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Pre-Chemotherapy Patient Education: It's Effect on the Pattern of Nausea and Vomiting

by

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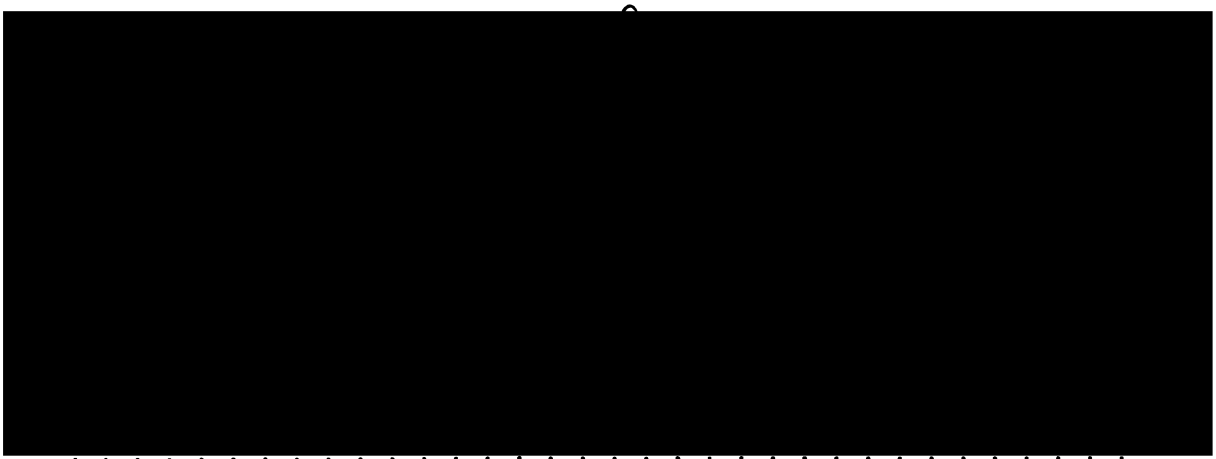

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Pre-Chemotherapy Patient Education: It's Effect on the Pattern of Nausea and Vomiting

PATRICIA PALMER, R.N., M.S.

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ABSTRACT

This study examined the effect of pre-chemotherapy patient education and support on the pattern of nausea and vomiting in 41 cancer patients who were receiving chemotherapy for the first time. A longitudinal experimental design was used to test the efficacy of a patient teaching intervention designed to disspell misconceptions and provide self-care interventions for the control of these two side effects. Forty-one patients with a variety of cancer diagnoses were randomly assigned to either the intervention group (n = 20) or control group (n = 21). The sample was selected from six physician's offices. The sample received a variety of chemotherapy agents. Patients received the antiemetic drug(s) standard to the setting. It was hypothesized that patients who receive pre-chemotherapy patient education would show significant reduction in the duration, frequency, distress and amount of nausea and vomiting attributed to chemotherapy as measured by the Rhodes Index of Nausea and Vomiting (RINV) and the Adapted Symptom Distress Scale (ASDS). Statistical data analysis failed to show a significant difference between groups for the dependent variables measured by the ASDS and RINV. Additional findings were that type of chemotherapy and cancer diagnosis were significantly related to nausea and vomiting (dependent variables). Antiemetic use by the treatment group was significantly higher ($p<.05$) than the use in the control group. Patients rated their Karnofsky performance status significantly lower than their physicians ($p<.05$). Difficulty with patient accural and a high number (N=11) of patients who refused to be a part of the study appear to have influenced the results of

the study. Recommendations for the clinical nursing role in side effect management and future research study design are made based on this study's findings.

SUMMARY

Despite an intensive search for effective antiemetic treatment of chemotherapy-induced nausea and vomiting, nausea and vomiting are still a problem for many cancer patients. Most patients expect chemotherapy to cause nausea and vomiting. Receiving chemotherapy for the first time, because it is known to cause side effects, is often frightening to patients. Physicians and nurses responsible for administering this chemotherapy also have a responsibility to research and put into practice techniques that will ameliorate or control these side effects. Research efforts have for the most part concentrated on single modality treatment (i.e. either antiemetic or behavioral modification techniques). There has been no research using a combined modality approach. Also research has shown that patients are influenced by their past perceptions about the side effects of chemotherapy. This study presents a combined modality of a patient education and support intervention prior to taking chemotherapy and antiemetics used to control nausea and vomiting. Using an experimental design patients were randomized to receive either this intervention or standard treatment in their setting. Forty-one patients with a variety of cancer diagnoses were selected from six physician's offices. The sample received Adriamycin, Cytoxan, Mitomycin, Nitrogen Mustard or Dacarbazine alone or in combination with Etopside (VP16), Vincristine, Prednisone, Methotrexate, Lomustine (CCNU), Procarbazine, 5-Fluorouracil and/or Bleomycin. The patients received either Compazine alone or in combination with Decadron as an antiemetic. Data were collected using a patient self report tool and analyzed using analysis of

variance techniques to examine the change over time in symptom distress (measured by ASDS) and duration, frequency, amount, and distress from nausea and vomiting (measured by RINV). Data analysis using parametric and non-parametric statistics failed to show a significant difference between groups for the dependent variables measured by the ASDS and RINV. Additional findings that were significant included antiemetic use by experimental group, patient rating of Karnofsky status, and relationship of type of chemotherapy and cancer diagnosis to nausea and vomiting. Recommendations for the clinical nursing role in side effect management and future research design are made.

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"Adastra per Aspera"

A patient and a friend, Dr. Dave Dozier Sr., shared this quote with me after hearing that I was writing this thesis, going to school one hundred miles from my home and was a wife and mother of two children. He shared the meaning as, "Reaching for the stars thru bricks and bars." With the completion of my thesis, I've grabbed one large star but I haven't been able to do it alone... So to all who have helped this work is for you!

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Finally to God.

> **You turned my wailing into dancing; you removed the sack cloth and clothed me with joy, that my heart may sing to you and not be silent. O Lord my God, I will give you thanks forever.**
>
> **Psalm 30:11-12**

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Introduction to the Problem

Nausea and vomiting induced by chemotherapy is often times the most unpleasant side effect patients who have cancer must endure (Seigel, 1981). When facing chemotherapy treatment of cancer, most patients have preconceived notions concerning these side effects. Those side effects most often anticipated by patients are nausea and vomiting (Zook & Yasko, 1983; Kennedy, Packard, Grant, & Padilla, 1981). Research indicates social conditioning by friends, family, medical and nursing staff and media may be an important factor in the development of chemotherapy related nausea and vomiting (Chang, 1983).

Although, management of chemotherapy-induced side effects is a primary goal for the medical and nursing management of the patient with cancer, nausea and vomiting are difficult to control. Once a pattern of nausea and vomiting becomes established or is conditioned during a period of ineffective antiemetic therapy, anticipatory nausea and vomiting (ANV) become a difficult management problem (Laszlo, 1983). Research has shown that patients with curable cancers may refuse treatment or may experience mental and physical complications secondary to nausea and vomiting caused by chemotherapy (Lazlo, 1983).

Statement of Problem

Despite an intensive search for effective antiemetic treatment, standard antiemetic therapy is of limited value with the new and more potent chemotherapeutic regimens (Siegel, 1981; Laszlo, 1983). Patients react individually and demonstrate variability in frequency and duration of

vomiting, as well as in their response to antiemetics (Zook & Yasko, 1983; Kennedy, et al., 1981). Nausea and vomiting have been reported to occur with drugs not expected pharmacologically to cause these effects and prior to the patient actually receiving the chemotherapy (Kennedy, et al., 1981). The act of vomiting from chemotherapy is thought, therefore, to be related to a number of mechanisms, both physiological and psychological. It has been hypothesized that a combination of antiemetics and behavioral modification techniques will reduce the incidence of nausea and vomiting from chemotherapy (Weddington, Miller, Sweet, 1982; Siegel, 1981; Maxwell, 1982; & Perontka, 1982).

Patients generally come to therapy with preconceived notions from sources commonly called "well meaning friends" (Zook & Yasko, 1983). Many patients begin therapy with the expectation that it will cause them to have nausea and vomiting. If in the course of therapy it does (a self-fulfilling prophecy) then a series of phenomena occur, including anticipatory vomiting, as well as chemically-induced vomiting. This often leads to the patient feeling "the treatment is worse than the malignancy" (Siegel, 1981, p. 1564; Knobf, 1979).

The use of a patient education session prior to the start of therapy may help to identify misconceptions about chemotherapy. The potential benefit of correcting misinformation that may lead to nausea and vomiting during these sessions is clear. The patient could then begin therapy with accurate expectations of the side effects, knowledge about the use and effectiveness of the interventions used to control chemotherapy induced side effects and knowledge of the treatment protocol to be given. This

information, coupled with prophylactic antiemetics, may help to stop the nausea and vomiting cycle before it is conditioned in the patient. It may be possible, then for a patient taking emetogenic chemotherapy to have minimal or no nausea and vomiting with therapy.

