlled by the participants. I was sensitive to the wishes of the participants and wanted them to feel at ease (Simon & Goes, 2012). The aim of the survey was to learn the feeling of the population through open-ended questions that gave them time to reflect, think about the questions, and provide answers that were as brief or detailed as they chose.

Data were collected through telephone interviews, and conversations were recorded with participants' permission. The recordings provided repeated listening time for organization, identification of themes, coding, and analysis (Creswell, 2007).

Research Design and Rationale

Research Questions

Research Question 1 (quantitative): Should MRI be used for screening women with DBT as an adjunct to conventional mammography?

H_0: MRI technique for screening women with DBT should be used as an adjunct to conventional mammography.

H_1: MRI technique for screening women with DBT should not be used as an adjunct to conventional mammography.

Research Question 2 (qualitative): What were the lived experiences of women with breast cancer in DBT prior to and after the breast cancer diagnosis?

Sub Question 1: What were the circumstances that prompted the need to screen for breast cancer?

Sub Question 2: How were the lives of women with a DBT cancer diagnosis impacted from the initial breast cancer screening to the final breast cancer diagnosis?

Sub Question 3: How does DBT with a cancer diagnosis affect the lives of women with the disease?

Sub Question 4: How can the addition of an adjunct imaging method such as MRI to the existing method help to bring a deeper understanding of the need for efficient screening methods and a definite diagnosis of cancer in DBT?

The independent variable was using MRI imaging techniques to screen women with DBT. The dependent variable was breast cancer detection for women with DBT.

Mixed Methods

The research design was a mixed methods explanatory approach (Creswell & Plano Clark, 2008). The quantitative strand was conducted first, and the qualitative strand was used to build upon the results of the quantitative strand. Mixed methods research is employed when the results of either a single quantitative and qualitative study does not provide a complete understanding of the research problem (NIH, 2013). I employed the quantitative approach to test the hypothesis with statistical analysis and the qualitative method to reveal data that reflect real life experiences of participants (NIH, 2013). Boeije, Slagt, and van Wesel (2013) employed mixed methods to study childhood trauma and found that the integration of the quantitative and qualitative strands provided additional knowledge about their research topic. Boeije et al. (2013) also found that using mixed methods allowed them to draw conclusions and make recommendations for improvement of the quality of life for their subjects. Heyvaert, Hannes, Maes, and Onghena, (2013) also supported the use of the mixed methods design and reported that it is useful in health and health-related subjects and can answer research questions in these fields. Pluye, Gagnon, Griffiths, and Johnson-Lafleur (2009), reported that a stringent

review that analyzed the mixed methods approach revealed "convenience, reproducible, and systematic" qualities (p. 532).

For the quantitative phase, I collected data using systematic random sampling to fulfill the equal likelihood chance of selection and randomness for the target population (Banerjee & Allen, 2010). The random sample was selected from a potential population of 10,000 women, ages 24–74, who had a consecutive mammogram within the past 2 years, and selection was every 20^{th} person in that population until the number selected for the sample was reached (Simon & Goes, 2012). The geometry of data collection can generate sufficient power so that results can be applied to the general population. Gay and Suskie (as cited in Simon & Goes, 2012) suggested that if a 250 effect-size sample is used for a study, results should be applicable to the general population of similar subjects.

The qualitative phase was purposeful sampling (Moustakas, 1994) because this strategy can yield a typical population (Creswell, 2007, p. 125; Moustakas, 1994). The phenomenological approach illuminates the research statement because experiences from participants can provide a better understanding of a topic through rich data collected during interviews. Twenty participants were selected for this portion of the study. According to Creswell (2007), a smaller sample allows a researcher to spend more time with each participant and potentially glean richer information. Participant data were collected from a full service breast imaging center in a specific demographic region of San Jose, California. Because of the California law requiring that women with a dense

breast finding on a mammogram must be reported to the California Department of Public Health (CDPH), data for this group were available and accessible.

I sent a letter of introduction with information about the study and its purpose and goal to potential participants. The letter included my contact information, asked if they wanted to participate, and asked them to call me if they wanted to be part of the study. One week after they responded in the affirmative, I called to confirm their acceptance and answer any questions they had. The process continued with informed consent material and ethical information. Upon receipt of the signed informed consent, I called again to determine the best time for a telephone interview. To eliminate bias, I called those who did not respond to confirm that they were not interested in participating, and added their responses to the total number of participants. With the permission of the interviewee, I recorded their answers, transcribed and coded them to protect identities, and stored the information for analysis using NVivo. Constructs that were used to measure qualitative data encompass "credibility, transferability, dependability, and conformability" (Rudestam & Newton, 2007, p. 112). This process should ensure the study can be considered believable and fulfills the requirements that data can be transferred for quality, trustworthiness, replication, and objectivity for a replicated study (Lincoln & Guba, 1985; Rudestam & Newton, 2007).

Results from both strands were combined to connect both datasets; the qualitative approach builds upon the quantitative phase and was used to support the results of the quantitative strand. Both phases were embedded to form a comprehensive representation

of the research problem (Boeije et al., 2013; Creswell, 2006; Franz et al., 2013; Heyvaert et al., 2013). The goal is to produce robust results that might not be attained using only one method.

Role of the Researcher

Creswell (1998) said a researcher must be aware of the basic fundamentals of the selected method of inquiry and must have a clear understanding of the research processes. For this study, I used quantitative data from cancer databases of the ACR, ACS, CDC, and the NCI for a specific area of California between 2010 and 2012. For the qualitative inquiry, I designed the questionnaire, pilot tested it, administered it, and then collected and analyzed resulting data (Creswell, 1998; Simon & Goes, 2013). For a robust experiment and outcome, the researcher must disclose biases, suppositions, and perspectives (Creswell, 1998; Simon & Goes, 2013). To assure my objectivity, I put aside personal biases during the interviews, did not lead participants to respond in a particular way, and kept a journal for personal reflections (Simon & Goes, 2013).

Methodology

Selection of Participants for Quantitative Data

Records of 10,000 women ages 24 to 74 were taken from the 2010-2012 databases of the ACR, ACS, CDC, CDPH, and NCI to identify those who had a diagnosis of DBT. From that group, every 20^{th} name was selected to participate, yielding a potential *N* of 500 (Trochim, 2001). The confidence level was expected to be 95% with a margin of error of 5% (Simon & Goes, 2013). A *t* test was used to measure two independent

samples of conventional mammography and MRI imaging methods (Simon & Goes, 2013). A broad age selection follows what breast cancer foundations and registries report and should reflect accurate application to both older and younger women. Younger women inherently have DBT, and most postmenopausal women who are not using hormone replacement therapy also have DBT (Berg, 2009). The systematic random sample means each woman with a dense breast finding has the same chance of being selected (Creswell, 2007). Power analysis was used to calculate an adequate sample size for a statistical test (Rudestam & Newton, 2007). If a sample size is too small, the investigation will not have enough power to answer the research question adequately. If a sample is too large, it can create inaccuracies by highlighting insignificant variables, making the goodness-of-fit test too sensitive and leading to the determination that 500 participants would be required (Rudestam & Newton, 2007; Simon & Goes, 2012). The quantitative survey (See Appendix B) consisted of 11 questions with a Likert rating scale of five choices. The survey is comprised of the following questions.

1. Is your age between 24 and 74 years?
2. Are you in good health?
3. Do you have a family history of breast cancer?
4. Have you lost a family member to breast cancer who had regular mammography screenings?
5. Do you regularly perform a breast self-exam?
6. Do you have an annual screening mammogram?

7. Have you had screening mammograms every year for the last 5 years?
8. Have you had an abnormal mammogram finding?
9. Did your doctor tell you that the result of your mammogram was not conclusive?
10. Is this the only available way you know of to screen for breast cancer?
11. Do you know women who had normal mammograms during their years of screening and have had a subsequent breast cancer diagnosis?

Qualitative Selection

Participant selection for interviews followed the guidelines for purposeful sampling (Creswell, 2007). Because this investigation follows the guidelines of phenomenology theory, a sample size of 20 participants was selected from the database of the California Department of Public Health (CDPH), from 2010 to 2012 using a full-service breast-imaging center in San Jose. California physicians are required to report dense breast findings, and as such, information for this region is accessible for research. General information for contacting participants is also available for research purposes. I secured permission to have access to the study population.

Qualitative recruitment began with an introductory letter e-mailed to 20 potential participants. The letter explained the study, who I am, and my contact information. Those who agreed to participate were sent an informed consent form that included a stamped, self-addressed envelope for returning the signed form. The informed consent explained the purpose of the study, what the findings will be used for, how information will be

collected, and the duration of the interviews. It also explain that there is no compensation for participation, that participation is voluntary, and that no personal information will be shared in any subsequent presentation of the results of the study. It also encouraged participation by telling participants the results might help other women who have had experiences similar to theirs. An informed consent document is shown at Appendix D. The respondents and researcher arranged the time for the interviews via e-mail. The semi-structured interview will follow a script (Appendix C) and consist of open-ended questions as follows:

1. Are you in the age group 24 to 74 years?
2. Do you perform routine breast self-exams?
3. Do you have a family history of breast cancer?
4. Do you have an annual mammogram?
5. Do you have DBT based on a mammogram?
6. Were you told by her doctor that you needed a repeat mammogram?
7. Have you had an ultrasound as a breast cancer screening? What was the finding?
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding?
9. Describe your emotions before your doctor diagnosed your breast cancer.
10. Do you believe your breast cancer could have been detected earlier if MRI was used after your initial cancer diagnosed accusing mammograms?

To eliminate bias, I sent a follow up e-mail to nonrespondents and added the numbers to the total number of participants.

Quantitative Instrumentation

Instrumentation followed the guidelines of the mixed methods explanatory research design, where quantitative data collection is followed by qualitative data. For the quantitative phase, the survey instrument collected data from women with DBT who had a mammogram between 2010 and 2012 from databases of the ACR, ACS, CDC, CDPH, and NCI. SurveyMonkey was used to send surveys and collect responses to record each answer (Simon & Goes, 2012). SurveyMonkey is a fee-for-service program that enables a researcher to design an instrument for a targeted group and direct responses to a secure online site for retrieval. SurveyMonkey was appropriate for the quantitative strand of this experiment because it generates closed-end questions and collects responses for large populations in a short time (Simon & Goes, 2012). SurveyMonkey was downloaded to SPSS for analysis. Quantitative design studies in the nursing discipline (Hardy, 2011), social media (Roe, 2013), and social research (Stein, 2011) that used SurveyMonkey for data collection and analysis demonstrated the validity and reliability of the instrument.

Validity and Reliability of the Quantitative Instrument

If an instrument executes what it is intended to evaluate, then it is considered valid (Creswell, 2007). The face and content validity for the survey instrument were be tested for strengths and weaknesses. Content validity was corroborated by the cover letter and the survey content and was pilot tested before it was sent to participants. Glicken

(2003) suggested that the sample size chosen for the experiment must represent the target population. As noted before, G*Power, a computer software tool, was used to calculate the sample size for the quantitative portion of the study.

Reliability of the survey instrument was measured for its reproducibility, stability, and consistency (Creswell, 2007). Test and retest were also used to measure reliability. with the determination that if same assessment were given to the same group, and the same procedures were replicated, then the results should be consistent, making the tool reliable (Creswell, 2007). SPSS was used to test the reliability of the Likert-type scale questions using Cronbach's alpha (Frankfort-Nachmias & Nachmias, 2007; Simon & Goes, 2013).

Qualitative Instrument

Qualitative data came from open-ended interviews (Patton, 2002, p. 4). Patton (2002) suggested that interviews provide responses that can lead to a better understanding of a research question. The interviews were guided by a short-answer questionnaire I conducted. The conversations with participants were recorded for later review. Creswell (2007) suggested that open-ended questions allow a researcher to control the questioning and prompt participants for more details (Creswell, 2007, p.179). I encouraged participants to speak freely about their experiences with the disease during the 30-minute interviews.

The questions I used were guided by a focus on the following:

1. What is the goal of the interview?

2. What am I attempting to find out?
3. Why is the information needed?
4. Are the questions reasonable?
5. How will the results help to identify additional breast cancer screening methods for women with DBT?

Validity and Reliability of the Qualitative Instrument

Credibility, conformability, consistency, and applicability are criteria used to test a qualitative instrument (Lincoln & Guba, 1985; Rudestam & Newton, 2007). The premise of qualitative research is to explain the phenomenon and to create a better understanding of the topic. Lincoln and Guba (1985) argued that an instrument must be believable. It must capture data in the correct setting, where correct procedures are followed for data collection, and the researcher must have participant consent for that data collection (1985). Credibility of the instrument can also lead to greater generalizability of the results (Johnson, 1997; Stenbacka, 2001).

The third test an instrument must undergo is conformability: A plan must be evident in the research report, and member checking of the answers must be done to eliminate researcher bias (Lincoln & Guba, 1985). If the researcher is biased, the bias may influence the data collection procedure and subsequent analysis, and the study may not be fundamentally solid. The fourth criterion is consistency. Campbell (1996) suggested that the consistency of the instrument can be validated by the assessment of source data and progression notes. This process was done by checking for missing data

sets, repeating questions for consistency, and clarifying answers with participants for transparency.

Procedures for the Pilot Study

Before any contact was made with participants, I had permission from the IRB at Walden University, IRB Approval # 10-07-14-0078441, to pilot test the questions before they were asked of participants. The purpose of this was to find and correct errors in content or wording, based on responses from the pilot study group (De Kok et al., 2010). Results were discussed with an experienced principal investigator to ascertain if responses given by the participants fit the criteria of credibility, conformability, consistency, and applicability that Lincoln and Guba (1985) proposed.

