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Weight gain in females with a diagnosis of breast cancer

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Therrien, Sheryl, M.S.N.

University of Nevada, Las Vegas, 1993

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Weight Gain in Females With a Diagnosis
of Breast Cancer

by

Sheryl Therrien

A thesis submitted in partial fulfillment
of the requirements for the degree of

Master of Science

in

Nursing

Department of Nursing

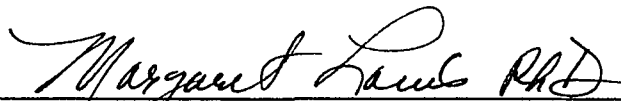
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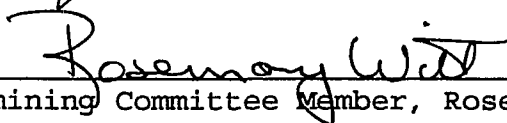
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ABSTRACT

A retrospective longitudinal study was done on 213 women with a diagnosis of breast cancer. The subjects' weights were tracked over one and two years after a diagnosis of stage I or stage II breast cancer. The subjects were identified from the medical records of the practices of two local Oncologists who agreed to participate in the study. The study tested the hypotheses: a.) Women with stage I or stage II breast cancer gain weight, b.) Women with stage I breast cancer gain more weight than women with stage II breast cancer, c.) Women with stage II breast cancer on adjuvant chemotherapy with Doxorubicin gain more weight than women with stage I or stage II breast cancer on Tamoxifen alone, and d.) Women with breast cancer who do gain weight do not lose the weight after chemotherapy treatment ends.

Findings failed to support null hypothesis in a and d, but b and c were retained. On the average women with a diagnosis of either stage I or stage II breast cancer did gain weight. By the end of twenty-four months women with stage I breast cancer on the average had gained more weight than women with stage II breast cancer but not at a statistically significant level. Women with stage II breast

cancer receiving adjuvant chemotherapy with Doxorubicin gained more weight than women who received Tamoxifen alone but not at a statistically significant level. At the twenty-four month mark women with stage II breast cancer had leveled off in weight gain but had not achieved their pre-diagnosis weight and women with stage I breast cancer were apparently on an upward curve of weight gain. The findings suggest more investigation into the cause of the weight gain as well as further investigation into actual weight gain in this population.

TABLE OF CONTENTS

Abstract.....	iii
List of figures.....	vii
Acknowledgments.....	viii
Chapter I.	
Introduction.....	1
Rationale & significance.....	2
Problem.....	4
Chapter II.	
Literature Review.....	6
Introduction.....	6
Dietary fat risk.....	7
Weight gain with adjuvant therapy.....	9
Weight gain and risk of recurrence.....	13
Weight loss.....	15
Summary.....	15
Theoretical Framework.....	16
Hypothesis.....	20
Definition of terms.....	20
Chapter III.	
Methodology.....	22
Design.....	22

Population and Sample.....	23
Procedure.....	23
Assumptions.....	26
Data collection.....	26
Chapter IV.	
Findings.....	28
Sample.....	28
Hypothesis Tested.....	32
Chapter V.	
Results.....	42
Discussion.....	42
Theoretical Framework.....	45
Limitations.....	47
Conclusions.....	47
Recommendations.....	51
References.....	53
Bibliography.....	57
Appendices.....	72
Appendix A Height and weight tables.....	73
Appendix B Neuman's Theoretical Framework.....	81
Appendix C Data collection tool.....	83
Appendix D Letters of permission.....	86
Appendix E Permission to use copyright.....	89
Appendix F Human subject rights paperwork.....	92
Appendix G T,N,M, staging method.....	101

LIST OF FIGURES

Figure 1	Mean weight for subjects 12 & 24 months.....	34
Figure 2	Stage I versus stage II 12 month mean weight...	37
Figure 3	Stage I versus stage II 24 month mean weight...	38
Figure 4	Chemotherapy versus TMX only mean weight.....	40

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CHAPTER I

INTRODUCTION

In 1992 thirty two percent of cancer incidence in females was in the form of breast cancer. Breast cancer is the second cause of death from cancer in females, with the first cause being lung cancer. There will be 182,000 new cases of breast cancer diagnosed in women in 1993. The statistics published by the American Cancer Society (1992) indicated that one in nine females would be diagnosed with breast cancer during their life time. Statistics released at the 1992 Scripps Oncology Conference suggest that this figure actually may be one in eight. These statistics suggest that breast cancer will impact nearly everyone at sometime in their life, if not with a personal experience then through a friend or relative.

In the past several years while working in an oncology practice, the researcher noted that a large number of patients with a diagnosis of breast cancer complained of gaining weight. In reviewing the literature, it was found a weight gain has been noted after diagnosis of breast cancer in females. In addition obesity and diets high in fat have been identified as risk factors for developing certain cancers such as breast and colon (Dollinger, Rosenbaum and

Cable, 1991). However, the literature does not provide data on why there is a weight gain after a diagnosis and treatment of stage II breast cancer, and if a weight gain also occurs after a diagnosis of stage I cancer.

RATIONALE AND SIGNIFICANCE OF STUDY

Boyd, Campbell, Germanson, Thompson, Sutherland & Meakin (1981) found that body weight, especially obesity was "strongly associated with disease recurrence" in seven hundred forty-nine women with breast cancer in stages I, II and III. The study concluded that weight loss for obese breast cancer patients could reduce the risk of recurrence. In a 1980 study these same authors reached the conclusion that improved survival time might be had by encouraging over-weight women with a diagnosis of breast cancer to lose weight.

Zumoff, Gorzynski, Katz, Weiner, Levin, Holland & Fukushima (1982) in a longitudinal study over a ten year period found that twenty-five female breast cancer patients who were normally weighted survived while only thirty-one percent of the over-weight women were alive ten years after diagnosis. Newman, Miller and Howe (1986) in a study of 100 newly diagnosed women matched with normal controls had similar findings.

Wynder and Cohen (1982) wrote an editorial proposing a diet low in fat be used as an adjuvant therapy in breast cancer to decrease recurrence and increase survival time. Their premise being that a high fat diet leads to weight gain and obesity, whereas a low fat diet promotes weight stability or loss thus helping to maintain normal weight. Gregorio, Emrich, Graham, Marshall & Nemoto (1985) demonstrated a "1.4 fold increase in estimated death risk for each 1,000 grams of fat intake per month" ($p = .02$) in a population of 953 women with a diagnosis of breast cancer. The subjects were accumulated over an eight year period from 1957 to 1965. The researchers then used data collected at the time of intake to time of death or last contact for this study. They observed an effect on survival time directly linked to dietary fat intake. Dietary fat intake also has a direct effect on body weight.

The literature has indicated that women with breast cancer do gain weight and that over-weight and obesity are poor prognostic indicators. The present longitudinal study will provide more detailed information as to when and in what stage women with a diagnosis of breast cancer gain weight.

PROBLEM

The literature review suggests limited study of what happens to women's weight after a diagnosis of breast cancer. The nursing studies are mostly written in narrative or anecdotal style with little or no information on data collection or statistical procedures. The medical studies are usually on animal models. Ancillary studies from other disciplines are supportive but tend to be tangential, with few directed to the actual problem at hand.

Dixon, Moritz and Baker (1978) while looking at cachexia in cancer patients in general found that breast cancer patients appeared to gain weight. The authors reported the above results in an article as an "unexpected finding". Following this landmark article many studies on why women gain weight after diagnosis of breast cancer have been completed. The subsequent studies indicate findings supportive of the hypothesis of weight gain within the first six months to a year after diagnosis of stage II breast cancer and adjuvant chemotherapy.

The question that thus arises is whether there is weight gain in all women with a diagnosis of either stage I or stage II breast cancer or is weight gain only in women

experiencing adjuvant chemotherapy for stage II breast cancer? This study proposes to answer that question.

CHAPTER II

LITERATURE REVIEW

INTRODUCTION

In 1988, cancer was the second highest cause of death in all age groups, with heart disease being the highest according to the American Cancer Society (Boring, Squires & Tong, 1992). The American Cancer Society projected 1,170,000 new cancer cases in 1993 with 526,000 deaths from cancer in that same time period. The incidence of cancer has increased by eleven percent in the last forty years. This increase is mostly in highly industrialized nations, such as the United States. More than 5,000,000 Americans are cancer survivors and 3,000,000 of these are over the five year mark in survival time. In 1930, one person in thirty could expect to be diagnosed with cancer but by 1985 three in eight persons could expect to develop cancer before they die. As these statistics indicate cancer has a vast effect on the population. Considering the impact of the cancer process anything that can be done to decrease incidence or prevent recurrence is important. The

institution of a program of primary intervention could be beneficial in preventing both incidence or recurrence. While the implications of the cancer process is too vast to study all at once, smaller problems may be studied to find the answers which will contribute to an overall knowledge base. This study examines one of these smaller problems, weight gain after diagnosis and treatment for breast cancer.

DIETARY FAT RISK

One of the first reports of the relationship of high fat diet and tumor growth was by Tannenbaum (1942). His study showed a positive correlation to dietary fat and cancer incidence. Following Tannenbaum's study there were several studies to confirm and verify his results. Many of these studies also found that there was a positive correlation between high dietary fat intake and obesity. Abe, Kumagai, Kimura, Hiroasaki & Nakamura (1976), Adami, Rimsten, Steinkuist & Vegelius (1977), Boyd, Campbell, Germanson, Thompson, Sutherland & Meakin (1980, 1981 & 1985), Brisson, Morrison, Kopans, Sadowsky, Kalisher, Twaddle, Meyer, Henschke & Cole (1984) and Carroll (1975), all found that obesity or body weight was a high risk factor for developing breast cancer. These investigators, plus multiple other studies, found that body weight is one of the risk factors in the development of breast cancer. Many

investigators also found a positive correlation between dietary fat intake and weight gain.