Much research has been done in the area of chemotherapy-induced nausea and vomiting with limited success in finding effective antiemetics (Siegel 1981; Laszlo, 1983). Researchers seem to be divided into two camps: one studying the control of nausea and vomiting with pharmaceuticals and one studying psychological interventions such as behavioral modification. These two interventions (pharmaceutical and psychological) have been shown effective for some of the patients treated for chemotherapy-induced nausea and vomiting but not all. There maybe two reasons for the failure of the aforementioned measures to consistently control nausea and vomiting: 1) Each patient is an unique individual with a unique socio-cultural orientation and set of past-life experiences (Orem, 1980; Steiger and Lipson, 1985); and 2) It has been identified by Borison (1983) that there are many physiological and psychological mechanisms that induce nausea and vomiting. Chemotherapy-induced nausea and vomiting is a multifaceted problem. Nausea and vomiting may be successfully controlled with a multifaceted approach using patient education, side effect management techniques and antiemetics. However, the efficacy of this approach needs to be studied further.

Purpose of the Study

The purpose of this study is to test the efficacy of a pre-chemotherapy patient education and antiemetic therapy on the pattern

of chemotherapy-induced nausea and vomiting in a sample of forty-one cancer patients.

Significance

Oberst identified in 1978 that oncology nurses ranked the problem of relieving chemotherapy or radiation-induced nausea and vomiting as the research question having the highest impact on patient welfare. Still in 1983 Grant and Padilla identified chemotherapy-induced nausea and vomiting as a major problem that faced nurses and identified many variables in need of further controlled, well designed research. These variables included teaching needs related to managing patients' responses to treatment and self-care needs, review and controlled research of previous study findings, study of nursing strategies in the control of nausea and vomiting as it relates to compliance with treatment and reduction of negative impact of side effects and quality of life.

Researchers who have studied chemotherapy-induced nausea and vomiting identify the need to study variables that modify nausea and vomiting associated with cancer chemotherapy (Siegel, 1981; Weddington, Miller, & Sweet, 1982; Scogna & Smalley, 1979; Maxwell, 1982; Oberst, 1978; Grant & Padilla, 1983). Since 1978, there have been numerous studies in medical and nursing literature looking at the antiemetic control of nausea and vomiting (Laszlo, 1983; Maxwell, 1982; 1983 Medicus Indicus). The importance of the control of nausea and vomiting to nurses and physicians has been presented at numerous professional oncology conferences, narrative reports and letters to the editor in professional oncology journals. Nurses have the most consistent ongoing contact with

the patient who is experiencing vomiting secondary to chemotherapy. The control of chemotherapy-induced nausea and vomiting presents a major nursing challenge for both practice and research (Kennedy, et al., 1981; Zook & Yasko, 1983; Scogna & Smalley, 1979; Maxwell, 1982).

For the patient coping with the stress of cancer and its treatment, the control of the distressing side effect of nausea and vomiting can make a significant impact on the quality of his/her life. Laszlo (1983) identified three consequences of inadequate antiemetic therapy: patient non-compliance, patient discomfort or diminished quality of life, and medical complications. In the areas of non-compliance and medical complications, patients could be hastening their death by declining potentially curative therapy or by experiencing life threatening complications, such as esophageal tears (Mallory-Weiss Syndrome), nutritional disturbances and electrolyte imbalance (Laszlo, 1981 and 1983). Three to four days of debilitating nausea and vomiting can often prevent the patient from working or attending to his needs or those of his family. These issues have a wide ranging effect on the patient, his family, and his position and purpose in society.

The "bad press" given chemotherapy has a direct effect on the patient's willingness to receive this treatment. Establishing effective methods for the treatment and control of nausea and vomiting will benefit this important area of cancer management. Once an effective antiemetic program is achieved, patients need to know that nausea and vomiting can be controlled and that it is possible to take chemotherapy without the occurrence of nausea and vomiting.

Assumptions

1) Information on potential side effects and side effects management techniques prior to the first chemotherapy treatment serves to decrease the psychological and anticipatory component of nausea and vomiting.

2) Chemotherapy-induced nausea and vomiting requires a multifaceted approach for control involving pharmacologic and psychologic dimensions.

3) Patient teaching prescribed by nurses is an important dimension in the control of nausea and vomiting in patients receiving chemotherapy.

Hypothesis

Randomly assigned cancer patients who received a patient education and support session and antiemetic therapy prior to receiving chemotherapy will experience a significant reduction in the duration, frequency, distress and amount of nausea and vomiting as compared to a control group of cancer patients receiving chemotherapy for the first time.

Definitions

Nausea: The awareness of the urge to vomit, associated with one or all of the following factors: increased salivation, pallor, tachycardia, and cold sweats that occur(s) more than 15 minutes after receiving chemotherapy (Borison, 1983), as measured by patient self reports using the Rhodes Index of Nausea and Vomiting (RINV) and Adapted Symptom Distress Scale (ASDS).

Vomiting: Sudden, forceful ejection of contents of stomach, duodenum, and proximal jejunum through the mouth (Beland, 1980). The

operational definition of vomiting is that it results from receiving antineoplastic drugs and occurs more than 15 minutes after receiving chemotherapy, as measured by patient self reports using the RINV and ASDS.

Retching: The forced rhythmic respiratory movement which may precede vomiting (Penta, Poster, Bruno, & MacDonald, 1981), as measured by patient self reports using the RINV.

Prophylactic Antiemetic: Antiemetic medication specific to each institution or private practice medical oncology office that is given to patients in both experimental and control groups prior to their first chemotherapy treatment, therefore, prior to the occurrences of nausea and vomiting.

Anticipatory nausea and vomiting: Nausea and vomiting in anticipation of chemotherapy prior to receiving chemotherapy drugs or during first 15 minutes after receiving chemotherapy.

Independent Variable: Patient teaching and support session prior to first chemotherapy treatment, given by the investigator, lasting 30-90 minutes (including chemotherapy information in general, specific chemotherapy side effects, self-care measures for nausea and vomiting and discussion of patient questions and concerns). This verbal information was supplemented by written information, including specific drug information sheets written by the investigator, a booklet Chemotherapy and You (Adria Labs), Self-Care of Nausea and Vomiting information sheet and Eating Hints Booklet (National Cancer Institute).

Co-Variables: These co-variables were chosen based on statistical significance. 1) Disease process: breast cancer compared to all other diagnosis. 2) Chemotherapy regimen: Cytoxan, Methotrexate, 5FU (CMF) compared to all other chemotherapy agents.

Dependent Variables: 1) Pattern (duration, frequency, distress and amount) of nausea, vomiting and retching before and at 12 hours, 24 hours and 36 hours after chemotherapy administration as measured by the Rhodes Index of Nausea and Vomiting. 2) Pattern of symptom distress before and at 12 hours, 24 hours and 36 hours after chemotherapy administration as measured by the Adapted Symptom Distress Scale.

Limitations and Delimitations

This study is limited by the self-report nature of the dependent variables. As such, there was no attempt to verify accuracy of this measurement by observation and interview with patients' family.

Other limitations include the variety of patients' diagnoses, chemotherapy regimens, and treatment setting. An attempt was made by the investigator to limit participants to three diagnosis (Breast cancer, Lung cancer, and Lymphoma), two chemotherapeutic agents (Adriamycin and Cytoxan), and two settings with very similar characteristics. However, accural of this study was very slow and difficult. After three months without referrals the study guidelines were modified to allow for greater variability in diagnoses, chemotherapy and settings.

An attempt was made by the investigator to limit antiemetics to prophylactic administration of Decadron 10 mgm I.V. push and Compazine 5 mgm I.V. push prior to the patient's first chemotherapy treatment.

However, the six settings used as a referral source for this study routinely used Compazine but did not routinely use Decadron and did not always give these drugs prophylactically. So to maintain accural, referrals were accepted from settings not giving Decadron and Compazine prophylactically prior to chemotherapy. Further, to reduce the risk of investigator bias no attempt was made to educate or change the antiemetic prescribing behavior of the physicians in settings using different antiemetics. Finally, this study is limited by the prolonged data collection period (10/84 to 12/84 pilot study and 6/85 to 3/86 actual study) necessary for accrual of 41 research subjects.

CHAPTER II

Review of Relevant Literature and Theory

Until the mid to late 70's, the treatment of chemotherapy-induced nausea and vomiting was virtually ignored in cancer related research. Penta, in 1983, reported that of 57 antiemetic studies in cancer patients between 1960 and 1981, 47 occurred between 1978 and 1981. Since 1981 medical and nursing journals have printed many controlled and uncontrolled studies, attempting to identify the antiemetic agents to control nausea and vomiting associated with chemotherapy.

A narrative article by Siegel and Longo (1981) outlined the physiology of emesis and the current state of antiemetic therapy, pointing to several areas of needed study. They called for well-controlled clinical trials of all antiemetic drugs to better outline their effectiveness, careful examination and definition of the mechanism of nausea and vomiting induced by chemotherapy, and examination of the sites of chemotherapy-induced vomiting. In addition, Siegel and Longo (1981) called for an examination of behavioral modification techniques as an adjunct to antiemetic therapy. Laszlo and Borison, participating in a 1983 symposium focusing on chemotherapy-induced emesis, recognized advances in the proper prescription of antiemetic therapy and the neuropharmacology of chemotherapy-induced emesis. However, Laszlo cited anticipatory nausea (nausea in anticipation of chemotherapy) as particularly refractory to antiemetic therapy.

