EFFECTS OF AN EDUCATIONAL INTERVENTION ON NURSE PRACTITIONERS' CLINICAL BREAST EXAMINATION TECHNIQUES AND ABILITY TO DETECT LUMPS IN SILICONE BREAST MODELS

A DISSERTATION

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To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Valarie P. Waldmeier entitled "Effects of an Educational Intervention on Nurse Practitioners' Clinical Breast Examination Techniques and Ability to Detect Lumps in Silicone Breast Models." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing.

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DEDICATION

To my mother who lost her battle with breast cancer because mammography could not detect her mass.

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ABSTRACT

VALARIE P. WALDMEIER

EFFECTS OF AN EDUCATIONAL INTERVENTION ON NURSE PRACTITIONERS' CLINICAL BREAST EXAMINATION TECHNIQUES AND ABILITIES TO DETECT LUMPS IN SILICONE BREAST MODELS

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Breast cancer continues to strike one in eight women during her lifetime in the United States. Until a cure is found, early detection offers the best treatment options and reduces mortality. The clinical breast examination has been found to be an effective screening tool for early detection. However, the technique has not been standardized in clinical trials, the literature, in training, or in practice even though research has suggested the most effective method for performing the technique.

This experimental equivalent groups posttest-only design study was done to determine the effects of the Gagnè Instructional Design Model of education on Louisiana nurse practitioners' clinical breast examination (CBE) technique and abilities to detect lumps in silicone breast models. Twenty-eight Louisiana nurse practitioners from varying specialties in two separate settings who agreed to participate were randomized into the control group or experimental group. Participants in the experimental group attended a 50-minute educational session promoting current recommended practice techniques for the CBE presented by the researcher based upon the Gagnè Instructional Design Model.

Participants were then asked to examine 6 silicone breast models marking where they felt a lump requiring follow-up. Participants in the control group were asked to examine the silicone breast models prior to attending the educational session.

Multiple one-way analysis of variance were done to separately determine the relationships between the educational intervention and the nurse practitioners' CBE technique, number of lumps detected, and number of false positives identified. Results indicated that the educational intervention significantly improved both the CBE technique and number of lumps correctly identified. The third analysis indicated no significant difference in the educational intervention and number of false positives detected.

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CHAPTER I

INTRODUCTION

Breast cancer accounts for over 40,000 deaths annually in the United States (U.S.) and over 211,000 new cases are diagnosed annually (National Cancer Institute [NCI], 2005). Until a cure is found, early detection offers the greatest chance of survival. Early detection also improves treatment options that are less toxic, less disfiguring, and more effective. In an effort to detect breast cancer at an early stage of progression, many leading health organizations recommend mammography combined with a clinical breast examination (CBE) at regular intervals for all women (Barton, Harris & Fletcher, 1999; Smith, Cokkinides & Eyre, 2003).

Several recent studies have described and illustrated CBE techniques and have provided the basis for recommendations concerning the specific way CBE should be performed (Barton, Harris & Fletcher, 1999; Coleman & Heard, 2001; McDonald, Saslow & Alciati, 2004). Currently, the literature indicates there are approximately 20 different CBE techniques that can be used by health care providers. In addition, the educational approaches to teaching CBE are just as numerous. Recognizing the need for CBE standardization, the American Cancer Society (ACS), in collaboration with the Centers for Disease Control and Prevention (CDC), initiated a panel of national and international experts well versed in CBE performance. The panel was charged with developing recommendations for health care providers and organizations that would enhance CBE performance and reporting (Saslow, Hannan, Osuch et al., 2004). Recommendations for performing the CBE include the specific pattern, number of fingers to be used, parts of the fingers to be used, motion, and pressure applied while performing the examination.

Nurse practitioners (NP) are expected to be the front line provider for primary care that focuses on health promotion and disease prevention (Towers, Dempster & Counts, 2003). As such, it is vitally important that nurse practitioners use the best technique to perform the CBE in order to detect breast cancer at the earliest possible stage. It is also important to develop standardized educational guidelines that are utilized by NP educational programs and certifying bodies. These guidelines must be developed utilizing evidence-based research within their practice. A standardized method for CBE training for nurse practitioners is one avenue to accomplish this goal.

Problem of Study

While CBE has been shown to be an integral aspect of breast cancer screening, standardized CBE training and techniques have not been established. The purpose of this study is to examine the effectiveness of Gagné's Instructional Design Model (1977) on Louisiana nurse practitioners' CBE techniques and abilities to detect lumps in silicone breast models.

Specific aims of the study include:

1. To test an educational intervention based upon the Gagne` Instructional Design Model.

2. To standardize participants' physical examination techniques in performing clinical breast examinations to the recommended technique.
3. To improve the accuracy of lump detection on silicone breast models during clinical breast examinations by participants.

Rationale for the Study

Clinical breast examinations have been shown to detect some cancers not found by mammography and may be important for women who do not receive regular mammograms or for whom mammography is not recommended (Saslow, et al., 2004). Presently, most research addressing technique and performance of the CBE focuses on physicians and medical students. Very little is known about nurse practitioners' performance related specifically to CBE technique.

Current large screening trials including the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) have standardized reporting, but the method of performing the CBE varies (Barton, Harris & Fletcher, 1999; Centers for Disease Control and Prevention [CDC], 2004; McDonald, Saslow & Alciati, 2004). This lack of standardization for performing the CBE is a weakness and brings to question validity of the findings.

Nurse practitioners are involved in the care of women in many settings in the U.S. and Louisiana. They are primary care providers in many communities throughout the state and are expert in health maintenance, health prevention, and health promotion. The rural and underserved nature of the state of Louisiana lends itself to susceptibility of poor health. In fact, Louisiana currently ranks 50th in the U.S. in health indicators on the Louisiana Health Report Card (Louisiana Department of Health and Hospitals [DHH], 2004). Nurse practitioners must be sufficiently trained in CBE to improve the health of the state's women by reducing breast cancer mortality.

There are many controversies surrounding the CBE. The variations in female breast anatomy, training of examiners, and recommended techniques render this an important subject to study. Approaches in performing the CBE vary among health care providers. Inspection and palpation are included in the physical examination however; individual practitioners utilize different techniques depending upon their training. Most physical assessment and physical diagnosis textbooks give directions for carrying out a breast examination that involve inspection then palpation and offer several patterns that can be utilized for the palpation. Descriptions of which fingers should be used or what part of the fingers should be used are scarcely mentioned (Bickley, 1999; Seidel, Ball, Dains & Benedict, 2003). According to Swartz (2002), the vertical strip method is the superior pattern for CBE; however, the author goes on to state that the method is more time-consuming and may be best used by women for breast self-examination.

Reportedly, the CBE may be accurate if done in a certain way and for a certain period of time (Barton, Harris & Fletcher, 1999; Fletcher, O'Malley & Bunce, 1985; Saslow, et al., 2004). Current evidence demonstrates that the sensitivity of CBE is far from perfect. In fact, studies have shown the overall sensitivity or lump detection ranges from 40 to 54 percent in female patients and from 40 to 71 percent on silicone breast models (Barton, et al., 1999; Fletcher, O'Malley, & Bunce, 1985; Miller, Baines & Wall, 2000) Thus, continuing education for nurse practitioners is vital in improving accuracy of CBE as well as finding the best standard for performing clinical breast examinations.

Theoretical Framework

Robert Gagné's Instructional Design Theory was used to design the educational intervention for the study. Gagné considers his theory an information-processing model of cognition, claiming that an instruction plan can generate both appropriate environmental stimuli and instructional interaction, and thereby bring about a change in cognitive structures of the learner. He proposed that events of learning and categories of learning outcomes together provide a framework for an account of learning conditions (Gagné, 1977). His model proposes that there are internal and external conditions of learning that affect the process of learning and make up the events of learning. Deliberate planning of these events constitutes instruction (Gagné, 1977).

According to Gagné (1974), instruction depends upon desired learning outcomes, rather than subject knowledge. His theory proposes that instructional design begins with defining the kinds of outcomes to be learned or taught. Analyzing the requirements for learning simply works back from the intended learning goal. He suggests that learning tasks can be organized into a hierarchy according to complexity. Significance of the hierarchy is to identify prerequisites that should be completed to facilitate learning at each level. Doing an analysis of a learning/training task may identify these prerequisites. Learning hierarchies provide the basis for the sequencing of instruction (Gagné, 1977).

Gagné's instructional theory consists of three components: taxonomy of learning outcomes, conditions of learning, and the nine events of instruction. His taxonomy of learning outcomes was originally proposed as a way of classifying the expected outcome of the instruction that was to be designed. In this way, the objectives of the instruction could be evaluated against the learner's perceived capabilities (Gagné, Briggs & Wager, 1992). The learning outcomes are listed in Table 1.

Table 1

Gagne' Learning Outcomes and Definitions (1977)

Learning Outcome	Definition
Verbal Information	The restating of previously learned information
Intellectual Skills	
Discrimination	Distinguishing between objects or features
Concrete concepts	Identifying classes of objects
Defined concepts	Classifying new ideas by definition
Rules	Applying a single rule to a class of problems or challenges
Higher order rules	Applying combinations of simple rules to solve complex problems
Cognitive Strategies	Learners guiding their own thinking in order to solve problems
Attitudes	Internal feelings or preferences that influence personal action towards a class of problems
Motor skills	Any activity that requires the use of coordinated muscular activity

Each of the learning outcomes has specific critical conditions associated with it that are necessary to properly present the information. The matrix of essential learning conditions matched to the five defined outcomes as presented by Gagné and Driscoll (1988) follows:

Intellectual Skill:

1. Call attention to distinctive features.
2. Stay within the limits of working memory.
3. Stimulate the recall of previously learned component skills.
4. Present verbal cues to the ordering or combination of component skills.
5. Schedule occasions for practice and spaced review.
6. Use a variety of contexts to promote transfer.

Cognitive Strategies:

1. Describe or demonstrate the strategy.
2. Provide a variety of occasions for practice using the strategy.
3. Provide informative feedback as to the creativity or originality of the strategy or outcome.

Attitudes:

1. Establish an expectancy of success associated with the desired attitude.
2. Assure student identification with an admired human model.
3. Arrange for communication or demonstration of choice of personal action.

4. Give feedback for successful performance; or allow observation of feedback in the human model.

Motor Skills:

1. Present verbal or other guidance to cue the executive subroutine.
2. Arrange repeated practice.
3. Furnish immediate feedback as to the accuracy of performance.
4. Encourage the use of mental practice.

Gagné's (1992) assertion was that instruction consists of a set of events that while external to the learner are structured to support the internal processes that constitute learning. He derived his nine events of instruction from this perception of learning and listed them in the order that they should occur when presenting information to a learner. However, he was careful to state that they are not a rigid, inflexible set of events and that the form of the events of instruction could not be specified in general for all instruction. Instead, the form must be decided upon for each learning objective and the communication to the learner should be chosen to fit each specific set of circumstances. The communications to the learner should also be designed to support the learning process (Gagné, Briggs, & Wager, 1992). Gagné's nine events of instruction are as follows:

1. Gaining attention.
2. Informing learner of the objective.
3. Stimulating recall of the prerequisite learning.

4. Presenting the stimulus material.
5. Providing learning guidance.
6. Eliciting the performance.
7. Providing feedback about the performance correctness.
8. Assessing the performance.
9. Enhancing retention and transfer. (Gagné, Briggs, & Wager, 1992).

Use of Gagné's theory for this study will provide an appropriate pedagogical framework from which to approach the design of the educational intervention.

Assumptions

For the purpose of this study, the following will be assumed:

1. The educational intervention is designed specifically for the intended learners, advanced practice nurses.
2. Objectives for the educational intervention are appropriate to the learner's level of comprehension.
3. Prerequisite knowledge of clinical breast examinations exists for each learner.

Hypotheses

The following hypotheses were tested at the level of significance of alpha = .05.

H 1 – Louisiana nurse practitioners that attend an educational intervention will score higher on CBE technique performance than those nurse practitioners that do not attend an educational intervention.

H 2 – Louisiana nurse practitioners that attend an educational intervention will score higher on the average number of silicone breast model lumps detected than those nurse practitioners that do not attend an educational intervention.

H 3 – The average number of silicone breast model false positives detected by Louisiana nurse practitioners that attend an educational intervention will be equal to those nurse practitioners that do not attend an educational intervention.

Definition of Terms

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

Nurse practitioners. Conceptually defined as registered nurses who have advanced education in nursing and clinical experience in a specialized area of nursing practice and have received recognition in the form of certification from an accrediting body such as the American Nurses Credentialing Center or the American Academy of Nurse Practitioners. The nurse practitioner is a skilled health care provider who utilizes critical judgment in the performance of comprehensive health assessments, differential diagnosis, and the prescribing of pharmacologic and non-pharmacologic treatments in the direct management of acute and chronic illness and disease (American Nurses Association [ANA], 1996). Operationally defined as nurse practitioners currently licensed in Louisiana and currently certified in one of the following specialties: family, adult, geriatric, pediatrics, psychiatric, or women's health as documented on the Demographic Tool.

Educational intervention. Conceptually defined as internal and external conditions of learning that affect the process of learning and make up the events of learning. Deliberate planning of these events constitutes instruction (Gagné, 1977). Operationally defined as an instructional session developed by the researcher, based on the Gagné Instructional Design Model, consisting of 30 minutes of instructor-facilitated lecture/discussion followed by 20 minutes of practice/feedback on the recommended CBE techniques.

Clinical breast examination (CBE) technique. Conceptually defined as a critical inspection and investigation of the breast, usually following a particular method, performed for diagnostic or investigational purposes by a health care professional (Anderson, 1998). Operationally defined as the score obtained on the Breast Examination Inventory adapted by the researcher from a tool developed by Coleman and Pennypacker (1991).

Lumps. Conceptually defined as piece or mass of indefinite size and shape (Merriam-Webster Online Dictionary, 2005) Operationally defined at the number of lumps documented on the Lump Detection Scoring Tools.

Silicone breast models. Conceptually defined as an imitation of the organ of milk secretion of the mature female made from a polymer of organic silicon oxides (Jacobs, 2005). Operationally defined as six different MammaCare® breast models, specially constructed to simulate the breast tissue of a 50-year-old woman. All of the models have a volume of 250 milliliters of silicone. Five of the models contain a variety of lumps ranging in size, number, and texture. The sixth model is lump free (MammaCare® UNC Breast Model Series Testing Protocol, 2005).

False positive. Conceptually defined as a test result that erroneously assigns a person to a specific diagnostic group (Jacobs, 2005). Operationally defined as the number of marks made on the silicone breast models indicating a lump where one is not present and documented on the Lump Detection Scoring Tools.

Limitations

The study was limited by the following:

1. Only nurse practitioners from Louisiana were included in the sample therefore, results can only be generalized to a similar population.
2. Two dates and two settings for the study were necessary to increase participation, which might have inadvertently led to discussion of the study between nurse practitioners.
3. Since both groups of nurse practitioners (treatment and control) were in the same facility, there might have been discussion of the study between the nurse practitioners.
4. The sample size was small due to low attendance at the two monthly meetings.

Summary

This chapter has introduced concerns about clinical breast examinations and the importance of performing the technique according to current recommended guidelines. The rationale for the study of nurse practitioners and their performance of the CBE was explained. Gagné's Instructional Design Theory was reviewed as a basis for developing the educational intervention to be used in the study. Assumptions for the study as well as definitions of terms were discussed. Finally, hypotheses to be tested were given and limitations were addressed.

CHAPTER II

LITERATURE REVIEW

Breast cancer will affect one in eight women during her lifetime (National Cancer Institute, 2004). Early detection offers the greatest chance of survival until a cure can be found. Early detection improves treatment options that are less toxic, less disfiguring, and more effective. Many leading health organizations such as the American College of Radiology (ACR), the National Cancer Institute (NCI), and the American Cancer Society (ACS) recommend mammography combined with a clinical breast examination (CBE) at regular intervals for all women to detect the cancer at the earliest possible time (Barton, Harris & Fletcher, 1999; Bobo, Lee & Thames, 2000; Smith, Cokkinides & Eyre, 2003). Other groups such as the United States Preventive Services Task Force (USPSTF) and the National Committee for Quality Assurance recommend mammography; however, neither recommends nor discourages routine CBE (Bobo, Lee & Thames, 2000; Humphrey, Helfand, Chan & Woolf, 2002; Smith, Cokkinides & Eyre, 2003).

Clinical breast examination refers to the traditional technique of physical examination of the breast by a health care provider. These examinations can be used either for screening purposes to detect breast cancer in asymptomatic women or for diagnosis to evaluate breast complaints to rule out cancer. Recommendations for specific screening modalities, age to begin screening, and prescribed intervals for screening differ greatly among experts and organizations. Two organizations, ACS and the USPSTF, agree that mammography should be used to detect breast cancer beginning at age 40 years. However, whereas the ACS recommends annual mammography exams the USPSTF recommends 1 to 2 year intervals between exams. The ACS recommends annual CBE every 1 to 3 years for women aged 20 to 39 years and then annually beginning at age 40. Again the USPSTF differs and states there is insufficient evidence to recommend for or against CBE (Humphrey, Helfand, Chan & Woolf, 2002; Smith, Cokkinides & Eyre, 2003). These differing opinions may be due to a lack of rigorous research surrounding breast cancer screening options.

This literature review will center on the value of the CBE in detecting breast cancer in women. The effectiveness, accuracy, and costs of the CBE will be discussed as well as current recommendations for performing the examination. Training methods for the CBE, using both silicone breast models and female patients, will be reviewed. And, finally, Gagné's Instructional Design Theory and its use in educational research will be reviewed as the theoretical framework for the study.

The collection of literature to review was accomplished by performing a computer search of bibliographic databases including: Academic Search Premier, CINAHL, Article First, Cochrane Library, ERIC, FirstSearch, Contemporary Women's Issues, Women's Studies International, and Web of Science. Keywords consisting of breast cancer, clinical breast examination, nurse practitioner, and silicone breast models were used to search each database and Boolean Operators were used to narrow the searches.

Clinical Breast Examination as a Screening Tool

Screening for breast cancer has its shortcomings primarily due to the variability in the anatomy of the female breast, examination techniques, and various types of cancers (Barton, Harris & Fletcher, 1999; Benson, Purushotham & Warren, 2000; Green & Taplin, 2003; McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004; Smith, Cokkinides & Eyre, 2003). However, every effort must be made to detect breast cancer early to improve mortality and morbidity associated with the disease.

All levels of health care professionals, including nurses, nurse practitioners, physician assistants, and physicians, perform clinical breast examinations. Currently there is insufficient evidence that performing CBE decreases morbidity and mortality for breast cancer patients (Berg, 2002; Green & Taplin, 2003; Humphrey, Helfand, Chan & Woolf, 2002; Miller, To, Baines & Wall, 2000). Clinical breast examination is the least studied of the modalities for breast cancer screening and there have been no randomized trials of CBE on which to base recommendations (Albert & Schulz, 2003; Barton, Harris & Fletcher, 1999).