The purpose of a pilot study is to test the achievability of the full scale study, determine the possibility of its success, and highlight barriers that may affect the progress and completion of the study (De Kok et al., 2010; Given, 2008). The pilot study questionnaire consisted of the following questions:

1. What age group are you?
2. What prompted you to get breast imaging?
3. Were you told that you have DBT?
4. What was your breast density measurement?
5. What kind of breast imaging did you have? Ultrasound or MRI?
6. Which one was first?
7. What did the uultrasound find? What did the MRI find?

8. How long did you wait before you were given a diagnosis?
9. Did you receive treatment?
10. What is your prognosis?

Based on responses to the pilot study, I determined the questions elicited the information I was seeking (De Kok et al., 2010). I then evaluated the answers and changed questions as necessary (Lincoln & Guba, 1985). To further authenticate the study, I requested a panel of three experts in the field of breast imaging and breast cancer research to provide expertise in their breast cancer imaging methods and imaging methods for DBT.

Panel of Experts

The expert panel for the pilot study was comprised of one breast cancer clinical physician, one radiologist who interprets breast cancer imaging examinations, and one PhD breast cancer researcher, as they know disease diagnosis, interpretation of imaging for breast cancer, and the research about the disease. I sent an introductory e-mail to each to achieve

1. An introduction to the researcher
2. The purpose of the pilot study.
3. An explanation of how their participation will help the study.
4. Determination of their interest in participating

Based on their responses, I called to confirm their interest and told them the deadline for completion and feedback for the questionnaire, that I would communicate

with them by e-mail, and that I would amend the qquestionnaire as needed based on their responses. The questionnaire for the expert panel is included at Appendix F.

Data Analysis Plan

Quantitative

The null and alternative hypotheses below were considered in the data analysis plan.

H_0: MRI technique for screening women with DBT should be used as an adjunct to conventional mammography.

H_1: MRI technique for screening women with DBT should not be used as an adjunct to conventional mammography.

Statistical Package for the Social Sciences (SPSS) was used for the data analysis for the quantitative strand. Data collected from the surveys reflected both respondents and nonrespondents will be added to the computation to eliminate bias, as referenced by Creswell (2009). Creswell suggested that the inclusion of nonrespondents could potentially address and eliminate bias in the study and could show whether the research findings might change the study.

The initial step in the data analysis process followed processes described by Trochim (2001), Creswell (2009), and Simon and Goes (2013). Data analysis followed the steps of data entry, data organization, data screening, and data cleaning. After I collected data, I organized and prepared it in a logical form using an Excel spreadsheet then screened and cleaned it by a visual check and comparison with the raw data I had

collected (Trochim, 2001). I further evaluated the information by a visual check of the printed data and used a text editor to check for inaccuracies and errors (Jarausch & Hardy, 1991, p. 53). Additionally, I cleaned data by checking for duplicate records, missing data sets, and inconsistencies. Any errors were corrected and reentered into SSPS (Jarausch & Hardy, 1991).

Data screening was used to check for data accuracy by use of histograms and charts. I also performed a visual check for admissible and impossible values in the datasets, a process that helped to locate and edit incorrect data (Jarausch & Hardy, 1991, pp. 40-41; Simon & Goes, 2012, p. 185). Interval data was the level of measurement because these kinds of data have an order that follows the Likert scale (Creswell, 2009; Simon & Goes, 2013). The sequence of quantitative data analysis for the study followed with the selection of the statistical test.

The two-tailed *t* test was then used to test the hypothesis that MRI or ultrasound should be used to screen for breast cancer in the dense breast population (Field, 2009). A two-tailed test was used because the hypothesis is nondirectional, meaning that the claim neither supports nor rejects the hypothesis (Field, 2009). Hypothesis testing was done with the use of the probability or *p* value method, a statistical test to show the power of what is being tested (Simon & Goes, 2013). If the *p* value has a value that is less than 0.01, there is a possibility that the null hypothesis will be rejected (Simon & Goes, 2013). Hypothesis testing for this study was done to accept or reject the null hypothesis (Field, 2009). I then organized the data for presentation in table format.

Qualitative

The initial step in data analysis is data review. For this process, I applied data reduction, where large amounts of data collected from the interviews were organized and prepared for analysis (Creswell, 2009). I then reviewed and examined the information to understand meanings and reveal concepts about what participants said about their experiences. I also followed the inductive process of axial coding. Creswell (2009), Trochin (2001), and Rudestam and Newton (2007) recommend axial coding as part of data analysis because the process can find commonalities. In addition, I used preset codes to find common words and phrases and looked for emergent codes that arose from the data. Axial coding, preset codes, and emergent codes identified specific words and phrases from the interviews. Although Creswell (2009) recommends that the emergent code method is commonly used for social science studies, preset codes for this mixed methods investigation illuminated the importance of the topic. At this juncture, Creswell (2009) also recommended that the researcher should review the coded data again for a holistic view of the research phenomenon, recheck the raw data collected from the interviews, and recheck codes assigned to data already reviewed, an additional step that aids a qualitative researcher to check for missed codes and perhaps add new codes to the data. The data were then checked for similarities, differences, patterns, and relationships by an Excel matrix to provide a holistic view of the phenomena (Miles & Huberman, 1994). Coded data were downloaded to NVivo for final analysis (Creswell, 2009). At this point, I review the findings, interpreted how the findings of the investigation supported or

did not help to support the research question, and drew implications from the findings to be represented in a narrative format (Krathwohl, 1988; Miles & Huberman, 1994). Creswell (2009) recommended that a researcher can present the findings of a qualitative study in narrative format and add tables, figures, and visuals as adjuncts to illustrate the findings.

Mixing the Qualitative and Qualitative Approaches

Integration of the quantitative and qualitative strands in social research is daunting, according to Creswell (2009). Among several mixed methods supporters, Creswell (2009), Creswell and Plano Clark (2007), and Mackay (2004) suggested that matrices such as timing, weighing, mixing, and theorizing (Creswell, 2009, p. 207) are essential criteria researchers can follow in a mixed methods approach. The sequential explanatory approach was used for this study because the quantitative approach alone was not adequate to answer the research question. Therefore, I also employed the qualitative to illuminate the findings of the quantitative findings. In addition, I used triangulation to strengthen the sequential explanatory approach of the investigation.

Threats to Validity

Validity is a measure that accurately represents the true premise and the soundness of the study (Hammersley, 1988). For a study to be valid, the researcher follows the appropriate steps to achieve validity. However, there are threats that can affect that validity (Creswell, 2009). The researcher must identify these threats and offer potential solutions to enhance the credibility and feasibility of the study. External validity

is a determination of how the precision of information and conclusions drawn from a study can be generalized to the population. If the study does not meet these criteria, then the study may be invalid (Seliger & Shohamy, 1989). Internal validity measures the accuracy of the data collected and conclusions gathered that represent the phenomena being studied. Internal validity also tests parameters within the design of the study itself for inconsistencies (Seliger & Shohamy, 1989).

External Validity

Trochim (2001) suggested that external validity is a measure of how accurate the data and the conclusion of the study are and whether they are generalizable to the population being studied. One threat to external validity can be small sample size (p. 42). For the quantitative strand of this study, I used random sampling so that each potential participant had the same chance of being selected (Creswell, 2009; Trochim 2001). A second threat to external validity could be lack of replicability or transferability. The researcher must be aware of the clarity and simplification of steps and must note them clearly for replicability (Creswell, 2009). The data collection instrument must do as it purports to do, or there may be an external threat to the validity of the study (Creswell, 2009). External validity in qualitative research is the transferability of the findings to analogous groups (Lincoln & Guba, 1986).

Construct Validity

A major threat to external validity could be construct validity, an assessment of how efficiently the tools used in the research measure what the researcher wants to

measure (Trochim, 2001). For this study, I used SurveyMonkey to collect quantitative data, semi-structured open-ended questions to collect qualitative data, and a panel of experts on the phenomenon being studied to triangulate the data. Wainer and Braun (1988) stated that there must be a detailed step-by-step process for a study. If the procedures are disorganized, a study can lose its credibility. Although Creswell and Miller (2000) suggested that external validity does not affect qualitative research, the researcher must be mindful of the sample size for the qualitative strand of the study. Data must be collected until there is a saturation point and a model arises. This maneuver will add to the credibility of the study and can show whether the researcher was scrupulous in data collection and analysis.

Internal Validity

Threats to internal validity include lack of credibility, transferability, dependability, or conformability. (Denzin & Lincoln, 1998; Guba & Lincoln, 1989; Hammersley, 1987; Mishler, 1990; Wolcott, 1990). I conducted external audit checks and triangulation to minimize threats to the study (Simon & Goes, 2013, p. 81). I also tested questionnaires for reliability by member checking (Simon & Goes, 2013, p. 81). I also used semi-structured, open-ended questions to collected data from participants; this tool was reviewed by experts for construct and face validity (Creswell, 2009) and whether they supported the phenomena I wanted to investigate.

Trustworthiness

I added to the credibility of the study by collecting rich data from participants who have lived with DBT, have been screened by traditional mammography, and may or may not have been screened by an alternate method. Trustworthiness was measured by transferability, in that the procedure could be shifted to another circumstance. I kept detailed records during the study and followed stringent guidelines for data collection and analysis processes.

Accuracy of transcriptions was determined by member checking to assure that I recorded my questions and participants' responses accurately. I sent transcripts of the interviews for participant review and corrected or changed their responses at their request. NVivo codes generated from themes in the data were recorded and applied consistently.

Ethical Procedures

Researchers must follow ethical guidelines for the entirety of the research process. I followed the guidelines of the Walden University IRB and collected data after I received approval to conduct the study. There was no physical harm or risk to participants in this study, and each gave signed consent and acknowledged that their participation was entirely voluntary. Participants were told they could withdraw from the study at any time. I identified participants by number only, and no personal information is linked to the study. All personal data was considered confidential and secured in a locked, fire-proof filing cabinet (Sieber, 1998). Data analysis results will be kept on a

password-protected computer that only I have access to. After 5 years, all data will be destroyed.

Summary

This chapter presented the methods used to determine from women with DBT what their experience has been with traditional mammography. The purpose of the study was to determine whether the health of women with DBT who are not part of the high-risk population is endangered because there is no alternative screening method used as an adjunct to traditional mammography.

Chapter 4 is a presentation of the results of the study and further observations.

Chapter 4: Results

Introduction

The purpose of this mixed methods study was to investigate to what extent mammograms can miss cancer in women with DBT and to find out if an adjunct method of imaging DBT might detect breast cancers that are missed by mammography alone. This chapter was organized to incorporate the research questions to determine which diagnostic technique other than conventional mammography was most effective to detect cancer in DBT. The two research questions were as follows:

Research Question 1: Should MRI be used for screening women with DBT as an adjunct to conventional mammography?

Research Question 2: What are the lived experiences of women with breast cancer in DBT prior to and after the breast cancer diagnosis?

A randomized survey research design was used to administer and collect quantitative data. A two-tailed *t* test was used to test H_0 using an Excel spreadsheet to organize, manage, and track data. The Statistical Package for the Social Sciences (SPSS), version 21, was used to analyze data collected. The second phase of the study utilized the phenomenological approach. The purpose of this qualitative strand was to learn, collect, and analyze lived experiences from participants between the ages of 24 and 74 years about dense breast imaging and explore which diagnostic imaging techniques were used to screen for breast cancer.

This chapter includes the setting of the study, a brief discussion of the expert panel, why the expert panel was used, participant demographics, data collection, and data analysis. As noted in Chapter 3, the mixed methods explanatory design was employed where data collection and analysis for the quantitative strand of the study was conducted in the first phase (Campbell & Fiske, 1959; Jick, 1959; Creswell, 2009, & Plano Clark, 2007). The results of the study conclude the chapter.

Expert Panel

Experts on breast cancer research and diagnosis were used in this study to check content validity of the research questions that I used for this study, to determine the possibility of its success and to highlight any barriers that might affect its success (De Kok et al., 2010; Given, 2008). All experts responded that the content of proposed questions was appropriate, that the content of questions was simple enough for participants and did not pose ambiguity. Based on this response from the expert panel, there was no change in the wording of the proposed questions for the quantitative survey and qualitative interview questions.

Setting

Surveys–Quantitative

I e-mailed surveys to a random sample of potential participants who had one week to complete and return them. The survey contained 11 closed ended questions (Appendix F). After 300 completed responses were received, I stopped recruitment.

Telephone Interviews–Qualitative

A recruitment poster (shown in Appendix C) was placed at a breast care center for 1 week, with information about the study and my contact information to respond to if there was interest in participating. At day four, I had received 10 responses. I contacted each of them to explain the study, sent them follow-up e-mails, received consent to participate in the study, and definite times were arranged to conduct the telephone interview.

There were no personal or organizational conditions I know of that might have influenced participants at the time of the study that may have affected my interpretation of the study results. Neither those in the quantitative and qualitative parts of the study were influenced or coerced to participate in the study as stated in the Consent Forms A and B that were provided for them (shown in Appendix D and E). Each participant understood that they had the option to withdraw from study participation at any time.

Participant Demographics

A sample size of 300 women participated in the quantitative part of the study and 10 respondents participated in the qualitative strand. A power analysis tool, G*Power was used to calculate the appropriate sample of 300 participants for the quantitative part of the study (Faul, Erdfelder, Lang, & Buchner, 2007). A sample size of 10 is judged sufficient for phenomenological investigations (Rudestam & Newton, 2007).

Participants for the quantitative portion were randomly selected from women who were residents of Santa Clara County in California, had a screening mammogram

between 2010 -2012, were between 24 and 74 years of age, had no history of breast cancer, and had a dense breast tissue finding. These criteria are outlined in Consent Form A.

Participants for the qualitative part of the study were purposely selected from the breast care center of Regional Medical Center of San Jose. They were residents of Santa Clara County in California, had a screening mammogram between 2010 and 2012, were between 24 and 74 years of age, had no history of breast cancer, and had a dense breast tissue finding. These criteria are outlined in Consent Form B.