Chang (1981) identified a purely psychological cause of vomiting which was related to the patients' denial of their cancer. Andrykowski, Redd, & Hatfield (1983) and Katz (1983), responded to Chang's contentions

and elaborated on the areas of classical conditioning as it relates to ANV and the mechanisms of nausea and vomiting. In a 1983 narrative response to Chang, Andrykowski supported that "social conditioning" by friends, family, medical staff and media may be an important factor in the development of chemotherapy related nausea and vomiting. They identified that this conditioning and resultant expectations increases the patient's overall level of emotional distress, which may exacerbate any psychologic factor present, and therefore lead to nausea and vomiting. Also, withholding information about the physiological effects of illness and treatment was identified with increasing emotional distress and less effective coping. They concluded that, "rather than avoiding discussion of the adverse side effects of chemotherapy, greater attention should be focused upon providing patients with realistic expectations concerning the potential for nausea and vomiting side effects" (page 274).

Scogna and Smalley (1979) in an exploratory survey study (N=41) evaluated four factors that might influence nausea and vomiting from chemotherapy. They failed to find a significant correlation between nausea and vomiting and any of the following factors: patients' subjective attitude toward treatment effectiveness, number of sleep hours, activity levels, or food intake prior to therapy. This study, however, was not based on a review of the relevant literature, citations ranged from 4 to 29 years old, and none were from oncology journals. This study did not state or imply a conceptual framework and all assumptions were based on personal experience and not previous research or existing theory. The methodology, data analysis or controls for internal and external validity issues were not

addressed. There cannot be any predictive power or generalizations made from this study on the basis of the conceptual and methodological issues discussed previously. At best this article can provide a narrative state of the art message for 1979.

Nesse, Carli, Curtis, & Kleinman in a 1980 case study survey approach (N=18), identified anticipatory nausea in 8 of 18 patients receiving Nitrogen Mustard, Oncovin, Prednisone and Procarbazine (MOPP) ($\underline{n}$=7) or Cytoxan, Adriamycin, Oncovin, Prednisone (CHOP) ($\underline{n}$=1) therapy for Hodgkins ($\underline{n}$=7) or non-Hodgkins lymphoma ($\underline{n}$=1). The patients with anticipatory nausea had significantly ($p<0.01$) more months of receiving chemotherapy ($\bar{X} = 9.3$), number of chemotherapy injections, reported a higher severity of post-treatment vomiting and a higher percentage of stage IV disease than those patients that did not have anticipatory nausea. This study had the following conclusions: 1) that anticipatory nausea was a classically conditioned response to several months of uncontrolled nausea and vomiting from emetogenic chemotherapy, 2) that anticipatory nausea occurred most commonly in patients who had received more than six months of chemotherapy, and 3) the incidence of anxiety-induced nausea in patients was low. Despite the small number of subjects, the patients who exhibited anticipatory nausea and those who did not were closely matched in demographics with no significant differences other than the ones mentioned. This study's conclusions appear to be valid in that the findings are repeated in narrative reports by Katz (1982) and Redd (1983).

In 1981 Kennedy, et al. conducted a descriptive survey of 18 hospitals and medical centers across the United States to identify the problems and

interventions related to nausea and vomiting from chemotherapy. Her sample consisted of 64 nurses and 115 patients. This sample represents a 39% response rate for nurses and 25% response rate for patients. Responses were coded and classified by similar responses to a given item. These responses were rank ordered from most common response to least common response and from most to least helpful in alleviating nausea and vomiting (Kennedy, et al. 1983). Patients and nurses identified antiemetics (53%), distraction (14%), and specific foods (12%) as the three most effective approaches to relieve nausea and vomiting. Patients received a variety of chemotherapy drugs and had a variety of cancer diagnoses. No demographic information was given about the nurses. Kennedy, et al. concluded that further study by nursing was needed in many areas including: interventions and approaches to prevent or alleviate nausea and vomiting from chemotherapy. Also they concluded that nurse-initiated interventions for nausea and vomiting should focus on the time period before and immediately following treatment because this was reported by 40% of the patients as the time of occurrence of nausea and vomiting. Forty-seven percent of patients reported the duration of vomiting as 12 hours or less.

Zook and Yasko (1983) investigated how psychologic factors effect nausea and vomiting experienced by patients receiving chemotherapy. The sample (N=26) was heterogenous (i.e. 19 to 78 years; 65% male; 60% of the sample has a diagnosis of either small cell carcinoma of the lung, Hodgkin's disease or non-Hodgkin's lymphoma; patients received one of four different chemotherapy drugs and a variety of antiemetic drugs). They considered

several variables: age, sex, client's past experiences with persons receiving chemotherapy, anxiety, hopelessness and pain. Significant correlation was found in two areas: negative perceptions of past experience with others treated with chemotherapy (n=5) ($p<0.01$) and women (n=9) experienced more vomiting than men (n=17) ($p<0.005$). An important finding in Zook and Yasko's study was that nausea and vomiting were separate unique symptoms that may or may not occur simultaneously in clients receiving chemotherapy. They found in an extensive literature review no specific studies comparing negative perceptions and the occurrence of nausea and vomiting.

Physiology and Neurophysiology of Emesis

The relationship of nausea and vomiting is well documented in the literature. In fact, they are almost always mentioned and defined together as one concept. This association is problematic because nausea and vomiting are separate concepts and for clarity need to be defined and treated separately (Zook & Yasko, 1983; Borison, McCarthy, 1983). Borison and McCarthy (1983) suggested, based on animal research, that nausea and vomiting may be separately vulnerable to pharmacological suppression and that neurologically each used separate pathways to mediate their effect.

Nausea, being a more subjective symptom, has been defined in many ways. Nausea has been described as the first of three stages of vomiting: nausea, retching and vomiting (Borison and McCarthy 1953 and 1983; Lumsden, 1969). Borison and McCarthy define nausea as a psychic experience of human beings, accompanied by several autonomic features: pallor, cold sweats, tachycardia and increased salivation. These autonomic

features help to make nausea measurable and they may or may not be associated with vomiting. Borison found that in rats these autonomic features provide evidence of a distinct nausea-directed limb of the reflex arc that induces nausea and vomiting, originating in the emetic circuit before the signal passes into the vomiting control mechanism. Rats are, therefore, unable to vomit but do exhibit signs and symptoms of nausea, which lends theorectical support to a separate neural mechanism in humans.

There is much literature support for the theoretical definition of vomiting, which is sudden, forceful ejection of the contents of the stomach, duodenum, and proximal jejunum through the mouth (Wyman, 1970; Borison, 1953 and 1983; Guyton, 1976; Lumsden, 1969; Beland, 1980). This ejection may be accompanied by retching and nausea, but not always (Siegel, 1981). Retching consists of rhythmic, labored, spasmodic respiratory movements that can precede or alternate with bouts of vomiting (Siegel, 1981; Borison, 1983).

Borison and Wang between 1949 and 1953 in what has become classic research into the cause of vomiting, identified two areas of central nervous system control. The vomiting center (VC) is located deep in the medulla oblongata which is a portion of the lateral reticular formation. (See Appendix A). The chemoreceptor trigger zone (CTZ) is located on the surface of the brain embedded in the area postrema where it can be reached simultaneously by the blood and cerebrospinal fluid. Vomiting occurs through somatic reflex action of the respiratory muscles because the neural controls of breathing and emesis are both located in the medulla

oblongota. The VC is described as the coordinator for the act of vomiting and is currently known to receive four major afferent stimuli which are converted to emetic action. These afferent pathways have been identified as spinal-visceral afferents, vagal-visceral afferents, vestibulo-cerebellar afferents and the CTZ (Borison and McCarthy, 1983). Each of these afferent pathways is thought to use one of many neurotransmitters to mediate its effect.

The entire area of neurotransmitter identification and their effect on nausea and vomiting is one of continued research and is far from being understood (Borison & McCarthy, 1983). It has been postulated by Borison and McCarthy (1983) that the vomiting center is stimulated by multiple sensory and noxious imputs rather than what has been the classic thought that the CTZ is the sole chemosensor for emesis and dopamine was the sole neurotransmitter. Current research of neurotransmitters has the potential of identifying many new substances and methods of mediating an effect on the VC and the CTZ. Armstrong, Pickel, Joh, Reis, & Miller, (1981) identified three catecholamine synthesizing enzymes; tyrosine hydroylase (TH), dopamine-betahydroxylase (DBH), phenylethanolamine-N-Methyetransterase (PNMT) and two neuropeptides; substance P and (leu^5)-enkephalin in varing concentrations distributed in the dorsal and centrolateral margins of the area postrema of rats. This study lends support to the hypothesis that in order to achieve a significant blockade of vomiting in cancer chemotherapy it may necessitate intervention at the site(s) of numerous neural inputs to the vomiting center (Borison & McCarthy, 1983). However, further study is needed to accurately plan this

intervention and investigate the potential problems this creates, specifically identification of the effects of functional overlap of vomiting with the control of breathing.

Guyton (1981) suggests that various psychic stimuli, including sights and smells, can cause vomiting theoretically through direct cortical stimulation of the VC. The precise explanation of the psychological effects of behavioral interventions for the treatment of nausea and vomiting is lacking in the literature. Further, the exact neurochemical mediation of the classical conditioning response seen in ANV is lacking. Future research is needed to close this knowledge gap and effectively plan combined antiemetic interventions for chemotherapy induced nausea and vomiting, as well as, ANV.