There are several recent studies that clearly show an added benefit of CBE for breast cancer detection when combined with mammography. The first study, the United Kingdom Trial of Early Detection of Breast Cancer (TEDBC) (Valero, Buzdar, Theriault, et al., 1999), investigated the effect on mortality of both mammographic screening in combination with CBE and education about breast self-examination over 16 years. The study included 236,103 women, aged 45 to 64 years, in eight geographic locations in

England and Scotland. Two centers performed alternating biennial screening of mammography with CBE and then only CBE annually. Two centers taught breast self-examination. Four centers served as comparison with no screening. As expected, the researchers found a reduction in mortality (27%) in women undergoing screening compared to those with no screening. The reduction in mortality was greatest (35%) in women aged 45 to 49 years. The invasive cancer detection rate for screening by CBE alone was reported at 1.0 per 1000 (Valero, et al., 1999).

In the second study, Bancej, Decker, Chiarelli, Harrison, Turner and Brisson (2003) monitored 300,303 women aged 50 to 69 years for 2 years who received dual screening with mammography and CBE. The setting for the study utilized four Canadian organized breast cancer-screening programs. They found that breast cancer would be missed without CBE, three cancers for every 10,000 screens and 3 to 10 small invasive cancers in every 100,000 screens.

Finally, in a similar study, researchers prospectively followed 61,688 women aged 40 years and over for 4 years who had undergone at least one screening examination with mammography and CBE. The study population was selected from women enrolled in the Breast Cancer Screening Program (BCSP) at Group Health Cooperative of Puget Sound. They found that sensitivity increased by 4 percent when adding CBE to mammography alone (Oestreicher, Lehman, Seger, Buist & White, 2005).

Conclusions of several authors of other literature reviews agree that there is considerable indirect evidence from studies that support the recommendation of screening with an annual CBE for public health benefit (Albert & Schulz, 2003; Barton, Harris & Fletcher, 1999; McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004; Smith, Cokkinides & Eyre, 2003).

While screening mammography detects more cancers than CBE, its role in reducing mortality is controversial depending upon the age of the female patient. Studies demonstrate evidence that mammography significantly reduces the breast cancer death rates in women between the ages of 50 and 89 years (Kerlikowske, Grady, Rubin, Sandrock & Ernster, 1995). Other studies suggest that screening mammography is minimally beneficial for women 69 years and older due to shortened life expectancy and competing risks of death (Kerlikowske, Salzmann, Phillips, Cauley & Cummings, 1999; Mittra, Baum, Thorton & Houghton, 2000). The findings that screening mammography reduces death rates from breast cancer would render a clinical trial comparing CBE to no interventional screening unethical in this country. Mittra and colleagues (2000) reported that there is sufficient circumstantial evidence to suggest that CBE is as effective as mammography in reducing mortality from breast cancer and that the time has come to compare these two screening methods directly in a randomized trial.

Only one study compared the role of CBE in reducing mortality with mammography. Miller, To, Baines and Wall (2000) performed a randomized trial with 40,000 women aged 50 to 59 years over a period of thirteen years and compared breast cancer mortality following annual screening of mammography plus CBE with CBE-only. The setting for the study included fifteen screening centers located in six Canadian provinces including Nova Scotia, Quebec, Ontario, Manitoba, Alberta, and British Columbia. Although the researchers found a lead-time in diagnosing breast cancer between the groups with the addition of mammography to be 2.1 years average; they found that the total number of deaths was similar in the mammography plus CBE and CBE-only groups with 734 and 690 deaths respectively. This study clearly shows that the CBE is a valuable tool in screening for breast cancer.

A recent study by Lawvere, Mahoney, Symons, Englert, Klein and Mirand (2004) examined nurse practitioners' knowledge and reported practices regarding breast cancer screening. Researchers distributed self-administered surveys to nurse practitioners' in an eight-county region of western New York State. A cross-sectional design was used to examine knowledge, attitudes, and self-reported behaviors relating to cancer screening and prevention among the primary care clinicians (n = 175). Findings revealed a marked variation in how breast cancer screening is approached by nurse practitioners providing primary care services. According to the researchers, the hypothesis for this variation in approaches was attributed, in part, to the lack of uniformity in breast cancer-screening guidelines across organizations. Additionally, findings revealed that 65% of the nurse practitioners reported using written guidelines. However, the sources of the guidelines were variable and included the ACS, the NCI, specialty societies, and health insurance companies. This study shows the existing confusion with the various guidelines.

Cost Effectiveness of Clinical Breast Examinations

Many undeveloped countries throughout the world do not have the amount of advanced technology that the wealthier developed countries enjoy. Thus, mammography may not be a practical screening tool. If mammography is available in these countries, should resources be spent on screening women every year? CBE is generally part of a routine examination and much less expensive. Two recent studies provide a perspective on the practicality of screening for breast cancer with a CBE.

Shen and Parmigiani (2005) used a microsimulation model to evaluate 48 screening strategies, depending on the age range, the examination interval, and whether mammography or CBE was given at every one or two exams. Data from population-level, randomized breast cancer screening trials, and large clinical trials were used to develop the model. Complete health histories for women undergoing various screening strategies were generated from the information. Outcomes for the study were measured in gain in quality-adjusted life years (QALYS) and expected total costs of examinations. For each screening interval and starting age, providing mammography at every two exams and CBE at every exam showed the lowest marginal cost per year of quality-adjusted life save; therefore it was found to be the most cost-effective strategy. They also found that providing both mammography and CBE at every exam had the highest marginal cost per year of quality-adjusted life saved and that giving mammography every two exams and CBE at every exam had comparable marginal QALYS as giving mammography at every exam and CBE every two exams (Shen & Parmigiani, 2005).

Completing a study conducted in Iran, Naderi and Bahrampoor (2003) reported a practical screening strategy to detect breast tumors in those who cannot be referred to specialists due to problems such as geographic location and economical obstacles. In Iran, health care providers, also called Behvarzes, perform most of the screening for women in health care centers throughout the country. The researchers tested the efficacy of Behvarzes in diagnosis of breast tumors compared to obstetricians who were considered the gold standard. Twenty Behvarzes were trained in methods of breast examination and screening of cases at high risk for breast cancer, including demonstration using silicone breast models and live models under an obstetrician's supervision. The Behvarzes then examined 2,000 women at 17 different health care centers and filled out a questionnaire with findings of the examination. Thereafter, the same obstetrician examined all women over a period of 30 sessions. The obstetrician completed a second questionnaire with findings from the examination. Results showed that Behvarzes were able to detect palpable masses in 162 cases compared with the obstetrician who found 169 masses. The comparison of positive reported cases by Behvarzes and obstetricians showed sensitivity of 95.8 percent and specificity of 99.56 percent for Behvarzes diagnosis (Naderi & Bahrampoor, 2003). This study suggests that health care providers can be trained to perform a competent CBE, which can be used as an effective screening tool for women in countries where regular mammography screening is too expensive and unobtainable.

Accuracy of the Clinical Breast Examination

Although CBE is a widely practiced tool for breast cancer screening, its effectiveness is difficult to determine because examination techniques vary considerably. Despite its importance, little is known about most health care providers' performance of the examination. The CBE may be accurate if done in a certain way and for a certain period of time (Barton, Harris & Fletcher, 1999; Fletcher, O'Malley & Bunce, 1985; Fletcher, O'Malley, Pilgrim & Gonzalez, 1989; McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004). To determine its accuracy as a valid screening test, CBE must be compared with a criterion standard. Neither mammography nor histology can be that standard. Cancers that are missed on mammography can be found with CBE and histology cannot be performed on all women whose abnormalities are detected by CBE. Barton and associates (1999) proposed a compromise criterion standard involving follow up of all screened women for a defined period. Those women diagnosed as having breast cancer must have histological proof and all cases of breast cancer among women screened during the follow up period must be counted. It seems that this is so stringent a standard; it would be difficult to meet.

Current evidence demonstrates that the sensitivity and specificity of CBE are far from perfect. Sensitivity is usually defined in studies as the numbers of cancers detected in women or lumps detected in silicone breast models. Specificity is most often defined in studies as the number of false positive reports in women and the detection of a lump that is not present in silicone breast models. Studies have shown the overall sensitivity or lump detection in females ranging from 40 to 54 percent and from 40 to 71 percent in silicone breast models (Barton, et al., 1999; Bobo, et al., 2000; Fletcher, et al., 1985; Fletcher, et al., 1989; Humphrey, et al., 2002; McDonald, Saslow & Alciati, 2004; Miller, et al., 2000; Saslow, et al., 2004; Smith, et al., 2003). Pooling data for several studies resulted in an overall estimate of 93 to 94 percent specificity for CBE performed on women (Barton, et al., 1999; Bobo, Lee & Thames, 2000; McDonald, Saslow & Alciati, 2004). Studies in humans and silicone models demonstrate several factors that influence the accuracy of the CBE. These factors include issues of both examiner and the female patient.

The examiner factors that correlate significantly with lump detection accuracy include duration of the examination, technique involving a systematic search pattern, thoroughness, varying palpation pressure, use of three fingers, use of finger pads, and circular motion (Barton, et al., 1999; Fletcher, et al., 1985; Fletcher, et al., 1989; McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004). It has also been shown that examiner experience or previous experience with abnormal breast lumps may be important in lump detection (Barton, et al., 1999; Fletcher, et al., 1985; Fletcher, et al., 1989).

Patient factors affecting the accuracy of the CBE include age of the patient. On average, younger women and those taking hormone replacement therapy (HRT) have denser breast tissue that make lump detection more difficult, whereas in older women and those not taking HRT, the breast becomes more fatty, making lump detection easier. Two studies using specially manufactured silicone breast modes to simulate premenopausal breast tissue and postmenopausal breast tissue validate the above statement. In both studies, physicians were able to significantly detect more lumps in the set of models simulating postmenopausal breast tissue than in the models simulating premenopausal breast tissue (McDermott, Dolan, Huang, Reifler & Rademaker, 1996; McDermott, Dolan & Rademaker, 1996; McDonald, et al., 2004). Sensitivity has also been found to be slightly lower in women with larger breasts and those with ill-defined fibrocystic changes or lumpy breasts (Barton, et al., 1999; McDonald, Saslow & Alciati, 2004).

Cancer characteristics may also affect sensitivity of the CBE. Breast cancers vary in size, mobility, hardness, depth, and location in the breast. Studies show that sensitivity for non-infiltrating cancers in women was 35 percent; for infiltrating cancers smaller than 1 centimeter in size, 36 percent; and for infiltrating cancers at least 1 centimeter in size, 52 percent (Barton, et al., 1999; McDonald, Saslow & Alciati, 2004). The first studies that tested health care providers' abilities to detect lumps utilizing silicone breast models found improvement in detection with increasing lump size and hardness. The researchers used models with embedded lumps varying in size, hardness, and placement and found that sensitivity increased with lump size from 14 percent for 3-millimeter lumps to 79 percent for 1-centimeter lumps and for hardness from 42 percent for soft-to-medium lumps to 72 percent for very hard lumps (Fletcher, et al, 1985; Fletcher, et al., 1989). These studies were done without any CBE training for participants, constituting a possible limitation of the study.

Accuracy of the CBE has also been measured in terms of specificity or the percentage of examinations without any false-positive detection. This is an important parameter to examine as false-positives cause fear and anxiety for patients and consumes scarce health care resources (Trapp, et al., 1999). Findings of the studies measuring specificity vary from improvement in false-positive detection after education to a decline in performance following education. One study reviewed found no difference in specificity between the experimental and control groups.

Bobo, Lee & Thames (2000), analyzed data from the National Breast and Cervical Cancer Early Detection Program on CBEs provided to low-income women from 1995 through 1998 for numerous parameters, one of which was specificity. They found that across all records in the dataset, specificity was 93.4% and increased with age, thus concluding that the CBE is important for older women.

In a related study, McDermott, Dolan, Huang, Reifler & Rademaker, 1996), compared sets of silicone breast models simulating premenopausal and postmenopausal breast tissue. This study showed the opposite results. Specificity was found to be significantly higher in models simulating younger tissue (82% versus 73%, $\underline{p} < .01$).

Fletcher, O'Malley, Pilgrim & Gonzalez (1989), used manufactured silicone breast models to compare the accuracy of breast examination by 300 laywomen and 62 internal medicine residents. Specificity was found to be low in both groups, but higher for women (66%) than for physicians (50%). This is an interesting finding given that the women in the study had no formal training in CBEs.

Two other studies measured specificity following CBE training. The first investigation by Vetto, Petty, Dunn, Prouser and Austin (2002), implemented a skills-based course for primary care providers. Pre- and post-course testing was performed on silicone breast models. Not only did the participants improve in lump detection, they also improved their ability to discriminate false lumps. The investigators found that false-positive reports significantly declined after completion of the CBE course by 41%. The second study by Campbell, McBean, Mandin and Bryant (1994), compared standardized and unstandardized methods of teaching clinical breast examinations and to determine whether trained non-medical women could teach as well as medical faculty. Findings revealed that specificity improved after training but remained low for both the students taught by the women (46%) and those taught by the faculty (49%). Although these studies indicate improvement in specificity, the outcomes remain inconclusive.

Two other studies suggest inconsistent findings for specificity. Campbell, Fletcher, Lin, Pilgrim and Morgan (1991) conducted a randomized trial to evaluate changes in physicians' and nurses' lump detection accuracy and examination skills after a training program. The mean specificity in the experimental group decreased by 15 percentage points to 41% and increased in the control group by 12 percentage points to 68%. The majority of the changes were attributed to physicians' false-positive reports. Their mean specificity was significantly lower for physicians (33%) than nurses (58%, $p = .03$).

Trapp, Kottke, Vierkant, Kaur and Sellers, 1999) conducted a study to evaluate a researcher-developed training on nurses' abilities to detect masses in breast models. They continued the study by comparing their findings to previous studies performed by Fletcher, O'Malley and Bunce (1985) and Campbell, et al. (1991) that evaluated physicians' and nurses' performance in detecting lumps in silicone breast models. The comparison with physicians in the Fletcher et al. (1985) study showed that although nurses were able to detect significantly more lumps, they also indicated significantly more false-positive detections ($p < 0.001$). On the other hand, when compared with findings from the Campbell, et al. (1991) study, the median number of breast models in which the nurses indicated false-positive detection was 1 while physicians made false-positive detections in two-thirds of the breast models. These studies indicate the uncertainty of the effect of training on specificity.

Finally, Lee, Dunlop and Doan (1998) studied the effects of stage of training, gender, and specialty interest on medical students' breast cancer knowledge, attitudes, and CBE skills. Premedical, first, second, and third year medical students ($n = 493$) participated in the study. The researchers found no significant difference in specificity among the four classes. This study adds to the uncertainty of training for the CBE as it relates to specificity. Due to the inconsistent findings of these studies; future investigations should address false-positive findings during CBE to improve clinicians' skills and recommend the most appropriate method for training.

Approaches for Performing the Clinical Breast Examination

Approaches in performing the CBE vary among health care providers. Inspection and palpation are included in the physical examination however; individual practitioners utilize different techniques depending upon their training. Currently, there is no standard approach to teaching CBE and practice relies on faculty's preference and experience. Table 2 compares the differing techniques available in physical examination textbooks. Whether the potential of the CBE can be realized depends on the examiners' skills (Weiss, 2003).

Table 2

CBE Techniques Recommended in Physical Examination Textbooks

Source	Positions	Perimeter	Patterns	3 Fingers	Pads of Fingers	Pressures
Berg (2004)	4	No	3	Yes	Yes	No
Bickley (1999)	4	Yes	3	No	No	No
Seidel, Ball, Dains and Benedict (2003)	5	No	3	No	Yes	No
Swartz (2002)	4	No	2	No	No	Yes

The important aspects of performing the CBE include visual inspection and palpation. Important variables in palpating the breast correctly include patient position, breast boundaries, examination pattern, finger position, movement, pressure, and duration of the examination (Barton, et al., 1999; McDonald, Saslow & Alciati, 2004; Pilgrim, Lannon, Harris, Cogburn & Fletcher, 1993; Saslow, et al., 2004).

There has been relatively little research done concerning the importance of visual inspection when performing the CBE. However, experts continue to advocate its use during the examination (McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004). They recommend that that a visual inspection should be performed with the patient in a sitting position with hands pushing tightly on hips and that the clinician assess symmetry in breast shape and skin changes from all sides (McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004).

Studies suggest that appropriate palpation includes the following five key characteristics (Barton, et al., 1999; Fletcher, et al., 1985; Fletcher, et al., 1989; Saslow, et al., 2004):

1. Position: Patients should sit for palpation of the axillary, supraclavicular, and infraclavicular lymph nodes and lie down for breast palpation with their ipsilateral hand overhead to flatten the breast tissue on the chest wall.
2. Perimeter: The clinician should use the following landmarks to cover all breast tissue: down the midaxillary line, across the inframammary ridge at the fifth/sixth rib, up the lateral edge of the sternum, across the clavicle, and back to the mid axillae.

3. Pattern of search: The entire extent of breast tissue should be searched using a vertical strip pattern.
4. Palpation: The finger pads of the middle three fingers should be used to examine one breast at a time. Over-lapping dime-sized circular motions should be used and tissue at and beneath the nipple should be palpated, not squeezed.
5. Pressure: Three levels of pressure should be applied at each area: light, medium, and deep. The palpation should be adapted to the size, shape, and consistency of tissue, and accommodate pressure to other factors such as breast size.

The average length of time physicians spend on the CBE is 1.8 minutes. There is evidence that a careful examination of average-sized breasts (brassiere cup size B) utilizing duration of at least 3 minutes per breast enhances lump detection (Barton, et al., 1999; Pilgrim, et al., 1993). Current studies and recommendations do not specify duration for the examination. Researchers and experts agree that if the above steps are done thoroughly, more time will be necessary for the examination. Also, as expertise with the procedure increases, the clinician will likely require less time to perform a thorough examination (McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004).

Training to Improve Clinicians' Clinical Breast Examination Technique

According to research findings, there is a need for CBE training both at the educational level and in the clinical setting (Lee, Dunlop & Dolan, 1998; Orsetti, Frohna, Gruppen & Del Valle, 2003; Warner, Worden, Solomon & Wadland, 1989). Since the CBE is a tactile skill, it may be necessary to practice the skill in order to become proficient. In an early survey study, Warner, et al. (1989) found that 75% of 141 participant physicians in the study did perform a CBE on women over age 50 however, did not believe CBE to be as effective as mammography or breast self-examination (BSE). Results of the survey indicated that becoming educated about breast cancer screening was a high priority for family physicians (Warner, et al., 1989).

A troubling study performed by Lee, Dunlop and Dolan (1998) assessed the effects of stage of training on medical students' breast cancer knowledge, attitudes, and CBE skills. The researchers administered questionnaires assessing breast cancer knowledge and attitudes to 493 premedical and first-, second-, and third-year medical students. Silicone breast models were used to test the CBE proficiency of 151 of the student participants at varying training levels. As expected, breast cancer knowledge was positively correlated with stage of training ($r = .62$), with significant differences between all levels of students ($p < .001$). However, lump-detection sensitivity significantly declined with higher level of training. First year medical students had the highest mean sensitivity (61.5%), followed by second year (53.9%) and third-year (43.5%). The difference was significant between the first- and third-year students with $p < .001$. Findings also indicate that lump detection did not correlate with reported confidence in the examination. These results suggest that while confidence and knowledge increase with training; skills in detecting lumps do not and, in fact decline. These results suggest the need for increased attention to palpation skills throughout clinical training.