In a longitudinal study, with data gathered over an eight year period, Willett, Hunter, Stampfer, Colditz, Manson, Spiegelman, Rosner, Hennekene & Speizer (1992) studied the connection between dietary fat intake and the incidence of breast cancer and found no relationship between the two variables. The population studied consisted of nurses, and the sample consisted of 121,700 females. The Willett, Hunter, Stampfer, Colditz, Manson, Spiegelman, Rosner, Hennekene & Speizer study found results which differ significantly from other research, but it may be premature to negate the findings of others. The write up of the findings leave several unanswered questions. First, since the subjects were nurses, were they more likely to eat a healthier diet than the normal population due to their knowledge from being in a health related profession? It was noted that only 1429 subjects were diagnosed with breast cancer, an incidence far below the statistical norm of one in nine. Second, in the presentation of the data the ages of the subjects was reported as a broad range, but the number of subjects which fell in each age range was not identified. Thus it is unknown how many subjects were in the older age range which is associated with an increased cancer risk. Third, the dietary fat intake was also reported as a wide range, but information as to how many

subjects fell in each range was omitted. Last, the data for approximately 28% of the respondents was incomplete.

While one has to agree this is a significant study due to the large sample size and the time frame the subjects were followed; it would also be premature to allow this one study to negate the multiple other studies with contrary findings without further investigation and replication. Further studies should also address the deficiencies identified in the report of Willett, Hunter, Stampfer, Colditz, Manson, Spiegelman, Rosner, Hennekene & Speizer (1992).

WEIGHT GAIN IN ADJUVANT THERAPY

DeGeorge (1989), in a study of seventy-three subjects, with stage II breast cancer, examined eating patterns and type of eating groups into which the subjects could be classified. DeGeorge found no significant difference between the eating groups, which were labeled inhibited (described as people who will gorge after being given a loading sample such as four ounces of ice cream) versus uninhibited (described as people who restrain their eating behavior after a loading sample such as four ounces of ice cream) eaters. DeGeorge also looked at different treatment modalities, i.e. Tamoxifen versus radiation versus chemotherapy in the stage II breast cancer patient to help

explain her findings. DeGeorge found no significant difference between the different groups in the study.

A weight gain in fifty to seventy five percent of women with stage II breast cancer on adjuvant therapy was found by Stevens and Gilmore (1986). They also found that post-menopausal women were less likely to gain weight than those who were pre- or peri-menopausal. These findings were the first to note a significant relationship between menopausal status and weight gain in subjects with a diagnosis of breast cancer. Based on the study findings the author included methods to prevent weight gain and gave practitioners direction in setting up primary and tertiary programs for the at risk population.

Huntington (1984) also found that about fifty percent of the twenty-nine subjects in his study gained weight and that pre- or peri-menopausal women were more likely to gain weight than post-menopausal women. This finding supports Stevens and Gilmore's findings and the findings of several other studies including Hernandez's 1983 study. However, there are gaps as to how Huntington reached his conclusion that weight gain was due to decreased activity in this population of women and seemed to be based on conjecture. Since Huntington presented no evidence to support his conclusion, logic indicates that all groups with decreased activity should gain weight.

Foltz (1984) examined the relationship between weight gain in women on adjuvant chemotherapy for stage II breast

cancer and five factors. These five factors were: activity, depression, intake, serum estradiol level and metabolic rate. Foltz found that four of the factors had no influence on the weight gain and could not identify a reason why the fifth, lower estradiol level, was positively correlated with weight gain. The above finding did not add to explaining lower weight gain among post-menopausal women with stage II breast cancer, than pre- or peri-menopausal women with the same disease.

Cruz, Muss, Brockschmidt & Evans (1990) found a significant weight gain in women with metastatic breast cancer who were given Megace. This finding is not surprising, since a well documented side effect of Megace is weight gain due to the drug's ability to increase appetite. Megace is often prescribed to help increase the appetite in cachectic cancer patients without a diagnosis of breast cancer.

Heasman, Sutherland, Campbell, Elhakim & Boyd (1985), studied two hundred thirty-seven women with stage II breast cancer on adjuvant chemotherapy and found that ninety-six percent gained weight during treatment and that none of the subjects lost weight. The subjects were followed for a period of at least twelve months. The researchers found no association between weight gain and whether the cancer recurred or not.

Goodwin, Panzarella & Boyd (1988) studied one hundred ninety-one women with stage II breast cancer on adjuvant

chemotherapy. A significant weight gain was noted in the study's sample, but the data did not support an association between weight gain and the treatment, nor was any prognostic value achieved by looking at women who gained weight over those who did not gain weight. Their rationale for not recommending further study was based on difficulties with data collection, reliability of data and their assumption that "weight gain during the first year" post breast cancer diagnosis appears to have no influence on "relapse or survival".

Whittenberg (1990) in writing about a study done in Canada reported a significant weight gain in women on adjuvant chemotherapy with stage II breast cancer. The reported weight gains were up to ten pounds per year after diagnosis. The study of the amount of weight gain had been ongoing for two years at the time of the report. The investigators were following weight change during adjuvant chemotherapy and after completion of chemotherapy to see if the subjects returned to pre-treatment weight. There was no report on whether the subjects returned to pre-treatment weight as the study was still in progress. These investigators also stated that a poorer prognosis was found among women who gained weight, than those who did not gain weight after a diagnosis of breast cancer. This finding suggested that further study be done to determine what are the detrimental prognostic factors.

WEIGHT GAIN AND RISK OF RECURRENCE

Knobf, Mullen, Xistris & Moritz (1983) studied eighty-seven women with stage II breast cancer on adjuvant chemotherapy and found weight gain among the sample. The authors suggested that a significant weight gain might lead to a greater chance of disease recurrence. Many studies support the observation of a greater chance of disease recurrence in obese women.

Bonomi, Bunting, Fishman, Wolter, Hernandez, Foltz, Shorey, Strauss, Anderson, Roseman & Economou (1984) studied women with stage II breast cancer and weight gain during the length of disease free survival, that is time from remission to recurrence of the breast cancer. Their data suggested that weight gain during adjuvant therapy may be detrimental. This information was reported in an abstract. Thus from the minimal information published, the quality of the data or the methodology of the study can not be determined.

Levine (1990) studied 33 women on adjuvant chemotherapy and found sixty-four percent gained weight. The author found that the women who gained weight showed more psychological stress and had a poorer self image, than those who did not gain weight. This finding supports the theory that stressors which impact what Neuman (1989) describes as

the flexible lines of defense and resistance as well as the lines of defense, impact the system leading to symptomatology. Levine's sample only included women with stage II breast cancer on chemotherapy. This raises the question if stage I patients perceive less psychological stress or have a better self image than stage II patients. Another factor could be that stage I patients know they have a better long term prognosis than stage II patients. Unfortunately this question remains to be answered.

Camoriano, Loprinzi, Ingle, Therneau, Krook & Veeder (1990) studied five hundred forty-five breast cancer subjects for a period of sixty weeks. The subjects had stage II breast cancer and were on adjuvant therapy study. The authors found that women who gained more than the median weight gain (5.9 kilograms in pre-menopausal subjects and 3.6 kilograms in post-menopausal subjects) had one and one half greater relapse rate than women who were at or below the median total weight of 64.8 kilograms. The authors concluded that weight gain increased the chance of relapse and death.

In a study of sixty-one women with stage II breast cancer on adjuvant chemotherapy Hernandez, Bonomi, Hoeltgen, Roseman, Slayton, Wolter & Foltz (1983) reported on the adverse prognostic effects of obesity and weight gain. No overt relationships were found between weight gain and several variables, including menopausal status and the fact that the subjects were on Tamoxifen.

WEIGHT LOSS

Rowland-Payne, Abbott, Jones, Powles & Coombes (1982) found a significant weight loss in women with advanced metastatic breast cancer. They studied sixty-two subjects for sixteen months who were on adjuvant chemotherapy. Their subjects lost an average of five kilograms during therapy. This was the only study found where a weight loss was found in women with stage II breast cancer who were on adjuvant chemotherapy. Data related to how advanced these stage II subjects were and estrogen and progesterone status was not reported. DNA phase, ploidy and number of positive lymph nodes were not included. The authors were not looking for a weight gain and there was no discussion as to why the findings in this study are in opposition to all of the other studies reviewed.

SUMMARY

A plethora of studies exist demonstrating a connection between weight gain and the diagnosis of stage II breast cancer. The weight gain appears to be a well established fact, but there is little explanation as to the cause of the

weight gain. Many women with stage I breast cancer also complain of gaining weight but few in depth studies have been related to this stage of the disease or the complaint of weight gain by this group. If both stage I and stage II breast cancer category women gain weight then the commonalties between the groups could be explored, rather than looking at treatment modes for the cause of weight gain. Since several investigators have noted a poorer prognostic outcome in overweight women, the ability to identify causative factors for this weight gain, would be beneficial to this population of patients. For example, a primary intervention teaching program could be developed to help women diagnosed with breast cancer avoid the weight gain thus increasing their chance of disease free survival and reducing the chance of disease recurrence.

THEORETICAL FRAMEWORK

This study uses Betty Neuman's (1989) theoretical framework as a guide. Neuman's theory, a systems model, provides the outline and methods utilized in this study. The framework also provides guidance on data collection, analysis, interpretation of the findings and suggestions for future study. The Neuman model can be used with groups or individuals and provides insights into several categories of

practice. The model can guide patient care and curriculum as well as research.

Neuman's conceptualization includes the idea of a basic core structure which is the elemental life force of an entity. The core is seen as necessary for survival and is also what makes the entity a unique being. The entity has an outer ring which is called the flexible line of defense and normally protects the entity from stressors. The flexible line of defense varies in response, according to where the entity is on the wellness continuum. If a stressor penetrates the flexible line of defense the entity will demonstrate signs of disease and may become ill.

Neuman also conceptualizes a normal line of defense inside the flexible line of defense which represents the entity as it is at present. This normal line of defense represents such things as coping mechanisms, and support systems which the entity can mobilize to defend against stressors penetrating the flexible lines of defense. If the line of defense is penetrated the entity becomes ill and requires intervention to rebuild the line of defense. The lines of resistance are the entity's coping mechanisms to fight off the disease or illness, for example the immune system. If the stressor continues and penetrates the lines of resistance the entity's very existence is threatened. If the stressors penetrate to the basic core structure death is frequently the outcome.