The Use of Pharmacologic Interventions to Control Chemotherapy-related Nausea and Vomiting

Antiemetic research has identified many effective antiemetic agents, their mechanism of action, toxicities and therapeutic effects (Appendix B). There are many classes of antiemetics; phenothiazines (dopamine antagonists), antihistamines, butyrophenones, anticholenergic agents, cannabinoids, sedatives, hypnotics, and a miscellaneous group consisting of trimethobenzamide (Tigan), benzquinamide (EmetiCon), metaclopramide (Reglan), and pyridexine (Vitamin B6) (See-Lasley and Ignoffo, 1981). These drugs mediate their effect through one or two of the afferent pathways effecting the VC or by directly effecting the CTZ. The commonly used phenothiazines are dopamine antagonists effecting only the dopamine mediated pathway(s). This knowledge of the site of action of

antiemetics is extremely important when evaluating why antiemetics used indiscriminately have been unsuccessful in control of chemotherapy related emesis.

The use of combined antiemetics considering the etiology of nausea and vomiting, the site of action and toxicity of the antiemetic has been proposed by See-Lasley and Ignoffo (1981) as one method of systematically treating nausea and vomiting in cancer patients. A patient may experience nausea and vomiting caused by one or more etiologies. Table 1 presents several etiologies and lists the antiemetic agents in order of efficacy in their use (See-Laskey and Ignoffo, 1981). In the case of patients suspected of having more than one cause of nausea and vomiting more than one drug may be required for treatment. Further the authors present guidelines for providing maximal antiemetic therapy with minimal side effects. These guidelines suggest that:

1. It is more effective to use prophylactic therapy to prevent nausea and vomiting then to treat it after it has begun.

2. The action of the antiemetic should match the determined etiology or etiologies of nausea and vomiting.

3. Onset and duration of nausea and vomiting should be documented. Most cancer chemotherapy agents do not produce sickness longer than 48 hours.

4. Antiemetic therapy should be started prior to the anticipated nausea and vomiting in a time interval at which it is certain a therapeutic blood level of the antiemetic will be present when vomiting is anticipated. The best time of administration may not be immediately prior to the

Table 1. Therapy for the management of nausea and vomiting*

Etiology	Adult
Radiation therapy	1. Haloperidol (Haldol) 2. Prochlorperazine (Compazine), Chlorpromazine (Thorazine) 3. Cyclizine (Merezine), Meclizine (Atarax, Bonine) +4. Ibuprofen (Motrin) 5. Pyridoxine (Vitamin B_6)
Chemotherapy	1. Prochlorperazine (Compazine), Thiethylperazine (Torecan), Perphenazine (Thorazine) 2. Chlorpromazine (Thorazine), Triflupromazine (Vesprin), Promazine (Sparine) 3. Haloperidol (Haldol) 4. Trimethobenzamide (Tigan) 5. Benzquinamide (Emete-Con) +6. Dexamethasone (Decadron) 7. Diphenidol (Vontrol) +8. Nabilone (not available)
Refractory vomiting	1. Delta-9-tetrahydrocannabinol (THC)
Cisplatin (vomiting refractory to standard antiemetics)	+1. Metoclopramide (Reglan) +2. Droperidol (Inapsine)
Therapy for breast cancer	1. Trimethobenzamide (Tigan)
Hormone therapy	1. Promethazine (Phenergan)
Psychogenic vomiting (anxiety, sight, (smell, taste, etc.)	1. Diazepam (Valium) 2. Chlordiazepoxide (Librium) 3. Phenobarbital (various)
Analgesic therapy (opiates):	
Nonambulatory vomiting	1. Benzquinamide (Emete-Con) 2. Prochlorperazine (Compazine), Thiethylperazine (Torecan) +3. Metoclopramide (Reglan)
Ambulatory vomiting	1. Promethazine (Phenergan), Cyclizine (Marezine), Meclizine (Antivert, Bonine)

*Drugs are listed in order of preference of author.
+Investigational.

Note: From Manual of Oncology Therapeutics. (p. 339) K. See-Lasley and R. Ignoffo, 1981. St. Louis:C.V. Mosby Company. Reprinted by permission.

injection of chemotherapy or other forms of therapy. The patient may have a characteristic pattern of not getting sick until 24 hours after therapy has been initiated. The best time of initiation will vary according to the patient.

5. The clinician may find that the patient has erratic vomiting that cannot be anticipated. In these cases, antiemetic therapy with constant therapeutic blood levels over 48 hours during the anticipated vomiting period is often found effective. Antiemetics therapy should be given through the entire anticipated duration of the nausea and vomiting, then discontinued.

6. To ensure constant therapeutic blood levels of an antiemetic in patients, dosage times of administration should be written on a sheet of paper or patient medication calendar to encourage the compliance of the patient.

7. Antiemetic agents given on a PRN basis should be avoided. Abuse of the drug is likely, since cancer patients do not have the knowledge of the drug to properly dose themselves. Most patients when left to themselves in this manner wait until they are too sick for drug administration. The patient often cannot keep his medication down in order to stop his sickness or he may take more than the amount of antiemetic required. (See-Lasley & Ignoffo, 1981, pg 340 & 348.)

Emetogenic Actions of Chemotherapy

A review of the literature concerning the emetogenic actions of chemotherapy reveals disagreement as to the severity and duration of these effects. There is variation evident from author to author and patient

to patient with any given drug. Factors that are thought to effect the emetic potential of chemotherapy agents are dosage of agent, method of delivery (bolus versus continuous infusion), and differing sites of administration (venous infusion versus hepatic artery infusion) (Yasko, 1985). There are also individual patient differences that may be related to their expectations about therapy, stage of disease, previous experience with chemotherapy and attitude of their health care provider. The confusion surrounding the true emetic potential of drugs and the duration of effects further complicates successful measures aimed at controlling nausea and vomiting experienced by the patient. Appendix C and D summarizes the emetic potential and duration of emesis according to three authors. The potential for and duration of nausea from chemotherapy has not been measured accurately, to date which probably reflects the difficulty in the measurement of nausea which will be discussed later in this thesis.

Harris (1982) presented a hypothesis about the neural mechanism of cytotoxic-therapy induced vomiting. He postulated that cytotoxic drugs may be exerting their emetic effects by inhibiting the enzymes (specifically enzymes that breakdown enkephalins) that break down neurotransmitters in the area postrema. Many chemotherapeutic agents are known to produce emesis at differing rates, Harris postulates that this is secondary to whether the drug effects DNA, RNA or protein synthesis. He suggested the following explanations for the effects of differing chemotherapeutic agents:

1. Cisplatin usually causes nausea and vomiting observed 2 - 4

hours after administration. This is felt to be the effect of the rapid enzyme inhibition of heavy metals.

2. Alkylating agents and DNA intercalating agents (e.g. doxorubicin) usually cause vomiting after 8 to 12 hours. The delay is probably secondary to the time it takes for enzyme levels to fall after transcription of mRNA is prevented.

3. Antimetabolites can in some cases cause vomiting but are less likely to because DNA synthesis is at a low level. The nausea and vomiting effects that 5FU, methotrexate, and cytarabine have is probably related to RNA synthesis.

4. Vinca alkaloids also do not cause nausea and vomiting because they inhibit mitosis only.

Placement of Study in Theoretical Framework

Maxwell (1982) examined the state of the art in antiemetic research. She outlined five principles of a well-designed clinical trial: 1) cooperation of the individuals with appropriate skills to all levels of planning and execution; 2) randomization; 3) "double blind" control; 4) statistical treatment of data; 5) cautious generalization. With few changes these principles could be extended to all research cited in this thesis. Two major problems in previous research are a lack of control of the many variables effecting the outcome of the study; specifically sampling involving patients with many different types of cancer, chemotherapy drugs and antiemetics and conclusions drawn from poorly designed research. In order to build a strong foundation for research, study designs and theoretical frameworks must be more rigorous.

Most of the studies to date use the Scogna & Smalley (1981) study for the basis of their research. As discussed previously this study's design (exploratory survey) is clearly weak and assumptions drawn from it will also be weak. Controlling the variation of chemotherapy and antiemetic drugs and disease sites will improve the internal and external validity of the study. This study's methodology considers these principles among others.

The Zook-Yasko (1983) study offers support for the tenet that negative past perceptions can increase nausea and vomiting in patients receiving chemotherapy, raising the question, can education alter this outcome? Most authors cited support the tenet that education can help in reaching positive treatment outcomes. These treatment outcomes include nausea and vomiting, as well as, compliance to therapy programs, and prevention or early treatment of chemotherapy induced side effects (i.e. leukopenia, constipation, diarrhea, etc.). There have been no documented studies specifically looking at the use of patient education as an adjunct to standard antiemetic therapy for chemotherapy-induced emesis. It would seem that education about chemotherapy-induced vomiting and correct use of antiemetics would positively effect ability of patients to perform self-care while receiving chemotherapy and therefore reduce the incidence of nausea and vomiting. To address specifically the issue raised by See-Lasley and Ignoffo (1981) patients could be taught how to correctly self administer antiemetic agents so that a therapeutic blood level could be achieved and maintained throughout the anticipated period of nausea and vomiting for that patient.