Data Collection

Quantitative

Three hundred participants for the quantitative were randomly selected from Santa Clara County in California, and data were collected via SurveyMonkey, an online data-collection service. All participants who agreed to participate in the study had the option to stop the process after reviewing the consent form shown in Appendix D. The survey contained 11 closed-end questions:

1. Is your age between 24 and 74 years?
2. Are you in good health?
3. Do you have a family history of breast cancer?
4. Have you lost a family member to breast cancer who had regular mammography screenings?
5. Do you regularly perform a breast self-exam?

6. Do you have a screening mammogram every year?
7. Have you had screening mammograms every year for the last 5 years?
8. Have you had an abnormal mammogram finding?
9. Did your doctor tell you that the result of your mammogram was not conclusive?
10. Do you think a screening mammogram is the only available way to screen women for breast cancer? Did you have an ultrasound ?

Each question had a choice of 5 responses that were based on a 5-point Likert scale, as shown in Appendix F. The five response choices were: strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree. E-mail invitations were sent between October 10-15, 2014. When respondent's participation reached the saturation point of 300 completed surveys, the participant field was closed. The online survey site was accessible by user identification and a unique password, and I had sole access to the completed surveys. I accessed the SurveyMonkey website and extracted the data. The aim of the survey was to specifically to capture women that fit the required criteria and the survey was formatted in such a way that prevented the participant to continue if the specified criteria were not met. These inclusion criteria are shown in Consent Form A.

Qualitative

Advertisement flyers were placed at the Regional Medical Center breast care center in Santa Clara County from November 3, 2014 to November 7, 2014 to recruit participants. This center was chosen because of its dedicated breast imaging center that

provide breast care services to a large community of women in Santa Clara County. Those who wanted to participate in the study responded to me by e-mail. I responded with Consent Form B (Appendix E), which specified they could withdraw from the study at any time for any reason.

Data collection for the qualitative part of the study was conducted by telephone from the first 10 respondents. The survey contained 5 open-ended questions as shown in Appendix F:

1. Are you in the age group of 24 and 74 years? Do you perform routine breast self-exams? Do you have a family history of breast cancer? Do you have an annual mammogram? Do you have dense breast tissue based on a mammogram? Were you told by her doctor that you needed a repeat mammogram?
2. Have you had an ultrasound as a breast cancer screening? What was the finding?
3. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding?
4. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer?
5. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed accusing mammograms?

Participants were allowed a maximum of 5 minutes to respond to each question; they were advised to set aside 30 minutes of uninterrupted time to complete the interview. At the agreed time, I contacted each participant by telephone;all responses were recorded by manual transcription. In addition, all interviewees were informed that they might be asked to review the transcribed interview for accuracy.

There were no unusual circumstances to report for the quantitative and qualitative data collection processes.

Data Analysis

The study employed a mixed methods explanatory approach (Creswell & Plano Clark, 2008) and a qualitative approach. Table 1 below shows the tool used to collect data, the scale used classify data collected and data analysis tool that were used for this study.

Table 1

Data Analysis Tools

Data collection	Measurement scale	Data analysis tools
Survey	String/numeric	SPSS version 21
Telephone interviews	String	NVivo 10

Quantitative Data Analysis Using SPSS

Responses that were received from 300 respondents, based on a 5 point Likert scale, were assigned a numeric code to match the actual participant response: 1= strongly agree ; 2= agree;3 = neither agree nor disagree; 4=disagree ; and 5 = strongly disagree. These values were entered to an Excel Spreadsheet and uploaded to a statistical software

program Statistical Package for the Social Sciences (SPSS) version 21. A total of 3,000 Likert scale responses were imported from an Excel sspreadsheet into the data view within the data editor of SPSS Version 2. Variables on the variable view of the data editor were labeled age, good health, family history of breast cancer, lost a family member to breast cancer, regular breast self-exams, annual screening mammogram, screening mammograms for the last five years, abnormal mammogram finding, and result of your mammogram abnormal. Importantly, on the variable view, each variable was assigned a type. This selection allowed for all string values to convert to numeric values in the data view of the data editor. The value label toggle selection in the data view allowed switching between string and numeric data in the date editor in the SPSS processor to allow numeric analysis of the total responses to each question. Two levels of data analysis were calculated: descriptive statistics and the *t* test.

A descriptive statistical analysis of responses from $N = 300$ was done for all queries to look at the distribution. SPSS produced an output statistical table that showed descriptive statistics for the minimum and maximum of the scale, mean and standard deviation of $N = 300$. The descriptive statistics table is shown in Appendix H. The sample mean was not adequate to reject H_0. Hence, the stem and lleaf plot analysis was done. This analysis considered the entire sample, analyzed to display all variables, data value, and their connection to other values such as confidence interval for mean, median, variance standard deviation, and skewness. The stem and leaf analysis also revealed whether there were problems with the distribution, such as extremes above and below the

H_0 that would stop the significance test. The stem and leaf analysis table is shown in Appendix H.

The *t* test was the final computation for *N* = 300. The one-sample two-tailed *t* test was employed to test the hypothesis for the research. The two-tailed *t* test was selected because it can detect deviation on either side of H_0. In the data view display within the data editor of SPSS, the one sample *t* test was selected. All variables were analyzed with a test value of 1. The test value 1 is not an arbitrary number and was selected because the H_0 =1. A one-sample sstatistics table and the one-sample test table were generated.

The one-sample sstatistics table, shown in Appendix J, displayed each variable that tested *N* = 300: mmean, sstandard ddeviation and the sstandard eerror mean. The importance of the one-sample sstatistics table is that it shows whether the correct sample was analyzed. The one-sample test table provided the *t* statistic, *df* (degrees of freedom), the significance (2-tailed) output, mean difference, and the confidence interval. Each variable was analyzed to determine if H_0 was rejected by this analysis.

The *t* statistic for each of the 10 items analyzed yielded values that range from 6.3 -104. Under H_0, the *t* statistic = 0. This distribution placed the values for the *t* statistic won the right tail of the distribution which means that H_0 can be rejected.

The *df, N*-1 = 299, is standard for a one-sample *t* test. This is an important variable in the analysis because *df t*ells the software which *t* distribution to look at to evaluate the *t* statistic.

The significance reported a *p* value of 0.00. The two-tailed test was selected to detect variations on either side of H_0, as if there are deviations above or below the mean, H_0 can be rejected, hence the purpose of a two-tailed test. As suggested in Chapter 3, if the *p* value has a value < 0.01, there is a possibility that the null hypothesis will be rejected (Simon & Goes, 2013). The *p* value in this analysis wass < 0.01. Therefore, H_0 was rejected. The research question as proposed by H_0 in Chapter 3 that MRI for screening women with DBT should be used as an adjunct to conventional mammography was rejected.

The *md* of the analysis reported values from 0.173–3.4. This represents the difference between the population and sample mean, as shown in Appendix I. If H_0 was true, *md* = 0. However *md* is not equal to zero, and H_0 can be rejected.

The analysis reported a 95% cconfidence interval, (CI) with llower and uupper bounds. The CI can be used to test H_0. If the *md* =0, under H_0 , 0 will not fall between the llower and uupper bounds of CI, but will fall outside of the CI. This is evidence to reject H_0 at the .05 level of the CI. With a CI of 95%, the llower and upper bounds will capture the true population mean, and in 5%, it will not.

As noted in Chapter 3, if the *p* value is < 0.01, will be rejected, H_1 will be upheld (Simon & Goes, 2013), and the investigation can continue to the second phase.

Qualitative Data Analysis Using NVivo

I transcribed telephone interviews with 10 participants and saved the data as a Word document. Data were organized by assigning a number to each participant, 1-10.

Ten word documents were created and named to match each participant and responses. To ensure accuracy of the responses, I e-mailed the transcribed responses to each participant and asked them to read their responses and check for accuracy.

Data were organized by numbers in NVivo 10 in the ssource workspace. Questions and responses from each interview that were saved previously to a Word document were imported and matched to the respective participant in the NVivo 10 workspace. When each participant was selected, the question and their responses were displayed. As I examined responses to the five questions I asked each participant, 11 themes emerged. Each theme was created and entered into the node workspace of the NVivo 10 program.

Question 1

Qualitative Research Question 2: "What are the lived experiences of women with breast cancer in DBT prior to and after a breast cancer diagnosis?" To answer this question participants were asked to respond to five questions (shown in Appendix F). The first question had six sub-questions. Six themes emerged from their answers. Each theme is discussed below.

Theme 1. *Are you in the age group 25 through 75 years?* Participants' ages ranged from 30 to 68. This age group is important for this investigation because younger women typically have dense breast tissue as do pre and post-menopausal women (ACR, 2012).

Theme 2. *Do you perform routine breast self-exam?* All participants responded that they performed breast self-exam. Participant 1 responded that she found a lump in her left breast during a self-exam. She was 68 years old, had had normal screening mammograms since she was age 40, but in her 50s, there was a dense breast finding. She had additional diagnostic imaging with a repeat mammogram and an ultrasound, but these exams did not yield more information about her abnormal mammogram finding. This is key to the study because their breast anomalies were missed with mammogram. Even though Participant 1 followed all the rules and had annual screening for 10 years, cancer had not been detected. The lump in her left breast was found when she did a breast self-exams.

Theme 3. *Do you have a family history of breast cancer?* All participants responded that there was no history of breast cancer. This was a criterion to participate in the study as proposed in Chapter 1. The study examined the purposeful sample that did not have a breast cancer history.

Theme 4. *Do you have an annual mammogram?* All participants responded positively to this question. This response met the inclusion criteria for the study also. The aim of this question is to find out if the outcome would be the same if these participants did not have a screening mammogram.

Theme 5. *Do you have dense breast tissue based on a mammogram?* All participants had a dense breast finding. The purpose of this question was to find out

which diagnostic imaging technique was used to image this group and if the finding was cancerous.

Theme 6. *Were you told by your doctor that you needed a repeat mammogram?* Participants 1, 2, 3, 4, 9 and 10 had repeat mammograms and reported that the repeat mammograms did not provide new information and that their doctors were not able to provide clarity. Their doctors recommended an additional diagnostic test.

Question 2

Theme 7. *Have you had an ultrasound as a breast cancer screening?* Two themes emerged from question2. Eighty percent of participants reported that an uultrasound exam was recommended after the second mammogram because the results of the screening and repeat mammograms were not conclusive. Participant 5 said her doctor was very conservative, but she agreed to go through with more testing, as she was only 55 years old and was the breadwinner in her family.

Theme 8. *What was the finding?* Participants reported being relieved that their physicians were not ignoring them and ordered more diagnostic tests to help make the diagnosis. Participants 1, 2, and 4, said the ultrasound results were not conclusive; Participants 3, 5, 6, and 7, said their ultrasound results said the area was too small, and Participants 8, 9, and 10 stated that the ultrasound did not give more information. I observed that these participants were well informed about dense breast findings and were willing to have additional diagnostic tests to find the answer.

Question 3

Theme 9. *Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding?* All participants expressed their dislike for the MRI scan. They reported that test took about 45 minutes to one hour to complete but that it provided more information that mammograms and ultrasound exams. The majority of participants said that the results of the MRI reported breast cancer or suggested breast cancer.

Question 4

Theme 10. *Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer?* The purpose of this question was to find out the emotional state of the women while they waited to schedule appointments for additional tests so that physicians could make a diagnosis. The common concern for all was the length of time they had to wait while they had repeated mammograms and ultrasound exams. They were concerned that the cancer was not diagnosed early enough or misdiagnosed and that they might not have enough time for treatment and recovery. Some were concerned that they could possibility need a mastectomy. One of the common concerns that all participants had was that there was too much time wasted on the repeat mammogram and ultrasound exams.

Question 5

Theme 11. *Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms?*

This question was included so I could learn whether participants were informed about breast cancer in dense breast tissue and diagnostic imaging techniques that are available for breast cancer screening. Most agreed that mammograms can miss anomalies in dense breast tissue and that they were not pleased to repeat the mammogram because of radiation. Additionally, more that 80 % of respondents said that the ultrasound did not give additional information because the technique is not useful for dense breasts. Although the MRI exam was very uncomfortable and look a long time, the majority of participants said that it was the most accurate test that confirmed breast cancer. Major themes are shown in Appendix K.

Evidence of Trustworthiness

This study fulfilled the construct validity by using the opinions from an expert panel: a radiologist, a research scientist, and a physician. Each member sent feedback that validated the content of the quantitative and qualitative survey tool. Member checking was used to confirm the accuracy of my transcriptions. Each transcribed telephone interview was sent to participants to review their answers to the interview questions. The study could be replicated in another case by following my detailed records.

Summary

To learn the lived experiences of women with dense breast tissue and breast cancer who had undergone tests for breast cancer, I conducted a qualitative study by interviewing 10 women. Answers to five open-ended questions and responses from interviews brought added clarity to the assertion that an adjunct imaging technique, in

addition to conventional mammography, is needed to screen women with dense breast tissue.

Chapter 5 will present an interpretation of the study, including limiting factors, recommendations for future research, and how the results of the study might effect positive social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

Breast cancer in DBT can go undetected with conventional screening methods (Are You Dense? 2013), yet there are no directives in place for agencies and organizations to screen women with DBT (ACR, 2013; ACS, 2012; CDC, 2013). Women with DBT who are not predisposed to breast cancer and do not have a breast cancer history are in the low-risk category and do not meet the standard for additional breast cancer screening. Conventional breast screening is the only screening technique that is used for this group; but using that technique alone can miss cancer in glandular tissues. Although conventional mammography is effective for regular breast cancer screening, this technique detects less than half of breast cancers in the population with DBT (Are You Dense? 2013). A mixed-methods, sequential, explanatory approach was used for this study because health studies are very complex, and it was believed that adopting this approach could maximize the strengths of quantitative and qualitative data collectively. The use of a single approach, quantitative or qualitative, would not have been sufficient to answer the research questions.