Neuman defines primary prevention as actions designed to keep the flexible line of defense intact and interventions to strengthen these lines. Secondary prevention is care after the flexible lines of defense have been penetrated and signs of disease and/or illness are present. Tertiary prevention is defined as help in rebuilding the line of defense and/or the lines of resistance after penetration. Tertiary prevention is assistance to help the entity regain its former state of wellness.

Stressors are defined as anything which attacks the flexible lines of defense, the line of defense or the lines of resistance. Stressors may be either positive or negative events. Stressors come in five categories: physical, psychological, social, developmental or spiritual. They can be interpersonal, intrapersonal or extrapersonal. This study will be dealing with all three categories of prevention. By virtue of being diagnosed with breast cancer it can be assumed that the lines of defense have been penetrated. The secondary prevention is related to the type of treatment they receive for the cancer process. Tertiary prevention is related to assisting the patients to regain their previous wellness and life-style. Primary prevention could include setting up a program to help prevent weight gain and therefore reduce the chances of recurrent disease.

Some identified stressors include the diagnosis of cancer, surgery, possible radiation, staging work-up,

chemotherapy and possible hormonal therapy. These stressors may be categorized as physical, psychological, social, developmental and spiritual in nature. The flexible lines of defense and the normal lines of defense have been broken. Secondary prevention is required to assist with repair of the lines. This study will help clarify the stressors and the response to the stressors. Suggestions for primary and tertiary prevention programs should arise from the results of this study. The main stressor considered in this study will be the incidence of weight gain as an additional stressor with the diagnosis of breast cancer.

This study address some of the concerns presented in a letter to the editor regarding the Dixon, Moritz & Baker (1978) article. Harris (1979) addressed concerns of a mixed population, a small sample size, unreported disease stage and menopausal status. The population of the study in question included several different types of cancer patients, including colon, lung and bladder. The total number of subjects in the Dixon, Moritz and Baker study was ninety-eight and of this thirty-two were breast cancer patients. The disease stage of the breast cancer patients was not given nor was the menopausal status. Both the stage and menopausal status have effected the results obtained and Harris raised questions about these unaddressed factors. The present study attempted to address these concerns.

HYPOTHESIS

The research hypotheses for this study are:

1. Women with stage I or stage II breast cancer gain weight.
2. Women with stage I breast cancer gain more weight than women with stage II breast cancer.
3. Women with stage II breast cancer on adjuvant chemotherapy with Doxorubicin gain more weight than women with stage I or stage II breast cancer on Tamoxifen alone.
4. Women with breast cancer who gain weight do not lose that weight after treatment ends.

DEFINITION OF TERMS

Weight Gain - after the first recorded office visit any gain, over the mean body weight.

Weight loss - after the first recorded office visit, any loss under the mean body weight.

Stage I disease - tumor confined to the affected breast with no positive axillary lymph nodes or distant metastasis, three centimeters or less in size.

Stage II disease - Tumor in the affected breast with positive axillary lymph nodes and no other local or distant metastasis.

Adjuvant therapy - Chemotherapy given in stage II disease to prevent recurrence when surgery was effective. These include 5-Flurouracil, Methotrexate, Doxorubicin, Cytosan and Tamoxifen. Women in a clinical trial utilizing any other drugs except those listed will be excluded.

Local therapy - surgery and radiation given after lumpectomy (these are mutually inclusive), or surgery such as a simple mastectomy, modified radical mastectomy or a Halsted radical mastectomy or radiation to the chest wall.

Systemic therapy - chemotherapy or hormonal therapy given by oral, intermuscular or intravenous route.

Tamoxifen alone - Tamoxifen is the only systemic therapy given. There is no other oral, intermuscular or intravenous chemotherapy given.

T,N,M staging method - Universal method of staging cancer by tumor size, nodal involvement and presence or absence of distant metastases (Appendix F).

CHAPTER III

METHODOLOGY

DESIGN

This study is a retrospective longitudinal study of women with a diagnosis of breast cancer, either stage I or stage II disease. Women in more advanced stages of the disease were not studied. The stage of disease was determined by the T,N,M staging method, which is a universal method of staging cancer by tumor size, nodal involvement and presence or absence of distant metastases (Appendix F), using data at the time of diagnosis, or as designated on the pathology report if T,N,M information was lacking.

Previous studies such as Dixon, Moritz & Baker (1978) have been criticized by Harris (1979) concerning the use of mixed diagnosis and stage of disease. The methodology for the present study addresses those concerns.

POPULATION AND SAMPLE

The subjects were all female patients diagnosed as having stage I or II breast cancer. The subjects were all patients of two private oncology practices located in a large southwestern city. Data were collected by reviewing medical records of eligible subjects, those diagnosed with either stage I or stage II breast cancer, prior to 1 September 1991. The date of diagnosis on one subject, the earliest sampled, was 1972. Women with stage II disease were eligible if they received 5-Flurouracil, Methotrexate, Doxorubicin, Cytosan or Tamoxifen singly or in any combination. Subjects were ineligible for inclusion if the medical record indicated they were participants in clinical trials including any other chemotherapeutic drug except those listed. All data were collected from the subject's medical record.

PROCEDURE

It is the practice of both offices to weigh patients on every office visit. Thus weight changes from first visit to most recent visit were available. It is assumed that the

patient's weight was always taken on the same scale. The scales, one in each office, are a balance beam type calibrated every six months by Associated Pathologists Biomedical Department, a firm licensed to certify the accuracy of the instrument. In each office a Registered Nurse weighed the patient and recorded the weight on a flow sheet. The flow sheet was used for all patients whether or not they received chemotherapy. The flow sheet recorded the patients height, weight, vital signs, laboratory test results and pertinent telephone conversation notes between office visits. The first office visit weight was used as the baseline weight since pre-diagnosis and/or pre-operative weight was not consistently available in the patient medical record. Other data came from laboratory records and operative records on the patient found in the patient medical record.

All female patients with a diagnosis of stage I or stage II breast cancer were eligible, if at least one year had elapsed since diagnosis so that weight trend data were available. In chemotherapy protocols the drugs are given for a minimum of six months to a maximum of twelve months and Tamoxifen is given for three to five years. It was determined that patients with less than one year elapsed time since diagnosis had insufficient data to identify a trend toward weight gain or loss. The use of the medical records of patients diagnosed prior to 1 September 1991 assured that one year elapsed since diagnosis. All

available eligible medical records from both medical practice sites were reviewed. This sampling technique provided a sufficient number of subject medical records, to address Harris's (1979) concern with sample size. The data collection procedure contained several steps. First, the medical records clerk in each office pulled all medical records of patients with a diagnosis of breast cancer. Second, the data collection team, consisted of Registered Nurses from each medical office. Then the medical record was checked for the date of diagnosis. Third the data collection team checked each medical record for treatment type and chemotherapy drugs used. The collector rejected any medical record that indicated that the patient had been prescribed any drug not within the inclusion criteria.

Chemotherapy protocols have remained relatively stable over the past five years in the most common protocols for breast cancer, one drug Methotrexate has been changed to Doxorubicin. This change was made about three years ago based on the recommendation of the National Cancer Institute following multiple studies. This change should not impact the focus of this study, weight gain, since the side effects of the combination of the chemotherapy agents are basically the same. The only different side effect is that Doxorubicin is an extravasator which can cause a burn if it is not given in the vein. The difference between the change from Methotrexate to Doxorubicin was noted in the data collection process and testing was done to assure equality.

ASSUMPTIONS

Several assumptions were made regarding the data collection and medical records. Since only a Registered Nurse, in each office, weighed the patient and recorded the information, it was assumed that the information was recorded accurately. It was also assumed that the nurse accurately weighed the patient even though there probably had been a series of nurses in each office. It was assumed patients provided an accurate pregnancy and family history because of the seriousness of the disease and the importance of accurate health history information.

DATA COLLECTION

The data were collected over a period of four weeks. A team of data collectors was instructed how to collect the data and what information was needed. A training session with each person was done prior to actual data collection. Each individual reviewed charts and had the results verified by the researcher to be sure the data were collected uniformly.

Demographic data were obtained from each subject's chart including age. The data on age of the subjects were collected and a mean age calculated to address Harris's (1979) concern, with mean age calculated from the mean year of birth of all subjects and common age of the at risk population. Harris felt that the explanation of the weight gain might be menopausal status. Other data collected included: menopausal status; type of surgery; receptor status; DNA information; type of treatment; number of pregnancies; length of time since diagnosis; recurrence; site of original tumor; size of original tumor; and family history of breast cancer.

CHAPTER IV

FINDINGS

The medical records of all the female breast cancer patients from two oncology practices served as the source of data. All medical records meeting eligibility requirements were included in the study thus providing 214 eligible records. Of the 214 medical records reviewed, one was not eligible due to data collection error, thus leaving 213 eligible subject medical records.

SAMPLE

The largest majority (85%) of the data were collected in the office of one practice, while the other oncology practice was the data collection site of 15%. This disparity was predicted at the onset of the study. The earliest year of diagnosis was 1972 and the latest was 1991 with mean year of 1988. The subjects ranged in age from 31 to 90 years old, with a mean age of 62 and a mean year of birth of 1931. The convenience sampling reflected a sample

which was 87% Caucasian. One would like a larger sample from other racial as well as socioeconomic groups to help round out the statistics and confirm the data. All subjects had insurance coverage for treatment. Consequently, it would be difficult to project the results of this study to the total population of women with breast cancer. A sample of 213 subjects is a good sample size but still small in view of the size of the effected population. Because the sample was all female, the less than one percent of the male population effected by breast cancer can not be considered. Approximately fifty-one percent of the subjects had stage I disease and approximately forty-nine percent had stage II disease. Treatment start dates for stage II disease ranged from 1978 to 1992 with the mean year of 1988. One hundred thirty-three subjects were still on active treatment at the time of data collection. Active treatment was noted when women had radiation prior to starting their chemotherapy protocol, had elected to wait to start their chemotherapy until completely surgically healed and those women who are on Tamoxifen which they take for a minimum of three years. One hundred twenty-seven subjects were or had received Tamoxifen. Twenty-seven subjects had received Doxorubicin, Cytosan and 5-Flurouracil while sixty-two subjects received Methotrexate, Cytosan and 5-Flurouracil. There were only four subjects in this study who received Prednisone as part of their treatment and seven who received Megace as part of their treatment. Since all but one of these eleven subjects

received either the Prednisone or Megace after the twenty-four month time frame when data were collected no separate analyses were done to exclude these subjects. One patient did receive Prednisone during the first twenty-four months post diagnosis as part of her treatment regime but it was felt that one subject would not skew the data so she was included in the final analysis. However, no conclusion can be made about the Prednisone impact on weight gain. Forty-one of the subjects had chest wall radiation of from 2500 to 6400 Rads (radiation absorbed dose) .