Another major weakness in previous research on the control of chemotherapy-related nausea and vomiting is that nausea and vomiting have been historically viewed as one phenomenon. Most studies measure the more objective phenomenon of vomiting, and translate this as a measurement of nausea and vomiting. Until recently there has been no instrument to measure nausea and vomiting as separate entities (Yasko, 1985). Rhodes, Watson, & Johnson (1983), developed and tested a reliable and valid nausea and vomiting assessment instrument that measures the patient's perceived duration, frequency, distress and amount of nausea, retching and vomiting separately. This tool the Rhodes Index of Nausea and Vomiting and the Adapted System Distress Scale were used in this study.

The nausea and vomiting experienced by patients who are receiving chemotherapy is a multifaceted problem that requires a multifaceted therapy approach. When the vast majority of studies are directed towards the chemical control of nausea and vomiting it would be refreshing, not to mention beneficial to the patient, to identify a simple non-chemical technique that would enhance the effectiveness of antiemetic medications. This study identifies an important role for nursing in the education and support of the patient receiving chemotherapy.

Conceptual Framework

Orem's Self-Care Model

The conceptual model for this study was provided by Orem's self-care model. Nursing is defined by Orem as, a creative effort of one human being to help another human being. The maintenance of self-care

activities that the individual needs continuously to sustain life and health, recover from disease and injury and cope with the effects, along with the self-regulation of the individual's self-care capabilities is the primary concern of the nurse in society. Patients are candidates for nursing if they have a self-care deficit (Orem, 1980). Self-care is a deliberate goal seeking action that individuals initiate and perform on their own behalf in maintaining life, health and well-being (Orem, 1980). A self-care deficit is defined as the qualitative or quantitative inadequacy of the self-care agency to meet self-care demands (Orem, 1980).

The nursing patient relationship is contractual, deliberate and goal seeking in nature. Deficits may be identified in any or all of the three areas of self-care requisites: universal, developmental, and health deviation (defined in Appendix E). The nursing process is accomplished in three steps: 1) diagnosis and prescription, 2) designing and planning, 3) production and management of systems of nursing assistance. Assuming that either nurses or patients or both can act to meet patients' self-care requisites, three nursing methods are recognized; wholly compensatory, partly compensatory, and supportive-educative. Nursing intervenes using one or all of five helping methods: Doing for or acting for another, guiding and directing another, providing physical and psychological support, providing an environment that supports development, and teaching. The nurse and patient role in each of these methods of helping and teaching is summarized in Table 2. These methods are prescribed based on the diagnosis of a deficit in any or all of the self-care requisites. The patients in this study were in the partly compensatory or supportive-educative

Table 2

Orem Self Care Model: Method of Helping

Methods of Helping	Nurse Role	Patient Role
Doing for or acting for another	Acts in place of and for the patient	Recipient of care to meet the therapeutic self-care demand and to compensate for self-care limitations. Recipient of services relevant to environmental control and resources.
Guiding and directing another	Provider of factual or technological information relevant to the regulation of self-care or the meeting of self-care requisites.	Receiver, processor, and user of information as self-care agent or as regulator of self-care agency.
Providing physical support	A partner, cooperating in performing self-care actions to regulate the exercise of or the value of self-care agency by the patient.	Performer of actions to meet self-care requisites or regulator of the exercise of or the value of self-care agency in cooperation with a nurse.
Providing psychological support	An "understanding presence"*; a listener, a person who can institute the use of other methods of helping if necessary.	A person confronting, resolving, and solving difficult problems or living through difficult situations.

(table continued)

Methods of Helping	Nurse Role	Patient Role
Providing an environment that supports development	Supplier and regulator of essential environmental conditions and a significant other in a patient's environment.	A person who is confronted with living and caring for himself or herself in a way and in an environment that supports and promotes personal development.
Teaching	Teacher of: Knowledge describing and explaining self-care requisites and the therapeutic self-care demand; Methods and courses of action to meet self-care requisites; Methods of calculating the therapeutic self-care demand; Methods of overcoming or compensating for self-care action limitations; Methods of managing self-care;	Learner, engaged in the development of knowledge and skills requisite for continuous and effective self-care.

* Adrian van Kaam, The Act of Existential Counseling, Dimension Books. Wilkes-Barre, 1966. The term "understanding presence" is from van Kaam.

Note: From Nursing: concepts of practice (p. 95) by D. E. Orem, 1980, New York: McGraw-Hill Inc. Copyright 1980 by McGraw-Hill Inc. Reprinted by permission.

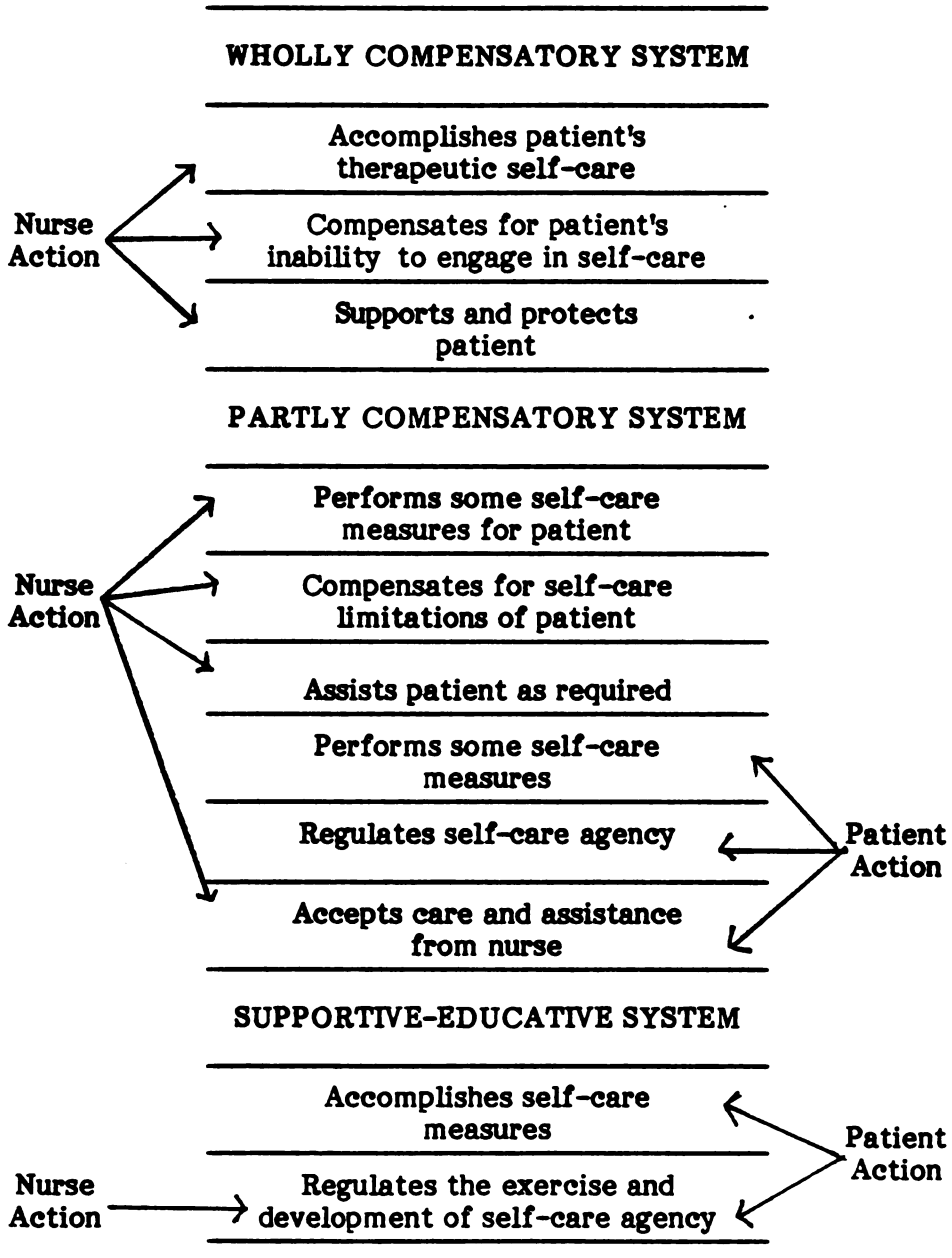
system. Patient's in the partly compensatory may require the use of all five helping methods at the same time and will require less help and self-care performed by nurse and more education as they move into the supportive-educative system (Table 3).

Orem describes man as a unity who functions biologically, symbolically and socially and initiates and performs self-care activities on his own behalf in maintaining life, health and well being. When this self care is not maintained, illness, disease or death will occur (Orem, 1980). Health is considered a state of wholeness or integrity of human beings structurally, as well as, functionally. This includes humans living in conjunction with physiological, psychophysiological, biological and interpersonal environments.

Providing a developmental environment is seen as an important role of the nurse. An environment conductive to development is also conducive to learning and is of value if used in conjunction with teaching (Orem, 1980). A developmental environment consists of environmental conditions that motivate the person being helped to establish appropriate goals and adjust behavior to achieve results specified by the goals (Orem, 1980).

Table 3

Orem Self Care Model: Nurse and Patient Actions for Self Care



Note: From Nursing: concepts of practice (p. 98) by D. E. Orem, 1980, New York: McGraw-Hill Inc. Copyright 1980 by McGraw-Hill Inc. Reprinted by permission.