This study was guided by two research questions: (a) Should MRI be used for screening women with DBT as an adjunct to conventional mammography? and (b) What are the lived experiences of women with breast cancer in DBT prior to and after the breast cancer diagnosis? In this chapter, I will discuss the purpose of the study, present

and interpret the findings, discuss limitations, and present the recommendations and implications of the findings.

Purpose and Nature of the Study; Key Findings

The purpose of this mixed methods study was to explore, investigate and examine to what extent mammograms and ultrasound techniques can miss cancer in women with DBT. Consequently, I wanted to find out if the application of MRI techniques in the DBT group might detect breast cancers that were undetected by mammogram and ultrasound. I also wanted to learn about the journey that women with DBT experienced when they found out that they had an abnormal finding and the process that they went through to get the breast cancer diagnosis.

The first strand, the quantitative part of the study, was done to find out how many abnormal findings there were in a random sample of 300 women. The second strand, the qualitative part, was done to learn about lived experiences of women with DBT and the journey they travelled to get to the cancer diagnosis. The purpose of the study was to add information deduced from this study to existing literature about the need to add an adjunct imaging technique to conventional screening methods to effectively screen women with DBT. The proposed adjunct screening is the use of MRI techniques.

In a conventional screening of a random, healthy sample of 300 women $N = 300$, with a DBT variable, 93% reported that they had abnormal breast findings. This analysis was provided by the application of a mathematical computation called SPSS (Table 2). This finding illuminates that there is a significant number of women with DBT. If there is

such a significant population with abnormal breast findings and since mammograms and ultrasound techniques can miss cancers with DBT (see the literature review for an exhaustive review), then there is a need for a technique that has a higher sensitivity to DBT.

Table 2

Abnormal Mammogram Findings 1

Scale	Frequency	Percent	Valid percent	Cumulative percent
Valid	40	13.3	13.3	13.3
	240	80.0	80.0	93.3
	3	1.0	1.0	94.3
	12	4.0	4.0	98.3
	5	1.7	1.7	100.0
	300	100.0	100.0	

Note: 93% of *N*=300 had an abnormal breast finding.

Findings from the qualitative portion revealed that women with DBT that do not have a breast cancer history may undergo arduous breast screening processes before an actual diagnosis. Repeat screening mammograms, diagnostic mammograms, and ultrasound are additional tests this group has to undergo. The results were that some women had screening reports with vague terminologies, findings that were inconclusive or unclear and the message that additional test are needed. Data analysis using NVivo concluded that 83% of the sample said they did not know the results of their screening mammogram.

Interpretation of the Findings

This study was based on two inquiries: Which breast imaging technique can detect cancers in DBT and can be an adjunct to conventional mammography to screen for breast cancer? Which imaging technique was utilized by a purposeful group of women with DBT to get a breast cancer diagnosis? As discussed in Chapter 2, the ACR (2012) reported that 80% of women have dense breast tissue, and Berg (2009) reported that conventional mammography which is the standard to screen for breast cancer can miss cancers that are in these tissues. This study revealed that more than 90% of $N = 300$ had an abnormal mammogram finding. Table 3 shown below shows that from a random sample of 300 participants, 280 women had an abnormal mammogram result.

Table 3

Abnormal Mammogram Findings 2

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	40	13.3	13.3	13.3
	2	240	80.0	80.0	93.3
	3	3	1.0	1.0	94.3
	4	12	4.0	4.0	98.3
	5	5	1.7	1.7	100.0
	Total	300	100.0	100.0	

This finding confirmed that a significant population of women has DBT and an abnormal mammogram. In addition, these findings suggest that there is a need for an adjunct screening method for women with DBT because conventional mammogram can miss anomalies in this kind of tissue (Berg, 2009). In Chapter 2, the ACS (2012) stated

that DBT is not a significant finding for women that are in the asymptomatic category, but data collected for this study revealed that women with DBT that had MRI, that confirmed breast cancer.

Qualitative data revealed that a significant number women that participated in the study in the age group 24–74, with dense breast tissue, without family history of cancer, and had annual screening mammograms, had breast cancer that was undetected. These women had breast screening with conventional mammogram and ultrasound. More than 50% of these women had repeat mammograms, diagnostic mammograms, and ultrasound exams. Results from these exams were "non-conclusive," "not clear," or "more tests were needed." All women had an MRI report of positive results. MRI has a high specificity to detect anomalies and cancers in granular tissues (Frank, 2011).

Limitations of the Study

One limitation is that e-mail surveys came only from residents of Santa Clara County, limiting the population to a small geographic area that may not be typical of women in general. Although statistics indicate that people are highly inclined to respond honestly to a survey like this, there is no way to determine if the questions asked were answered truthfully.

Ultrasound can also produce false positive results (Berg, 2008) due to the lack of proficiency of operators and lack of standardized protocols. Berg (2008) also suggested that the quality of an ultrasound depends on the skill of the operator. All participants had an ultrasound after the screening mammogram. There was no way to measure the skill of

the technologist or know what protocols were used. MRI can also produce false positive results. Descriptive statistics collected from the 20% of the women who participated in the qualitative part of the study showed they had breast biopsies to confirm breast cancer. The reason for a biopsy was unclear.

After I had 10 positive responses, I stopped recruiting participants. These were all patients of one breast cancer center. There was no way to tell if the sample was slightly larger than 10 and what descriptive data might yield from a larger sample. It is also not clear if these results can be applied to the general population.

The weight of the methodology possibly weighed slightly heavily towards the quantitative than qualitative data.

The final limitation for the study could be the right point in data collection to mix results of collection, analysis, or interpretation (Creswell, 2009). Quantitative data were analyzed first.

Recommendations

The findings of this study prompted several recommendations. That health organizations and agencies set a standard that MRI screening should be used with conventional mammograms to screen women with DBT for breast cancer because of its high sensitivity to DBT (Berg, 2009; Frank, 2011). Health care providers, however, should be aware of the significant number of women that are diagnosed with DBT (ACR, 2012), and are positive for breast cancer, even though they do not have a family history of cancer. MRI is an effective screening method to detect cancers in DBT and

organizations should add this technique to conventional mammogram to screen for breast cancer.

The mixed methods sequential explanatory approach was the most appropriate for this type of health investigation as it strengthened the robustness of the quantitative and qualitative strands (Creswell, 2009). The quantitative paradigm guided data collection and analysis, while the qualitative design guided the in-depth interviews and data analysis. Quantitative data were used to test H_0 and explore the determination that more thorough and complete data are needed to determine without question that an adjunct imaging method is needed to screen women with dense breast tissue.

Further research is needed to screen various groups of women with DBT, to compare the combination of the effectiveness or not of mammograms and ultrasound versus mammograms and MRI techniques. In addition, there was a low participation response for the women 25–50 for this study; therefore, the outcome for this group could not be measured.

Implications

Breast cancer, with a high mortality in the United States, is the second-most deadly disease in women (NCI, 2012). But if it is detected in an early stage, it can be treated effectively, and a positive prognosis is more likely. If MRI is used as an adjunct to conventional mammograms, accurate breast cancer results may be produced, a condition that might lead to a rapid breast cancer diagnosis, potentially lowering mortality rates for this group of women and bringing about the social change of reduced preventable early

death. This is not to diminish the importance of breast self-examination and annual mammography screening processes that continue to be highly recommended.

Conclusion

Early detection of breast cancer can result in earlier treatment and decreased mortality rates for women with DBT. Imaging of DBT utilizing MRI has yielded accurate findings for breast cancer among the group of women with DBT and a lower number of false positive cases. MRI has a higher sensitivity for imaging DBT because it has unique characteristics to see inside dense tissues. If MRI is added to conventional mammography, there should be a higher diagnosis rate for breast cancer, and the disease can be treated in the early stages. Utilizing MRI to image women with DBT would bring social change to the individual, families of women with DBT, and the breast cancer community.

References

ACR. (2013). The ACR breast imaging reporting and data system (BIRADS). Retrieved from http://www.acr.org/Quality-Safety/Resources/BIRADS/About-BIRADS

ACR. (2012a). Breast cancer screening. ACR appropriateness criteria. Retrieved from http: /~/media/ACR/Documents/AppCriteria/ Diagnostic/BreastCancerScreening.pdf

ACR. (2012b). BI-RADS FAQa—The American College of Radiology BI-RADS ATLAS and MQSA: Frequently asked questions. Retrieved from http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources /BIRADS/BIRADSFAQs.pdf

ACS. (2014). Can breast cancer be found early? Retrieved from http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-detection?rnav=cri

Aebi, S., Davidson, T., Gruber, G., & Castiglione, M. (2010). Primary breast cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. *Annals of Oncology, 21*(suppl. 5), 9-14. doi: 10.1093/annonc/mdq159

American Cancer Society. (2013a). American Cancer Society recommendations for early breast cancer detection in women without breast symptoms. Retrieved from http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast-cancer-early-detection-acs-recs

American Cancer Society. (2013b). Breast cancer: Early detection. Retrieved from http://www.cancer.org/cancer/breastcancer/moreinformation/breastcanceearlydetection/breast-cancer-early-detection-other-screening-tests

American Cancer Society. (2013c). Can breast cancer be found early? Retrieved from http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-detection

American Cancer Society. (2013d). *Breast cancer facts & figures* 2013-2014. Atlanta, GA: American Cancer Society, Inc.

American Cancer Society. (2012a). Retrieved from http://www.cancer.org/cancer/breastcancer/moreinformation/breastcanceearlydetection/breast-cancer-early-detection-acs-recs-mammograms

American Cancer Society. (2012b). Retrieved from http://www.cancer.org/cancer/breastcancer/moreinformation/breastcanceearlydetection/breast-cancer-early-detection-acs-recs-mammograms

American College of Radiology. (2012). Breast density. Breast cancer screening. Retrieved from http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/Breast%20Imaging/Breast%20Density%20bro_ACR_SBI_lores.pdf

Are You Dense? (2013). Exposing the best-kept secret. Retrieved from http://www.areyoudense.org/

Auntminnie. (2008) Reimbursement. Retrieved from http://www.auntminnie.com/index.aspx?sec=spt&sub=bmr&pag=dis&itemId=82207

Banerjee, A., & Chaudhury S., (2010). Statistics without tears: Populations and samples Ind Psychiatry J, 19(1), 60–65. doi: 10.4103/0972-6748.77642

Bernardi, D., Errante, D., Gallligioni, E., Crivellari, D., Bianco, A., L., . . .Fentiman, I. S. (2008). Treatment of breast cancer in older women. *Acta Oncologica, 47*(2), 187-198.

Berg, W. A. (2003). Rationale for a trial of screening breast ultrasound: American College of Radiology Imaging Network (ACRIN) 6666. *American Journal of Roentgenology*, *180*(5), 1225-1228.

Berg, W. A. (2009). Tailored supplemental screening for breast cancer: What now and what next? *American Journal of Roentenology, 192(*2), 390-399.

Berg, W. A., Zhang Z., Lehrer D., Jong, R., Pisano, E. D., Barr, R., . . . Gabrielli, G. (2012). Breast density and supplemental screening breast ultrasound: *Journal of the American Medical Association*, *307*(13), 1394-1404. doi:10.1001/jama.2012.388

Berg, W. A., Blume, J. D., Cormack, J. B., Mendelson, E. B., Lehrer, D., Böhm-Vélez, M.,…Pisano, E. D. (2008). Combined Screening With Ultrasound and Mammography vs Mammography Alone in Women at Elevated Risk of Breast Cancer. *Journal of the American Medical Association, 299*(18):2151-2163. doi:10.1001/jama.299.18.2151

Bevers, T. B., Anderson, B. O., Bonaccio, E., Buys, S., Daly, M. B., Dempsey, P. J., & Yankeelov, T. (2009). Breast cancer screening and diagnosis. *Journal of the*

National Comprehensive Cancer Network, *7*(10), 1060-1096.

Boeije, H., Slagt, M., & van Wesel, F., (2013). The contribution of mixed methods research to the field of childhood trauma: A narrative review focused on data integration. *Journal of Mixed Methods Research, 7*(4), 347-369. doi: 10.1177/1558689813482756

Boyd, N. F., Martin, L. J., Bronskill, M., Yaffe, M. J., Duric, N., & Minkin, S. (2010). Breast tissue composition and susceptibility to breast cancer. *Journal of the National Cancer Institute*, *102*(16), 1224-1237.

Boyd, N., Martin, L., Chavez, S., Gunasekara, A., Salleh, A., Melnichouk, O., . . . Bronskill, M. (2009). Breast-tissue composition and other risk factors for breast cancer in young women: A cross-sectional study. *Lancet Oncology*, *10*(6), 569-580. doi: 10.1016/S1470-2045(09)70078-6

Boyd, N., Martin, L., Gunasekara, A., Melnichouk, O., Maudsley, G., Peressotti, C., & Minkin, S. (2009). Mammographic density and breast cancer risk: Evaluation of a novel method of measuring breast tissue volumes. *Cancer Epidemiology Biomarkers & Prevention, 18(*6), 1754-1762. doi: 10.1158/1055-9965. EPI-09-0107

Braun, S. (2003). History of breast cancer advocacy. *Breast Journal, 9,* 101-103.

Breast Cancer.Org. (2012). Breast cancer statistics. Retrieved from http://www.breastcancer.org/symptoms/understand_bc/statistics

Breast Cancer Research. (2008). Mammographic density. Measurement of

mammographic density: *Breast Cancer Research, 10*(209), doi: 10.1186/bcr2102 Retrieved from http://breast-cancer-research.com/content/10/3/209.