Two of the subjects refused surgery beyond a fine needle biopsy, one hundred eighty-five had a modified radical mastectomy, twenty had a lumpectomy with axillary node dissection, four had a Halsted radical mastectomy and four had a simple mastectomy. The four subjects who had a simple mastectomy had pathologically proven intraductal disease only and simple mastectomy is considered the standard treatment for this population, which is diagnosed as stage I disease.

One hundred seventy subjects had been pregnant at least once. The number of pregnancies ranged from one to fifteen with a mean of 2.5 pregnancies per subject. Thirty-three subjects had never been pregnant and pregnancy information was missing on ten subjects. Age at first pregnancy ranged from 16 to 42 with a mean age at first pregnancy of 25.

A family history of at least one first degree relative with a diagnosis of breast cancer was found in 64 of the

subjects. The information on family history of breast cancer was missing in nine of the subject charts. A breakdown of family history of breast cancer shows 19 had at least one sister, 21 had a mother, 2 had a daughter, 11 had a grandmother and 23 had at least one aunt with a history of breast cancer.

Breast involvement showed 103 subjects with just the left breast, 88 with the right breast, 19 had involvement of both breasts. For three subjects this information could not be found in the chart. The size of the primary tumor ranged from less than one centimeter to eleven centimeters with the mean size of 2.3 centimeters. Nodal involvement ranged from zero nodes to thirty-five nodes with the mean number of nodes being 2.8. Estrogen receptor test was positive for 150 subjects and 119 were progesterone receptor positive. DNA histogram information was collected when available but since this is a fairly new procedure only those subjects diagnosed since 1988 had this information and then not consistently until 1990. Aneuploid tumors were identified in 30 subjects, 4 had intermediate stage tumors and 55 had diploid tumors. Ploidy is a fairly new prognostic testing method where the pathologist looks at how the tumor cells appear. Diploid tumor cells appear nearly normal and are the best prognostic stage, intermediate look less normal and have a less favorable prognosis where aneuploid cells are the most abnormal looking cells and have the worst prognosis. In 21 subjects S-phase was high,

intermediate in one subject and low in 38 subjects. Like the ploidy of the cells the number of cells in S-phase are prognostic with high S-phase being the ones with the worse prognosis. Menopausal status showed 45 pre-menopausal, 14 peri-menopausal and 137 post-menopausal with this information missing on 17 subjects. Menopausal status was collected with the demographic data from the chart by date of last menstrual period then applying the criteria outlined for menopausal status (definitions).

Recurrence of their tumor was noted for 39 subjects and 17 were receiving treatment for the recurrence. These were subjects who had recurred at least twelve months after the original diagnosis so that this event did not influence the weights on which this study was focused.

HYPOTHESES TESTED

The Statistical Program for Social Sciences software was used to run all statistical analysis on the data collected.

The first null hypothesis tested was women with stage I or stage II breast cancer do not gain weight over a two year period post diagnosis.

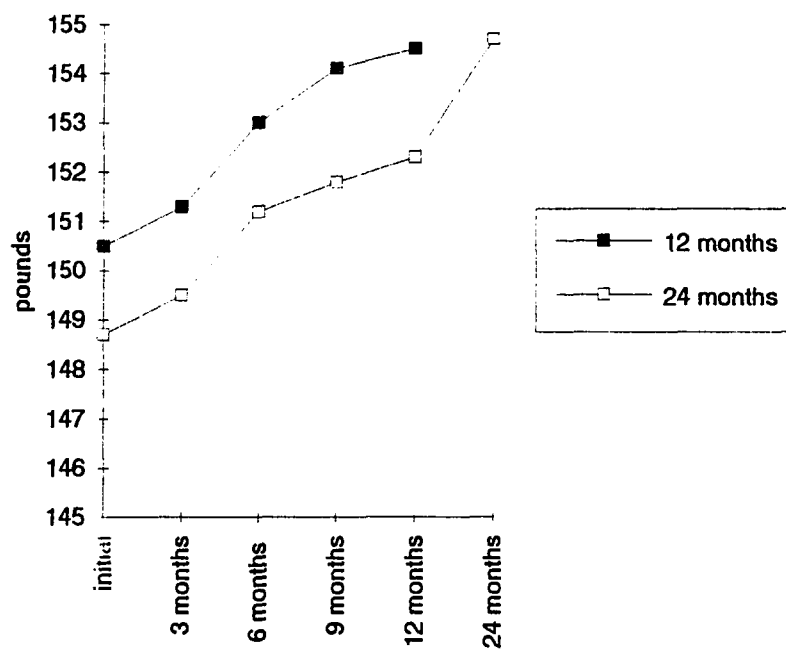
The data showed a mean weight gain of approximately three pounds at the end of twelve months and four pounds by

the end of twenty-four months. To test the null hypothesis MANOVAs with repeated measures were run (Stevens, 1992).

Two separate MANOVAs were run due to the fact that patients who were less than two years since diagnosis were included in the sample. One MANOVA was run including all weights, initial through twenty-four months, and another was run on weights initial through twelve months.

The MANOVA for repeated measures using initial weight through twenty-four months identified one hundred eleven subjects with complete data. The mean initial weight for this group was 148.7 pounds, and the mean weight at twenty-four months for this group was 154.7 pounds. This is a mean weight gain for this group of six pounds. The standard deviation ranged from 27.9 to 28.3 on the means of the six weight periods. There may have been some violation of sphericity but the Greenhouse-Geisser Epsilon (.67) showed this was within tolerances for multiple analysis rather than single analysis (Stevens, 1992). The overall Wilks was calculated for the twenty-four month time period. Wilks = .7101, $F = 8.814$, $df = 5, 108$, $p = .000$. The overall significant statistic allows rejection of the null hypothesis. To further analyze the data the mean weights were tested for difference by time periods. Helmert Contrasts (Stevens, 1992) show the mean weights that had changed from the initial weight were three months with $F = 14.55$, $p = .000$; six months with $F = 14.64$, $p = .001$; nine months with $F = 11.49$, $p = .001$; twelve months $F = 12.087$,

Figure 1: Mean weight for subjects at only 12 (N = 161) and 24 months (N = 111)



$p = .001$ and twenty-four months with $F = 14.204$, $p = .000$.

The MANOVA for repeated measures using initial weight through twelve months identified one hundred sixty-one subjects with complete data. The mean initial weight of this group was 150.5 pounds and the mean weight at twelve months was 154.5 pounds for a mean weight gain of four pounds. The sphericity of this sample was more nearly normal but may again have been violated. The Greenhouse-Geisser Epsilon was .67.

The MANOVA resulted in Wilks Lambda = .8268, $F = 8.376$, $df = 4, 160$, $p = .000$. Again the Helmert Contrasts for this group showed the mean weight change at three months was significant with $F = 16.307$, $p = .000$; six months $F = 18.13$, $p = .000$; nine months $F = 11.56$, $p = .001$ and twelve months $F = 10.416$, $p = .226$. Consequently this null hypothesis is rejected and allows support that women with breast cancer of either stage I or stage II do gain weight at twelve and twenty-four months after diagnosis. The power of weight change by time ranged from a low of .90 to a high of .96.

The second null hypothesis tested was there is no difference in weight gain between women with stage I breast cancer and women with stage II breast cancer.

A MANOVA for repeated measures was run separating stage I from stage II subjects. For the twelve month period there was a total of 161 subjects, with 76 in the stage I group and 85 in the stage II group. Standard deviations for both groups were within a few tenths of each other, (stage I

SD= 24.4 to 25.5 and stage II SD= 33.2 to 33.7). The results showed that over the first twelve months stage II subjects gained more weight than stage I subjects by a mean difference of about two pounds (figure 2). Stage I subjects' mean initial weight was 148.2 pounds and mean weight at the twelve months was 151.4 pounds which is a mean weight gain of 3.2 pounds. Stage II subjects' initial weight was 152.6 pounds and a mean weight at twelve months of 157.3 pounds or a mean weight gain of 4.7 pounds. The MANOVA of one hundred sixty-one subjects with twelve month data resulted in a Wilks= .82723, $F = .22$, $DF = 1,109$, $P = .64$.

For the twenty-four month period a total of 111 subjects with 60 in the stage I group and 51 in the stage II group. As with the 12 month group standard deviations were within a few tenths of each other (stage I SD= 25.1 to 25.9 and stage II SD= 30.6 to 31.7). Stage I subjects' mean initial weight was 150.2 pounds and the mean weight at the end of twenty-four months was 156.1 pounds which is a mean weight gain of approximately six pounds. Stage II subjects' mean initial weight was 147 pounds and the mean twenty-four months weight was 153.7 pounds with a mean weight gain of 4.7 pounds (figure 3).