Likewise, a study was done at the University of Michigan Internal Medicine Residency program to determine the impact of a 3-year continuity clinic based at a Veterans Affairs (VA) hospital on residents' self-reported competencies in women's health. Comparisons were made with two other sites consisting of a university hospital-based clinic and a university-affiliated community clinic. Seventy-two of 109 residents in the program from the three sites completed a survey designed to address the knowledge-base domain, assessing self-reported knowledge in 6 core competencies of women's health. Findings revealed a substantial difference in self-reported competence in women's health in knowledge base, counseling skills and physical examination skills for residents with a VA clinic when compared to residents with university or community-based clinics (Orsetti, et al., 2003). Residents in the VA clinic reported 33% less confidence in the competencies surveyed. These studies indicate the need for accurate and adequate training of the CBE using a standardized method for all health care providers.

Several research studies testing medical students and physicians indicate that formal training can improve knowledge of breast cancer screening, CBE, and BSE. Participants' knowledge was shown to improve significantly following CBE training using a variety of methods such as home-study modules, video presentations, lecture, silicone breast models and standardized patient models (Chart, Franssen, Darling & MacPhail, 2001; Lane, Messina & Grimson, 2001; Madan, Colbert, Beech & Beech, 2003).

Differing educational techniques for CBE training have been utilized in research studies to include didactics, demonstration, and practice for varying time frames. These methods have usually been combined for the intervention in many studies (Campbell, Fletcher, Lin, Pilgrim & Morgan, 1991; Campbell, McBean, Mandin & Bryant, 1994; Coleman, et al., 2004; Constanza, et al., 1999; Vetto, Petty, Dunn, Prouser & Austin, 2002; Warner, et al., 1993). Other studies have used the MammaCare® teaching method as the intervention, which includes a videotape and practice models (Herman, et al., 1998; Trapp, Kottke, Vierkant, Kaur & Sellers, 1999). The teaching model includes the elements previously discussed as the recommended technique for performing the CBE. The MammaCare® teaching method has been extensively tested primarily for BSE (Atkins, Solomon, Worden & Foster, 1991; Fletcher, et al., 1990; Saunders, Pilgrim & Pennypacker, 1986; Worden, et al., 1990).

One study utilizing the MammaCare® teaching method for training nurses in a state-wide public health arena in North Carolina found that participants (n = 1,122) completing the course were more likely to rate their skills as excellent or very good as compared to those participants who did not complete the course (Herman, et al., 1998). Another study utilizing the same method of instruction by Trapp, et al. (1999), found that 34 trained nurses were able to detect masses in breast models at high rates and compared positively with physicians' abilities. The mean for overall lump detection was 13.7 for the nurses whereas the mean for physicians (n = 80) was 8.0.

Most other studies discussing training for CBEs used combined methods of instruction/lecture, demonstration, and practice. Length of time for the different educational interventions ranged from 45 minutes to 5 hours (Campbell, et al., 1991; Campbell, et al., 1994; Constanza, et al., 1999; Vetto, et. al., 2002; Warner, et al., 1989). Most studies in this group used the recommended elements mentioned previously for performing a CBE as part of the instruction as well as the demonstration (Campbell, et al., 1991; Constanza, et al., 1999; Vetto, et al., 2002; Warner, et al., 1989). The one remaining study did not contain specific information regarding the elements of the educational intervention (Campbell, et al., 1994). Results for all studies in this group showed a consistently significant improvement in lump detection for health care providers in the interventional group as compared to those participants in the experimental group (Campbell, et al., 1991; Campbell, et al., 1994; Constanza, et al., 1999; Vetto, et al., 2002; Warner, et al., 1989).

Standardized patients (SPs) are lay people trained, using standardized protocols and checklists, to portray a patient encounter accurately and consistently for teaching or evaluation purposes (Coleman, et al., 2004; Heard, et al., 1995). They can also teach and assess clinical skills and practice patterns of health care providers in the ambulatory setting or in the area of private practice. The most common use of SPs is to train students in breast and pelvic examination and have been serving as a tool in medical education since the early 1960s (Coleman, et al., 2004). Standardized patients have been used in many research studies both to teach the CBE and to test participants' skills in performing the examination. Evidence suggests that SPs can be as effective as faculty in effecting behavioral changes in students' observed skills. Studies using SPs as part of the CBE-training for health care providers consistently found significant improvement in the palpation skills of participants (Coleman, et al., 2004; Constanza, et al., 1999; Warner, et al., 1989).

Other studies have used silicone breast models for training and testing CBE skills (Benincasa, et al., 1996; Campbell, et al., 1991; Campbell, et al., 1994; Fletcher, et al., 1985; Fletcher, et al., 1989; Herman, et al., 1998; Trapp, et al., 1999; Vetto, et al., 2002). Mammatech® corporation manufactured the silicone breast models for all of these published studies and ones mentioned previously. Each set contained six models with each having a volume of 250 milliliters. The models in these studies were designed to simulate the breast tissue of a 50-year-old woman (postmenopausal). The six models contained 18 lumps varying by size (1.0, 0.5, and 0.3 centimeters in diameter), hardness (60, 40, and 20 durometers), and depth of placement (medium and deep). A lump of each size was located at each of the two depths, and all models contained simulated background fibroadenomatous tissue. Five models contained between one and five lumps each and one model contained no lumps (Campbell, et al., 1991; Campbell, et al., 1994; Fletcher, et al., 1985; Fletcher, et al., 1989; Herman, et al., 1998; Trapp, et al., 1999; Vetto, et al., 2002). The models were developed by Pennypacker and associate at the University of Florida in the 1970s and have undergone extensive testing and comparisons with actual breast tissue in women (Fletcher, et al., 1985; Fletcher, et al., 1989; Madden, et al., 1978; Stephenson, Adams, Hall & Pennypacker, 1979). While training methods varied between studies using the models, improvement in the ability to detect lumps was consistently significant for all (Benincasa, et al., 1996; Campbell, et al., 1991; Campbell, et al., 1994; Herman, et al., 1998; Trapp, et al., 1999; Vetto, et al., 2002). These studies suggest that silicone breast models manufactured by Mammatech® are beneficial for improving lump detection for health care providers.

A different silicone breast model was developed and tested by Gerling, Weissman, Thomas and Dove (2003). This dynamic training model is a prototype silicone breast model with 15 lumps that can be individually inflated, to known, controllable levels of hardness used to test its effectiveness in improving lump detection and lowering false detections of CBE. The researchers compared the newly developed breast model to a static silicone breast model composed of embedded lumps that cannot be manipulated. Medical students ($n = 48$) were divided into either the control or experimental group. Each group performed two pretests, a training session, and three posttests. Results revealed that training on the dynamic breast model leads to higher lump detection and greater skill transfer across breast models compared to training with a static breast model ($p = .008$). Results also revealed that false positive detections significantly decreased after dynamic breast model training ($p = .0277$). This study raises the question about what breast models are best for training.

Studies focusing specifically on nurse practitioners' knowledge and performance of CBE are limited, include small samples, and have only recently begun to appear in the literature. Nurse practitioners receive training in advanced nursing practice usually by completing a master's degree and obtaining board certification within their chosen specialty. There are specialties in family, adult health, pediatrics, women's health, and geriatrics. Nurse practitioners have the authority to make autonomous decisions regarding patient care and are totally accountable for their actions (Anderson, 1998). Nurse practitioners act as primary care providers and are very often the first point of contact for patients with undifferentiated problems. In rural areas, they often provide the only contact with patients and their families for health care. As such, it is vitally important that they are proficient at performing physical examinations to include the CBE.

Coleman, Coon and Fitzgerald (2001), compared the efficacies of two methods of teaching breast cancer screening to primary care trainees. The sample included 51 nurse practitioner students and 47 medical residents who were randomized to receive either a lecture-demonstration class or individual/small-group instruction from a standardized patient. Participants were tested prior to instruction and one year later by written test to assess knowledge and evaluation of skills by a standardized patient. Findings revealed no difference between the two groups' mean scores on the written pretest or posttest. Furthermore, they found no significant difference between the two groups' total mean scores on the performance test on the pretest or posttest. Overall, participants did significantly improve their total performance. This study suggests that nurse practitioner students compare with medical residents in both their knowledge and performance of

CBE. It further suggests that both types of education are equally valuable in improving knowledge and performance of CBE.

Likewise, a one-group quasi-experimental study by Lannotti, Finney, Sander and DeLeon (2002) found that training in CBE for 34 nurse practitioners resulted in significant improvement in perceived competence. Participants attended a 4-day training session that included using the vertical strip pattern technique and utilized silicone breast models and live patients. Trainees perceived a significant decrease in the size of breast lesion they could detect after training.

In another nurse practitioner study, researchers performed a prospective audit of the clinical competence of a nurse practitioner in breast and axillary clinical examination following an 18-month period of clinical training and supervision by two consultant breast surgeons. The nurse practitioner in the study was part of a nurse-led breast clinic staffed by specialist nurses. The nurse practitioner carried out supervised clinical breast and axillary examinations and received immediate feedback on the clinical findings from one of two consultant breast surgeons. Feedback was also obtained from the mammogram and ultrasound findings, as well as core biopsy results. Following the training, 103 new patients were seen by the nurse practitioner prior to examination by the consultant breast surgeon. Each recorded examination findings separately using categories of examination, five-point scoring system used to document level of clinical suspicion, and final diagnosis. The results were then compared and analyzed, revealing a complete concordance in terms of clinical suspicion between the nurse practitioner and consultant in 183 of 206 (89%) breast examinations and 200 of 206 (97%) axillary examinations. The cases in discordance, was only by a factor of one thus showing little difference in clinical suspicion when comparing the findings of both examiners (Chapman, Purushotham& Wishart, 2002). Although the study included only one nurse practitioner, the number of cases compared in the study suggests that nurse practitioners, when trained, can become as proficient as breast specialists in performing a CBE.

Gagné and the Instructional Design Model

Robert M. Gagné was a behavioral psychologist, thus initially his instructional design theories were heavily rooted in that domain as evidenced with this first book *The Conditions of Learning* in 1965. However, subsequent editions of his book revealed the evolution to incorporate cognitive psychology into his theories, specifically the information-processing model of cognition (Gagné, 1974, 1977 & 1985). His theory claims that an instruction plan can generate both appropriate environmental stimuli and instructional interactions, and thereby bring about a change in cognitive structures of the learner. He proposed that events of learning and categories of learning outcomes together provide a framework for an account of learning conditions (Gagné, 1977). His model further proposes that there are internal and external conditions of learning that affect the process of learning and make up the events of learning. Deliberate planning of these events constitutes instruction. Gagné (1977) defines instruction as events external to the learner, which are designed to promote learning.

Later writings addressed the requirements of adequate preparedness for new learning and proposed that these requirements are different for each of five kinds of learning outcomes: intellectual skills, information, cognitive strategies, attitudes, and motor skills (Gagné & Briggs, 1974). He proposed that the central instructional event of learning guidance usually requires a preceding incident called *recalling prerequisite learnings* on the part of the student and vary with the kind of learning outcome expected. He emphasized that the importance of student preparedness for new learning is an essential element in instructional planning (Gagné, 1980).

In a 1988 comparison of instructional design and procedures advocated and validated for mastery learning, Gagné proposed that his model had a great deal in common with Bloom's model advocating learning to a criterion of 100 percent, or *learning for mastery*. He stated that "mastery should be achievable for virtually all students, provided suitable provisions can be made in the *time* allowed for learning and provided that the *quality of instruction* be held at a high level" (Gagné, 1988). He classified objectives as different types of learning outcomes because they require different instruction for greatest effectiveness. These learning outcomes consist of: verbal information, intellectual skills, cognitive strategies, attitudes, and motor skills. He further explained that two sources comprise the events of instruction – empirical observations of the procedures of instruction, and the information-processing model of human learning and memory. These nine events may be used in any order depending upon learners' needs and include: gaining attention, informing the learner of the objective, stimulating recall of prior learning, presenting the stimulus, providing learning guidance, eliciting the performance, giving informative feedback, assessing performance, and enhancing retention and transfer. He concluded that his model could be used to promote mastery learning because it promoted similar concerns that designers and teachers make use of the alterable variables for students (Gagné, 1988).

In 1990, Gagné and Merrill worked together to identify learning goals that required an integration of multiple objectives. They proposed that the need for multiple objectives frequently occurs when instruction must reach beyond the individual topic or single lesson to the module, section, or course. They termed such integration of objectives as an *enterprise* and defined it as the pursuit of a comprehensive purpose in which the learner is engaged (Gagné & Merrill, 1990). They further defined the integrated single objectives as constituents of an *enterprise schema.* They described three categories of enterprise and their associated enterprise schemas, designated by their goals as *denoting, manifesting,* and *discovering* (Gagné & Merrill, 1990). This work was an example of how the evolution from the past instructional design methodology focused on components such as generalities and examples that were geared for promoting acquisition of single objectives to a more holistic student interaction using enterprises as integrated wholes (Gagné & Merrill, 1990).

Jacke (1985), found ambiguity in the Gagné and Briggs model between the differences in rule learning and defined concepts learning, thus performed a study to explore this apparent ambiguity. He used content for defined concept learning from Latin and Greek morphographs and used treatments that contrasted expository and guided discovery forms of presentation for grade 6 level children. He proposed that if expository methods were shown to be more effective, support would be provided for the view that defined concept learning involves processes different from rule learning. Alternately, if the guided discovery method was found to be more effective, there would be evidence that defined concepts and rules should be combined in the model. The results showed no difference between the two treatments; however significant gains in performance were made under both expository and guided discovery methods (Jacke, 1985).

Most research utilizing the Gagné Instructional Design Model currently centers on distance education and its use with technology. One such study by Hannon, Umble, Alexander, et al. (2002), proposed that as the events of learning are clearly defined in the model, it is compatible with Web-based courses. The researchers evaluated five public health core courses offered online during the 1999 – 2000 academic year at the University of North Carolina. The courses were developed using an instructional design template and five instructional events. A total of 214 students enrolled in the courses were asked to complete an online evaluation at the end of the semester. Results indicated that students' perceptions of their achievement of course objectives were high. As a high percentage of students also passed the courses, results suggest that students were able to learn effectively online. Student satisfaction for the courses was high as well for most instructional events. The learning event that generated the lowest item rating and highest number of negative comments was providing feedback (Hannon, et al., 2002). Overall, results indicate that the instructional design model is effective in course development for online courses.

In another exploration, Deubel (2003) linked Gagné's theory with practice in effective interactive multimedia instructional design. She proposed that screen design serves the role of gaining attention in Gagné's events of instruction and its organization of presentation stimuli influences how students process information. She further demonstrates that multimedia use in an interface enable interaction, which is an integrated form of Gagné's events of instruction and the interface can be designed with scaffolding that shows students what to do as users need support for learning (Deubel, 2003). This exploration reveals the importance of using theoretical perspectives to optimize the use of new technology in teaching and learning.

Health care education for students as well as patients have been designed based upon Gagné's work. Recently, Boendermaker, Ket, Düsman, et al. (2002) developed a quality measure based on the Gagné and Briggs model for the design of instructional events for educational encounters between a trainer and a trainee in vocational training for general practice in the Netherlands. In order to identify which elements characterize the quality of the educational encounter in vocational training, a log diary with an item list was developed. Forty-five first year trainees returned their log diaries with a total of 323 encounters. Several factors were found to contribute to higher instructional quality and included: the number of instructional media used; types of instructional media such as patient files and professional guidelines; number of follow-up activities, such as self-study; active role in the encounter by the trainee; total time of the encounter; feedback on what was done correctly; discussion of medical content; planned encounters; and, encounters where the trainer observed the trainee with discussion of findings (Boendermaker, et al., 2002). Although a small study with only first year trainees, this study has implications for health care education throughout the world.

A strategy to provide health educators with a complete set of theory-driven instructional strategies was offered by Kinzie (2005). Her work draws upon recommendations of Rosenstock's Health Belief Model, Bandura's Social Cognitive Theory and Dearing's Diffusion Theory and uses a modified *Events of Instruction* framework adapted from Gagné. She uses the following framework for strategies to assist health educators to elicit health behavior change: gain attention (convey health threats and benefits); present stimulus material (tailor message to audience knowledge and demonstrate); elicit performance and provide feedback (to enhance trialability, develop proficiency and self-efficacy); and enhance retention and transfer (provide social supports and deliver behavioral cues). She provides extensive sample applications for these strategies. In order to study the strategies used and outcomes obtained, she reviewed research done for a single application of health education for adolescent smoking prevention. She incorporated the instructional strategies for health behavior change with CDC guidelines for adolescent smoking prevention and the above-mentioned theories to review literature focused on smoking prevention in adolescents. She found that the strategies used in the literature were inconsistently applied and mostly focused on the negative health effects of smoking. She also found that there was limited attention paid to encouraging the maintenance of non-smoking behavior through provision of social supports and on-going cues. The study reviewed that incorporated seven of the nine strategies was most successful in encouraging less smoking behavior (Kinzie, 2005). The results of this research suggest valuable strategies for developing educational interventions that may lead to health behavior change.

Summary

Summing up the study results discussed above, the CBE is an effective screening tool for breast cancer when done utilizing the recommended guidelines for position, perimeter, pattern of search, palpation, and pressure. CBE and mammography evaluate different breast tissue characteristics; thus, cancer detection rates may be increased when screening for breast cancer includes both examinations. Health care providers including nurse practitioners can improve their CBE techniques and abilities to detect lumps with training. To date, the literature reveals poor standardization of training in the CBE for all levels of health care providers. Even randomized control trials in the detection of breast cancer utilize various methods for performing the examination leading to questions of the validity of the research.

A standardized method for performing the CBE must be found based on further research. Effective training following recommended techniques must be used in educating health care providers within their perspective training programs to increase the likelihood that breast cancer is detected early. Educational training for the CBE based on the Gagné Instructional Design Model may be an effective tool for training nurse practitioners in CBE techniques.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

An experimental equivalent groups posttest-only design was used for this study. This design was chosen to negate an interaction effect between testing and the independent variable (Norwood, 2000). The study was done to compare the consistency of the CBE according to recommended techniques between groups and to compare the number of breast lumps and false positives detected in silicone breast models between groups. This chapter includes detailed information related to setting, sampling, instrumentation, data collection, and treatment of data.

Setting

The setting for the study consisted of two separate regional meeting locations of the Louisiana Association of Nurse Practitioners (LANP). They gave their support for the study through approval by their Board of Directors. Appendix A. This group assisted in providing the settings and recruiting participants for the study. The rationale for using two meeting locations was to increase sample size as NPs (nurse practitioners) in the state have been displaced and have relocated while rebuilding from hurricane damage.

The first setting for the study was the Baton Rouge/Hammond regional meeting of the LANP, which physically meets each month at the Baton Rouge campus of Southeastern Louisiana University. This regional meeting usually has approximately 60 to 70 NPs in attendance. However, in the past 12 months attendance has been affected by the two hurricanes the state endured.