Teaching-Learning Theory

A major concern of nursing is teaching patients about health, illness and treatment (Steiger, Lipson, 1985; & Rickel, 1981). Teaching is a valid method of helping a patient who needs instruction in order to develop knowledge or particular skills that will assist them during phases of disease and illness (Orem, 1980). Watson (1982) used the Orem self-care model and developed guidelines to describe the different phases of disease or illness, the methods of assisting, teaching and learning and the perceptions of the patient during each phase (Table 4). Patients newly diagnosed with cancer or with a cancer recurrence frequently experience some degree of life modification when facing their first treatment with chemotherapy.

The patients in this study will be primarily in the partially compensatory and supportive educative nursing system. The wholly compensatory nursing system is defined as all actions and interactions of nurses and patients when a patient cannot or should not perform any self-care actions, thus the nurse must perform them. The partially compensatory nursing system stands for all actions and interactions of nurses and patients when the patient can perform a few, but not all, self-care actions (Orem, 1980). The supportive-educative nursing system is selected when the patient can and should perform all self-care actions (Orem, 1980). Teaching is prescribed during this intermediary phase because the patient does not know what he needs to know or does not know how to do self-care actions he needs in order to take care of himself (Watson, 1982). Prior to the prescription of teaching the nurse must assess the patient self-care skills, knowledge, beliefs and learning methods;

Table 4

Teaching as a Method of Assisting Cancer Patients during the Phases of Disease and Illness

	Phase I	Phase II
Stage of disease	Diagnosis and acute induction; initial treatment.	Remission; consolidation treatment or adjuvant therapy.
Perception of patient	Patient sees self as sick.	Patient beginning to see self as well or becoming well.
System of care	Wholly compensatory —— Partially compensatory —— Supportive (Education)	
Focus	Facilitate diagnosis and treatment; enhance patients' strategies for coping with the physical and psychological crises.	Patient's resumption of responsibility for self-care. Problem-solving skills needed for self-care and coping.
Method of assisting	Doing for patient, establishing a protective environment, guidance and some teaching.	Teaching, support, guidance.
Teaching	Teaching to have patient acquire enough understanding of disease and treatment to gain consent for treatment; corporation with some participation in treatment program. Teaching to alleviate anxiety when appropriate.	Teaching to enable patient to retain knowledge and skill of self-care and to transfer to other settings, such as home and work.
Learning	Expect everything learned to be forgotten or repressed. Keep all information simple and concise. Conserve patient's energy to cope with hospitalization, disease, and treatment.	Expect patient to learn and take responsibility for own care. Build patient's expectations of same. Retention and transfer require repetition, reinforcement, and follow-up outside the acute care setting. Complexity and variations are built into the learning situations. The patient should be given practice in solving self-care problems that are likely to occur.

From Patient Education: The Adult with Cancer by P. Watson, (1982), Nursing Clinics of North America, 17. Reprinted by permission.

matching types of learning needed with learning activities (Watson, 1982; Orem, 1980; Steiger & Lipson, 1985). Watson advocates keeping teaching on a very concrete level and providing for retention and transfer of learning by return demonstration, written materials and follow up contact. The partially compensatory stage is an intermediary phase between Phase I and II in Table 4 and Appendix F.

Teaching, guiding and counseling are the primary methods of assisting the patient to enhance the patient's ability to resume self-care. Teaching methods, however, may still be a combination of methods from Phase I or II depending on the system the patient is found to be in.

The prescription of teaching in Phase I of cancer diagnosis and staging results in only short term learning of facts and concepts essential to patient's understanding of his/her disease and treatment. As the patient moves into Phase II he/she will begin to see himself/herself as moving beyond the initial crisis of cancer diagnosis. The prescription of teaching at this phase is aimed at retention, transfer, problem solving and learning self-care for the future. The patient at this stage, while still anxious, is better equipped to establish a relationship with the nurse and participate in the education process. A state of anxiety and acute problems provides a fertile field for learning (Bevis, 1982). In the event that the patient remains in the wholly compensatory nursing system, the family is included in the session to serve as the dependent care agent. The family also serves a supportive and educative role, as they often retain information the patient is unable to.

The role of the nurse-teacher in patient-education and support

session is one of facilitator of the patient's learning and self-care behavior. The nurse-teacher must posses three attitudinal qualities; 1) realness, 2) non-possessive caring, prizing, trust and respect, and 3) empathic understanding and sensitive and accurate listening in order to establish a relationship with the patient-learner (Knowles, 1979). The nurse-patient relationship then allows the patient and nurse to participate in identifying existing, continuing or changing requirements for self-care and their roles in the continuous provision of care (Orem, 1980).

The subjects in this study will be adults and as such have different teaching-learning needs than children. Knowles (1978) identified a unifying theory for adult education that was defined as any intentional and professionally guided activity that aims for change in adult persons. Knowles identifies four assumptions about the adult learner. First, a person becomes an adult when he achieves self-direction or ceases to be a dependent personality. Second, experience is a major influence in the quality of new learning. Third, as an individual matures, his readiness to learn is increasingly the product of the developmental tasks required for the performance of evolving social roles. Finally, adults are motivated to learn subjects or skills that will help them overcome a perceived problem. These assumptions were considered when developing the teaching strategies for the patient education intervention used in this study.

Learning is defined as a change in behavior, attitude or a combination of these that can be repeated when the need is aroused (Bevis, 1982). Orem states that learning may not take place if the patient is not in a state of readiness to learn, is unaware that he/she does not know, or is not

interested in learning. Watson (1982), along with Dodd & Mood (1981) and Dodd (1982) identified that information given patients in the early phase of his/her diagnosis and treatment will be quickly forgotten unless reinforced.

Explanation of Patient Education and Support Intervention

Newly diagnosed cancer patients may find themselves dependent upon the health care team and overwhelmed with feelings of fear, anxiety, anger, helplessness and hopelessness (Watson, 1982). Patients are likely to experience health-deviation self care deficits in two areas. One, lack of awareness of an attention to or regulation of the discomforting or deleterious effects of medical care measures performed or prescribed by the physician. Secondly, inability to live with the effects of pathological conditions and states, and the effects of medical diagnosis and treatment measures in a lifestyle that promotes continual personal development (Orem, 1980). Patients may also experience individual deficits in any or all of the other self-care requisite areas. The goal of nursing in this patient education and support session, then, is to maintain the patient in, or return them to, a state where self-care abilities with respect to the control of health are maximally retained by the patient.

Each patient is a unique individual with a unique socio-cultural orientation and set of past-life experiences. These elements may influence both the nurse and patient's ability to fulfill their roles. These concepts are especially important if the socio-cultural orientation is different from the nurse or if past-life experiences have resulted in negative attitudes.

For the purpose of this research a 30-45 minute patient education and support session was developed using principles from Orem's self-care

model. The nurse met with the patient and family (who may act as the dependent care agent if the patient is unable to perform self-care), prior to starting chemotherapy treatment for cancer, to deliver this session. This meeting generally occurred in the patient's home to provide an environment that supports patient's development. A contractural, deliberate and goal seeking relationship was established with the patient and questions and concerns that the patient had about chemotherapy were elicited. Based on these questions the patients were then instructed in these areas in addition to areas deemed by the investigator as necessary for promoting safe patient self-care while receiving chemotherapy (these will be elaborated in the methods section). Written materials were given to the patient to facilitate retention of important information given during the patient teaching and support session (Appendix G, H, I).