The MANOVA of the 111 subjects with twenty-four month data resulted in a Wilks= .956, $F = .97$, $df = 5,107$, $p = .438$, none of the weight by stage data was significant. Weight alone gave a Wilks= .714, $F = 8.56$, $df = 5,107$, $p = .000$. All

Figure 2: Stage I (N = 76) versus stage II (N = 85)
subjects 12 month mean weight

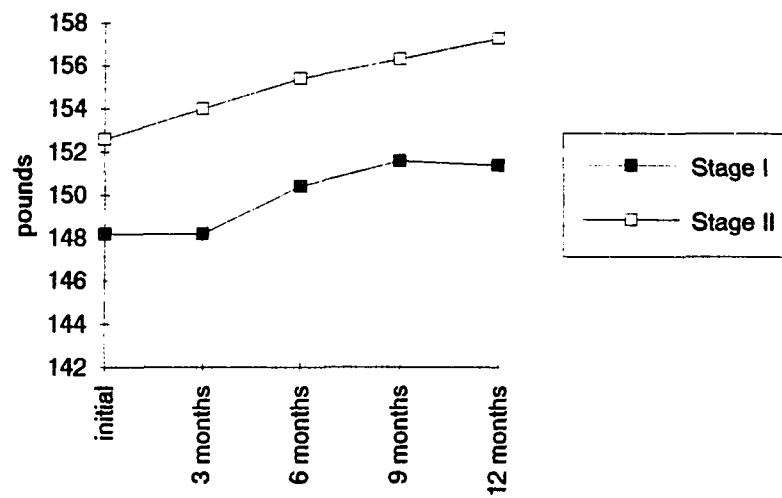
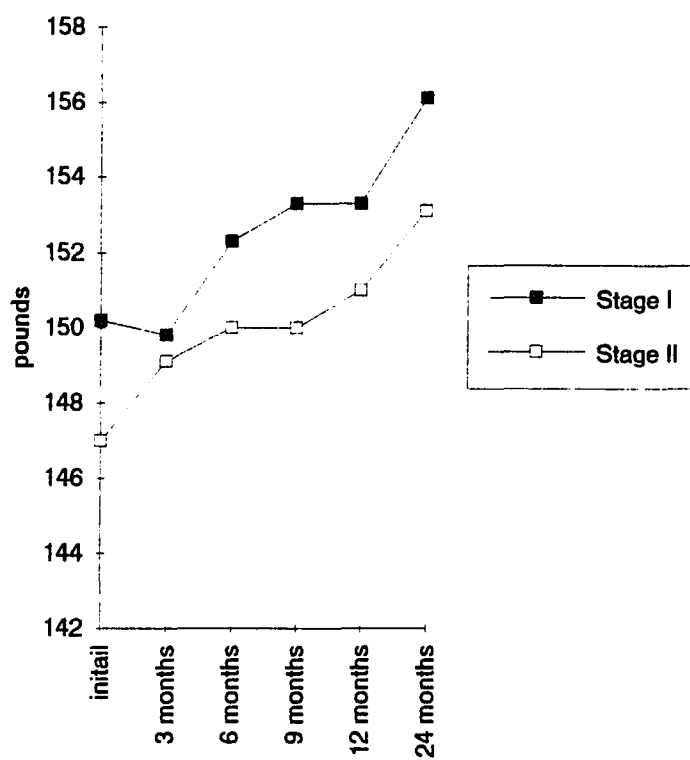


Figure 3: Stage I (N = 60) versus stage II (N = 51) 24
month mean weights



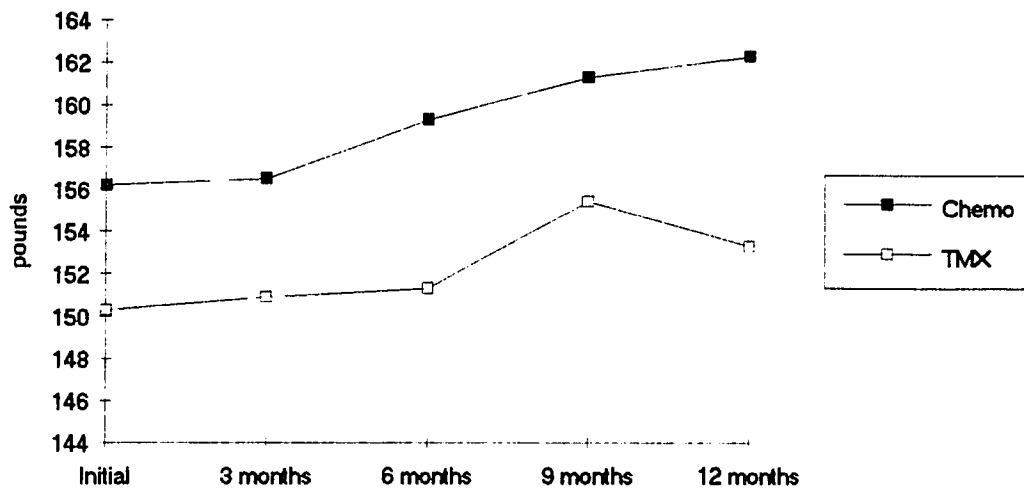
weights were different with $df= 1,111$, $p= .000$ to $.001$. The power by stage was $.046$ at the highest level. Consequently the null hypothesis of no difference in weight gain between women with stage I and women with stage II breast cancer was retained.

The third null hypothesis tested stated that there will be no difference in weight gain between women with stage II breast cancer on adjuvant chemotherapy with Doxorubicin and women with stage I or stage II breast cancer on Tamoxifen alone.

A MANOVA for repeated measures was run on all subjects receiving chemotherapy for stage II breast cancer. Twenty-seven subjects receiving chemotherapy with Doxorubicin had a weight increase of six pounds over the twelve month time span. One hundred twenty-seven subjects who received Tamoxifen alone showed no greater weight gain than those who had not received Tamoxifen. The group who received Tamoxifen had an initial mean weight of 147 pounds and at twenty four months their mean weight was 153 pounds. The group who did not receive Tamoxifen had an initial mean weight of 151 pounds and their twenty-four month mean weight was 157 pounds (figure 4). Each group gained approximately six pounds. No statistical difference was found between the these groups $F= .69$, $df= 1\ 109$, $p= .406$. Therefore the null hypothesis was retained.

The fourth null hypothesis tested was that women with

Figure 4: chemotherapy with Doxorubicin (N = 27) versus
Tamoxifen (N = 127)



breast cancer who gain weight will have no difference in weight from initial weight after treatment begins. A paired t-test for both the twelve and twenty-four month groups was run (Stevens, 1992).

Data for the twelve month group of 193 subjects found an initial mean weight of 149.35 pounds, SD= 30.49 and the twelve month mean weight of 153.29 pounds, SD= 31.05. The paired t-test analysis was $t = -5.41$, $df = 192$, two tailed $p = .000$. Data for the twenty-four month group of one hundred forty-six subjects was initial mean weight 149.11 pounds, SD= 30.37 and the twenty-four month mean weight 154.76, SD= 30.37. The paired t-test analysis was $t = 6.48$, $df = 145$, two tailed $p = .000$. A paired t-test was then done on one hundred thirty-four subjects comparing the twelve month weight with the twenty-four month weight. The twelve month mean weight was 151.05 pounds with SD= 28.92 and the twenty-four month mean weight was 153.12 pounds with SD= 28.97. The $t = -3.37$, $df = 133$ and the two tailed $p = .001$. Thus the null hypothesis was rejected.

In summary null hypothesis one and four were rejected and two and three were retained.

CHAPTER V

RESULTS

DISCUSSION

The purpose of this study was to test four null hypotheses. The first and fourth null hypotheses were not supported. The second and third were retained.

The first null hypothesis was women with stage I or stage II breast cancer do not gain weight. The data show that they do gain weight at a statistically significant level. Therefore the null hypothesis is rejected allowing support of the hypothesis that women with breast cancer gain weight through the twenty-four month period. This supports findings by Dixon, Moritz & Baker (1978), Stevens and Gilmore (1986), Goodwin, Panzarella and Boyd (1988), Heasman, Sutherland, Campbell, Elhakim & Boyd (1985), Knobf, (1985), and Huntington (1984). This study included stage I subjects as a comparison looking for diagnosis or disease process as a possible answer to the weight gain versus treatment medications.

To further determine weight gain relationship the second null hypothesis, there is no difference in weight gain between women with stage I and women with stage II breast cancer, was tested. This hypothesis was retained for the first twelve month period as both gained weight. Women with stage I breast cancer catch up and surpass the stage II women in weight gain by the end of twenty-four months and appear to be on an upward course (figure 2, chapter 4). Since the literature on weight gain in stage I women with breast cancer is sparse there was no literature found to support this finding. Dixon, Moritz & Baker (1975) reported weight gain as an ancillary finding in her study and is the only study where early disease is mentioned. Early disease is presumed to mean stage I by context though it is not specifically stated. The finding that stage II women gain weight supports the information found in the literature, such as Heasman, Sutherland, Campbell, Elhakim & Boyd (1985), Huntington, (1985), Stevens and Gilmore, (1986) and Goodwin, Panzarella and Boyd, (1988).

The third null hypothesis was, there is no difference in weight gain between women with stage II breast cancer on chemotherapy with Doxorubicin and women with stage I or stage II breast cancer who are given Tamoxifen alone. The null hypothesis was retained. However the data show that women receiving chemotherapy with Doxorubicin gain more weight than those on Tamoxifen alone but not a statistically significant level..

Knobf (1985) observed an average weight gain of four pounds in women on Cytosan, 5-Fluorouracil and Methotrexate. Heasman et al (1985) found a mean weight gain of 4.3 kilograms in 237 subjects on Cytosan, 5-Fluorouracil and Methotrexate. Goodwin, Panzarella and Boyd (1988) found that women on Cytosan, 5-Fluorouracil and Methotrexate gained weight, did not lose the weight and that there was no effect on prognosis due to the weight gain. There were no studies found on the effect of Doxorubicin, Cytosan and 5-Fluorouracil and weight gain.

This study suggests weight gain by both groups of study subjects is not different. This was an unexpected finding since one of the side effects of chemotherapy is a significant amount of nausea.

The fourth null hypothesis was women with a diagnosis of breast cancer will have no difference in weight from initial weight after treatment ends. The findings supported rejecting the null hypothesis. Stage I breast cancer patients show a continual weight gain through twenty-four months while stage II breast cancer patients appear to have leveled off in their weight gain sometime before twenty-four months (figure 2, chapter 4).