The second setting for the study was the Lafayette regional meeting of the LANP, which physically meets each month at a local restaurant. This regional meeting usually has approximately 30 to 35 NPs in attendance. Again, Hurricanes Katrina and Rita have affected attendance.

The local university in Baton Rouge was used for the study as it offered separate classrooms and appropriate audio-visual equipment. Two large classrooms were scheduled for the study. One was used for testing and one was used for the interventional education presentation. The classrooms were physically separated from each other to allow for separation between testing and the educational presentation. A third room was set up for participants to rest and have refreshments. The university gave their approval for use of their facilities. Appendix B.

A regular monthly meeting date and time for the region was used to schedule the data collection. As the monthly meetings generally take place on the first Thursday of the month and begin at 6:30 pm; the date for data collection was set for August 10, 2006. Meetings are used for educational purposes the majority of the time and last approximately 2 ½ to 3 hours. LANP business is briefly conducted at the beginning of the meetings and usually takes15 minutes. The regional representative agreed to begin the meeting for data collection at 6:00 pm and use approximately 10 minutes for announcements concerning LANP prior to data collection. The researcher and two trained assistants traveled to Baton Rouge to conduct the testing.

A regular monthly meeting date and time for the Lafayette region was used to schedule the second data collection for September 21, 2006 at 6:00 pm. Again, the regional representative agreed to use 10 minutes for announcements and LANP business. The researcher and two trained assistants traveled to Lafayette to conduct the testing.

The local restaurant in Lafayette had a small room and a large room available for the study. The small room was used for testing and the large room was used for the educational intervention. Participants mingled at a large table in the main dining area prior to the study. The control group had a meal from the restaurant following testing while the experimental group attended the educational session. The experimental group had a meal from the restaurant following testing while the control group attended the educational session. The researcher provided the audiovisual equipment for the educational intervention.

Population and Sample

The target population for this study was nurse practitioners that perform clinical breast examinations. The sample size for this study was based on a pilot test of the methodology and instruments conducted by the researcher. A sample of 10 NPs from southwest Louisiana was recruited for the pilot. These nurse practitioners represented the most common specialty in Louisiana, which is family (LANP, 2006). The participants worked in a variety of settings. After signing informed consent, the NPs participated in the pretest procedure of examining the silicone breast models and marking the number of assessed lumps. The NPs were then randomly assigned to either the experimental group or the control group. The experimental group attended a 55-minute educational session including a 20-minute practice time with the instructor. Immediately following the session, the NPs were instructed to utilize the new techniques and re-examined the silicone breast models and marked the number of detected breast lumps. The control group was retested as well. The pretest mean number of detected lumps for the 2 groups was 19.6 ($SD = 4.88$) for the experimental group and 18.6 ($SD = 3.29$) for the control group. The posttest mean number of detected lumps was 10.2 ($SD = 3.35$) for the experimental group and 1.2 ($SD = 1.1$) for the control group. The calculated conservative *ES* was 2.72 ($SD = 3.3$). According to Cohen (1988), this is a large effect size with the experimental group detecting 9 more lumps than the control group. Using Lipsey (1990), for power .80, alpha = .05, 1 or 2-tailed, the estimated sample size would be 5 in each group for a total of 10 participants. Using Cohen (1988), the results are the same.

The sample was recruited from the Louisiana Association of Nurse Practitioners (LANP) as well as NPs who attend LANP meetings. Currently there are over seven hundred members in the LANP consisting of advanced practice nurses from all specialties recognized by the American Nurses Credentialing Center and the Louisiana State Board of Nursing.

Participants were licensed nurse practitioners in Louisiana and certified in any specialty, which includes family, adult, geriatric, pediatric, psychiatric, and women's health. The LANP member listserve was used to recruit participants; however participants were not required to be members of the organization to participate in the study.

Protection of Human Subjects

The current rules and regulations of the Institutional Review Board (IRB) at Texas Woman's University were maintained during this study. Approval was obtained from the IRB prior to any data collection. An addendum for the second data collection was obtained prior to recruiting additional participants. Informed consent for each participant was obtained and all data was confidential and kept under lock and key by the researcher. All trained assistants participated in the National Institutes of Health (NIH) training for Human Participants Protection prior to data collection.

Instrumentation

Instruments for the study consisted of a demographic tool to describe the sample, silicone breast models, a Breast Examination Inventory to document and score participants' CBE techniques while observed, and lump detection scoring tools. Each will be described separately with discussion of validity and reliability.

Demographic Tool

A demographic tool developed by the researcher was given to each participant to fill out prior to testing. The tool was used to gather demographic data to describe the sample and determine homogeneity of the groups. Information on the tool included certification information, gender, age group, work setting, and years in practice as a nurse practitioner. Participants also addressed past CBE training, type of training, and use of the skill in their practice. Participants were asked what motivated them to attend the study and what they hoped to learn by attending the study. An example of the tool may be seen in Appendix C.

Silicone Breast Models

Silicone breast models purchased from Mammatech® were used to test participants' CBE technique, number of breast lumps detected and number of false positives. These specially manufactured silicone breast models were developed at the University of Florida by Pennypacker and associates and introduced in the late 1970s. They have been refined over a number of years and have been extensively evaluated. There are six breast models constructed to simulate the breast tissue of a 50-year-old woman and all have a volume of 250 milliliters. One model is lump free. The other five models contain from one to five lumps each. Altogether, the models contain 18 lumps characterized by three different sizes (1.0, 0.5, and 0.3 centimeters), three degrees of hardness (60, 40, and 20 durometers), and two depths of placement (medium and deep). Using a grid system and a table of random numbers, the 18 lumps were distributed so that across the five models with lumps, a lump of each size and hardness was located at each of two depths.

Reliability and validity of Mammatech® silicone breast models began with their initial construction and has evolved over many years of testing within a variety of research studies. Madden and associates (1978) began the construction of model human female breasts consisting of a thin silicone membrane surrounding a silicone gel containing simulated tumors. To qualitatively test the models, medical doctors specializing in surgery, obstetrics, and gynecology evaluated each model as being representative of the tactile resistance of the human breast to deformation by palpation. All participants expressed approval of the model as representative. For a more quantitative evaluation of the accuracy of the models with respect to mechanical deformation, compressive load-deformation tests were performed on both the models and on human subjects by means of an engineering mechanical apparatus. The resulting curves for the models fell within the range of curves generated by the same test on human breast tissue.

Stephenson, Adams, Hall and Pennypacker (1979) then utilized the models to test the effects of certain training parameters on detection of simulated breast cancer. Two sets of five models each were used with breast lumps simulated by steel spheres attached to self-adhesive foam pads. The simulated lumps were varying in size and location. One set was used in the testing trials and the other set was used in the practice trials. The lumps were randomly placed in the models. Findings revealed that performance increased significantly by number of lumps detected following training ($p<0.01$) for the experimental group ($n = 24$) as compared to the control group ($n = 20$). This study led to the development of the models manufactured today by Mammatech® with randomly placed lumps differing in hardness, size and depth. This study also led to the development of the MammaCare® training method for breast-self examination.

Hall and associates (1980) then tested twenty female volunteers' abilities to detect lumps in actual female breasts after training with silicone breast models manufactured by Mammatech®. All 20 participants who did not work nor had any training in health care were given a pretest and two posttests. Group A ($n = 10$) had training with the silicone breast models between the pretest and the first posttest and Group B ($n = 10$) had training with the silicone breast models between the two posttests. All testing was performed with actual female breasts containing known lumps of varying size, depth, and location. For Group A, detection accuracy increased after training and remained stable after an intervening no-practice period. Group B showed little difference in detection accuracy after a no-practice period and increased in accuracy after training. The analysis of variance (ANOVA) for the effect of training on percentage of accurate detections revealed that the post-training change was significant ($F\ (1, 16) = 11.85, p < .003$). These findings suggest that there is a direct relationship between ability to detect lumps in silicone models and detection of lumps of various sizes, shapes, and consistencies in natural breast tissue. Also, the data compare favorably to those of Wolfe (1974) who found that 50% of lesions less than 1.0 centimeter were palpable by experienced physicians; whereas this study revealed that trained participants were able to palpate 57.5% of lesions less than 1.0 centimeter (Hall, et al., 1980).

In a study by Fletcher, O'Malley, Pilgrim and Gonzalez (1989), manufactured silicone breast models from Mammatech® were used to compare the accuracy of breast examinations by 300 women and 62 internal medicine residents. As part of the study, participants were asked how the models compared with actual female breasts. Almost all women (93%) and physicians (92%) reported that the models were lifelike in comparison to female breasts. In another study using the manufactured breast models, Fletcher and associates (1989) compared three methods for teaching breast self-examination with 300 female participants. Of the three groups one year later, women in the MammaCare® group found more lumps (*M* = 57%; 95% *CI*, 54% to 60%) than did those in the traditional (*M* = 47%; *CI*, 44% to 51%) and control (*M* = 45%; *CI*, 42% to 48%) groups. These findings suggest that silicone breast models from Mammatech® are a valid and reliable tool in improving breast lump detection. Also, detection results obtained in the study, both overall and for small (< 1 centimeter) lumps, were similar to sensitivities for examinations reported in several other studies. The comparisons of sensitivity of lump detection may be seen in Table 3. Validity and reliability of the silicone breast models by Mammatech® can also be seen in light of the many other research studies utilizing the models with significant improvement in breast lump detection (Campbell, Fletcher, Lin, Pilgrim & Morgan, 1991; Fletcher, O'Malley & Bunce, 1985; Fletcher, O'Malley, Pilgrim & Gonzalez, 1989; McDermott, Dolan, Huang, Reifler & Rademaker, 1996; McDermott, Dolan & Rademaker, 1996; Stephenson, Adams, Hall & Pennypacker, 1979). Comments from these experts suggest across studies that the models are very useful in training the techniques of CBE and improving lump detection.

Table 3

Sensitivity for Lump Detection

Study	Sample Size	Training Intervention	Silicone Models Natural Breast	Overall lump Detection	Lump <1cm Detection
Hall, Et al., (1980)	20	Yes	Both	Pretest 26.5% Posttest 49%	Pretest 10% Posttest 57.5%
Fletcher, O'Malley, Bunce (1985)	80	None	Both	44%	33%
Fletcher, O'Malley, Pilgrim, Gonzalez (1989)	300 women 62 medical residents	None	Models	Women 40% Residents 58%	Women 21% Residents 41%

Table 3 (*continued*).

Study	Sample Size	Training Intervention	Silicone Models Natural Breast	Overall lump Detection	Lump <1cm Detection
Campbell, Fletcher, Pilgrim, Morgan, Lin (1991)	32 nurses 64 medical residents	Yes	Both	Pretest Control 57% Experiment 57% Posttest Control 57% Experiment 63%	Posttest Control 39.5% Experiment 50%
Campbell, McBean, Mandin, Bryant (1994)	124 medical residents	Yes 2 Models	Models	Teaching 1 71% Teaching 2 55%	Teaching 1 62% Teaching 2 45%

The silicone breast models are delivered with six models, labeled A, B, C, D, E, or F and testing papers containing front (nipple) and back views of the six breast models. To ensure accuracy of the models; the researcher must look at the back or flat side of each of the models and make sure the location of each lump in each model matches the location of each lump in the corresponding back view graphic. The manufacturer recommends placing the models on a surface that mimics the firmness of a woman's chest wall such as mouse pads that are at least ¼ inch thick.

These models were used in a pilot study following the manufacturer's recommendations after ensuring accuracy with each corresponding graphic. There was a 98% satisfaction from participants who stated that the silicone breast models were representative of actual breast tissue.

Breast Examination Inventory

Numerous research studies have suggested that utilizing recommended techniques for the CBE improve clinicians' abilities to detect breast abnormalities (Barton, et al., 1999; Fletcher, et al., 1985; Fletcher, et al., 1989; Saslow, et al., 2004). The Breast Examination Inventory has been adapted for this study from a scoring system developed by Coleman and Pennypacker (1991) to document and score each participant's observed CBE technique according to these current recommendations.

1. Perimeter: The clinician should use the following landmarks to cover all breast tissue: down the midaxillary line, across the inframammary ridge at

the fifth/sixth rib, up the lateral edge of the sternum, across the clavicle, and back to the mid axillae.

2. Pattern of search: The entire extent of breast tissue should be searched using a vertical strip pattern.
3. Palpation: The finger pads of the middle three fingers should be used to examine one breast at a time. Over-lapping dime-sized circular motions should be used and tissue at and beneath the nipple should be palpated, not squeezed.
4. Pressure: Three levels of pressure should be applied at each area: light, medium, and deep. The palpation should be adapted to the size, shape, and consistency of tissue, and accommodate pressure to other factors such as breast size.

Originally the tool included patient position and ways hands were used for the BSE. These two parameters have been eliminated for this study. The Breast Examination Inventory addresses each recommended area as it pertains to silicone breast models. A score was assigned to each participant as the researcher or trained assistant observed the examination. The tool may be seen in Appendix D.

With respect to the reliability and validity of the tool, Coleman and Pennypacker (1991) used a paired comparisons procedure to provide a rank ordering on an interval scale of eight components. Area, duration, and pressure type were numerical variables and the remaining five variables were dichotomously scored. This method was used as a way to give each component a weight. They combined the weights to produce a value on an interval scale. The rank ordering of stimuli with respect to an attribute and the distance between stimuli are known with an interval scale; however, no information is available regarding the absolute magnitude of the attribute for any stimulus (Norwood, 2000). The researchers constructed a paired comparisons survey instrument presenting each of the eight components in all possible pair combinations. One pair of components was listed twice on the survey instrument to serve as a useful check on the reliability. The survey was then sent to 20 female experts in teaching the MammaCare® method of breast self-examination (BSE). All participants were health professionals and trained specialists in teaching BSE. The test-retest reliability was 95% for the survey. Weights for each of the components on the evaluation tool were obtained by dividing the total number of responses that each component received by the overall total of all responses (Coleman & Pennypacker, 1991).

In order to validate the scoring system, Coleman, Riley, Fields and Prior (1991) used the method to score BSE performance in an experimental study. The study was designed to determine whether there was a difference in BSE performance between women who are taught individually using self-modeling in addition to a breast model and women taught BSE in a group using a breast model. Observers for the study were trained to ≥95% agreement on the number of palpations and 95% agreement on the area of the examination. The study was designed to perform a pretest then posttest immediately after the instruction (group 1 had individual instruction; group 2 had group instruction) and again 3 months later. Participants were observed performing examinations on her own breast and on a silicone breast model. Findings revealed improvement in the mean performance scores of each group on the first and second posttest after teaching when compared with the scores before teaching. The average score of women who had been individually taught was 0.852 (*SD* = 0.161, 95% *CI* of 0.530-1.174) on the first posttest and 0.657 (*SD* = 0.256, 95% *CI* of 0.145-1.169) on the second posttest but only 0.199 (*SD* = 0.123, 95% *CI* of –0.047-0.445) on the pretest. Findings of the women who had been taught in a group showed an average score of 0.661 (*SD* =0.262, 95% *CI* of 0.137-1.185) on the first posttest and 0.501 (*SD* = 0.291, 95% *CI* of -0.081-1.083) on the second posttest but only 0.147 (*SD* = 0.072, 95% *CI* of 0.003-0.291) on the pretest. Thus, the study shows that this method of determining a score for BSE worked when used for women who had been taught by two different methods.

The Breast Examination Inventory has since been utilized in scoring CBE techniques in a study to test a multi-method approach designed for rural healthcare providers to increase breast cancer screening among low-income, African American, and older women. Coleman and associates (2003) used standardized patients to observe and record 224 healthcare providers' performances of CBE, followed by direct feedback. Randomly assigned participants in the experimental group were pre-tested, given a CBE training intervention and then a posttest. The control group was given a pretest, an interval of unrelated activity, a posttest, and then the CBE training. Testing occurred in the healthcare providers' office setting in Arkansas. Analysis of the data revealed an overall significant improvement in breast cancer screening practice, as observed and scored by the standardized patients on the Breast Examination Inventory, after participating in the intervention ($t = 4.3, p < 0.0001, power = 0.99$).

The researcher has tested this tool during a pilot study with 98% congruence between the researcher and a trained assistant. Scores for participants' performance of CBE technique in the study correspond to the previous study mentioned with the ANOVA significant ($F\,(1, 8) = 32.66, p = .00$).

For this study, the researcher trained two assistants and interrater reliability was assessed prior to data collection. The assistants were nurse practitioners licensed in Louisiana with specialties in family practice. They were trained in structured observational techniques with the researcher explaining informed consent procedures, observational techniques that are silent, neutral and nonjudgmental, testing procedures, and data collection. Each observer practiced with the researcher until performance was deemed acceptable. Each observer participated in the National Institute of Health (NIH) training for the protection of human rights prior to data collection.

Interrater reliability was established at 90% congruence between all observers to be deemed appropriate. Reliability between observers was done in the following manner: First, three nurse practitioner volunteers were videotaped examining the six silicone breast models. Next, the researcher and two assistants viewed the videotapes separately. Finally, the researcher and two assistants scored the volunteers on all six models independently according to the recommended CBE techniques. The 54 scores were analyzed for congruence. Initially the interrater reliability was 63%. The only parameter with zero variance was the number of fingers used. The researcher and two assistants met, practiced on the silicone models, and discussed the videotaped examinations. A second set of three volunteers was videotaped examining the six silicone breast models and again reviewed by the researcher and two assistants. The subsequent 54 scores were analyzed for congruence resulting in an interrater reliability of 99%. Nine out of ten parameters had zero variance on the second coefficient alpha. The only parameter not in 100% agreement was palpation with a less than 1% disagreement. Interrater reliability was deemed appropriate and the study continued.

Lump Detection Scoring Tool

A second observational instrument is a variation of data collection sheets for lump characteristics included with the silicone breast models by Mammatech®. Each of the six silicone breast models includes a corresponding graphic depiction of lump characteristics (size, hardness and depth) and location. The researcher varied the tools to include participant code numbers and instructions for data collection along with the total number of lumps detected. A previous pilot study has found these tools to be 100% congruent in accuracy of the grids and graphic representation of lump placement.

There are six separate tools corresponding with each model and labeled A, B, C, D, E, or F. The previous pilot study utilized the tools with 10 nurse practitioners. Participants placed stickers indicating lumps in the silicone breast models and were recorded on the graphic depictions corresponding with the specific model following each

CBE by the researcher or trained assistant. The total number of lumps detected for each model was counted and documented on the corresponding tool. Then the numbers were added together to obtain the total lump detection score. During the study both the researcher and trained assistant were congruent 100% of the time on each of the Lump Detection Scoring Tools. The researcher has added a section to address the number of false positives detected in order to determine the effect of the educational intervention on specificity of the CBE. Specificity refers to the detection of a lump that is not present in silicone breast models. The Model Specific Data Collection Sheets for Lump Detection and Characteristics may be seen in Appendix E - J.