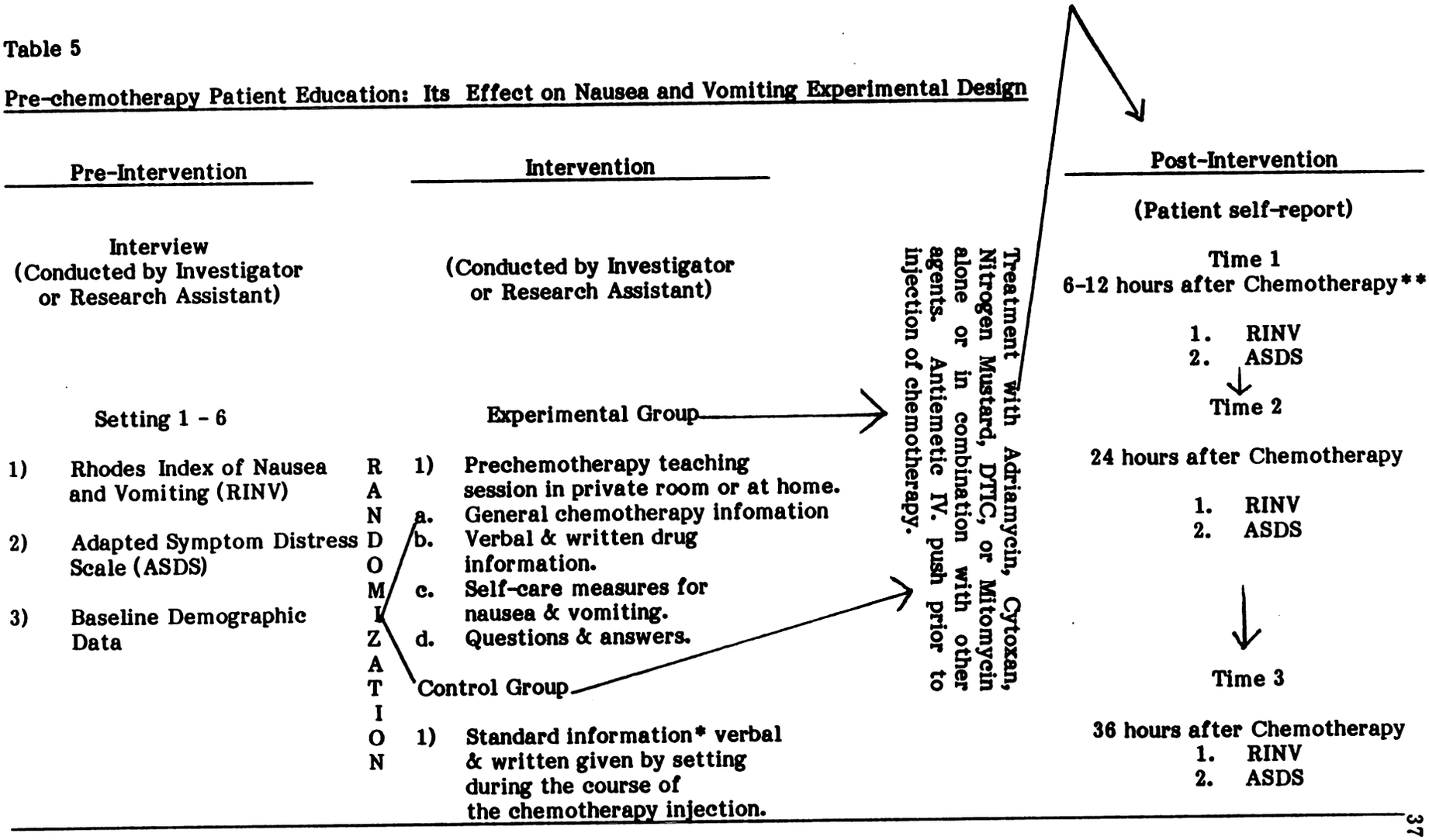
CHAPTER III

Research Method and Design:

The research method used in this study was experimental design (Table 5). The experimental design is the most powerful method available to scientists for testing hypotheses of cause and effect relationships between variables. In this study the investigator exerts control over threats to internal validity by use of random assignment of subjects, manipulation of the independent variable and the existence of a control group. Data was collected from the subjects during a 36-hour period after receiving their chemotherapy, therefore, controlling for history, maturation and mortality. The study controlled for selection bias by means of a table of random numbers assuring an equal chance for patients to be assigned to either group (experimental or control). The patient education session was conducted by the investigator (92.7%) and research assistant (7.3%) from a written script to assure reliability. This script was reviewed by a panel of Oncology Nurse experts for content validity (Appendix J). Original selection criteria limited chemotherapy drugs to Cytoxan or Adriamycin given alone or in combination. Selection criteria was modified after three months because of no patient accrual. Revised selection criteria required patients to receive at least one of the following drugs: Cytoxan, Adriamycin, Mitomycin, Nitrogen Mustard, or Dacarbazine (DTIC). Because of the increasing use of combination chemotherapy in order to accrue patients to this study in a timely manner they also could receive any of the following in combination with the drugs listed above: Bleomycin, CCNU, VP16, Vincristine, Prednisone, Methotrexate, Procarbazine, 5FU. The disease sites commonly treated with these

Table 5

Pre-chemotherapy Patient Education: Its Effect on Nausea and Vomiting Experimental Design



*Brief explanation of side effects while injecting chemotherapy.
Written drug information sheets given to all patients in some (not all) settings.
**Depending on patient convenience.

medications are breast, lung, and lymphoma. These diagnoses (breast, lung and lymphoma) represented the major (75.6%) diagnoses in this study. All data were collected by patient self-report questionnaires. The intervention session was conducted away from the patients doctors' office to control for the nurses in the setting hearing the patient education session and changing their teaching strategies as a result of this information. The patients randomized to the control group were asked to participate by the nurses or MD in their setting and then given the questionnaires to fill out. The investigator had phone contact with 6 patients randomized to the control group to briefly explain the project and obtain informed consent to participate in the study. Investigator contact with the control group was kept to a minimum to prevent any investigator influence on those patients.

Setting

The original design of this study called for the use of two private practice medical oncology offices (setting A and B) that shared many similar patient treatment practices (i.e. drug protocols, pre-chemotherapy patient education, experience of nurses administering chemotherapy and use of standard prophylactic antiemetics prior to starting chemotherapy). As previously mentioned accrual of patients was extremely slow and design criteria had to be modified to accrue patients in a timely manner. The design was expanded to include six private and university based medical oncology physician practices (Table 6) which will be described considering the following variables; type of practice, nursing staff support, nursing patient education practices, and use of antiemetics. All patients in all settings received informed consent education about side effects from their physician prior to starting chemotherapy.

Table 6

Number of Patients Accrued from Each Referral Site

Site	Frequency	Percent
1	7	17.1
2	6	14.7
3	2	4.9
4	12	29.3
5	10	24.4
6	4	9.7
Total	41	100.0
Valid cases	41	Missing cases 0

Setting 1 (originally setting A) was a community based private practice (CBPP) of three physicians and three registered nurses. The nurses had worked in oncology 10, 5 and 2 years respectively, with most of their experience in this setting. All patients were given Decadron 10mgm and Compazine 10mgm I.V. push prior to the injection of chemotherapy. Nurses gave brief patient education during the injection of chemotherapy and reinforced this with written drug information sheets. Seven out of forty-one patients were referred from this setting or 17.1% of the sample.

Setting 2 (original setting B) also was a CBPP of three physicians and one registered nurse. This nurse had three years of oncology experience with one year in this setting. Most patients were given Decadron 10mgm

and Compazine 5mgm I.V. push prior to the injection of chemotherapy. Patient education consisted of brief verbal information and written drug sheets were given to the patient to read at home. Six out of forty-one patients were referred from this setting or 14.7% of the sample.

Setting 3 was also a CBPP of three physicians (with only one physician referring patients to this study) and three registered nurses. This physician had a turn over of nurses during the study with each of the two nurses having less than one year experience in this setting. A variety of antiemetics were used with P.O. compazine being the primary drug used to treat nausea and vomiting. Patient education was given by the nurse at time of injection and no written material was given to patients as reinforcement. Two out of forty-one patients were referred from this setting or 4.9%.

Setting 4 was a new CBPP (one year duration) of one physican and no registered nurses. Patient education consisted of the physician reviewing the side effects during patients physical examination. The physician administered the chemotherapy and antiemetics (compazine was used primarily and not prophylactically). No written patient education material was given to the patients. Twelve out of forty-one patients were referred from this setting or 29.3% of the sample.

Setting 5 was a new CBPP of one physician and one LVN (who had no previous oncology experience). Patient education consisted of review of side effects by the physician for informed consent prior to chemotherapy. The physician administered his own chemotherapy. Compazine was the antiemetic of choice and P.O. and IM routes were used prophylactically

prior to chemotherapy administration. No written chemotherapy information was given to patients. Ten out of forty-one patients were referred from this setting or 24.4% of the sample.

Setting 6 was a university based cancer clinic of four physicians (Hematology and Oncology), two fellows and two registered nurses. The registered nurses each had five years experience in the clinic setting administering chemotherapy. Patients were given Decadron 10mgm and Compazine 5mgm I.V. push prior to starting chemotherapy. Patient education was given while injecting chemotherapy and was reinforced with written handouts. Four out of forty-one patients were referred from this setting or 9.7% of the sample.

A two sample T-test was performed to determine if the variable of setting had an influence on the dependent variables (DV) at each of the three data collection points; ASDS Total Score Time 2, 3, and 4; RINV Total Score Time 2, 3, and 4; and RINV Distress from Nausea and Vomiting Time 2, 3, and 4. For the purpose of performing the two sample T-test the settings were grouped according to similar characteristics (i.e. size of office, presence or absence of RN, and pre-chemotherapy education). Settings 4 and 5 were grouped together and Settings 1, 2, 3, and 6 were also grouped together. The variable of setting was not found to be a significant influence on any of the DV tested (Table 7). A Chi-square statistic was used to determine if each setting differed significantly in number of patients assigned to either experimental and control group and no significant differences were found (Table 8). Therefore, during further statistical analysis in this study the groups were combined regardless of setting.

Table 7

Effects of Referral Site on Dependent Variables

Variables	Data Collection Point	setting*	n	mean	Std dev	F value	2-tail prob	T value	Degrees of freedom	2-tail prob
ASDS Total Score	Time 2	1	21	14.5	10.1	1.1	.82	-.01	35.5	.99
		2	18	14.5	10.6					
RINV Total Score	Time 2	1	21	4.6	7.7	1.5	.36	.66	36.9	.51
		2	18	3.1	6.2					
ASDS Total Score	Time 3	1	21	13.7	10.2	1.3	.58	-.55	36.1	.58
		2	19	15.6	11.6					
RINV Total Score	Time 3	1	21	5.8	8.1	1.1	.89	.43	37.3	.67
		2	19	4.7	8.3					
ASDS Total Score	Time 4	1	21	14.4	8.9	2.1	.10	-.34	31.4	.74
		2	19	15.6	12.9					
RINV Total Score	Time 4	1	21	5.2	7.0	1.3	.53	.52	37.9	.60
		2	19	4.1	6.0					

(table continued)

Variables	Data Collection Point	setting*	n	mean	Std dev	F value	2-tail prob	T value	Degrees of freedom	2-tail prob
RINV Total Distress (Nausea & Vomiting)	Time 2	1	21	1.4	2.8	1.5	.40	.39	36.9	.69
		2	18	1.0	2.3					
RINV Total Distress (Nausea & Vomiting)	Time 3	1	21	1.9	3.2	1.3	.56	.24	36.0	.81
		2	19	1.7	3.7					
RINV Total Distress (Nausea & Vomiting)	Time 4	1	21	1.7	2.4	1.0	.94	.38	37.7	.70
		2	19	1.4	2.4					

*Setting 1 = Sites 4 and 5.