Brower, V. (2013). Breast density legislation fueling controversy. *Journal of the National Cancer Institute, 105(*8), 510-511. doi:10.1093/jnci/djt086

Bulu, H., Alpkocak, A., & Balci, P. (2013). *Uncertainty modeling for ontology-based mammography annotation with intelligent BI-RADS scoring*. Retrieved from http://www.u1027.inserm.fr/59527262/0/fiche_pagelibre/&RH=1304948096435

Business Wire. (2010). Supporting a breast cancer screening clinical study for women with dense breast tissue. Retrieved from http://www.somoinsightstudy.org

Campbell, T. D., Fiske, D. (1959). Convergent and discrimination validation by the multistrait-multimethod matrix. *Psychological Bulletin, 56*, 81-105.

Carp, S. A., Sajjadi, A. Y., Wayno, C. M., Fang, Q., Spect, M., Sharpira, L., . . . Moy, B. (2013). Hemodynamic signature of breast cancer under fractional mammographic compression using a dynamic diffuse optical tomography system. *Biomedical Optics Express*, *4*(2), 2911-2924. Retrieved from doi.org/10.1364/BOE.4.002911

CDC. (2013a). Breast Cancer. Screening. Retrieved from http://www.cdc.gov/cancer/breast/basic_info/screening.htm

CDC. (2013b). Breast Cancer. Basic information about breast cancer. Retrieved from http://www.cdc.gov/cancer/breast/basic_info/index.htm

CDC. (2012). Morbidity and mortality weekly report (MMWR). Cancer screening-United States, 2010. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6103a1.htm#figCDC (2011).

Crawford, R. R., & Naval Postgraduate School Monterey. (1981). *An application of living systems theory to combat models*. Ft. Belvoir, VA: Defense Technical Information Center.

Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches*. (3rd ed.). Thousand Oaks, CA: Sage.

Creswell, J. W. (2007). *Qualitative inquiry & research design. Choosing among five approaches.* (2nd ed). Thousand Oaks, CA: Sage.

Creswell, J. W., & Miller, D. L. (2000). Determining validity in qualitative inquiry. *Theory Into Practice, 39*(3), 124-131.

Creswell, J. W., & Plano Clark, V. L. (2011). *Designing and conducting mixed methods research.* Thousand Oaks, CA: Sage Publications, Inc.

Creswell, J. W., & Plano Clark, V. L. (2008*). The mixed methods reader.* Thousand Oaks, CA: Sage Publications Inc.

Cuzick, J., Warwick, J., Pinney, E., Duffy, S. W., Cawthorn, S., Howell, A., … Forbes, J. F. (2011). Tamoxifen-induced reduction in mammographic density and breast cancer risk reduction: A nested case–control study. *JNCI Journal of the National Cancer Institute, 103*(9), 744-752. doi: 10.1093/jnci/djr079

Cummings, S. R., Tice, J. A., Bauer, S., Browner, W. S., Cuzick, J., Ziv, E., . .

Kerlikowske, K. (2009). Prevention of breast cancer in postmenopausal women: Approaches to estimating and reducing risk. *Journal of the National Cancer Institute, 101*(6), 384-398. doi: 10.1093/jnci/djp018

Dense breast tissue: You NEED to know. (2011). Retrieved from http://hendaslaw.com/hendas-law/

De Kok, M., Sixma, H. J. M., van der Weijden, T., Kessels, A. G. H., Dirksen, C. D., Spijkers, K. F. J., . . . van de Velde, C. (2010). A patient-centered instrument for assessment of quality of breast cancer care: Results of a pilot questionnaire. *BMJ Quality & Safety. 19*(40). doi:10.1136/qshc.2007.025890

Denzin, N. K., & Lincoln, Y. S. (1998). *Collecting and interpreting qualitative materials*. Thousand Oaks, CA: Sage.

Diagnostic Imaging. (2012) Connecticut's dense breast legislation: Three years later. Retrieved from http://www.diagnosticimaging.com/articles/connecticuts-dense-breast-legislation-three-years-later

Dixon-Woods, M., Tarrant, C., Willars, J., & Suokas, A. (2010). How will it work? A qualitative study of strategic stakeholders' accounts of a patient safety initiative. *Quality and safety in health care, 19*, 74-78. doi:10.1136/qshc.2008.029504

Drukteinis, J. S., Mooney, B. P., Flowers, C. I., & Gatenby, R. A. (2013). Add title of the article. *Beyond Medicine, 126*(6), 472-479. doi:10.1016/j.amjmed.2012.11.025

Elmore, J. G., Barton, M. B., Moceri, V. M., Polk, S., Arena, P. J., & Fletcher, S. W. (2013) . Ten-year risk of false positive screening mammograms and clinical breast examinations. *The New England Journal of Medicine*, *338*(16), 1089-1096. doi:10.1056/NEJM199804163381601

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods, 41*(4), 1149-1160. doi: 10.3758/BRM.41.4.1149

FDA. (2013) FDA approves Perjeta for neoadjuvant breast cancer treatment. Retrieved from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements /ucm370393.htm

FDA. (2012a). FDA approves first breast ultrasound imaging system for dense breast tissue. Retrieved from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm 319867.htm

FDA. (2012b). News and events. FDA approves first breast ultrasound for dense breast tissue. Retrieved from http://www.fda.gov/NewsEvents/ Newsroom/PressAnnouncements/ucm319867.htm

FDA. (2012c). Radiology advisory panel meeting. U-Systems somo-v Automated Breast Ultrasound System (ABUS) FDA Review. Retrieved from http://www.fda gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/UCM300833.pdf

FDA. (2012d). Radiation-emitting products. Guidance (MQSA). Retrieved from http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/default.htm

FDA. (2012e). Radiation-emitting products. Guidance Mammography Quality Standards Act (MQSA). Retrieved from http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110823.htm

Field, A. (2009) *Discovering statistics using SPSS.* (3rd ed.). Thousand Oaks, CA: Sage.

Fifth International Congress on MR-Mammography Jena, Germany. (2009). *European Radiology*, *19*(4), 765. Retrieved from doi.org/10.1007/s00330-009-1569-1 PB

Florida Senate. (2013). 2013 SB 126 by Senator Ring. Retrieved from http://www.flsenate.gov/Session/Bill/2013/0126/BillText/Filed/PDF

Frank, E. (2011). *Merrill's atlas of radiographic positioning and procedures: 3-volume set. (12th* ed*.).* Philadelphia, PA: Elsevier Health Sciences.

Frankfort-Nachmias, C., & Nachmias, D. (2007). *Research methods in the social sciences* (7th ed.). New York, NY: Worth.

Franz, A., Worrell, M., & Vögele C. (2013). Integrating mixed method data in psychological research: Combining Q methodology and questionnaires in a study investigating cultural and psychological influences on adolescent sexual behavior. *Journal of Mixed Methods Research, 7*(4), 370-389, doi: 10.1177/1558689813483368Frels, R. K., & Onwuegbuzie, A. J. (2013). Administering quantitative instruments with qualitative interviews: A mixed research approach. (Research Report). *Journal of Counseling and Development, 2*, 184.Giuliano, V., & Giuliano, C. (2012). Improved breast cancer detection in asymptomatic women using 3D-automated breast ultrasound in mammographically dense breasts. *Clinical Imaging*, *37*(3), 480-486. doi:10.1016/j.clinimag.2012.09.018

Given L. M. (2008). *The SAGE encyclopedia of qualitative research methods.* Thousand Oaks, CA: SAGE Publications. doi.org/10.4135/9781412963909

Glaser, B. G., & A. Strauss. (1967). *The discovery of grounded theory: Strategies for qualitative research.* Chicago, IL: Aldine.

Glicken, M. D. (2003). *Social research: A simple guide*. Boston, MA: Pearson Education.

Goodman, A. (2008). Two breast cancer studies: Controversial new imaging system aims to coordinate MRI & ultrasound. MRI found better than mammography for diagnosing pure DCIS. *Oncology Times*, *30*(13), 50-51. doi: 10.1097/01.COT.0000327555.82686.f2

Gotzsche, P. C., Jorgensen, K. (2013) Screening for breast cancer with mammography. *Cochrane Database Systematic Reviews*. Issue 6. Art. No.: CD001877. doi:10.1002/14651858.CD001877.pub5

Guba, E. G., & Lincoln, Y. S. (1989). *Fourth generation evaluation*. Newbury Park, CA: Sage.

Hammersley, M. (1987). Some notes on the terms 'validity' and 'reliability. *British Educational Research Journal, 13*(1), 73-81.

Harris, C. H. (2010, Sept. 14). New imaging tools address challenges of dense breast tissue. Retrieved from http://www.auntminnie.com/index.aspx?d=1&sec=spt&sub=mbi&pag=dis&itemID=91901

Harrison, V. S. (2013). "The community is speaking loud and clear": Susan G. Komen for the Cure, Planned Parenthood, and the crisis of public opinion. *Case Studies in Strategic Communication, 2,* 61-92. Retrieved from http://cssc.uscannenberg.org/wp -content/uploads/2014/01/v2art4.pd

Hardy, L. K. (2011). *Cultural competence and racist attitudes of direct patient care registered nurses in a midwestern state.* (Order No. 3464866, University of Northern Colorado). ProQuest Dissertations and Theses, 294. Retrieved from http://search.proquest.com/docview/886777781

Harvard Health Publications (2013). MRIs Emerging Role In Breast Cancer Screening. Retrieved from http://www.health.harvard.edu/newsletters/harvard_womens_health_watchHeyvaert, M., Hannes, K., Maes, B., & Onghena, P. (2013). Critical appraisal of mixed methods studies. *Journal of Mixed Methods Research, 7*(4), 302-327. doi: 10.1177/1558689813479449

Hoare, Z., & Hoe, J. (2013). Understanding quantitative research, part 2. (Learning zone: Continuing professional development). *Nursing Standard*, *18*, 48.

Houghton, C., Casey, D., Shaw, D., & Murphy, K. (2013). Rigor in qualitative case study research. *Nurse Researcher*, *4*, 12.

ITN. (2013). Breast density inform: 2013 and beyond. The time has come for national standardized breast density notification. Retrieved from http://www.itnonline.com/article/breast-density-inform-2013-and-beyond

ITN. (2012). Dense breast tissue: Supplemental imaging. An evidence-based approach to supplemental imaging methods for women with dense breast tissue. Retrieved from http://www.itnonline.com/article/dense-breast-tissue-supplemental-imaging

Ivankova, N., V. (2013). Implementing quality criteria in designing and conducting a sequential QUAN → QUAL mixed methods study of student engagement with learning applied research methods online. *Journal of Mixed Methods Research 7*(4). doi: 10.1177/1558689813487945

Jarausch, K. H., & Hardy, K. A. (1991). *Quantitative methods to historians: A guide to research, data, and statistics.* Atlanta, GA: UNC Books.

Jemal, A., Siegel, R., Ward, E., Hao, Y., Xu, J., & Thun, M. J. (2009). Cancer statistics 2009. *CA: A Cancer Journal for Clinicians*, *59*(4), 225–249. doi:10.3322/caac.20006

Jemal, A., Siegel, R., Xu, J., & Ward, E. (2010). Cancer statistics, 2010. *CA: A Cancer Journal for Clinicians 60*(5), 277–300. doi:10.3322/caac.20073

JNCI Natl Cancer Inst. (2013). *Breast density legislation fueling controversy, 105*(8): 510-511. doi:10.1093/jnci/djt086

Jick, T. D. (1979). Mixing qualitative and quantitative methods: Triangulation in action: *Administrative Science Quarterly, 24,* 602-611. doi=10.1.1.317.1797&rep=rep1&type=pdfhttp

Johnson, B. R. (1997). Examining the validity structure of qualitative research. *Education*, *118*(3), 282-292.

Jones, R. W., Lowe, A., & Harrison, M. J. (2002). A framework for intelligent medical diagnosis using the theory of evidence. *Knowledge-based Systems, 15,* 77- 44. doi.org/10.1016/S0950-7051 (01)00123-X

Karellas, A., & Vedantham, S. (2008). Breast cancer imaging: A perspective for the next decade. *Medical Physics, 35*(11), 4878–4897. doi:10.1118/1.2986144

Kataja, V., & Castiglione, M. (2009). Primary breast cancer: ESMO clinical recommendations for diagnosis, treatment and follow-up. *Annals of Oncology*, *20* (suppl. 4), iv10-iv14. doi: 10.1093/annonc/mdp114

Kelly, K. M., Dean, J., Comulada, W. S., & Lee, S. J. (2010). Breast cancer detection using automated whole breast ultrasound and mammography in radiographically dense breasts. *European Radiology*, *20*(3), 734-742. doi: 10.1007 /s00330-009-15880-y

Kerlikowske, K., Cook, A. J., Buist, D. S. M., Cummings, S. R., Vachon, C., Vacek. P., & Miglioretti, D. L. (2010). Breast cancer risk by breast density, menopause, and postmenopausal hormone therapy use. *Journal of Clinical Oncology, 28*(24), 3830-3837. doi: 10.1200/JCO.2009.26.4770

Kloten, V., Becker, B., Winner, K., Schrauder, M. G., Faschin, P. A., Anzeneder T., . . . Dahl E. (2013). Promoter hypermethylation of the tumor-suppressor genes *ITIH5, DKK3*, and *RASSF1A* as novel biomarkers for blood-based breast cancer screening. *Breast Cancer Research*, *15*(4). doi: 10.1186/bcr3375

Komen, S. G. (2012). Breast density on a mammogram. What is breast density? Retrieved from http://ww5.komen.org/BreastCancer/HighBreastDensityonMammogram.html

Komen, S. G. (2013). The ABCs of breast density. Retrieved from http://ww5.komen.org/Content.aspx?id=19327353285

Komen, S. G. (2013a). Accuracy of mammograms. Retrieved from http://ww5.komen.org/BreastCancer/AccuracyofMammograms.html

Koskey, K. L. K., & Stewart, V. C., (2013). A concurrent mixed methods approach to examining the quantitative and qualitative meaningfulness of absolute magnitude estimation scales in survey research. *Journal of Mixed Methods Research, 8*(1): 180-202. doi: 10.1177/1558689813496905

Koutsojannis, C., & Hatzilygeroudis, I. (2006). Fuzzy-evolutionary synergism in an intelligent medical diagnosis systems. *Knowledge-based intelligent information and engineering systems lecture notes in computer science, 4252*, 1313-1322. Retrieved from http://link.springer.com/chapter/10.1007/11893004_166

Krathwohl, D. R. (1988). *How to prepare a research proposal: Guidelines for funding and dissertations in the social and behavioral sciences.* Syracuse, NY: Syracuse University Press.