Two studies found in the literature Heasman, Sutherland, Campbell, Elhakim & Boyd (1985) and Goodwin, Panzarella and Boyd (1988) support this finding. Both of these studies found a weight gain in women with breast cancer on adjuvant chemotherapy and both studies found that

the weight was not lost at the end of the chemotherapy treatments.

THEORETICAL FRAMEWORK

The Neuman Systems Model (1989) identifies five variables comprising the system of the client entity. All five variables impact on the system and affect the system. The five variables are defined as physiological, psychological, sociocultural, developmental and spiritual. Stressors and stressor responses can be from any or all of the five variables. The physiological variable is probably the one variable most addressed by this study. The stressor is a diagnosis of breast cancer to which the system responds. Both the lines of defense and the flexible lines of defense are breached as are the lines of resistance. Body structure and function are compromised by surgery which is disfiguring even if only a lumpectomy is done. Following surgery the woman is attempting to rebuild her lines of resistance, lines of defense and flexible lines of defense while at the same time those same lines are being breached by the post-surgical treatment itself.

The weight gain identified in this study and others may be the attempt to return to wellness. The fact that there is a weight gain suggests that there is a physiological response to a stressor. Neuman's Model predicts and

explains the response to a stressor in the system as action attempting to rebuild the flexible lines of defense.

Neuman's sociocultural and developmental variables while not a focus of this study were in the demographic data collected. Sociocultural variables were limited in that the majority of subjects were white and all had insurance coverage. The developmental variable as age and menopausal status data were collected. This study did not address the significance of this data but plans are to address it in a future study. The psychological and spiritual variables were not included in this study as these variables were not pre-identified as impacting nor answering the questions raised by the hypotheses.

While this study mainly focused on the physiological variable of weight gain in women who are diagnosed with breast cancer. The four variables not addressed by the present study certainly will guide the direction of future studies designed to determine why the weight gain occurs.

As one can see Neuman explains possible factors for the physiological response of the weight gain found in this study and gives direction to future study as to why this population gains weight.

LIMITATIONS

This study had several limitations such as: a sample of convenience, some missing weight data, a racially biased subject population and not a long enough time span over which data were collected. It would perhaps have been better to collect data for five years after the initial visit than just twenty-four months to plot a more comprehensive trend in the weight change over time.

The mean age of the group was 61 years with 64% of the subjects falling in the post-menopausal group. Harris's (1978) concern that the weight gain Dixon, Moritz & Baker (1978) noted may have been due to menopausal status rather than disease is a valid concern. Data for this study was collected to address this concern. Possible explanations will be addressed in a later study since the current study focused only on whether there was or was not an actual weight gain.

CONCLUSIONS

Women in this study diagnosed with breast cancer did gain weight. Women with stage I breast cancer took longer

to gain the weight but the study indicated that the weight gain was on an upward swing at twenty four months while stage II women appeared to level off somewhere between the twelve month and twenty-four month time frame. Women with stage I breast cancer had a mean initial weight approximately four pounds less (148.2) than women with stage II breast cancer (152.6). This is an interesting finding and should be studied in more depth in the future. Since both groups gained approximately six pounds this difference in initial weight may have no significance at all. The interesting factor here is the apparent catching up in weight and even surpassing the stage II subjects by the stage I subjects at the twenty-four month mark. Having a diagnosis of breast cancer with the response of a weight gain suggests this is a stressor which affects the flexible line of defense causing a reaction in the system evidenced by weight gain. This also suggests that the stressor may be the disease process rather than the treatment itself since stage I women who did not receive chemotherapy or hormonal therapy also gained weight.

Neuman model variables like developmental, age and menopausal status, may help explain the reason for the weight gain. The spiritual variable to which self image, support structure and belief systems belong also may give us clues as to where to look for the reason for the weight gain.

This study supported the findings in the literature of weight gain among women with stage II breast cancer on adjuvant chemotherapy. Interestingly those women treated with Doxorubicin, the one chemotherapeutic drug which causes the most nausea, gained the most weight in the chemotherapy group. This study did not find a greater weight gain in women on Tamoxifen contrary to what was expected from the literature and drug side effect information listed in the drug information insert and literature produced by the pharmaceutical manufacturer.

With the twenty-four month time line allowed in this study, the researcher was unable to observe if there was a loss of weight after treatment, with the subject returning to baseline or initial weight. In fact the stage I group appear to continue to gain weight at this time marker. The appearance of a leveling out sometime after the twelfth month by stage II women could be related to recurrence and that we start losing them to their disease at this point. Further study is needed to confirm this however.

The statistical significance of the weight gain in women with both stage I and stage II breast cancer warrants further study. Future study should include a more randomly selected sample more fully representing the general population of women diagnosed with breast cancer. Future samples should include both a larger number of subjects of ethnic and racial backgrounds. Subjects in socioeconomic groups who do not have a insurance would also answer some of

the questions both raised and left unanswered by the present study.

The weight gain could be considered a response to a stressor and identification of the stressor would be instrumental in developing an alternate response to the stressor. Some possibilities suggested by observation, literature review, interaction and interviews with women diagnosed with breast cancer are a perception of lack of self image, food as a defense mechanism, a spiritual response and in the case of those women on Doxorubicin, is it an attempt to curb the nausea? Some patients say they eat so they do not get that "queasy" feeling. This may be the normal line of defense responding to the "queasy" stressor.

Even though there was no statistical difference between the weight gain of women with stage I and stage II breast cancer the data are very interesting and should be studied further over a longer time frame. This particular group of subjects could be followed over the next five to ten years. A longitudinal study might answer the unanswered questions related to return to pre-diagnosis weight and also show if the apparent upward trend of weight gain in stage I women continues over time or levels off as apparently occurs in stage II women. It also might show if the leveling off of stage II women is due to recurrence and disease process.

RECOMMENDATIONS

Suggestions for future study include: continue to follow this particular subject group over the next several years, start a study with a new group of subjects and follow them for the next five to ten years, attempt to define what the stressors are so a plan to assist these women in coping with the stressors can be found.

Look to each of Neumans' five variables for explanation of the weight gain by stressor identification and for assistance to help women with breast cancer cope with the diagnosis in a form other than eating.

While this information gathering proceeds health professionals can begin to educate this population of women that a weight gain occurs and provide information on weight control. A self help group could be set up through the Mastectomy Society. As for the actual study group of subjects we have already begun an educational program. Each of the women, seen by either of the physicians whose case load was used for this study, with a diagnosis of either stage I or stage II breast cancer is informed of this study's findings and a packet of information is given out. This packet includes information on nutrition, antiemetics and nausea prevention and exercise. Both physicians are

prescribing increased doses of antiemetics and allow their patients to follow a good commercial diet program if the patient so requests.

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APPENDICES

APPENDIX A

HEIGHT AND WEIGHT TABLES

Table 1

Height in inches for all subjects

HEIGHT	FREQUENCY	PERCENT
53	1	.5
57	1	.5
59	3	1.4
60	13	6.1
61	16	7.5
62	33	15.5
63	28	13.1
64	28	13.1
65	28	13.1
66	18	8.5
67	20	9.4
68	11	5.2
69	4	1.9
70	3	1.4
missing	6	2.8
	213	100

Mean = 63.8

SD = 2.6

N = 207

Table 2

Weight at time of first office visit for all subjects

WEIGHT IN POUNDS	FREQUENCY	PERCENT
<100	2	1
100 - 110	12	5.1
111 - 120	14	8.6
121 - 130	20	9.4
131 - 140	32	15.1
141 - 150	46	22.2
151 - 160	22	10.4
161 - 170	18	8.4
171 - 180	15	7.1
181 - 190	5	2.4
191 - 200	7	3.3
201 - 210	4	1.9
211 - 220	3	1.4
221 - 230	3	1.4
231 - 240	3	1.4
241 - 250	3	1.4
251 - 260	1	.5
	210	100

Mean = 150.9

SD = 31.2

N = 213

Table 3

Weight at three months for all subjects

WEIGHT IN POUNDS	FREQUENCY	PERCENT
<100	1	0.5
100-110	11	5.7
111-120	11	5.7
121-130	22	11.4
131-140	28	14.5
141-150	32	16.6
151-160	27	14
161-170	22	11.4
171-180	17	8.8
181-190	5	2.6
191-200	2	1.0
201-210	4	2.1
211-220	1	0.5
221-230	4	2.1
231-240	3	1.5
241-250	2	1.1
251-260	1	0.5
missing	20	
	213	100

Mean = 151.3

SD = 30.1

N = 193

Table 4

Weight at six months for all subjects

WEIGHT IN POUNDS	FREQUENCY	PERCENT
<100	2	1.0
100-110	10	5.0
111-120	9	4.5
121-130	25	12.5
131-140	31	15.5
141-150	28	14.0
151-160	26	13.0
161-170	21	10.5
171-180	24	12.0
181-190	4	2.0
191-200	5	2.5
201-210	4	2.0
211-220	2	1.0
221-230	2	1.0
231-240	3	1.5
241-250	3	1.5
251-260	1	0.5
missing	13	
	213	100

Mean = 152.4

SD = 30.4

N = 200

Table 5

Weight at nine months for all subjects

WEIGHT IN POUNDS	FREQUENCY	PERCENT
<100	3	1.6
100-110	6	3.3
111-120	8	4.9
121-130	20	12.8
131-140	27	14.6
141-150	33	17.8
151-160	21	11.4
161-170	14	8.1
171-180	25	13.0
181-190	7	3.7
191-200	2	1.1
201-210	7	3.8
211-220	2	1.1
221-230	0	.0
231-240	5	2.7
241-250	3	1.6
251-260	2	1.1
missing	28	
	213	100

Mean = 155.6
SD = 32.2
N = 185

Table 6

Weight at twelve months for all subjects

WEIGHT IN POUNDS	FREQUENCY	PERCENT
<100	3	1.6
100 - 110	6	3.1
111 - 120	15	7.7
121 - 130	21	10.9
131 - 140	28	14.5
141 - 150	35	18.2
151 - 160	19	9.8
161 - 170	14	7.3
171 - 180	24	12.4
181 - 190	12	6.2
191 - 200	1	.5
201 - 210	3	1.6
211 - 220	4	2.1
221 - 230	0	0
231 - 240	4	2.0
241 - 250	3	2.1
251 - 260	0	0
missing	20	
	213	100