Interrater reliability for the Lump Detection Scoring Tool was deemed acceptable with 90% congruence between the researcher and the two trained assistants. Interrater reliability was tested in the following manner: First, three nurse practitioner volunteers examined each silicone breast model and marked any detected lumps with a small sticker. Next, the researcher and trained assistants documented the number of lumps detected and the number of false positives. This was done separately and independently. Finally, the nine scores were analyzed for congruence. The interrater reliability for the Lump Detection Scoring Tool was 100% congruence with the first testing.

Data Collection Procedures

Data collection began with recruiting participants from the LANP electronic listserve two months in advance of the scheduled date for the Baton Rouge regional meeting. LANP members statewide were invited to attend the event. Announcements by the LANP regional representative and flyers were used at the two meetings prior to data collection. Email reminders were sent again one week prior to data collection. The Regional Representative agreed to assist with contacting the members via email with date, time, place and purpose for the data collection approximately one to two weeks prior to the event as a reminder.

A list of open meeting dates and times was obtained from both the Baton Rouge and Lafayette regional representatives of LANP. The dates and times were coordinated to offer convenience for participants. The date was advertised with a call for volunteers both regionally and on the LANP listserve. Participants were given 3.9 continuing education credits applicable to advanced practice for participating in the study. A meal was also provided to attract participation.

As participants arrived at the meeting, they were randomized to either the control or experimental group by every-other-one. The participants in the control group were sent to the area with refreshments designated for them to wait prior to testing and the participants in the experimental group were sent to the educational intervention room.

Both settings had two rooms available separated geographically within the same building. There were also separate waiting areas for participants in the control group and experimental group where refreshments/meals were provided. Participants were randomized to either the experimental or control group by every-other-one upon arrival and escorted to the appropriate area.

The testing area contained two private areas separated by dividers and at opposite sides of the room. Each testing area contained a table, a chair for the research assistant, six silicone breast models with marked mouse pads ¼ inch thick, small stickers, and the data collection tools. The educational room was set up as a classroom with PowerPoint presentation equipment and screen provided by the institution or researcher. There was also a table with six silicone breast models set up as a practice area.

As participants arrived, the researcher escorted them to the proper location and provided them with the informed consent and demographic tool. The researcher answered questions concerning the study and informed consent, collected the consent and the demographic tool. Both forms were placed in a locked file immediately. All data was kept confidential by the researcher and trained assistants. The participants in the control group were tested while the participants in the experimental group attended the educational intervention. The experimental group was tested immediately following the educational session. The participants in the control group then attended the educational session while the experimental group was being tested and after they had completed testing.

The following procedure was utilized for model testing setup and sequence:

1. Place the model on the mouse pad.
2. Randomly place models on the table close to the participant's examining side to enhance comfort while performing the exam.

3. Place model-specific data collection sheets in corresponding order with the models.
4. Provide several sheets of small stickers beside each model for participants to mark lumps and replace as needed during testing.

The following procedure was followed for each participant:

1. The nurse practitioner participants examined all 6 models.
2. The initial order of presentation of the models was randomly determined and systematically rotated for each subsequent participant.
3. Each model was placed flat on a table in front of the participant. He/she was instructed to assume that you are about to examine a 50-year-old woman who is asymptomatic for breast complaints, has no family history of breast cancer, no personal history of breast cancer and has not specifically requested a breast exam.
4. Each participant was advised that each model may or may not contain lumps.
5. Each participant was asked to use the CBE technique as close as possible to the one used with actual patients.
6. Participants were instructed to mark the model's surface with removable stickers when any lump is detected that requires further evaluation. (Further evaluation is defined as any non-routine follow-up such as a repeated examination, radiologic studies, or biopsy.)

Each trained assistant and researcher utilized the following procedure:

1. Introduce yourself to the participant and thank them for agreeing to participate.
2. Explain the purpose and procedures of the study.
3. Ask if they have completed the demographic data form and have signed the informed consent.
    a. If so: collect the forms and place them in the locked file.
    b. If not: provide the forms, go over each of them and allow time for questions. If they agree to participate, have them sign the consent and complete the demographic information. Collect the forms and place them in the locked file.
4. Explain the procedures for the test.
5. Explain that you will be present during the examination performing data collection.
6. Observe each examination and record the findings on the Breast Examination Inventory.
7. Document the total number of lumps detected and false positives from each model.
8. Allow each participant to view the models with the stickers in place to see where they both correctly and incorrectly identified a lump as immediate feedback.

9. When the participant has completed the examinations and review, direct them to the refreshment area.

The experimental group attended an educational session developed and presented by the researcher based upon Gagné's Instructional Design Theory. The educational session was 30 minutes in length followed by 20 minutes of practice/feedback on the silicone breast models. A written pretest was given to bring attention to previously learned material and gain attention. It was used strictly by the participants and not turned in to the researcher. The pretest may be seen in Appendix K.

Learning outcomes for the educational session based on Gagné's Instructional Design Theory consisted of the following:

1. Choose to perform clinical breast examinations following currently recommended guidelines.
2. Demonstrate proper techniques for clinical breast examinations.
3. Increase accuracy of lump detection on silicone breast models through instruction and practice.

Learning objectives for the educational session include:

1. Explain why a clinical breast examination is an essential element of a breast cancer early detection program.
2. Improve proficiency in four essential elements of a CBE:
    a. Perimeter
    b. Palpation

c. Pattern

d. Pressure

3. Improve proficiency in palpation skills for lump detection and discrimination on silicone breast models.

The following content was explained during the educational intervention:

Recommended CBE technique. Performing a physical evaluation of a female breast in the systematic method suggested superior to others by current research. The following steps are utilized for the examination:

Visual Inspection

a. Assess symmetry in breast shape or contour

b. Assess skin changes

Palpation Technique

a. Position: Patients should be sitting for palpation of the axillary, supraclavicular and infraclavicular lymph nodes. Patients should be lying down for breast palpation, with their ipsilateral hand overhead to flatten the breast tissue on the chest wall, thereby reducing the thickness of the breast tissue being palpated.

b. Perimeter: All breast tissue falls within a pentagon shape. The examiner should use the following landmarks to cover all of this area: down the midaxillary line, across the inframammary ridge at the $5^{th}/6^{th}$ rib, up the lateral edge of the sternum, across the clavicle, and back to the midaxilla.

c. Pattern of search: The full extent of breast tissue should be searched using a *vertical strip* pattern. The search should begin in the axillae.

d. Palpation: The examiner should use the finger pads of the middle three fingers to palpate one breast at a time. Palpate with overlapping dime-sized circular motions. Tissue at and beneath the nipple should be palpated, not squeezed. Breast tissue in the upper outer quadrant and under the areola and nipple should be thoroughly searched, as these are the two most common sites for cancer to arise.

e. Pressure: As each area of tissue is examined, three levels of pressure should be applied in sequence: light, medium, and deep, corresponding to subcutaneous, mid-level, and down to the chest wall. Adapt the palpation to the size, shape and consistency of tissue, and accommodate pressure to other factors such as breast size and the presence of breast implants (Saslow, et al., 2004).

Recommended CBE technique for silicone breast models. Performing a physical evaluation of a silicone breast model in the systematic method suggested superior to others by current research as applies to the models.

a. Perimeter: The thoroughness of the examination as defined by the number of grid areas covered on each of the silicone breast models.

b. Pattern of search: Whether the participant uses the following patterns to examine the breast models: vertical strip, circular, radial, horizontal strip, random, or combination.
c. Palpation: Whether the participant uses three middle fingers, the pads of the fingers, overlapping circular dime-sized motions to examine each silicone breast model.
d. Pressure: Whether the participant uses 3 varying amounts of pressure to examine each silicone breast model.

The experimental group was tested in the same manner as the control group following the educational session. The control group attended the educational session after testing. All participants received 3.9 contact hours and a notebook with a PowerPoint presentation and written materials to enhance retention of the education.

Participants were given the opportunity to have results of the study mailed to them individually if desired. Formal presentations of the results will be given at regional LANP meetings following completion of the study.

A pilot study was performed prior to development of the proposed study. An experimental two-group pretest posttest design was used to compare southwest Louisiana nurse practitioner's CBE technique and number of lumps detected in silicone breast models. The control (n=5) and experimental (n=5) groups were tested by the researcher and scored on their CBE techniques following recommended guidelines and number of lumps detected. The experimental group then attended an educational session based on

Gagné's Instructional Design Theory. The researcher tested the two groups again independent of each other. A one-way analysis of variance (ANOVA) was conducted to test if there was a difference between the control group and experimental group in CBE techniques and number of lumps detected in silicone breast models with alpha $< .05$. The independent variable, nurse practitioners, included two levels: control group ($n = 5$) and experimental group ($n = 5$). The dependent variable was the difference between pretest scores and posttest scores. The ANOVA was significant, $F(1, 8) = 32.66$, $p = .00$. The strength of the relationship between the educational intervention and improvement in CBE technique and lump detection, as assessed by η^2, was strong, with the educational intervention accounting for 80% of the variance of the dependent variable. There were significant differences in the number of lumps detected between the group that received the educational intervention ($M = 10.2$) and the group that did not receive the intervention ($M = 1.2$). The test of homogeneity of variance was nonsignificant, $p = .075$, indicating the variances of the two groups was equal.

Based on the outcomes of the pilot study, the design for the proposed study was revised to a posttest only to avoid sensitization to the test. Inclusion of false positive detection will be added to the Lump Detection Scoring Tools to evaluate both the sensitivity and specificity of participant's abilities to detect lumps in the silicone breast models and compare groups.

Treatment of Data

Descriptive statistics was used to describe and evaluate the sample. Nonparametric testing was done to determine the homogeneity of groups between the two settings and between the control and experimental groups. Means between settings were compared, as were means between and within the control and experimental groups. The two settings were then combined prior to further analysis. A one-way ANOVA was conducted to test the differences in CBE techniques between a group of nurse practitioners who received an educational intervention and a group that did not receive the intervention with alpha $< .05$. A one-way ANOVA was also conducted to test the differences in number of lumps detected in silicone breast models between a group of nurse practitioners who received an educational intervention and a group that did not receive the intervention with alpha $< .05$. A subsequent one-way ANOVA was performed to test the differences in number of false positives in silicone breast models between a group of nurse practitioners who received an educational intervention and a group that did not receive the intervention with alpha $< .05$. The ANOVA was chosen to test for differences between means and determine whether the samples were drawn from the same population, thus having the same population mean (Green, Salkind & Akey, 2000).

Summary

This chapter has reviewed the procedure of collection and treatment of data. Included in the review are the setting, population and sample. Protection of human participants has been discussed. Each instrument utilized in the study has been explained as have the data collection procedures. Finally, the treatment of the data has been discussed.

CHAPTER IV

ANALYSIS OF DATA

Two separate settings were utilized for the study. A convenience sample of all nurse practitioners that were recruited from both settings was obtained (Figure 1). Participants were selected in the same manner for both settings and were randomized into control and experimental groups in a consistent manner. Setting 1 consisted of 4 volunteers, all of whom met the criteria to participate. None of the 4 volunteers withdrew from the study. Two participants were randomized to the control group and two participants were randomized to the experimental group. Setting 2 consisted of 24 volunteers who were all eligible to participate as well. None of the 24 volunteers withdrew from the study. Twelve participants were randomized to the control group and twelve participants were randomized to the experimental group. Prior to combining findings from the 2 settings, the groups were compared for homogeneity utilizing a Mann Whitney *U* test. All parameters for both settings were measured and all were non significant at alpha $< .05$. This indicated that the two settings were homogeneous and could be combined for further analysis. Results of the Mann Whitney *U* tests may be seen in Tables 4, 5, and 6.

A total of 28 Louisiana nurse practitioners participated in the study. Two trained observers in addition to the primary researcher scored participants' clinical breast examination technique and number of lumps detected on silicone breast models. The number of false positives was also documented for each participant. Demographic characteristics, previous training in CBE, and participants' motivation for attending the study were collected from participants.

Figure 1

Flow of Participants in the Trial

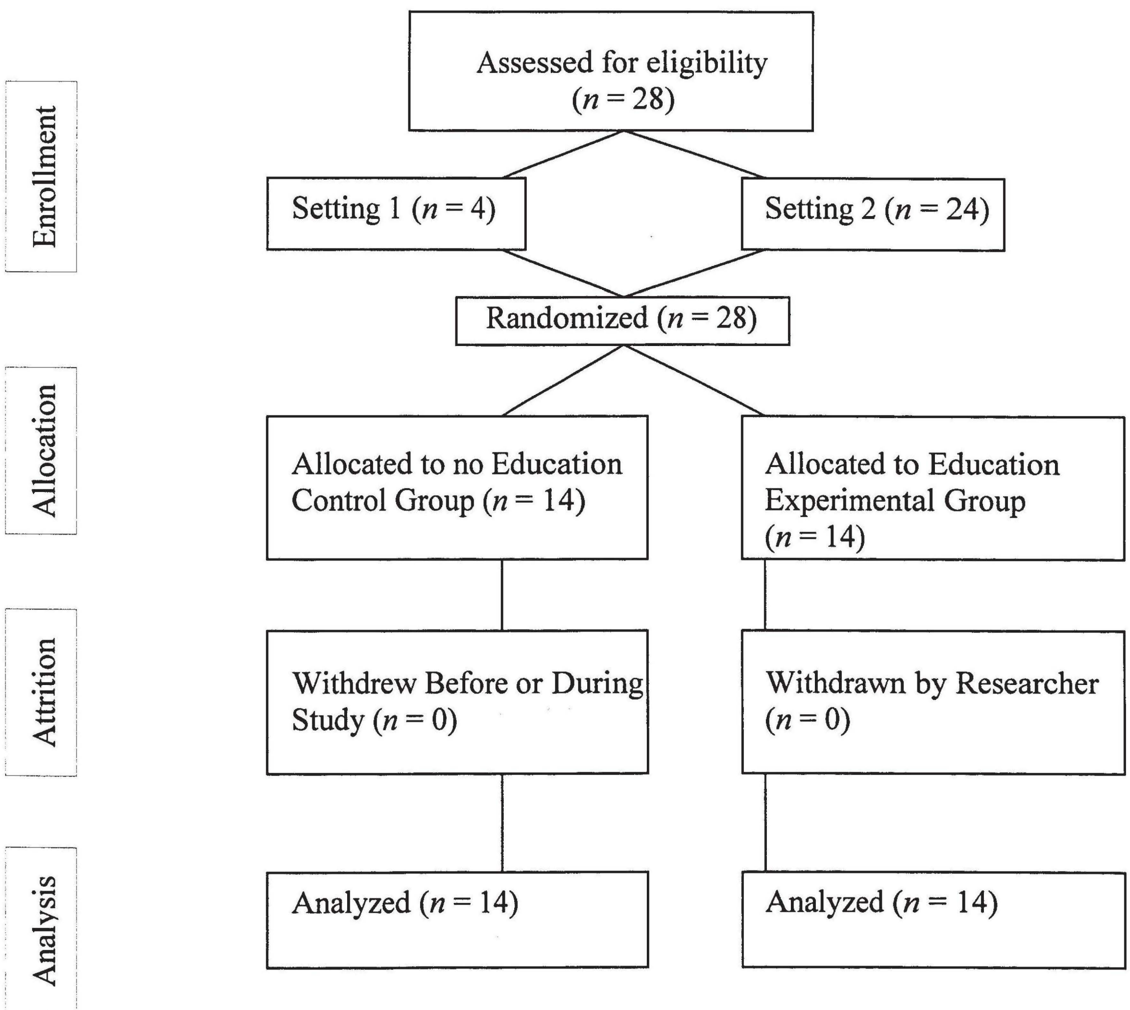


Table 4

Frequency Distribution of Mean and Standard Deviation (SD) Certification, Gender, Age, Years of Practice and Practice Site

Variable	Setting 1 ($n = 4$)	Setting 2 ($n = 24$)	Statistics
Certification:	3.25 (2.21)	1.63(1.06)	U=23.5, Z=-1.83, p=.110
Family	1	16	
Geriatric	1	0	
Women's Health	1	3	
Psychiatric	1	0	
Adult	0	4	
Pediatric	0	1	
Gender:	1.00(.00)	1.38(.495)	U=30.0, Z=-1.46, p=.262
Male	0	9	
Female	4	15	
Age:	2.50(.577)	3.00(.659)	U=29.0, Z=-1.40, p=.235
31 – 40	2	5	
41 – 50	2	14	
51 – 60	0	5	
Years of Practice:	5.75(3.10)	6.42(3.44)	U=43.0, Z=-.332, p=.776
2	0	1	
3	1	4	
4	1	2	
5	0	7	
6	1	1	
7	0	2	
8	0	1	
9	0	1	
10	1	1	
>10	0	2	
Practice Site:	2.5(1.00)	2.04(1.20)	U=32.5, Z=-1.08, p=.322
Rural clinic	0	11	
Urban clinic	3	6	
Hospital	0	2	
Other	1	5	

Table 5

Frequency Distribution of Mean and Standard Deviation (SD) Training Variables

Variable	Setting 1 (n = 4)	Setting 2 (n = 24)	Statistics
Received training	1.00(.000)	1.00(.000)	U=48.0, Z=.000, p=1.00
Positioning	1.00(.000)	1.00(.000)	U=48.0, Z=.000, p=1.00
Perimeter	2.00(.000)	1.50(.511)	U=24.0, Z=-1.84, p=.126
Vertical strip	1.50(.577)	1.29(.464)	U=38.0, Z=-.811, p=.547
Circular pattern	1.00(.000)	1.00(.000)	U=48.0, Z=.000, p=1.00
Radial pattern	1.25(.500)	1.29(.464)	U=46.0, Z=-.168, p=.924
Finger pads	1.00(.000)	1.00(.000)	U=48.0, Z=.000, p=1.00
Middle 3 fingers	1.25(.500)	1.21(.415)	U=46.0, Z=-.185, p=.924
Correct motion	1.75(.500)	1.5(.511)	U=36.0, Z=-.911, p=.465
Levels of pressure	2.00(.000)	1.92(.282)	U=44.0, Z=-.588, p=.825
Routinely perform	1.25(.500)	1.25(.442)	U=48.0, Z=.000, p=1.00

Table 6

Frequency Distribution of Mean and Standard Deviation (SD) Technique, Lumps Detected and False Positives

Variable	Setting 1 ($n = 4$)	Setting 2 ($n = 24$)	Statistics
Technique	18.0(5.77)	20.7(2.76)	U=36.0, Z=-.844, p=.465
Lumps Detected	10.0(7.12)	12.3(4.29)	U=39.5, Z=-.561, p=.590
False Positives	5.75(3.77)	5.29(6.13)	U=35.5, Z=-.836, p=.427

Description of the Participants

Table 7 presents the demographic profiles for both the experimental and control groups. The participants' ages ranged from 31 to 60 years. The largest proportion in both groups was in the 41 to 50 year age bracket (57.1%). The majority of participants was female (67.9%) and was certified as a family nurse practitioner (60.7%). Years of practice as a nurse practitioner ranged from 2 to 15 years with the majority of participants practicing 5 years or less (57.2%). Participants in the control group had practiced from 3 to 10 years and participants in the experimental group had practiced from 4 to 6 years. Most participants worked in either rural or urban clinics (39.3% and 32.1% respectively). There were 21.4% of participants that stated they worked in school-based clinics, academia, or sleep disorder centers.