Lee, C. H., Dershaw, D. D., Kopans, D., Evans, P., Monsees, B., Monticciolo, D., . . . Burhenne, L. W. (2010). Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. *Journal of American College of Radiology, 7*(1): 18-27. doi:10.1016/j.jacr.2009.09.022

Likert, R. (1932). A technique for the measurement of attitudes. *Archives of Psychology, 140* (1932), 1-55.

Lincoln, Y. S., & Guba, E. G. (1986). But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. In D. D. Williams (Ed.), *Naturalistic evaluation* (pp. 73-84). New Directions for Program Evaluation, 30. San Francisco, CA: Jossey-Bass.

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. Beverly Hills, CA: Sage

MacKay, K. J., & Campbell, J., M. (2004). *A mixed-methods approach for measuring environmental impacts in nature-based tourism and outdoor recreation settings. Tourism Analysis, 9*(3), 141-152.

Madden Yee, K. (2013). New breast MRI exam ready to screen women with dense breasts. Retrieved from http://www.auntminnie.com/index.aspx?sec=ser&sub=def&pag=dis&ItemID=105131

Mandelblatt, J. S., Cronin, K. A., Bailey, S., Berry, D. A., de Koning, H. J., Draisma G., . . . Huang, H. (2009). Effects of mammography screening under different screening schedules: model estimates of potential benefits and harms. *Annals of Internal Medicine 2009, 151*(10), 738-747. doi:10.7326/0003-4819-151-10-200911170-00010

Maxwell, J. A. (1992). Understanding and validity in qualitative research. *Harvard Educational Review, 62*(3), 279-300.

Mayo Clinic. (2013). BRCA gene test for breast cancer. Retrieved from http://www.mayoclinic.com/health/brca-gene-test/MY00322

Mayoh, J., & Onwuegbuzie, A. J., (2013). Toward a conceptualization of mixed methods phenomenological research *Journal of Mixed Methods Research 7*(4). doi: 10.1177/1558689813505358

Medical Device Daily (2013). GE discusses several technologies in cancer screening portfolio. Retrieved from http://www.highbeam.com/doc /1G1-319252295.html

Medscape reference drugs, diseases & procedures. (2012). Retrieved from http://emedicine.medscape.com/article/1948269-overview

Miller, J. (1978). *Living systems*. New York, NY: McGraw-Hill.

Miles, M. B, & Huberman, A. M. (1994). *Qualitative data analysis,* 2nd Ed., 10-12. Newbury Park, CA: Sage.

Mishler, E. G. (1990). Validation in inquiry-guided research: the role of exemplars in narrative studies. *Harvard Education Review, 60*, 415-442.

Molecular Breast Imaging. (2012). New imaging tools address challenges of dense breast tissue. Retrieved from http://www.auntminnie.com/index.aspx?d=1&sec=spt&sub=mbi&pag=dis &itemID=91901

Moon, W. K., Shen, Y., Bae, M. S., Huang, C., Chen, J., & Chang, R. (2013) Computer-aided tumor detection based on multi-scale blob detection algorithm in automated breast ultrasound images. *Medical Imaging, (32)*7, 1191-200. doi: 10.1109/TMI.2012.2230403

Moustakas, C. (1961). Heuristic research. In J. Bugental (Ed.), *Challenges of humanistic psychology*. New York, NY: McGraw-Hill.

National Cancer Institute. (2012). National cancer institute fact sheet. Breast cancer risk in American women. Retrieved from http://www.cancer.gov/cancertopics/factsheet/Detection/probability-breast-cancer

National Cancer Institute. (2012a). Cancer research highlights. Retrieved from http://www.cancer.gov/ncicancerbulletin/040312/page3

National Cancer Institute. (2012b). Copyright and reuse of graphics and text. Retrieved from http://www.cancer.gov/global/web/policies/copyright

NCI. (2012a). Fact Sheet. Mammograms. Retrieved from http://www.cancer.gov/cancertopics/factsheet/detection/mammograms

NCI. (2012b). SEER stat fact sheets: Breast. Retrieved from http://seer.cancer.gov/statfacts/html/breast.html

Nelson, H. D., Tyne, K., Naik, A., Bougatsos, C., Chan, B., Nygren, P.,…. Humphrey L. (2009). Screening for breast cancer: an update for the U.S. Preventive Services Task Force. *Annals of Internal Medicine, 151*(10):727-37, W237-42. doi: 10.7326/0003-4819-151-10-200911170-00009

NIH. (2013). National Institutes of Health. Best practices for mixed methods in the health sciences. Retrieved from http://obssr.od.nih.gov/scientific_areas/methodology /mixed_methods_research section2

Norkett, L. (2013). Quantitative research. This practice profile is based on NS673 Hoe J, Hoare Z (2012) Understanding quantitative research: part 1. Nursing Standard. 27, 15-17, 52-57. *Nursing Standard*, *27*(43), 59. doi:10.7748/ns2013.06.27.43.59.s52

Nothacker, M., Duda, V., Hahn, M., Warm, M., Degenhardt, F., Madjar, H., . . .Albert, U. -S. (2009). Early detection of breast cancer: Benefits and risks of supplemental breast ultrasound in asymptomatic women with mammographically dense breast tissue. A systematic review. *BioMed Central BMC Cancer*, *9*(335). doi: 10.1186/1471-2407-9-335

NPCR Education and Training Series (NETS) Module 9: Breast Malignancies Part 2: Diagnosis–nets9_2.pdf. Retrieved from http://www.cdc.gov/cancer/npcr/training/nets/module9/nets9_2.pdf

Olson, J. E., Sellers, T. A., Scott, C. G., Schueler, B. A., Brandt, K. R., Serie, D. J., . . . & Vachon, C. M. (2012). The influence of mammogram acquisition on the mammographic density and breast cancer association in the mayo mammography health study cohort. *Breast Cancer Research*, *14*(6), R147. doi: 10.1186/bcr3357

OncoLink. (2013). Cancer resources for patients and healthcare professionals. Retrieved from http://oncolink.org/types/article.cfm?c=65&aid=338&id=9657

Padilla, F., Roubidoux, M. A., Paramagul, C., Sinha, S. P., Goodsitt, M. M., Le Carpentier, G. L., … Carson, P. L. (2013). Breast mass characterization using 3D automated ultrasound as an adjunct to digital breast tomosynthesis: A pilot

study. *Journal of Ultrasound in Medicine : Official Journal of the American Institute of Ultrasound in Medicine*, *32*(1), 93–104. Retrieved from http://www.jultrasoundmed.org/content/32/1/93.short

Patton, M. Q. (2002). *Qualitative research and evaluation methods* (3rd ed.). Thousand Oaks, CA: Sage.

Patton, M. Q. (1987). *How to use qualitative methods in evaluation* (2nd ed.). Newbury Park, CA: Sage Publications.

Petro-Nustas, W., Tsangari, H., Phellas, C., & Constantinou, C. (2013). Health beliefs and practice of breast self-examination among young Cypriot women. *J Transcult Nurs*, *24*(2), 180-188. doi: 10.1177/1043659612472201

Pluye, P., Gagnon, M. P., Griffiths, F., & Johnson-Lafleur, J. (2009). A scoring system for appraising mixed methods research and concomitantly appraising qualitative, quantitative and mixed methods primary studies in mixed studies reviews. *International Journal of Nursing Studies*, *46*(4), 529-546, doi:10.1016/j.ijnurstu.2009.01.009

R2tech. (2013). Introduction to mammography. Retrieved from http://www.r2tech.com/Radiologyingo.org (2013). Magnetic Resonance Imaging (MRI) – Breast http://www.radiologyinfo.org/en/info.cfm?pg=breastmr.

Radiologyinfo.org. (2013). Mammography. Retrieved fromhttp://www.radiologyinfo.org/en/info.cfm?pg=mammo

Ravert, P. K., & Huffaker, C. (2010). Breast cancer screening in women: An integrative literature review. *Journal of the American Academy of Nurse Practitioners, 22*(12), 668–673. doi: 10.1111/j.1745-7599.2010.00564.x

Riss, I. (2014). Living systems: Theory and typology of migrations. *System Research and Behavioral Science, 31*(1), 67–76. doi: 10.1002/sres.2160

Robb-Nicholson, C. (2010). A doctor talks about: Screening mammography- Harvard Health. Retrieved from http://www.health.harvard.edu/newsletters/Harvard_Womens_Health_Watch/2010/February/a-doctor-talks-about-screening-mammography

Roe, J. A. (2013). *Donor perceived relationships with nonprofits using social media: A quantitative correlational study.* (Order No. 3567155, Capella University). *ProQuest Dissertations and Theses,* 161. Retrieved from http://search.proquest.com/docview/1417086173?accountid=14872

Rosenfeld, S., & Kapetanovic, I. (2008). Systems biology and cancer prevention: All options on the table. *Gene Regul Syst Bio. 2008, 2,* 307-319. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2733099/?report=classic

RSNA. (2013). Radiology info. Ultrasound breast. Retrieved from http://www.radiologyinfo.org/en/info.cfm?pg=breastus#part_two

Rudestam, E. K., & Newton, R. R. (2007). *Surviving your dissertation: A comprehensive guide to content and process*. Thousand Oaks, CA: Sage.

Sabih, D. (2013). Medscape reference drugs, diseases and procedures. Breast Ultrasonography. Retrieved from http://emedicine.medscape.com/article/1948269-overview

Santa Clara County. (2013). U. S. Census Bureau: State and county quickfacts. Retrieved from http://quickfacts.census.gov/qfd/states/06/06085.html

Santa Clara County, CA Census Statistics (2010). Retrieved from http://census-statistics.findthedata.org/q/233/495/How-many-women-live-in-Santa-Clara-County-Ca

Saslow, D., Boetes, C., Burke, W., Harms, S., Leach, O, M., & Lehman, D. C. (2009). American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. *C: A Cancer Journal for Clinicians, 57*(2), 75-89. doi: 10.3322/canjclin.57.2.75

SB 1538 Senate Bill- Bill Analysis. (2012) Retrieved from http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_1501-1550/sb_1538_cfa_20120416_103147_sen_comm.html

SB 1538. (2012a). Breast Cancer Detection Bill. State Senator Joe Simitian, Eleventh District California. Retrieved from http://www.senatorsimitian.com/entry/simitian_breast_cancer_detection_bill_signed_by_governor/

SB 1538. (2012b). Comprehensive breast tissue screening. State Senator Joe Simitian, Eleventh District California. Retrieved from http://www.senatorsimitian.com/entry/sb_1538_comprehensive_breast

_tissue_screening

SBI. (2012). Society of Breast Imaging. Retrieved from http://sbi-online.org/displaycommon.cfm?an=1&subarticlenbr=157.

Shellock, F. (2012). MRIsafety.com. Retrieved from http://www.mrisafety.com/

Sieber, J. E. (1998). Planning ethically responsible research. In L. Bickman & D. J. Rog (Eds). *Handbook of applied social applied research methods* (pp. 69-100). Thousand Oaks, CA: Sage.

Siegel, R., Naishadham, D., & Jemal, A. (2013). Cancer statistics, *A Cancer Journal for Clinicians, 63*(1), 11-30. doi: 10.3322/caac.21166

Simon, M. K., & Goes, J. (2013). *Dissertation & scholarly research. Recipes for success: 2013 edition.* San Bernardino, CA: Create Space Independent Publishing Platform.

Smigal, C., Jemal, A., Ward, E., Cokkinides, V., Smith, R., Howe, H. L., & Thun, M. (2006). Trends in breast cancer by race and ethnicity: Update 2006. *CA: A Cancer Journal for Clinicians*, *56*(3), 168-183. doi 10.3322/canjclin.56.3.168

Smith, R. A., Cokkinides, V., & Eyre, H. J. (2007). Cancer screening in the United States: A review of current guidelines, practices, and prospects. *CA: A Cancer Journal for Clinicians, 57*(2), 90–104. doi: 10.3322/canjclin.57.2.90

Sree, S. V., Ng, E. Y., Acharya, R. U., & Faust, O. (2011). Breast imaging: A survey *World Journal of Clinical Oncology, 2*(4), 171–178. doi:10.5306/wjco.v2.i4.171

Stein, D. D. (2011). *What motivates people to volunteer? A survey research study to analyze characteristics and motives of individuals that donate time.* (Doctoral dissertation, Capella University, 2011). Retrieved from http://search.proquest.com/docview/919023081?accountid=14872

Stenbacka, C. (2001). Qualitative research requires quality concepts of its own. *Management Decision*, *39*(7), 551-555. doi: 10.1108/ EUM0000000005801

Sirgy, J. M. (1988), Strategies for developing general systems theories. *Syst. Res.*, *33*. 25–37. doi: 10.1002/bs.3830330103

SurveyMonkey. (2013). Create surveys. Get answers. Retrieved from https://www.surveymonkey.com/mp/audience/

SurveyMonkey. (2009). SurveyMonkey brand use permission request form https://smforms.wufoo.com/forms/surveymonkey-brand-use-permission-request-form/

Susan G. Komen for the Cure founder to visit Oklahoma State University. (2009, November 5). [Television series episode] In *Dolan Media Newswires*. Oklahoma City, OK.

Susan G. Komen. (2012a). Facts for life. Breast density. Retrieved from http://ww5.komen.org/uploadedFiles/Content_Binaries/Breast%20Density%20KOMEED 084200.pdf.