Mean = 153.2

SD = 31.0

N = 193

Table 7

Weight at twenty-four months for all subjects

WEIGHT IN POUNDS	FREQUENCY	PERCENT
<100	1	0.7
100-110	5	3.4
111-120	11	7.5
121-130	13	8.9
131-140	18	12.4
141-150	19	13.0
151-160	26	17.8
161-170	16	11.0
171-180	10	6.8
181-190	11	7.5
191-200	5	3.5
201-210	4	2.7
211-220	0	.0
221-230	1	.7
231-240	4	2.7
241-250	2	1.4
251-260	0	.0
missing	67	
	213	100

Mean = 154.7
SD = 30.3
N = 146

APPENDIX B

NEUMAN'S THEORETICAL FRAMEWORK
DIAGRAM

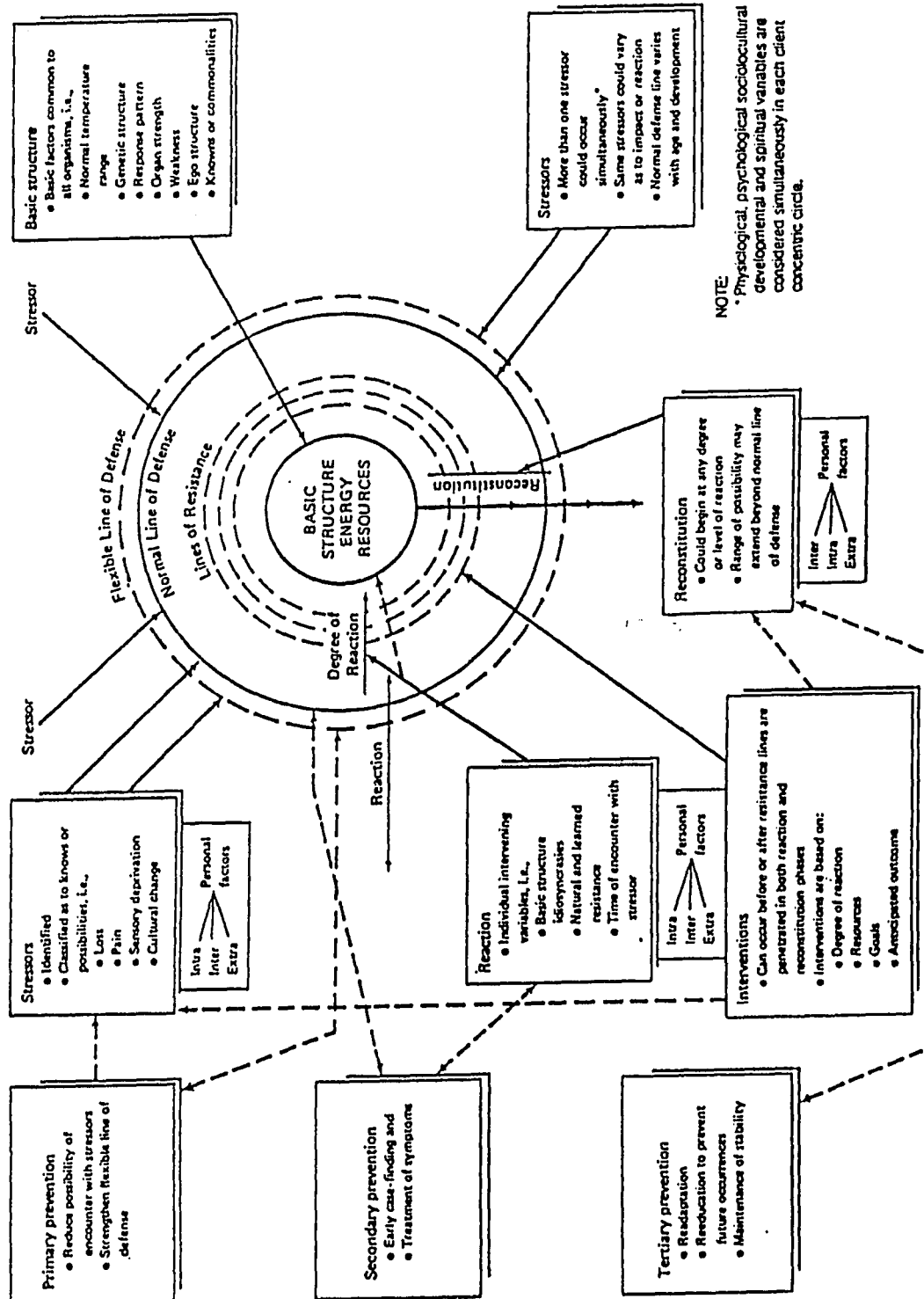


Figure 1-3. The Neuman Systems Model. Original diagram copyright © 1970 by Betty Neuman.

APPENDIX C

DATA COLLECTION TOOL

DATA INFORMATION SHEET

ID # _____ MD _____ Stage _____

Year Dx _____ Date therapy started _____

Date therapy ended _____

Drugs used Tamoxifen _____ Megace _____ Prednisone _____
Doxorubicin _____ Cytosan _____ Methotrexate _____
5-Flurouracil _____

Year of birth _____

Race Black _____ White _____ Oriental _____ Spanish _____

Native American _____

Treatment Radiation _____ Chemotherapy _____ Hormonal _____

Surgery _____

Type of surgery Modified Radical _____

Lumpectomy w Axillary node dissection _____

Radical Mastectomy _____ Simple Mastectomy _____

Pregnancy Y _____ N _____ number _____

Age at first pregnancy _____

Family History of breast cancer Y _____ N _____

Sisters _____ Mother _____ Daughters _____

Grandmother _____ Aunt _____

Number of positive axillary nodes _____

Breast	Location	Size in cm.
--------	----------	-------------

Left	Upper Outer	_____
Right	Upper Inner	_____
Both	Lower Outer	_____
	Lower Inner	_____

Dose of XRT _____ Rads

Receptor status ER+ ____ ER- ____ PR+ ____ PR- ____

Menopausal status Pre ____ Post ____ Peri ____

DNA ploidy _____ S phase _____

Recurrent disease Y ____ N ____

Treatment _____

Ht. _____

Wt. initial _____

Three months _____

Six months _____

Nine months _____

Twelve months _____

Eighteen months _____

Twenty-four months _____

Secondary Diagnosis _____

APPENDIX D

LETTERS OF PERMISSION

HEATHER J. ALLEN, M.D., LTD.

Oncology and Hematology

3006 S. Maryland Parkway, Suite 205, Las Vegas, Nevada 89109

(702) 735-4002

7 September 1992

To whom it may concern:

Sheryl Therrien, a graduate student at University of Nevada Las Vegas, has my permission to review the charts of breast cancer patients in my office for the purpose of collecting data for her master's thesis. I understand that the data does not include any identifying data and that patient confidentiality will therefore be maintained. I understand that Sheryl is looking at a relationship between breast cancer diagnosis and weight gain.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather Allen", written in a cursive style.



ARNOLD WAX, M.D.

RR

BOARD CERTIFIED INTERNAL MEDICINE
BOARD CERTIFIED MEDICAL ONCOLOGY

(702) 898 8001
Hours By Appointment Only

7 September 1992

To whom it may concern:

Sheryl Therrien, a graduate student at University of Nevada Las Vegas, has my permission to review the charts of breast cancer patients in my office for the purpose of collecting data for her master's thesis. I understand that the data does not include any identifying data and that patient confidentiality will therefore be maintained. I understand that Sheryl is looking at a relationship between breast cancer diagnosis and weight gain.

Sincerely,

APPENDIX E

PERMISSION TO USE COPYRIGHT

Permission to Use Copyrighted Material

I, Betty Neuman, holder of copyright on material
 entitled The Neuman Systems Model Diagram
 authored by Betty Neuman
 and originally published in Nursing Research

_____, hereby
 give permission for the author to use the above-described material
 in total or in part for inclusion in a master's thesis/doctoral
 dissertation at the University of Nevada, Las Vegas.

I also agree that the author may execute the standard contract with
 University Microfilms International for microform reproduction of
 the completed thesis/dissertation, including the materials to which
 I hold copyright.

Signature:

Betty Neuman

Date:

9/28/92

Name (typed):

Betty Neuman

Title:

RN, Ph.D. Consultant

Representing:

Self

The Graduate College
 University of Nevada, Las Vegas
 4505 Maryland Parkway
 Las Vegas, Nevada 89154

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OCT 2 1992

GRADUATE COLLEGE

10 September 1992

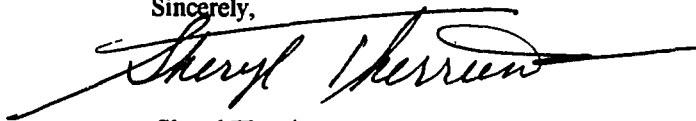
Sheryl Therrien
2039 Civic Center Drive # 157
North Las Vegas, Nevada

Betty Neuman, Ph.D.
Box 488
Beverly, Ohio

Dear Sirs,

I am a graduate student at the University of Nevada Las Vegas. I am currently in the process of writing my thesis for completion of a master's in science, nursing. I am using your Model to guide my thesis project on weight gain in breast cancer. In writing the rationale for using your model I find I need to reproduce the diagram of the model in my appendices. I am writing you to request your permission to reproduce the model from your publication: The Neuman Systems Model (second edition), 26, figure 1-3. I thank you for your consideration of this request and look forward to an answer soon. If I can answer any questions or expedite this permission in any way please let me know. I wrote to Appleton and Lange first and their reply was that they could not give me permission to use the diagram as you own the copyright. Thank you in advance for your consideration of my request. I look forward to hearing from you.
Again thank you for your help and time.