Table 7

Demographic Characteristics of the Participants

Variables	Experimental Group (n = 14)	Control Group (n = 14)
Age		
31 – 40	4	3
41 – 50	6	10
51 – 60	4	1
Gender		
Female	11	8
Male	3	6
Certification/Specialty		
Family	9	8
Adult	2	2
Geriatric	0	1
Women's Health	1	3
Psychiatric	1	0
Pediatric	1	0
Years in Practice		
2	0	1
3	2	3
4	3	0
5	4	3
6	2	0
7	1	1
8	0	1
9	0	1
10	1	1
<10	0	2
Practice Site		
Rural Clinic	5	6
Urban Clinic	6	3
Hospital	1	1
Other	2	4

Previous Clinical Breast Examination Training

Table 8 presents participants' experiences with previous training in clinical breast examination. All participants stated that they had received training in CBE (100%). All participants stated that they had also received training in positioning for the exam (100%). The majority of participants indicated that they had not received training covering the current recommended guidelines for perimeter of the examination (57.1%). Varying results regarding the patterns of the examination training were found: circular pattern 100%; vertical strip pattern 67.9%; and, radial pattern 71.4%. All participants were taught to use the pads of the fingers with 78.6% taught to use the middle 3 fingers. Over-lapping dime-sized circular motions were taught to 46.4% of participants and only 7.1% stated they were taught to use three levels of pressure. Most participants stated that they routinely perform CBE in their practices.

Table 8

Previous Training for Clinical Breast Examinations

Variables	Experimental Group (n = 14)	Control Group (n = 14)
Did you receive training in CBE?		
Yes	14	14
Were you taught positioning for performing the CBE?		
Yes	14	14
Were you taught to cover the entire perimeter?		
Yes	8	4
No	6	10
Which pattern(s) were you taught?		
Vertical strip	10	9
Circular	14	14
Radial	10	10
Were you taught to use the pads of your fingers?		
Yes	14	14
Were you taught to use the middle 3 fingers?		
Yes	10	12
No	4	2
Were you taught to use a circular dime-sized motion?		
Yes	7	6
No	7	8
Were you taught to use 3 levels of pressure?		
Yes	2	0
No	12	14

Table 8 (*continued*).

Variables	Experimental Group (n = 14)	Control Group (n = 14)
Do you perform CBEs in your practice?		
Yes	10	11
No	4	3

Motivation to Participate and Learn

Table 9 shows participants' motivation and describes what they hoped to learn by attending the study. The majority of participants stated that they were motivated to attend to gain knowledge and improve skills (60% and 53.5% respectively). Others stated that they were motivated to attend to obtain continuing education credit (21%). Several participants stated that they hoped to learn the correct way to perform breast examinations (53.5%) while others stated that they hoped to learn how to find smaller lumps during CBE (60%).

Table 9

Participants' Motivation and What They Hoped to Learn

Variables	Experimental Group (n = 14)	Control Group (n = 14)
What motivated you to attend the study?		
Gain knowledge	10	7
Improve skills	7	8
Obtain CEUs	4	2
Network with other NP's	3	5
Free food	1	0
What do you hope to learn by attending?		
Correct way to perform CBE	8	7
Detect smaller lumps	3	6
Improve patient care	2	0
Increase accuracy in lump detection	1	1

Findings of the Study

A one-way ANOVA was conducted to evaluate the relationship between an educational intervention and Louisiana nurse practitioner's CBE techniques on the Breast Examination Inventory with alpha > .05. The nurse practitioners were randomized to either the control group (n = 14) or the experimental group (n=14). The ANOVA was significant, F (1, 26) = 45.07, p = .000. The strength of the relationship between the educational intervention and performing the CBE on the Breast Examination Inventory, as assessed by η^2 (.634) was strong with the educational intervention accounting for 63% of the variance. There were significant differences in the means between the group that received the educational intervention (M = 22.9) and the group that did not receive the intervention ($M = 17.7$). Results of the ANOVA may be seen in Table 10. A box plot graph of mean group comparisons may be seen in Figure 2.

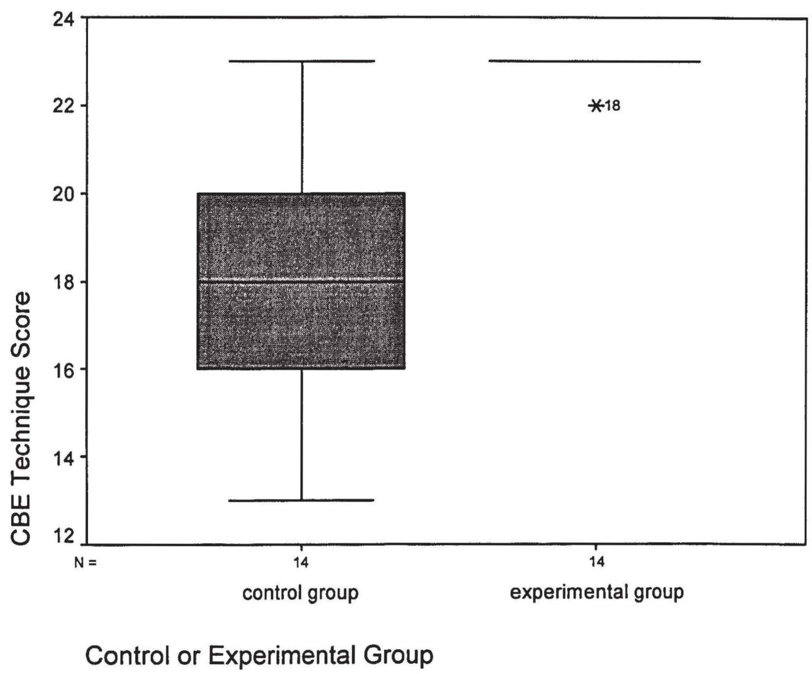
Table 10

One-way ANOVA Relationship Between Educational Intervention and CBE Technique

Variable	Control Group ($n = 14$)	Experimental Group ($n = 14$)	Statistics	
Technique	17.71(2.90)	22.92(.267)	CI=-6.81,-3.62	$F(1, 26)=45.07$, $p=.000$

Figure 2

Box Plot Graph Mean Group Comparisons: CBE Technique



The test of homogeneity of variance was significant, $p = .00$, indicating the variances of the two groups was not equal. The assumption that the groups were equal was not supported; thus a Mann Whitney *U* test was performed to compare ranks between the control and experimental groups. This revealed no significance between the control and experimental groups for all descriptive parameters. The results of the Mann Whitney *U* test may be seen in Tables 11, 12 and 13. Means between and within the groups were then compared for homogeneity. These results also revealed no significance between the control and experimental groups for descriptive parameters. However, significant differences were found between groups for specific parameters concerning the CBE technique. In fact, five parameters were significant: pattern of search ($p < .000$), palpated in dime-sized circles ($p < .031$), used 1 second per motion ($p < .000$), incorporated nipple compression ($p < .012$), and used deep pressure ($p < .000$). The results of the means comparison with ANOVA may be seen in Table 14.

Table 11

Frequency Distribution of Mean and Standard Deviation (SD) Certification, Gender, Age, Years of Practice and Practice Site

Variable	Control Group(n = 14)	Experimental Group (n = 14)	Statistics
Certification:	1.71(.995)	2.00(1.66)	U=97.5, Z=-.026, p=.982
Family	9	8	
Geriatric	0	1	
Women's Health	1	3	
Psychiatric	1	0	
Adult	2	2	
Pediatric	1	0	
Gender:	1.43(.514)	1.21(.426)	U=77.0, Z=-1.19, p=.352
Male	3	6	
Female	11	8	
Age:	2.86(.535)	3.00(.785)	U=88.0, Z=-.516, p=.667
31 – 40	4	3	
41 – 50	6	10	
51 – 60	4	1	
Years of Practice:	7.00(3.96)	5.64(2.56)	U=83.5, Z=-..674, p=.511
2	0	1	
3	2	3	
4	3	0	
5	4	3	
6	2	0	
7	1	1	
8	0	1	
9	0	1	
10	1	1	
>10	0	2	
Practice Site:	2.21(1.31)	2.00(1.04)	U=93.5, Z=-.218, p=.839
Rural clinic	5	6	
Urban clinic	6	3	
Hospital	1	1	
Other	2	4	

Table 12

Frequency Distribution of Mean and Standard Deviation (SD) Training Variables

Variable	Control Group (n = 14)	Experimental Group (n = 14)	Statistics
Received training	1.00(.000)	1.00(.000)	U=98.0, Z=.000, p=1.00
Positioning	1.00(.000)	1.00(.000)	U=98.0, Z=.000, p=1.00
Perimeter	1.71(.469)	1.43(.514)	U=70.0, Z=-1.50, p=.210
Vertical strip	1.36(.497)	1.29(.469)	U=91.0, Z=-.397, p=.769
Circular pattern	1.00(.000)	1.00(.000)	U=98.0, Z=.000, p=1.00
Radial pattern	1.29(.469)	1.29(.469)	U=98.0, Z=.000, p=1.00
Finger pads	1.00(.000)	1.00(.000)	U=98.0, Z=.000, p=1.00
Middle 3 fingers	1.14(.363)	1.29(.469)	U=84.0, Z=-.905, p=.541
Correct motion	1.57(.514)	1.50(.519)	U=91.0, Z=-.372, p=.769
Levels of pressure	2.00(.000)	1.86(.363)	U=84.0, Z=-1.44, p=.541
Routinely perform	1.21(.426)	1.29(.469)	U=91.0, Z=-.429, p=.769

Table 13

Frequency Distribution of Mean and Standard Deviation (SD) Technique, Lumps Detected and False Positives

Variable	Control Group (n = 14)	Experimental Group (n = 14)	Statistics
Technique	17.7(2.90)	22.9(.267)	U=7.50, Z=-4.45, p=.000
Lumps Detected	8.50(3.82)	15.5(2.18)	U=9.50, Z=-4.09, p=.000
False Positives	5.36(3.13)	5.36(7.75)	U=70.5, Z=-1.29, p=.210

Table 14

Comparisons of Means CBE Technique

Variable	*df*		Mean Square		F	p
	Between	Within	Between	Within		
Perimeter	1	26	.571	.264	2.17	.153
Pattern	1	26	5.14	.071	72.0	.000
Palpate	1	26	5.14	.989	5.20	.031
Motion	1	26	9.14	.527	17.3	.000
Nipple	1	26	.893	.124	7.22	.012
Pressure:						
Deep	1	26	17.29	.363	47.7	.000
Medium	1	26	.036	.036	1.00	.327
Light	1	26	.036	.036	1.00	.327

A second one-way ANOVA was performed to evaluate the relationship between an educational intervention and Louisiana nurse practitioners' abilities to detect lumps in silicone breast models manufactured by Mammatech® with alpha $< .05$. Again, the ANOVA was significant, $F(1, 26) = 35.53$, $p = .000$. The strength of the relationship between the educational intervention and lump detection, as assessed by η^2 (.577), was somewhat strong, with the educational intervention accounting for 58% of the variance. There were significant differences in the means between the group that received the intervention ($M = 15.5$) and the group that did not receive the intervention ($M = 8.5$). Results of the ANOVA may be seen in Table 15. A box plot graph of mean group comparisons may be seen in Figure 3. The test of homogeneity of variance was again significant, $p = .021$, indicating the variances of the two groups was again unequal. A means comparison with ANOVA was done to compare between and within group differences for number of lumps detected on each silicone breast model. Findings were significant for each model for number of lumps detected: model A ($p < .000$), model B ($p < .000$), model C ($p < .000$), model D ($p < .001$), and model E ($p < .004$). Results of the means comparison with ANOVA may be seen in Table 16.

Table 15

One-way ANOVA to Evaluate Relationship Between Educational Intervention and Lump Detection

Variable	Control Group (n = 14)	Experimental Group (n = 14)	Statistics	
Lump Detection	8.50(3.82)	15.5(2.18)	CI=-9.41, -4.59	$F(1, 26)$=35.5, p=.000

Figure 3

Box Plot Graph Mean Group Comparisons: Lump Detection

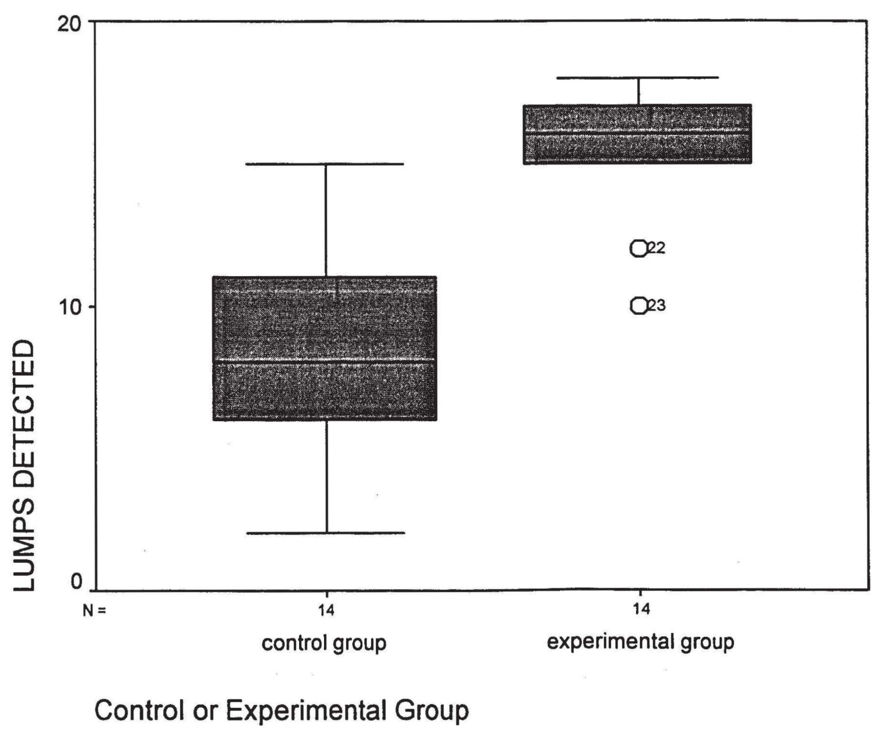


Table 16

Comparison of Means: Lump Detection

Variable	*df* Between	*df* Within	Mean Square Between	Mean Square Within	*F*	*p*
Model A	1	26	34.3	1.34	25.55	.000
Model B	1	26	17.3	.940	18.40	.000
Model C	1	26	18.9	.772	24.47	.000
Model D	1	26	9.14	.676	13.53	.001
Model E	1	26	1.29	.132	9.75	.004

A third one-way ANOVA was performed to evaluate the relationship between an educational intervention and the number of false positives indicated by Louisiana nurse practitioners on silicone breast models manufactured by Mammatech® with alpha < .05. The ANOVA was not significant, $F(1, 26) = .000$, $p = 1.00$. There were no differences in the means between the experimental group ($M = 5.35$) and the control group ($M = 5.34$). The test of homogeneity of variance was not significant, $p = .235$. Results of the ANOVA may be seen in Table 17. A box plot graph of mean group comparisons may be seen in Figure 4.

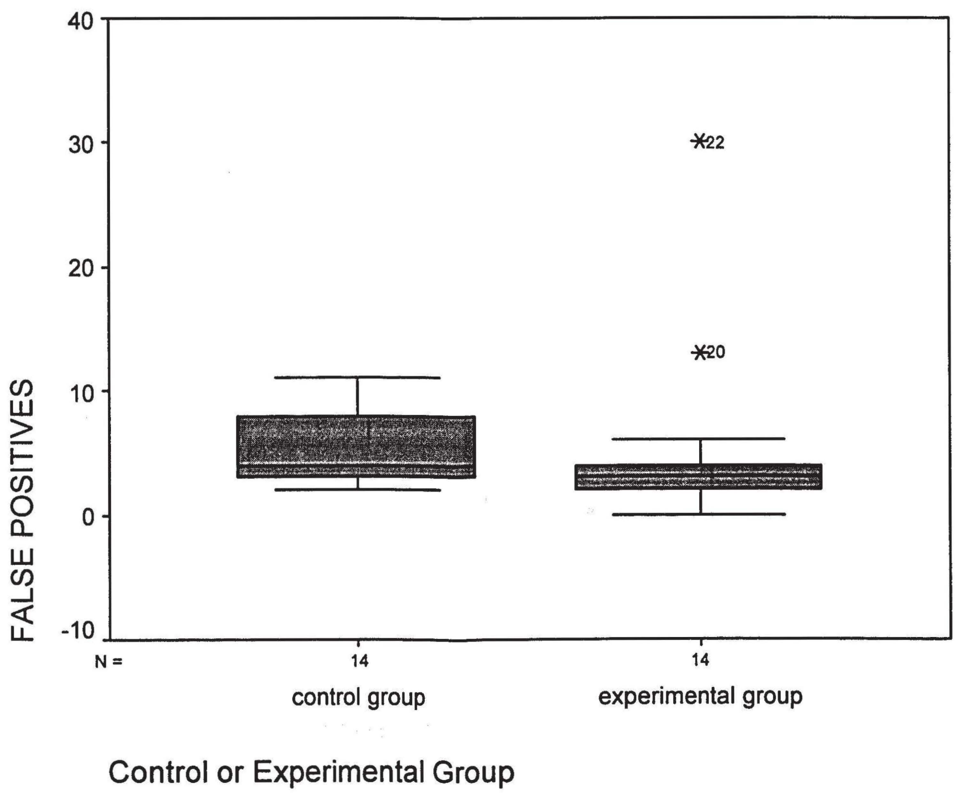
Table 17

One-way ANOVA to Evaluate Relationship Between Educational Intervention and False Positives.

Variable	Control Group (n = 14)	Experimental Group (n = 14)	Statistics	
False Positives	5.36(3.13)	5.36(7.75)	CI=-4.59, 4.59	$F(1, 26)$=.000, p=1.00

Figure 4

Box Plot Graph Mean Group Comparisons: False Positives.



Reliability of Instrumentation

Interrater reliability for the Lump Detection Scoring Tool was deemed acceptable with 90% congruence between the researcher and the two trained assistants. Interrater reliability was tested in the following manner: First, three nurse practitioner volunteers examined each silicone breast model and marked any detected lumps with a small sticker. Next, the researcher and trained assistants documented the number of lumps detected and the number of false positives. This was done separately and independently. Finally, the nine scores were analyzed for congruence. The interrater reliability for the Lump Detection Scoring Tool was 100% congruence with the first testing.

The Breast Examination Inventory addresses each recommended area of the CBE technique as it pertains to silicone breast models. A score was assigned to each participant as the researcher or trained assistant observed the examination. The tool may be seen in Appendix D. The researcher has tested this tool during a pilot study with 98% congruence between the researcher and a trained assistant. Scores for participants' performance of CBE technique in the study correspond to the previous study mentioned with the ANOVA significant ($F\,(1, 8) = 32.66, p = .00$). This latest study also supports the reliability of the Breast Examination Inventory for scoring CBE performance with the ANOVA significant ($F\,(1, 26) = 45.07, p = .000$).