Susan G. Komen. (2013). The ABCs of breast density. Retrieved from http://ww5.komen.org/Content.aspx?id=19327353285

Susan G. Komen. (2013a). Accuracy of mammograms. Retrieved from http://ww5.komen.org/BreastCancer/AccuracyofMammograms.html

Tahir, M., Robinson, T., & Stotter, A. (2011). How not to neglect the care of elderly breast cancer patients. *The Breast, 20*(4), 293–296. doi:10.1016/j.breast.2011.03.003

Teddlie, C., & Tashakkori, A. (2009) *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences.* Thousand Oaks, CA: Sage.

Thayer, D., Unlu, B., Chen, J., Su, M., Nalcioglu, O., & Gultekim, G. (2010). Development of a combined multifrequency MRI-DOT system for human breast imaging using a priori information. *Multimodal Biomedical Imaging, 75571*, doi:10.1117/12.842764

The Cochrane collaboration. (2013). About us. Retrieved from http://www.cochrane.org/about-us.

Trochim, W. M. K., & Donnelly, J. P. (2007). *The research methods knowledge base* (2nd ed.). Mason, OH: Atomic Dog.

Turnbull, L. W. (2009). Dynamic contrast-enhanced MRI in the diagnosis and management of breast cancer. *Nuclear Magnetic Resonance in Biomedicine, 22*(1), 28-39. doi: 10.1002/nbm.1273

U.S. preventive services task force. (2013a). Retrieved from http://www.uspreventiveservicestaskforce.org/

U.S. Preventive Services Task Force. (2013b). Screening for breast cancer. Retrieved from http://www.uspreventiveservicestaskforce.org/

U.S. Preventive Services Task Force (2009). Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine. 151*(10), 716-726. doi:10.7326/0003-4819-151-10-200911170-00008

U-Systems. (2013). ABUS dense breast screening. Retrieved from http://www.u-systems.com/product/somo-v-abus

U.S. Department of Health and Human Services (2012). National Institutes of Health. National Cancer Institute. *The future of cancer research: Accelerating scientific innovation.* Retrieved from http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp10-11rpt/FullReport.pdf

Van de Water, W., Markopoulous, C., Van de Velde, J. H. C., Seynaeve, C., Hasenburg, A., . . . Rea, D., (2012). Association between age at diagnosis and disease-specific mortality among postmenopausal women with hormone receptor–positive breast cancer. *Journal of the American Medical Association, 307,* 590-597. doi: 10.1001/jama.2012.84

Van Goethem, M., Verslgers, I., Biltjes, I., Hufkens, G., & Parizel, P. M. (2009). Role of MRI of the breast in the evaluation of the symptomatic patient. *Current Opinion in Obstetrics & Gynecology, 21*(1), 74-9. doi:10.1097/GCO.0b013e328321e45e

Vinitha Sree, S., Yin-Kwee Ng, E., Acharya, R., & Faust. O. (2011). Breast imaging: A survey. *World Journal of Clinical Oncology, 4*, 171-178. doi: 10.5306/wjco.v2.i4.171

Von Bertalanffy, L. (1968). *General systems theory: Foundations, development, applications.* New York, NY: George Braziller.

Wainer, H., & Braun, H. I. (Eds.). (1988). *Test validity*. Hillsdale, NJ: Lawrence Erlbaum Associates.

Wang, H., Singh, A, P., St. Luce, S. A., & Go, A. R. (2011). Breast cancer treatment practices in elderly women in a community hospital. *International Journal of Breast Cancer*, 2011, Article ID 467906, doi.org/10.4061/2011/467906

WebMD. (2013a). Breast cancer health center. Tools & resources. Retrieved from http://www.webmd.com/breast-cancer/guide/preventive-mastectomy

WebMD. (2013b). Information and resources. Magnetic resonance imaging (MRI). Retrieved from http://www.webmd.com/a-to-z-guides /magnetic-resonance-imaging-mri

Wood, A. M., Medved, M., Bacchus, I. D., Al-Hallaq, H. A., Shimauchi, A., Newstead, G. M.,….Karczmar, G. S. (2013). Classification of breast lesions pre-contrast injection using water resonance line shape analysis. *NMR Biomedicine*., *26*, 569–577. doi: 10.1002/nbm.2893

Wolcott, H. F. (1990). On seeking--and rejecting--validity in qualitative research. In E. W. Eisner & A. Peshkin (Eds.), *Qualitative inquiry in education: The continuing debate* (pp. 121-152). New York, NY: Teachers College Press.

Yaffe, M. J. (2008). Review. Mammographic density. Measurement of mammographic density. *Breast Cancer Research, 10*(3), 209. doi: 10.1186/bcr2102

Yaghjyan, L., Colditz, G., Collins, L., Schnitt, S., Rosner, B., Vachon, C., & Tamimi, R. (2011). Mammographic Breast Density and Subsequent Risk of Breast Cancer in Postmenopausal Women According to Tumor Characteristics. *JNCI Journal of the National Cancer Institute, 103*(15), 1179-1189. doi: 10.1093/jnci/djr225

Youk, J. H., & Kim, E. K. (2010). Supplementary screening sonography in mammographically dense breast: Pros and cons. *Korean Journal of Radiology, 11*(6), 589-93. doi: 10.3348/kjr.2010.11.6.589

Appendix A: Cover Letter to Expert Panelists

Dear Potential Participant,

I am a doctoral student in the Walden University Health Services program. The university has approved my request to conduct research by granting me IRB approval number 10-07-14-0078441 to conduct this study. The reason for the survey is to fulfill the university's requirement for the PhD and to request your expert opinion on the following question: Can or should MRI techniques be used with conventional mammograms to screen women with dense breast tissue for breast cancer?

If you would like to participate in the study, please complete the enclosed six-question survey. The anticipated time to complete this survey is no longer than 15 minutes, and the results will be used to support a larger study. After you complete the survey, please used the stamped, self-addressed envelope and mail your response within 7 days. Your identity and responses will be kept confidential. If you are interested in participating, please send an e-mail to rachel.connett@waldenu.edu.

Thank you for participating.

Rachel Connett

PhD Candidate

Appendix B: Cover Letter to Participants for Quantitative Data Collection

Dear Participant,

I am a Ph.D. graduate student with Walden University, Health Services program and I am covered by IRB Approval # 10-07-14-0078441 to conduct this study. This purpose of this study is to determine if MRI techniques can be used along with conventional mammograms to screen women with dense breast tissue for breast cancer detection. The primary reason of the study is to fulfill the university's requirement for the student to gain her Ph.D.

The survey will be done by an online survey company called SurveyMonkey. If you choose to participant in this study, you will be sent login information to access the website. The survey will have 11 questions with five options for your response. The survey should take about 30 minutes to complete. Your personal information will not be used and your responses will be kept confidential. If you would like to participate in the study, please send an e-mail to rachel.connett@waldenu.edu.

Thank you for your participation,

Signature

Rachel Connett

Ph.D. Candidate

Appendix C: Cover Letter to Participants for Qualitative Data Collection

Dear Participant,

I am a Ph.D. graduate student with Walden University, Health Services program and I am covered by IRB Approval # 10-07-14-0078441 to conduct this study. This purpose of this study is to determine if MRI techniques can be used along with conventional mammograms to screen women with dense breast tissue for breast cancer detection. The primary reason of the study is to fulfill the university's requirement for the student to gain her Ph.D.

The survey will be done by the researcher through telephone interviews to collect responses to 5 questions. Each question will be given a response time of 3 to 5 minutes. The entire survey will take about 30 minutes to complete.

Your personal information will not be used and your responses will be kept confidential. If you would like to participate in the study, please send an e-mail to rrachel.connett@waldenu.edu.

Thank you for your participation,

Signature

Rachel Connett

Ph.D. Candidate

Appendix E: Telephone Script for Researcher

Hello Ms. Doe, thanks for taking the time to speak with me. My name is Rachel Connett, and I am a Ph. D. student and researcher with Walden University. I would like to understand the process from the time you began breast cancer screening until now as it is relevant to the different screening imaging techniques that were used to image dense breast tissue. Your feedback will help me to understand which technique, ultrasound or MRI, is more effective to use with conventional mammogram for breast cancer detection in dense breast tissue. The information gathered will help women with dense breasts and the dense breast cancer community make an informed decision about the most effective imaging option they can make when they are presented with a dense breast diagnosis.

Your participation in this interview and your responses will remain confidential. Thank you for your participation,

Rachel Connett

Ph.D. Candidate

Appendix F: Research Study Questions for the Expert Panel

How many years of experience have you had in interpreting screening mammographic images?

How many years of experience have you had in interpreting MRI images for breast cancer?

Was there a high percentage for repeat mammograms due to glandular breast tissue with conventional mammogram?

Elaborate on conventional mammogram and ultrasound as screening methods for dense breast tissue.

Does MRI have a higher specificity for dense breast tissue?

Does MRI of glandular tissues yield more findings for breast cancer?

Questionnaire for Quantitative Participants

1. Is your age between 24 and 74 years?
2. Are you in good health?
3. Do you have a family history of breast cancer?
4. Have you lost a family member to breast cancer who had regular mammography screenings?
5. Do you regularly perform a breast self-exam?
6. Do you have a screening mammogram every year?
7. Have you had screening mammograms every year for the last five years?
8. Have you had an abnormal mammogram finding?
9. Did your doctor tell you that the result of your mammogram was not conclusive?
10. Do you think a screening mammogram is the only available way to screen women for breast cancer and did you have an ultrasound ?

Likert scale:

Strongly agree =1	Agree=2	Neither=3	Disagree=4	strongly disagree=5

Survey questions
Item
Is your age between 24 and 74 years?
Are you in good health?
Do you have a family history of breast cancer?
Have you lost a family member to breast cancer?
Do you regularly perform a breast self-exam?
Do you have a screening mammogram every year?
Have you had screening mammograms every year for the last five years
Have you had an abnormal mammogram finding
Did your doctor tell you that the result of your mammogram
Do you think a screening mammogram is the only available way to screen women for breast cancer and did you have an ultrasound

Questionnaire for Qualitative Participants:

1. Are you in the age group of 24 to 74 years?
2. Do you perform routine breast self-exams?
3. Do you have a family history of breast cancer?
4. Do you have an annual mammogram?
5. Do you have dense breast tissue based on a mammogram?
6. Were you told by her doctor that you needed a repeat mammogram?
7. Have you had an ultrasound as a breast cancer screening?
8. What was the finding?
9. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding?
10. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer.

Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms

Appendix G: Expert Panelists

Dr. Jafi Jipson, MD (Radiologist)

Dr. Thomas Huang, MD (Clinician)

Dr. Ann Shimakawa PhD (Research Scientist)

Appendix H: Descriptives

	N	Minimum	Maximum	Mean	Std. Deviation
Age	300	1	5	1.17	.473
Good health	300	1	5	1.63	.594
Family history of breast cancer	300	1	5	4.40	.567
Lost a family member to breast cancer	300	1	5	4.40	1.085
Regularly self-breast exam	300	1	5	1.92	.456
Screening mammogram every year	300	1	5	1.69	.572
Screening mammograms every year for the last five	300	1	5	2.84	1.570
Abnormal mammogram finding	300	1	5	2.01	.674
Result of your mammogram abnormal	300	1	5	4.12	1.296
Ultrasound after the screening mammogram	300	1	5	1.97	.767
Valid N (listwise)	300				

Appendix I: *t* Test One-Sample Statistics

	N	Mean	Std. deviation	Std. error mean
Age	300	1.17	.473	.027
Good health	300	1.63	.594	.034
Family history of breast cancer	300	4.40	.567	.033
Lost a family member to breast cancer	300	4.40	1.085	.063
Regularly self-breast exam	300	1.92	.456	.026
Screening mammogram every year	300	1.69	.572	.033
Screening mammo every year for the last 5 years	300	2.84	1.570	.091
Abnormal mammogram finding	300	2.01	.674	.039
Result of your mammogram abnormal	300	4.12	1.296	.075
Ultrasound after the screening mammogram	300	1.97	.767	.044

Appendix J: One-Sample *t* Test

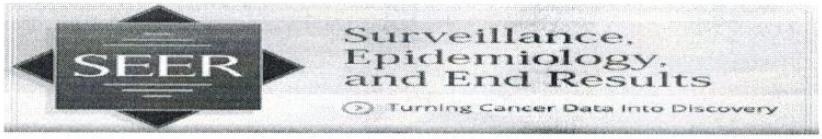
Variable	Test value = 1					
	t	*df*	Sig. (2-tailed)	Mean difference	95% confidence interval of the difference	
					Lower	Upper
Age	6.343	299	.000	.173	.12	.23
Good health	18.453	299	.000	.633	.57	.70
Family history of breast cancer	103.930	299	.000	3.400	3.34	3.46
Lost a family member to breast cancer	54.238	299	.000	3.397	3.27	3.52
Regularly self-breast exam	34.971	299	.000	.920	.87	.97
Screening mammogram every year	20.999	299	.000	.693	.63	.76
Screening mammograms every year for the last five	20.263	299	.000	1.837	1.66	2.02
Abnormal mammogram finding	25.854	299	.000	1.007	.93	1.08
Result of your mammogram abnormal	41.732	299	.000	3.123	2.98	3.27
Ultrasound after the screening mammogram	21.987	299	.000	.973	.89	1.06

Appendix K: Major Themes

Participants Age Health Status Annual Screen Repeat Mammo US exam Abnormal MRI
P1
P2
P3
P4
P5
P6
P7
P8
P9
P10

Appendix L: Letters of Cooperation:

1. SEER
2. CCR
3. RMC



Sept 10, 2014

Applied Research Program
Division of Cancer Control and Population Sciences, National Cancer Institute
9609 Medical Center Drive, MSC 9762
Bethesda, MD 20892

Dear Ms. Connett,

Re: Letter of Cooperation

After reviewing your research proposal and discussion of your proposed research project MRI as an Adjunct to Conventional Mammography to Screen for Cancer in Dense Breast Tissue, the Surveillance Epidemiology and End Results (SEER) has agreed to be your community sponsor to assist you to obtain data for your study.