Sincerely,



Sheryl Therrien

Done request: permission granted
Betty Neuman, R.N., Ph.D.
9/16/92

APPENDIX F

HUMAN SUBJECT RIGHTS PAPERWORK

SUBMIT TO OFFICE OF THE GRADUATE DEAN: Original and 11 copies of the Protocol Form (pp. 1-3) plus one copy of the entire research proposal.

APPENDIX C

DATE RECEIVED: _____

LOG # _____

TYPE OF REVIEW

() Expedited

() Regular

FUNDING SOURCE:

() University

() State

() Federal

(XX) Other/None

UNIVERSITY OF NEVADA, LAS VEGAS

PROTOCOL FORM

FOR RESEARCH INVOLVING HUMAN SUBJECTS

INVESTIGATORS: List person principally responsible for the investigation on line a). If principal investigator is a student, list faculty advisor on line b).

Investigator

Department

Phone

- a) Sheryl Therrien, RN
- b) Margaret Louis, Ph.D.
- c)
- d)

UNLV status of Principal Investigator (circle): Faculty/Post-doctoral/Graduate
/Undergraduate/Other _____

TITLE OF PROJECT Weight Gain in Women With Breast Cancer

NAME AND ADDRESS of sponsoring agency or foundation (if other than UNLV) _____
None

CONTRACT OR GRANT NUMBER (if known) None

DURATION OF STUDY (Protocols must be renewed annually) 9/92 Start 12/92 Conclude

TYPE OF SUBMISSION XX New Renewal (attach progress report)
 Continuation Modification
 Previous Log # (if any)

LOCATION(S) OR FACILITIES where study will take place Heather Allen, MD and Arnold Wax, MD office, 3006 S. Maryland Parkway, Las Vegas, Nevada.

25 september 1992
Date

10-20-92
Date

10-20-92
Date

Sheryl Therrien
Principal Investigator's Signature

Rosemary Witt
Department Chair or Unit Head's
Signature

Margaret Louis
Faculty Advisor's Signature
(if warranted)

SUBJECTS: (Please estimate numbers.)

_____ Patients as experimental subjects	_____ Prisoners, incarcerated subjects
_____ Patients as controls	_____ Normal adult volunteers
_____ Minors (under 18)	_____ Persons whose first language is not English.
_____ UNLV Students	_____ Other (please specify)
_____ Pregnant women or fetuses	MedicalRecords 200
_____ Mentally disabled	
	<u>XXX</u> TOTAL ANTICIPATED SUBJECTS
	<u>200</u>

PROCEDURES: (ATTACH relevant materials, such as questionnaires, interview schedules, written test instruments, etc.)

_____ Survey, questionnaire(s)	_____ Investigational Drug*
_____ Interview: phone/in-person	_____ Approved Drug, New Use*
<u>XXX</u> Medical or other personal records	_____ Investigational Device (Attach relevant info.)
_____ Filming, taping, recording	_____ Placebo
_____ Observation	_____ Ionizing Radiation (Attach CURRENT approval)
_____ Participant observation	_____ Surgery
_____ Anthropological fieldwork	_____ In vitro fertilization
_____ Psychological intervention	_____ Venipuncture
_____ Incomplete disclosure of purpose	_____ Other body fluids, excreta
_____ Payment of subjects	_____ Abortus, placenta, excess tissue
_____ Costs to subjects/third parties	_____ Other (please specify)
_____ Brief Explanation of Procedures:	

UNIVERSITY OF NEVADA, LAS VEGAS
PROTOCOL FORM APPROVAL SHEET
FOR RESEARCH INVOLVING HUMAN SUBJECTS

Log Number: _____

Title of Project: Weight gain in women with breast cancer

Investigator: Sheryl Therrien

After reviewing this proposal, the members of the
Review Committee have indicated below their approval/disapproval of this proposal.

Signature of Committee Members

Approve Disapprove

Susan Michael

☒

☐

Sue Witt

☒

Margaret Louis

☒

The above named project is hereby approved/disapproved (circle one)

Date: 10/27/92

Margaret Louis
Committee Chairman's Signature



ASSOCIATE VICE PRESIDENT FOR RESEARCH

UNIVERSITY OF NEVADA, LAS VEGAS
4505 MARYLAND PARKWAY • LAS VEGAS, NEVADA 89154-1002 • (702) 597-4240 • FAX (702) 597-4242

TO: Sheryl Therrien

FROM: Dr. William E. Schulze, Director, Research Administration

DATE: November 4, 1992

RE: Status of human subject protocol entitled:
"Weight Gain in Women with Breast Cancer"

The protocol for the project referenced above has been reviewed by the Office of Research Administration, and it has been determined that it meets the criteria for exemption from full review by the UNLV human subjects committee. Except for any required conditions or modifications noted below, this protocol is approved for a period of one year from the date of this notification, and work on the project may proceed.

Should the use of human subjects described in this protocol continue beyond one year from the date of this notification, it will be necessary to request an extension.

If you have any questions or require any assistance, please give us a call.

According to Nevada revised statutes health care records are the property of the physician or agency caring for the client and the have the right to allow inspection of the charts for statistical and study purposes providing client confidentiality and privacy are maintained.

NRS 629.051 Health care records: Retention. Each provider of health care shall retain the health care records of his patients as part of his regularly maintained records for five years after their receipt or production. Health care records may be retained by microfilm or any other recognized form of size reduction which does not adversely affect their use for the purposes of NRS 629.061.

NRS 629.061 Health care records: Inspection; use in public hearing; immunity of certain persons from civil action for disclosure.

1. Each provider of health care shall make the health care records of a patient available for physical inspection by:

a. The patient or a representative with written authorization from the patient;

b. An investigator for the attorney general or a grand jury investigating an alleged violation of NRS 422.540 to 433.570 inclusive; or

c. Any authorized representative or investigator of a state licensing board during the course of any investigation authorized by law.

The records must be made available at a place within the depository convenient for physical inspection, and inspection must be permitted at all reasonable office hours and for a reasonable length of time. The provider of health care shall also furnish a copy of the records to each person described in paragraphs a and c of this subsection who requests it and pays the actual cost of postage, if any, the costs of making the copy, not to exceed sixty cents per page for photocopies and a reasonable cost for copies of x-ray photographs and other health and care records produced by similar processes. No administrative fee or additional service fee of any kind may be charged for furnishing such a copy.

2. Each person who owns or operates an ambulance in this state shall make his records regarding a sick or injured patient available for physical inspection by:

a. The patient or a representative with written authorization from the patient; or

b. Any authorized representative or investigator of a state licensing board during the course of any investigation authorized by law.

The records must be made available at a place within the depository convenient for physical inspection, and inspection must be permitted at all reasonable office hours and for a reasonable length of time. The person who owns or operates an ambulance shall also furnish a copy of the records to each person described in paragraphs a and b of

this subsection who requests it and pays the actual cost of postage, if any, and the costs of making the copy, not to exceed sixty cents per page for photocopies. No Administrative fee or additional service fee of any kind may be charged for furnishing a copy of the records.

3. Records made available to a representative or investigator must not be used at any public hearing unless:

a. The patient named in the records has consented in writing to their use; or

b. Appropriate procedures are utilized to protect the identity of the patient from public disclosure.

This subsection does not prohibit a state licensing board from providing to a provider of health care or owned or operator of an ambulance against whom a complaint or written allegation has been filed, or to his attorney, information on the identity of a patient whose records may be used in a public hearing relating to the complaint or allegation, but the provider of health care or owner or operator of an ambulance shall keep the information confidential.

4. A provider of health care or owner or operator of an ambulance, his agents and employees are immune from any civil action for any disclosures made in accordance of this section or any consequential damages.

NRS 630.254 Active Licensees: Report of change of location or close of office; location of records.

1. Any licensee who changes the location of his office shall notify the board of the change before practicing at the new location.

2. Any licensee who closes his office shall:

a. Notify the board of this occurrence within fourteen days after the closure; and

b. For a period of five years thereafter keep the board apprised of the location of the medical records of his patients.

NRS 457.230 Establishment and maintenance of system for reporting information; objectives.

1. The state health officer shall, pursuant to regulations of the state board of health, establish and maintain a system for the reporting of information on cancer.

2. The system must include a record of the cases of cancer which occur in this state along with such information concerning the cases as may be appropriate to form the basis for:

a. Conduct of comprehensive epidemiologic surveys of cancer and cancer related diseases in the state; and

b. Evaluation of the appropriateness of measures for prevention and control of cancer.

APPENDIX G

T,N,M STAGING METHOD

T,N,M, Staging

T Primary tumors

- T1 Tumor 2 cm. or less in its greatest dimension
- a. No fixation to underlying pectoral fascia or muscle
 - b. Fixation to underlying pectoral fascia or muscle
- T2 Tumor more than 2 cm. but not more than 5 cm. in its greatest dimension
- T3 Tumor more than 5 cm. in its greatest dimension
- a. No fixation to underlying pectoral fascia or muscle
 - b. Fixation to underlying pectoral fascia or muscle
- T4 Tumor of any size with direct extension to chest wall or skin
- a. Fixation to chest wall
 - b. Edema, ulceration of the skin of the breast, or satellite skin nodules confined to the same breast
 - c. Both of above
 - d. Inflammatory carcinoma

N Regional lymph nodes

- N0 No palpable homolateral axillary nodes
- N1 Movable homolateral axillary nodes
- a. Nodes not considered to contain growth
 - b. Nodes considered to contain growth
- N2 Homolateral axillary nodes containing growth and fixed to one another or to other structures
- N3 Homolateral supraclavicular or infraclavicular nodes containing growth or edema of the arm

M Distant metastases

- M0 No evidence of distant metastases

M1 Distant metastases present, including skin involvement beyond breast area

Stage I	T1a or T1b	N0 or N1a	M0
Stage II	T0	N1b	M0
	T1a or T1b	N1b	M0
	T2a or T2b	N0, N1a or N1b	M0
Stage III	T1a or T1b	N2	M0
	T2a or T2b	N2	M0
	T3a or T3b	N0, N1 or N2	M0
Stage IV	T4	any N	any M
	any T	N3	any M
	any T	any N	M1

Approved by both the International Union against cancer and the American joint commission on cancer staging and end reports.