Validity and reliability of the silicone breast models by Mammatech® can be seen in light of the many other research studies utilizing the models with significant improvement in breast lump detection (Campbell, Fletcher, Lin, Pilgrim & Morgan, 1991; Fletcher, O'Malley & Bunce, 1985; Fletcher, O'Malley, Pilgrim & Gonzalez, 1989; McDermott, Dolan, Huang, Reifler & Rademaker, 1996; McDermott, Dolan & Rademaker, 1996; Stephenson, Adams, Hall & Pennypacker, 1979). This study also supports the validity and reliability of the silicone breast models with significant improvement in breast lump detection in the experimental group.

Summary of the Findings

A summary of the findings as they relate to the study hypotheses follows:

H 1 – Louisiana nurse practitioners that attend an educational intervention will score higher on CBE technique performance than those nurse practitioners that do not attend an educational intervention.

A one-way ANOVA revealed that Louisiana nurse practitioners who attended an educational intervention ($n = 14$) scored statistically higher on CBE technique performance than those nurse practitioners who did not attend an educational intervention ($n = 14$) as scored on the Breast Examination Inventory ($F(1, 26) = 45.07$, $p = .000$). Therefore this hypothesis is supported.

H 2 – Louisiana nurse practitioners that attend the educational intervention will score higher on the average number of silicone breast model lumps detected than those nurse practitioners that do not attend the educational intervention.

A one-way ANOVA revealed that Louisiana nurse practitioners who attended an educational intervention ($n = 14$) scored statistically higher on the average number of silicone breast model lumps detected than those nurse practitioners who did not attend the educational intervention (n =14), (F (1, 26) = 35.53, p = .000). Therefore this hypothesis is also supported.

H 3 – The average number of silicone breast model false positives detected by Louisiana nurse practitioners that attend the educational intervention will be equal to those nurse practitioners that do not attend the educational intervention.

A one-way ANOVA revealed that the average number of silicone breast model false positives detected by Louisiana nurse practitioners who attended the educational intervention (n = 14) were equal to those nurse practitioners who did not attend the educational intervention (n = 14), (F (1, 26) = .000, p = 1.00). Therefore, this hypothesis is supported as well.

CHAPTER V

SUMMARY OF THE STUDY

This study was conducted to evaluate the relationships of an educational intervention on Louisiana nurse practitioners' CBE techniques and abilities to detect lumps in silicone breast models. In this chapter, important test results are reviewed, conclusions drawn from the study are discussed, implications for nursing are presented, and recommendations for future research studies are delineated.

Summary

This posttest-only study involved 28 nurse practitioners in two settings in Louisiana who were randomized to either the experimental group or control group. Participants from the two settings were found to be homogeneous and thus combined for statistical analysis. The experimental group attended an educational session prior to testing. The researcher presented the educational session based on Gagnè's Instructional Design Model. The control group attended the educational session following testing. Participants were tested using 6 silicone breast models while being observed by the researcher or trained assistant. The Breast Examination Inventory was used to score participants' CBE technique. The participants placed stickers where they felt a lump that would require further evaluation. The researcher or trained assistant then documented the number of lumps correctly identified and the number of false positives marked on model-specific lump detection scoring tools.

Discussion of the Findings

Clinical breast examinations have been shown to be a vital element in women's health care to detect breast cancer early. National and international organizations have issued current recommendations for performing the CBE. In order to improve this important physical assessment, current recommended guidelines for CBE should be taught to all health care providers involved in treating women.

This study was designed to explore the relationships between CBE education following current recommended guidelines and nurse practitioners' CBE technique and abilities to detect lumps in silicone breast models. An exploration was also done to determine if the education affected the specificity or number of false positives of lump detection.

Clinical Breast Examination Technique

Assessing the effectiveness of the CBE is difficult because examination techniques vary considerably. Studies show that students preparing for the role of health care provider are currently taught varying methods for performing the examination (Lee, Dunlop & Dolan, 1998; Orsetti, Frohna, Gruppen & Del Valle, 2003; Warner, Worden, Solomon & Wadland, 1989). Results of this study support previous research as the majority of participants indicated they were not trained to perform the CBE following recommended guidelines. Although all participants were trained to perform the CBE, not all were taught the correct technique as evidenced by the following:

1. 42% were taught what perimeter should be examined

2. 68% were taught the vertical strip method

3. 79% were taught to use 3 fingers

4. 46% were taught to use over-lapping dime-sized circular motions

5. 7% were taught to use three levels of pressure

This startling information exhibits the improvement desperately needed in training programs for nurse practitioners.

Current evidence demonstrates that the sensitivity of the CBE is far from perfect. Previous studies have shown the overall sensitivity or lump detection in females ranging from 40 to 54 percent and from 40 to 71 percent in silicone breast models (Barton, et al., 1999; Bobo, et al., 2000; Fletcher, et al., 1985; Fletcher, et al., 1989; Humphrey, et al., 2002; McDonald, Saslow & Alciati, 2004; Miller, et al., 2000; Saslow, et al., 2004; Smith, et al., 2003). This study shows comparable findings with the sensitivity of the control group ranging from 33 to 38 percent and the experimental group ranging from 62 to 67 percent. Although the experimental group performed significantly better than the control group, they were far from perfect. This reinforces the notion that improvement is greatly needed for CBE training.

The CBE may be accurate if done in a certain way and for a certain period of time (Barton, Harris & Fletcher, 1999; Fletcher, O'Malley & Bunce, 1985; Fletcher, O'Malley, Pilgrim & Gonzalez, 1989; McDonald, Saslow & Alciati, 2004; Saslow, et al., 2004). Similar research suggests that appropriate palpation includes the following five key characteristics: position, perimeter, pattern of search, palpation, and pressure (Barton, et. al., 1999; Fletcher, et al., 1985; Fletcher, et al., 1989; Saslow, et al., 2004). The educational intervention for this study incorporated the five key characteristics mentioned above, which improved the accuracy in lump detection significantly for the experimental group; thus supporting the previous research that incorporates key characteristics and recommended techniques for CBE.

Investigations measuring specificity, or the percentage of models examined without any false-positive detection, have been inconclusive when utilizing education of CBE. Several studies reported an improvement in specificity (Campbell, McBean, Mandin & Bryant, 1994; Vetto, et al., 2002) while others reported a decrease in specificity (Campbell, Fletcher, Lin, Pilgrim & Morgan, 1991). Still other studies reported no significant difference in specificity following an educational intervention (Lee, Dunlop & Dolan, 1998). The specificity of the groups in this study was far from perfect with the control group ranging from 33 to 55 percent and the experimental group ranging from 46 to 67 percent. Although not statistically significant, the experimental group detected more false positives than the control group indicating the need for a specific educational component addressing specificity.

Clinical Breast Examination Training

Education of health care providers concerning the CBE usually consists of combined methods of teaching including instruction/lecture, demonstration, and practice. Recommended guidelines for performing the CBE have been incorporated into these combined teaching strategies (Campbell, et al., 1991; Constanza, et. al., 1999; Vetto, et al., 2002; Warner, et. al, 1989). Results from these previous studies show a consistently significant improvement in lump detection. The educational intervention for this study incorporated the above teaching strategies based on the Gagné Instructional Design Model resulting in significant improvement in lump detection for the experimental group (M = 15.5) as compared to the control group (M = 8.5). These results also support the previous research that education can improve lump detection, thus assisting health care providers in detecting breast cancer early for their female patients.

Numerous studies utilizing silicone breast models for training and testing CBE skills have consistently found significant improvement in the palpation skills of participants (Benincasa, et al., 1996; Campbell, et al., 1991; Campbell, et al., 1994; Fletcher, et al., 1985; Fletcher, et al., 1989; Herman, et al., 1998; Trapp, et al., 1999; Vetto, et al., 2002). This study continues to support these findings as the same type of breast models from Mammatech® were utilized in this study with significant improvement in lump detection.

Gagné Instructional Design Model

Gagné (1977) proposed that there are internal and external conditions of learning that affect the process of learning and make up the events of learning. He further proposed that there should be preparedness for new learning and that central to this preparedness is a preceding incident called *recalling prerequisite learnings.* The participants in this study were given a pretest to assist them in recalling previous knowledge. To further prepare them for learning, the internal conditions of learning were addressed through two questions: 1) what motivated you to attend the study? 2) What do you hope to learn by attending the study? The majority of participants indicated that their motivation for attending was to gain knowledge (60%) and improve skills (53%). They stated that they hoped to learn how to improve their CBE skill; thus meeting the internal conditions of learning and leading to significant improvement in both technique and lump detection.

Gagné further suggested that outcomes for learning should be established, then work backwards to the specific objectives required to meet those outcomes. The educational outcomes were established prior to the content of the intervention and included improvement in CBE technique and lump detection. Objectives and content surrounding those objectives were then developed with inclusion of the nine events of learning. This method was successful in meeting the established outcomes as evidenced by the significant improvement between the experimental and control groups in CBE technique and lump detection.

Conclusions

This study was conducted to explore the relationships between an educational intervention based on the Gagné Instructional Design Model and Louisiana nurse practitioners' CBE techniques and abilities to detect lumps in silicone breast models. The first conclusion of the study is that training of nurse practitioners for CBE is inconsistent and does not incorporate current recommended guidelines. Most participants were trained to perform multiple patterns and were not trained to utilize 3 depths for the examination.

The second conclusion is that Gagné's Instructional Design Model is a valid option for designing education/training to improve nurse practitioners' CBE technique. Furthermore, it can be concluded that Gagné's Instructional Design Model is a valid option for physical examination instruction in CBE technique for nurse practitioners in order to improve sensitivity. Additionally, although educational training for CBE did not significantly increase the incidence of false positive detection in silicone breast models, the training did not improve specificity. And finally, it may be concluded that silicone breast models from Mammatech® are a reliable tool for training nurse practitioners in CBE techniques.

Implications for Nursing

Based on the conclusions of the study, the following nursing implications may be made for clinical breast examinations. First, curriculum design for nurse practitioner programs should include current physical assessment guidelines for training students to perform the CBE. Furthermore, curriculum design should include instruction as well as practice and feedback for the CBE. Other implications include the use of life-like breast models for training and practice. Models should contain lumps of varying sizes, depth, and hardness to increase sensitivity. Nursing faculty responsible for teaching physical assessment skills should use textbooks containing current CBE guidelines. And finally, research using the CBE as a measure or method should ensure standardization of the technique by incorporating current guidelines.

Recommendations for Further Study

This study explored the relationship between an educational intervention and Louisiana nurse practitioners' CBE technique and abilities to detect lumps in silicone breast models. Based on the study results, the following recommendations are proposed for future research. Similar research with larger sample sizes and various settings to complement the limitations of this study should be conducted in order to generalize the findings. Further investigations and comparisons of current CBE educational/training methods and their outcomes should be done to determine which is most successful. Future studies are also suggested to determine how well training in CBE is retained for health care providers of women. Further recommendations include repeating large-scale randomized control studies using a standardized CBE technique to determine the efficacy of the examination. Still other recommendations include performing comparisons between silicone breast models and real breasts to determine the optimal choice for training health care providers. Finally, performing research in the training of nurse practitioners to appropriately respond to a breast mass if detected would help assure that women have access to high-quality breast carcinoma screening services.

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APPENDIX A

Letter of Support from the Louisiana Association of Nurse Practitioners

April 10, 2006

Louisiana Association of Nurse Practitioners

1200 S. Acadian Thruway, Suite 206, BR, La. 70806
(225) 381-7200

Institutional Review Board Committee
Texas Woman's University
1130 John Freeman Blvd
Houston, TX 77030

Greetings,

This letter is to acknowledge that LANP supports the research project of Valerie P. Waldmeier, APRN, C-FNP entitled: Effects of an instructional design educational intervention on nurse practitioners' abilities to detect lumps in silicone breast models. She will be able to recruit volunteers from our membership and collect data at LANP meetings. Please contact me if you have any questions.

Thank you,

Joni Nickens MSN, APRN, C-FNP

President LANP

APPENDIX B

Letter of Permission to use space at Southeastern Louisiana University

SOUTHEASTERN
LOUISIANA UNIVERSITY

Valarie P. Waldmeier, APRN-BC, FNP, ANP
Graduate Nursing Program
McNeese State University
Box 90415
Lake Charles, LA 70609

April 28, 2006

Dear Valarie Waldmeier:

This is to confirm your request for room arrangements at the Baton Rouge Center of Southeastern Louisiana University School of Nursing, hereby granting permission for use of two rooms in dissertation research data collection with groups of subjects during a mutually agreeable time and date. The building is usually open from 8 AM until @ 8 PM Monday through Thursdays, with closure by 4:30 PM each Friday. Please confirm a final prescheduled date and specific room reservations with Ms. Sharron Brunswick or Ms. Elaine Vance or myself. Please inform your participants regarding parking in the designated Student Parking lot adjacent to the building. The BRC campus security officer has been notified of your participants' anticipated presence on site. We are pleased to assist you in this important component of your doctoral studies, and would be interested in learning the outcome of your research endeavors. Best wishes as you move toward completion of your doctorate degree.

Sincerely,

Cynthia

Cynthia Logan, PhD, RN
Associate Professor of Nursing
Coordinator, Baton Rouge Center
Phone: 225-765- 2324
Email: clogan@selu.edu

School of Nursing • Baton Rouge Center • 4849 Essen Lane •Baton Rouge, LA 70809 • 225-765-2324 • Fax: 225-765-2315
A member of the University of Louisiana System

TOTAL P.02

APPENDIX C

Demographic Tool

DEMOGRAPHIC TOOL

Code Number: ________________

Certification/Specialty Area: (circle one)

FNP (1) WHNP (2) ANP (3) GNP (4) Pediatric NP (5)

Psych NP (6) Other (7) Specify: ________________________________

Gender: (circle one)

Female (1) Male (2)

Age: (circle one) _____________Years

Years of practice as NP _________

Practice site: (circle one)

Rural clinic (1) Urban clinic (2) Hospital (3)

Other (4) Specify: ____

Did you receive training in clinical breast examinations in your NP program? (circle one)

Yes (1) No (2)

If yes, which of the following were addressed in your training? (circle all that apply)

Position (1) Perimeter (2) **Pattern**: Vertical strip (3) Circular (4) Radial (5)

Palpation: Finger pads (6) Middle 3 fingers (7) Over-lapping dime-sized circular motions (8)

Pressure: 3 levels of pressure (9)

Do you routinely perform clinical breast examinations in your practice? (circle one)

Yes (1) No (2)

What motivated you to participate in this study?

What do you hope to learn by participating in this study?

APPENDIX D

Breast Examination Inventory

BREAST EXAMINATION INVENTORY

Code Number: ______________________

PERIMETER	**Circle number most appropriate**
Examined all grid areas on models	6
Examined cone only	4
PATTERN OF SEARCH	**Circle pattern used most often**
Used Vertical strip pattern	3
Used systematic, nonvertical strip	2
MOTION OF FINGERS	**Circle motion used most often**
Palpated in small circles (dime size)	3
Used 1 second per motion	2
Nipple compression	1
PART OF FINGERS USED	**Circle part of fingers used most often**
Used pads of fingers	3
NUMBER OF FINGERS USED	**Circle number used most often**
Used 3 fingers (or 2 large fingers)	1
PRESSURE	**Circle number most appropriate**
Used deep pressure	2
Used medium pressure	1
Used light pressure	1