A data use agreement between you and SEER is retained on record at SEER.

Please be reminded that you agreed that the variables of the target population released to will not be used to identify any individual cancer patient, hospital or physician. That you will publish findings from this analysis at a sufficient level of aggregation to make it impossible to identify individual patients and providers, and you will not make public any information that may result in the identification by others of individual patients, hospitals or physicians. That you understand that you can only access the SEER-Medicare data to work on the project as described in your application. Furthermore, the dataset with restricted variables can be used only for this particular project and cannot be used for any subsequent analysis.

SEER's information technology contractor will provide an invoice to cover the costs of creating the requested data files and send an invitation letter on your behalf.

Sincerely,

Angela Meknes,
angela.meknes@imsweb.com
Information Management Systems, Inc

1825 Bell Street, Suite #102,
Sacramento, CA 95825.

Sept 11, 2014

Dear Ms. Connett,

In our recent communication, and review of your research proposal, the California Cancer Registry will work with you to conduct the study MRI as an Adjunct to Conventional Mammography to Screen for Cancer in Dense Breast Tissue within the confine of the California Cancer Registry.

You inquired if CCR can send an invitation letter to the group you want to study: Yes, CCR provides an additional cost service where an invitation letter can be sent on your behalf to the group you want to study.

Your signed Confidentiality Agreement for Disclosure of CCR Data is on file at CCR.

I wish you success with your research.

Sincerely,

Stephen Fuchslin
EurekaInfo@ccr.ca.gov
Information Systems Chief

Regional Medical
Center of San Jose
Dedicated To Your Well Being.

225 N Jackson Ave,
San Jose, CA 95116
(408) 259-5000

Sept 11th. 2014

Dear Ms. Connett,

Thank you for your email regarding placing information at the Breast Care Center, located at 200 Jose Figueres Ave.

Francia Cruz, Radiology floor Supervisor, has been notified by me to help facilitate this.

Please contact me if you have further questions.

Good luck with your project.

Sincerely,

Rani Kaur, MS, RDMS, RVT,
rani.kaur@hcahealthcare.com
(408) 259-5000
Director of the Center for Advanced imaging

Appendix O: Responses from Qualitative Interviews

Participant 1:

1. Are you in the age group 24 to 74 years? Yes, I am 68 years old.
2. Do you perform routine breast self-exams? Yes, I do. That is how I found the lump in my left breast.
3. Do you have a family history of breast cancer? No, my family does not have breast cancer.
4. Do you have an annual mammogram? I have always had an annual mammogram, since I was in my 40s.
5. Do you have dense breast tissue based on a mammogram? Yes. I think I was in my 50s when my doctor told me I had "granular breast tissue." He said there were areas in my left breast that he could see through.
6. Were you told by your doctor that you needed a repeat mammogram? Yes, I had a repeat mammogram, which did not give more information than the previous one.
7. Have you had an ultrasound as a breast cancer screening? An ultrasound exam was recommended. What was the finding? Not much different that the two mammograms that I had. My doctor recommended that if I am okay with it, that an MRI can be done to get more information, and a biopsy of the area can be done to get more information.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? The uultrasound exam did not give new information, but the MRI did. The MRI was very uncomfortable: I was given an injection and had to lie on my chest for about 45 minutes. Then the doctor took a sample of my breast tissue and sent it to the lab. Thankfully, the area in question was very small and was taken out. I had radiation to kill any cancer cells that were there after the surgery.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? It was very scary and nerve racking to wait for the results. I was upset because for so long I took good care of my health: annual physicals, blood tests, mammograms, and now, breast cancer. The good news is that the cancer did not spread, and my lymph nodes are ok. Now, all I have is an MRI every year, just to check for change.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? I think so. It seems like I was not diagnosed properly or misdiagnosed, and I wasted my time with the ultrasound especially, which was a waste of time. The MRI is not easy, but my doctor told me it is the best exam for my checkups.

Participant #2

1. Are you in the age group of 24 to 74 years? I am 60 years old

2. Do you perform routine breast self-exams? Yes, since my children were born.
3. Do you have a family history of breast cancer? No, neither side of my family. We have other things though: diabetes.
4. Do you have an annual mammogram? Every year since I was 40.
5. Do you have dense breast tissue based on a mammogram? Yes, my mammograms were clear until last year.
6. Were you told by her doctor that you needed a repeat mammogram? Yes, my doctor ordered a diagnostic mammogram. At first, they diagnosed the areas as calcium, but continued to order more tests. Have you had an ultrasound as a breast cancer screening? I had an ultrasound exam which did not do much good, and the doctor said it looked suspicious. My doctor said it would be best to do more tests. He wrote a script for an MRI.
7. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? It was the most awful exam I ever had. It took so long. They made me lie on my chest, for a very long time. Then, the doctor took a tissue sample. My doctor's office called me to come in to talk about the results. The results came back positive for cancer.
8. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? I was very scared. The time to wait for the results was almost two weeks.
9. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms?
10. I do not get it. How did the mammogram miss the cancer? I have so many questions about this. Needless to say, my annual breast screen is done with MRI only.

Participant #3

1. Are you in the age group of 24 to 74 years? I am 55 years old.
2. Do you perform routine breast self-exams? Yes I do, every month.
3. Do you have a family history of breast cancer? No family history, both sides.
4. Do you have an annual mammogram? Yes, since age 40.
5. Do you have dense breast tissue based on a mammogram? Yes. When I turned 50, my mammogram result was not conclusive and I had to do a repeat mammogram because my breast tissue was dense.
   Were you told by your doctor that you needed a repeat mammogram?
6. I had a repeat mammogram. The technician said they needed more close up shots of the dense areas.
7. Have you had an ultrasound as a breast cancer screening? I had an Ultrasound exam after the second mammogram. My doctor said the area was too small to diagnose, so I had an MRI exam.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? Yes, the MRI and some kind of special software helped the doctor to figure

it out. Thank God, the area that they were not sure about was small, and the tumor was taken out.

9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? I was totally scared. I have 2 children, both in college, and was scared of what I did not know.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Absolutely. Not sure why the MRI was not done after the first mammogram. Since my diagnosis, I always get an MRI for my checkup.

Response from Participant #4:

1. Are you in the age group of 24 to 74 years? I am 45
2. Do you perform routine breast self-exams? Yes. I am a nurse.
3. Do you have a family history of breast cancer? No.
4. Do you have an annual mammogram? Yes, since I was 35 years old
5. Do you have dense breast tissue based on a mammogram? Yes, and my doctor told me it was ok, not to worry.
   Were you told by her doctor that you needed a repeat mammogram? Two years ago, my mammogram result was BI-RADS 4.
6. Have you had an ultrasound as a breast cancer screening? Yes, and my doctor said he was not satisfied because the test did not give more information that the first mammogram
7. What was the finding? Inconclusive.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? Yes. The mammogram and ultrasound were both inconclusive.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? I thought I was taking good care of myself when I started breast cancer screening at age 35. It was very frustrating to know that the mammogram did not detect the cancer earlier.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes. I believe that the mammogram was ok, but the Ultrasound was useless, and that an MRI should have been ordered after the mammogram.

Response from Participant #5:

1. Are you in the age group of 24 to 74 years? 55 years.
2. Do you perform routine breast self-exams? Yes
3. Do you have a family history of breast cancer? No.
4. Do you have an annual mammogram? Yes, since I was 40.
5. Do you have dense breast tissue based on a mammogram? Yes. When I was 45.

Were you told by her doctor that you needed a repeat mammogram? Yes. My doctor said my mammogram was not clear because of the dense tissue.

6. Have you had an ultrasound as a breast cancer screening? Yes, after the second mammogram.
7. What was the finding? Not much else that the mammogram which was BI-RAD4.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? The MRI was a horrible test. I had to lay to lay on my chest for over one hour. The biopsy came back positive for breast cancer.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? The wait was the worst part. My family and I suffered because it took over one week to get the results. We kind of kneww after the tests that something was not right.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes. If the MRI was done right after the first mammogram. I would have known the results and would have had the conversation with my doctor.

Response from Participant #6:

1. Are you in the age group of 24 to 74 years? I am 49.
2. Do you perform routine breast self-exams? Yes, all the time.
3. Do you have a family history of breast cancer? No cancer in the family, both sides are clear.
4. Do you have an annual mammogram? Yes, since I was 40.
5. Do you have dense breast tissue based on a mammogram? Yes. When I was 45, my mammogram came back with a BI-RADS4. The doctor explained that this number was too high and that I needed more tests.
   Were you told by her doctor that you needed a repeat mammogram? Yes, I had a diagnostic mammogram.
6. Have you had an ultrasound as a breast cancer screening? An Ultrasound exam was recommended.
7. What was the finding? The report said inconclusive, but suggest that there could be cancer.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? Yes. Although the MRI was a hard test, they took a breast tissue after the MRI and sent it to the lab.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? It took several weeks to get all the tests and the lab work done. The wait was terrible because I did not know.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes. If the MRI

was done after the first mammogram, I would have need so devastated. The ultrasound did not find much.

Response from Participant #7:

1. Are you in the age group of 24 to 74 years? I am 48 years old.
2. Do you perform routine breast self-exams? Yes
3. Do you have a family history of breast cancer? No.
4. Do you have an annual mammogram? Yes, since I was 40 years old
5. Do you have dense breast tissue based on a mammogram? Yes, dense breast tissue was the finding three years ago.
   Were you told by her doctor that you needed a repeat mammogram? Yes. My mammograms were normal, but when I was 45, I had the bad news that I had to do more tests because there was an area in my left breast that was suspicious.
6. Have you had an ultrasound as a breast cancer screening? Yes, an Ultrasound exam was recommended after the last mammogram.
7. What was the finding? Inconclusive, because the area was too small for the ultrasound exam.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? Yes, after both the mammogram and ultrasound exams and a biopsy, the result was cancer.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? It took a toll on my health that something was wrong. I was a basket case. My family was affected so much because I have small children and I wanted to be around to take care of them. I was too young to die.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes. I still do not understand how my mammograms were normal for five years and suddenly became abnormal. My doctor should have ordered an MRI sooner.

Response from Participant #8:

1. Are you in the age group of 25 and 75 years? I am 57 years old
2. Do you perform routine breast self-exams? Yes, every month.
3. Do you have a family history of breast cancer? No history, thank God.
4. Do you have an annual mammogram? Yes, since I was 40.
5. Do you have dense breast tissue based on a mammogram? Yes. When I turned 50, my mammogram result changes from normal to dense.
   Were you told by her doctor that you needed a repeat mammogram? Yes, I had repeat test.

6. Have you had an ultrasound as a breast cancer screening? After the repeat mammogram, my doctor was not convinced with the results and said an ultrasound exam was needed.
7. What was the finding? My doctor said he was not convinced that the ultrasound gave better results.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? I had an MRI and a biopsy that confirmed that the breast tissue was cancerous.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? I waited almost one month to get approval and appointments to get all the tests done. It was mentally draining to know something was wrong, but did not know what.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes, if the MRI was done after the first abnormal mammogram result, the stress would have been lessened for me and my family. The ultrasound did not find much.

Response from Participant #9:

1. Are you in the age group of 24 to 74 years? I am 57 years old.
2. Do you perform routine breast self-exams? Yes, religiously.
3. Do you have a family history of breast cancer? None.
4. Do you have an annual mammogram? Every year since I was 40.
5. Do you have dense breast tissue based on a mammogram? Not at first, but as I got older. I believe when I was 52, that was five years ago. I do not understand this. What in my body changed?
   Were you told by her doctor that you needed a repeat mammogram? Yes, I had a follow up repeat mammogram, where I had zoomed in pictures. I had BI-RADS4 result.
6. Have you had an ultrasound as a breast cancer screening? Yes. The BI-RADS 4 prompted more testing. My doctor recommended an ultrasound exam.
7. What was the finding? Not much more than the mammogram. And my doctor ordered an MRI test.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? Yes. Although the MRI test was very hard for me to do, as I have problems with small spaces, I managed to finish the exam. The doctor took a tissue sample and sent it to the lab. The exam suggested breast cancer.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? Very scared and devastateded. I felt like the doctors took too long and did tests that were not needed.

10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes. I believe that the second exam should have needed an MRI.

Response from Participant #10:

1. Are you in the age group of 24 to 74 years? I am 30 years old.
2. Do you perform routine breast self-exams? Yes, that is when found a lump. I had a sore area, and when I pressed on it, it was painful.
3. Do you have a family history of breast cancer? Not at all
4. Do you have an annual mammogram? Since I was 25 years old.
5. Do you have dense breast tissue based on a mammogram? Yes. When I felt the lump, I made an appointment with my GP, and she wrote a script for a mammogram.
   Were you told by her doctor that you needed a repeat mammogram? I had to repeat the mammogram because I have dense tissue, and the mammogram was not able to see through the tissue and I was still having pain in my right breast.
6. Have you had an ultrasound as a breast cancer screening? The radiologist recommended an ultrasound exam.
7. What was the finding? Very technical jargon…but not conclusive. And I was still having pain.
8. Did an MRI confirm your breast cancer diagnosis after the abnormal mammogram finding? The MRI showed that I had a small area that was suspicious for cancer and I had a biopsy which showed cancer cells.
9. Explain how you felt emotionally during the time it took for your doctor to make a diagnosis for your breast cancer? It was nerve racking. I have no cancer history on both sides of my family, which puzzled my doctors.
10. Do you believe that your breast cancer could have been detected earlier if MRI was utilized after your initial cancer diagnosed using mammograms? Yes, and a biopsy were done at the same time. The time it took to get in to do the tests was long. It seemed that my test was not urgent enough. If the MRI was done early, I would not be so stressed.