TOTAL SCORE ______________________

APPENDIX E

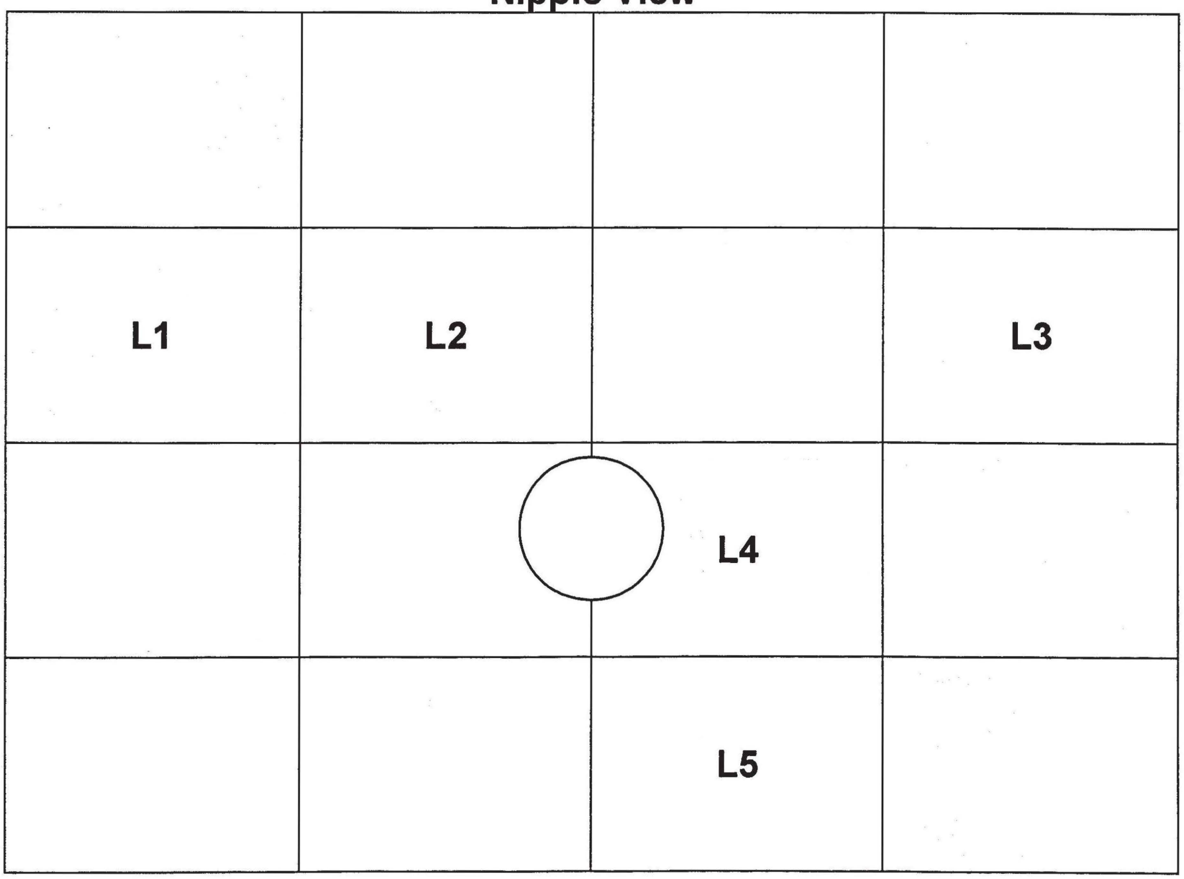
Lump Detection Scoring Tool – Model A

Lump Detection Scoring Tool – Model A

Code # ____________________

1. **Circle the area(s) marked by the participant.**

Nipple View



L1 5mm 40M
L2 10mm 20M
L3 3mm 60M
L4 3mm 20D
L5 10mm 40D

Total lumps found: ________________________

Total number of false positives: ___________

APPENDIX F

Lump Detection Scoring Tool – Model B

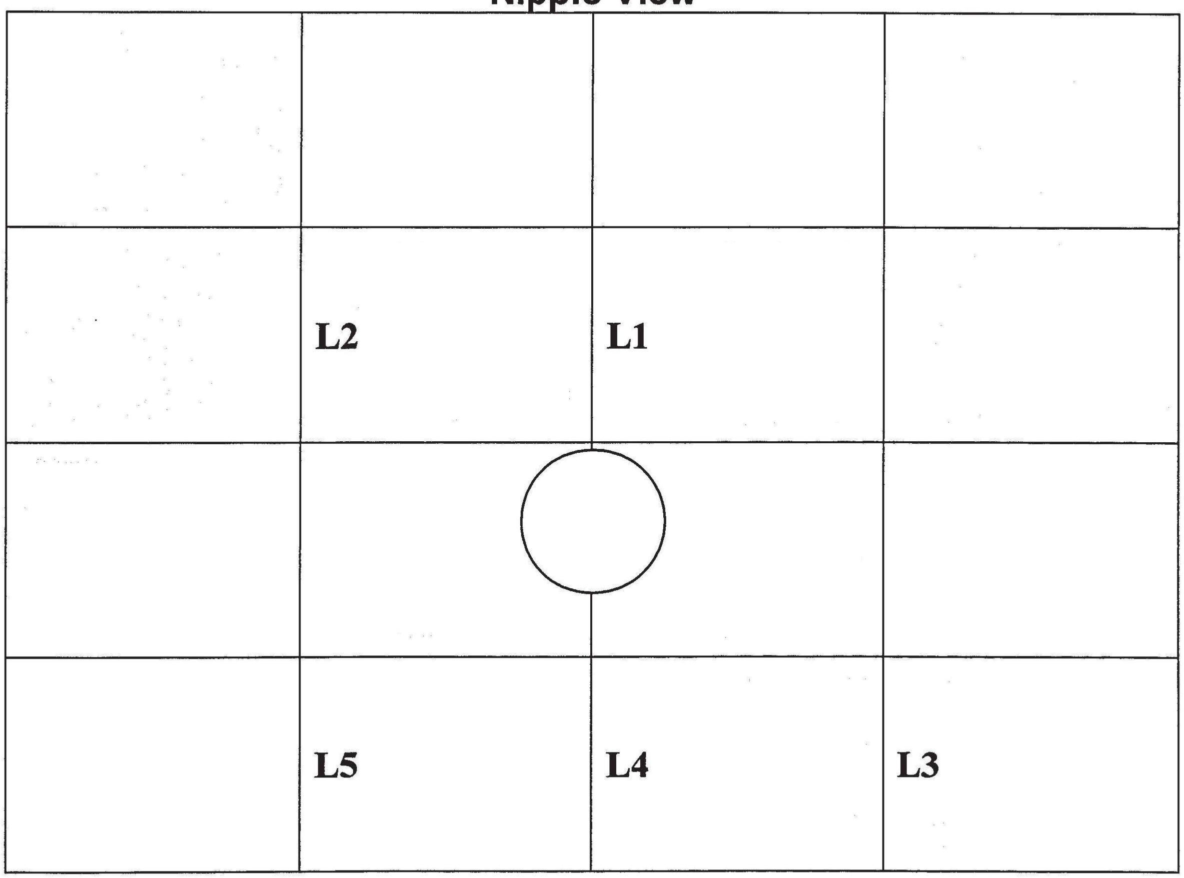
MODEL B

Code # ____________________________

2. Circle the area(s) marked by the participant.

MODEL # B

Nipple View



L1 5mm 60M
L2 10mm 60M
L3 10mm 40M
L4 5mm 20D
L5 3mm 60D

Total lumps found: ____________________

Total number of false positives: __________

APPENDIX G

Lump Detection Scoring Tool – Model C

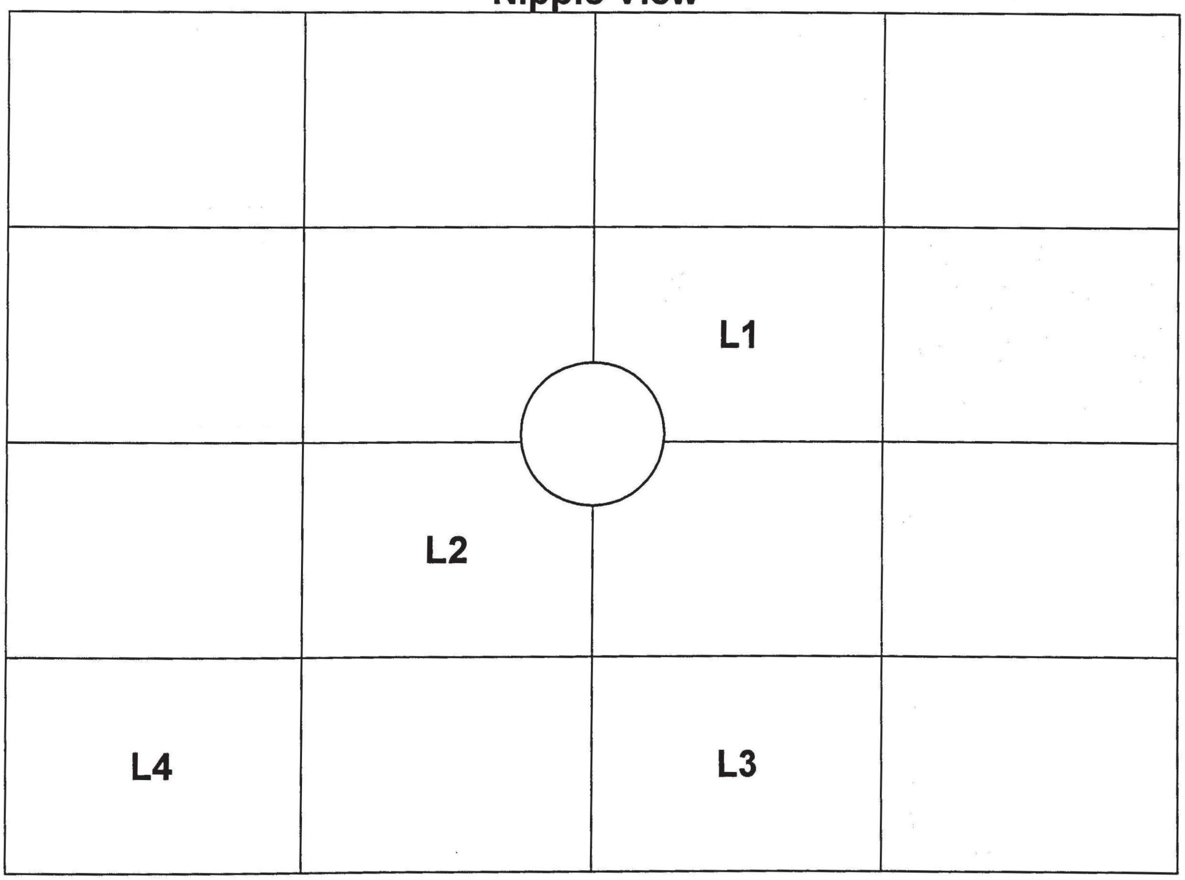
MODEL C

Code # ____________________

3. Circle the area(s) marked by the participant.

MODEL# C

Nipple View



L1 10mm 20D
L2 3mm 40M
L3 5mm 60D
L4 5mm 20M

Total lumps found: ____________________

Total number of false positives: __________

APPENDIX H

Lump Detection Scoring Tool – Model D

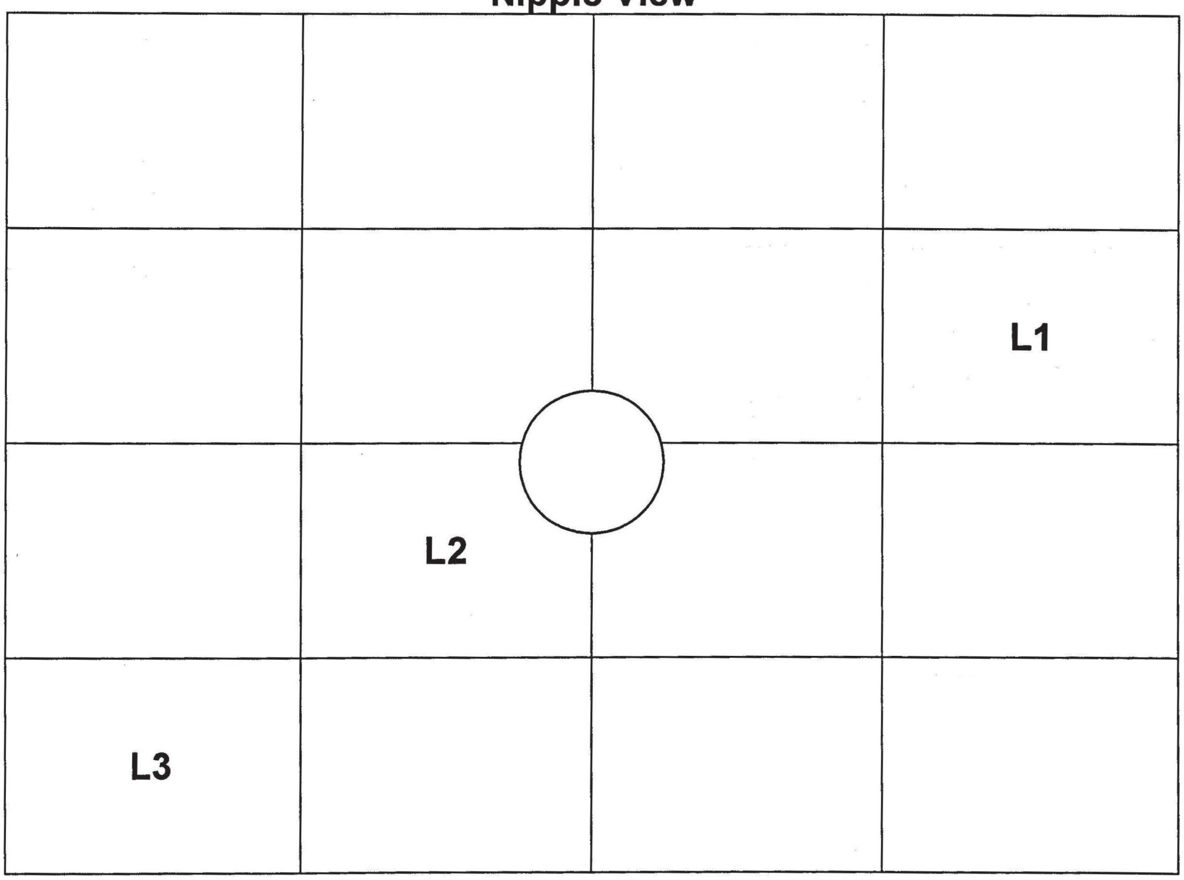
MODEL D

Code # ____________________

4. Circle the area(s) marked by the participant.

MODEL# D

Nipple View



L1 3mm 20M **Total lumps found:** ____________________

L2 10mm 60D
L3 5mm 40D **Total number of false positives:** __________

APPENDIX I

Lump Detection Scoring Tool – Model E

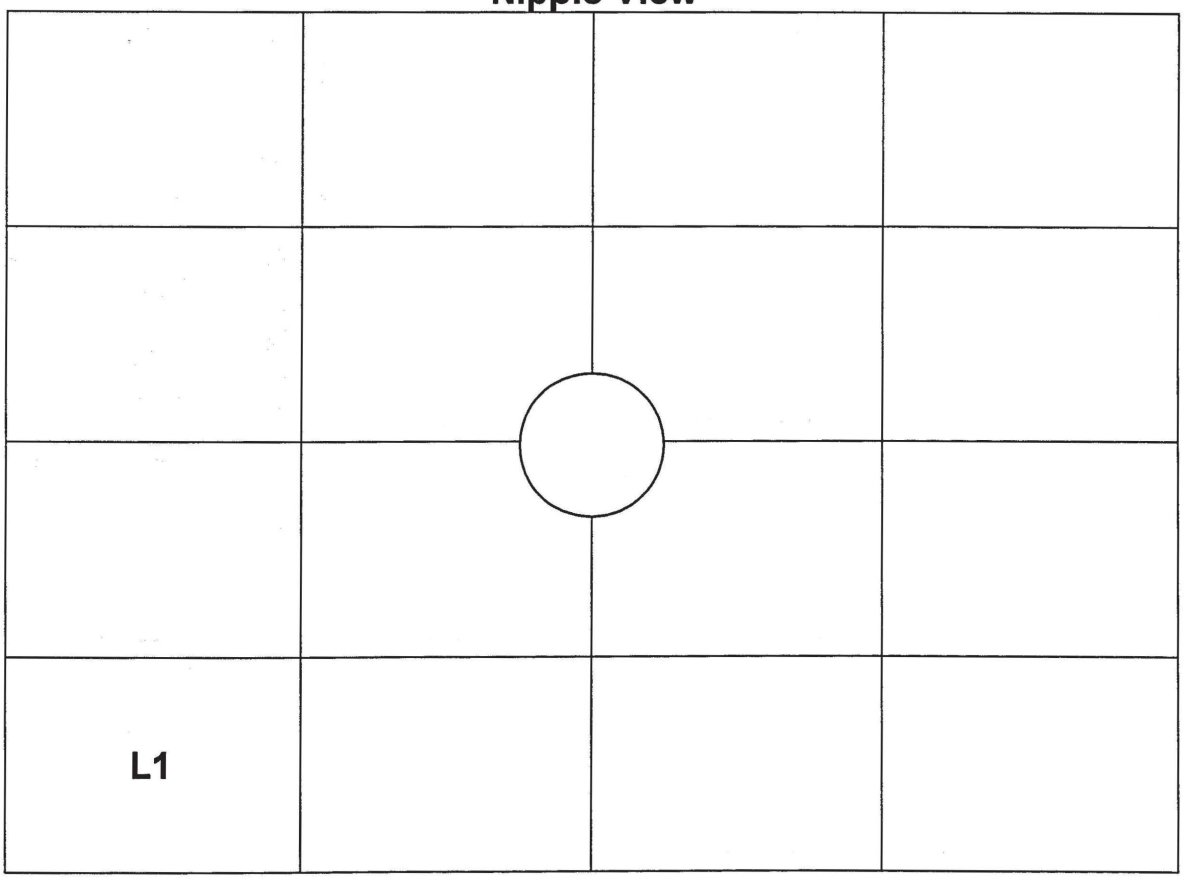
MODEL E

Code # ____________________________

5. Circle the area(s) marked by the participant.

MODEL# E

Nipple View



L1 3mm 40D **Total lumps found:** ________________________

Total number of false positives: __________

APPENDIX J

Lump Detection Scoring Tool – Model F

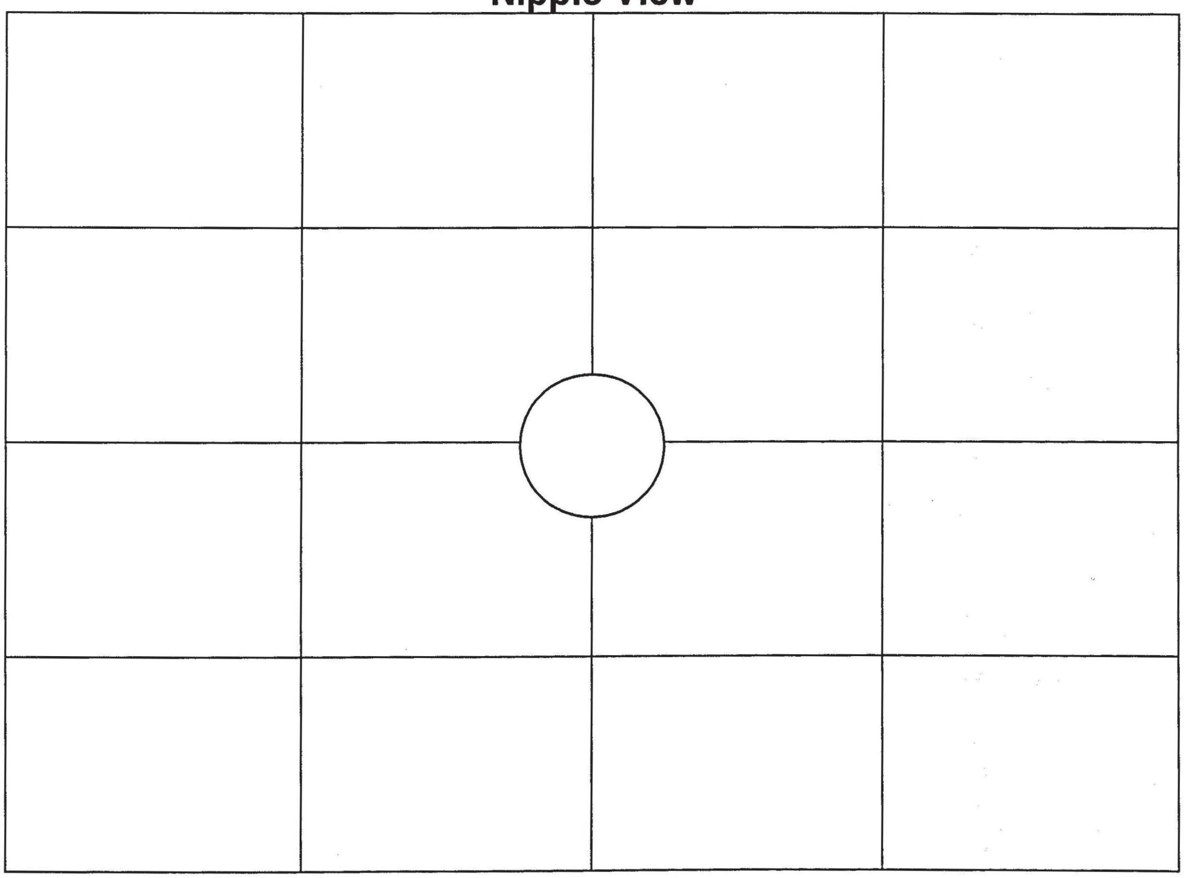
MODEL F

Code # ______________________

1. **Circle the area(s) marked by the participant.**

MODEL# F

Nipple View



No lumps **Total number of false positives:** ____________

APPENDIX K

Pretest

Pretest: This is a multiple-choice test. Please choose the **best** answer. **You will not be required to turn in the test.** It is to enhance your learning.

1. The best pattern to use when performing a clinical breast examination is:
   a. Concentric circles
   b. Radial spokes
   c. Vertical strip
   d. Any of the above
2. What is the correct number(s) of finger(s) to use when performing a clinical breast examination?
   a. One
   b. Two
   c. Three
   d. Four
3. What portion of the finger(s) should be used to perform a clinical breast examination?
   a. Tips
   b. Pads
   c. Palm
   d. Nails
4. Differing levels of pressure should be used to perform a clinical breast examination.
   a. True
   b. False
5. The perimeter or shape of a woman's breast that should be examined may be thought of as a:
   a. Octagon
   b. Square
   c. Triangle
   d. Pentagon
6. Patient positioning for a clinical breast examination may be different for women depending upon breast size.
   a. True
   b. False
7. The goal for positioning for a clinical breast examination is to spread the breast tissue evenly over the chest wall.
   a. True
   b. False