Setting 2 = Sites 1, 2, 3 and 6.

Table 8

Chi-Square Comparison of Distribution of Experimental and Control Subjects by Referral Site

Referral Site	Treatment Group 1 (Experimental)	Treatment Group 2 (Control)	Row Total
1 (Sites 4 & 5)	12 60.0	10 47.6	22 53.7
2 (Sites 1,2,3,6)	8 40.0	11 52.4	19 46.3
Column Total	20	21	41
Percentage	48.8	51.2	100.0

Chi-square	D.F.	Significance	Min E. F	Cells with E. F < 5
0.23	1	0.63	9.3	none

Sample:

1. Size: An experimental group (n=20) and (n=21) control group was obtained by referral from 6 Oncologists in private practice. Total: N=41. The sample was accrued sequentially upon presentation to and referrals from the physician's office. All patients who met the selection criteria were asked to participate in the study. Eleven patients refused to participate in the study. The most common reason (n=9) given by the patients who refused was increased anxiety about new cancer diagnosis, one control group patient stated she was too sick to fill out the forms and one expressed worry that his answers would not be confidential, one patient consented to be a part of the control group but only partially completed his self report form. He is, therefore, listed for a portion of the demographic analysis, but is primarily listed as "missing" data for the bulk of the data analysis.

2. Criteria: a) Eighteen years of age or older; b) receiving chemotherapy for the first time; c) receiving one or all of the following chemotherapy drugs: Cytoxan, Adriamycin, Mitomycin, Nitrogen Mustard, or DTIC given alone or in combination with Bleomycin, CCNU, VP16, Vincristine, Prednisone, Methotrexate, 5FU or Procarbazine; d) free from nausea and vomiting prior to chemotherapy administration; e) histologically confirmed cancer; f) patients evidencing metastatic disease of the brain or obstruction of the alimentary canal were excluded from study; g) oriented to time, place and person; able to comprehend and complete self-administered questionnaires; h) verbal consent to be a research subject; and i) patient not receiving concurrent radiotherapy to abdomen,

spine or brain.

3. Human subjects assurance: a) Both the experimental and control group received the level of medical and nursing care and antiemetics standard for the setting they were referred from; b) The patients' responses are confidential. Patient were assigned code numbers and all reporting of data are by this number; and c) There were no known risks to patient for participating in this study.

Demographic

Descriptive statistics (mean, standard deviation, range) were performed on the sample (N=41) for the following ordinal variables; age, number of medicines currently taking not including chemotherapy, performance status rated by patient and physician, months since cancer diagnosis (Table 9). A two sample T-test was then performed to test the significance of differences between the experimental and control group for these variables (Table 10). Frequency statistics were performed for the following nominal variables: sex, treatment group, race, cancer diagnosis, medical diagnosis in addition to cancer, educational level, cancer prognosis by patient and MD, purpose for treatment by patient and MD, chemotherapy, previous cancer treatment, site of interview, antiemetic given to patient prior to chemotherapy, clarity of explanation of chemotherapy's risks and side effects by MD or nurse, cancer history in patient's family and friends, preferred method of learning, marital status, living arrangement, concurrent cancer treatment and previous cancer treatment (Tables 11 - 22).

Table 9

Descriptive Statistics for Ordinal Demographic Variables

Variable	Mean	Std Dev	Minimum	Maximum	n
Age (In years)	54.8	11.9	27	77	40
Number of Routine Meds (Besides chemotherapy)	2.7	2.5	0	8	40
Performance Status (Rated by Patient)	81.0	16.6	40	100	38
Performance Status (Rated by M.D.)	89.6	14.9	40	100	40
Time Since CA Diagnosis (in months)	6.6	19.8	0	120	40
Length of Education Session* (in minutes)	60.7	19.1	30	90	20
Number of Family Present	1.1	1.4	0	5	20
Time Between Session and Treatment (in days)	1.6	2.9	0	14	20

*Experimental group only

Table 10

2 Sample T-Test Demographic Variables

Variable	Group*	n	mean	Std dev	F value	** 2-tail prob	T value	Degrees of freedom	2-tail prob
Age	1	20	53.2	13.6					
					1.82	.20	-.83	38	.41
	2	20	56.3	10.1					
Number of	1	20	2.9	2.5					
Current					1.12	.81	.45	38	.66
Meds	2	20	2.5	2.4					
Performance	1	19	83.1	17.6					
Status Rated					1.28	.60	.78	36	.44
by Patient	2	19	78.9	15.6					
Time Since	1	20	8.1	26.6					
Cancer					7.39	.000	.44	24.0	.66
Diagnosis	2	20	5.2	9.9					

* Group 1 = Experimental, Group 2 = Control

** If significant a separate variance estimate T-test was performed.

Table 11

Frequency Statistics for Nominal Demographic Variables

Variable	Group	Frequency	Percent
Treatment	1 (Experimental)	20	48.8
Group	2 (Control)	21	51.2
Sex	Male	10	24.4
	Female	31	75.6
Race	Caucasian	38	92.7
	Asian	2	4.9
	Other	1	2.4
Current Cancer	None	36	90.0
Treatment	Radiation	4	10.0
Previous Cancer	None	9	22.5
Treatment	Surgery	28	70.0
	Radiation	1	2.5
	Radiation & Surgery	2	5.0

(Table continued)

Variable	Group	Frequency	Percent
Site of	Hospital	3	7.3
Interview*	Home	15	36.6
	Work	2	4.9
	Control Patient	21	51.2
Cancer in	Yes	32	78.0
Family?	No	5	12.2
	Missing	4	9.7
Marital Status	Single	1	2.5
	Married	24	60.0
	Divorced	9	22.5
	Widowed	6	15.0
Living	Alone	8	20.0
Arrangement	With Spouse	22	55.0
	With Family	6	15.0
	Other	4	10.0

* Experimental patients only

Table 12

Frequency Statistics for Cancer Diagnosis

Cancer Diagnosis	Frequency	Percent
Breast	21	51.2
Lung, Oat Cell	6	14.6
Lymphoma	4	9.8
Colon with Liver Met	3	7.3
Hodgkins Disease	2	4.9
Prostate	2	4.9
Leukemia	1	2.4
Melanoma	1	2.4
Pancreas	1	2.4
Total	41	100.0
Valid cases	41	Missing cases 0

Table 13

Frequency Statistics for Medical Diagnosis Secondary to Cancer

Medical Diagnosis	Frequency	Percent	Valid Percent
None	18	43.9	45.0
Cardiac	3	7.3	7.5
GI	3	7.3	7.5
Respiratory	3	7.3	7.5
Neuro	1	2.4	2.5
Endocrine	1	2.4	2.5
Orthopedic	1	2.4	2.5
Secondary Cancer	1	2.4	2.5
Hematologic	1	2.4	2.5
GI, Endo, Ortho, 2nd Cancer	1	2.4	2.5
Gyn	1	2.4	2.5
Resp, GI, Opthal	1	2.4	2.5
Resp, 2nd Cancer	1	2.4	2.5
Ortho, ETOH	1	2.4	2.5
Endo, Ortho	1	2.4	2.5
Resp, Cardiac	1	2.4	2.5
Endo, Cardiac	1	2.4	2.5
	1	2.4	Missing
Total	41	100.0	100.0
Valid cases	40	Missing cases	1

Table 14

Frequency Statistics for Education

Highest Grade Completed	Frequency	Percent	Valid Percent
Up to 8th Grade	1	2.4	2.5
Some High School	6	14.6	15.0
High School Grad	9	22.0	22.5
Some College	17	41.5	42.5
College Grad	2	4.9	5.0
Other	5	12.2	12.5
	1	2.4	Missing
Total	41	100.0	100.0
Valid cases	40	Missing cases	1

Table 15

Frequency Statistics for Cancer Prognosis Per Patient

Cancer Prognosis		Frequency	Percent	Valid Percent
Limited		21	51.2	53.8
Advanced		14	34.1	35.9
Unsure		2	4.9	5.1
No Answer		1	2.4	2.6
Intermediate*		1	2.4	2.6
		2	4.9	Missing
	Total	41	100.0	100.0
	Valid cases	39	Missing cases	2

* Intermediate grade Lymphoma

Table 16

Frequency Statistics for Cancer Prognosis Per M.D.

Cancer Prognosis		Frequency	Percent	Valid Percent
Limited		22	53.7	55.0
Advanced		18	43.9	45.0
		1	2.4	Missing
	Total	41	100.0	100.0
	Valid cases	40	Missing cases	1

Table 17

Frequency Statistics for Purpose of Treatment Per Patient

Purpose of Treatment	Frequency	Percent	Valid Percent
Cure	20	48.8	50.0
Control, No Cure	9	20.0	22.5
Unsure	4	9.8	10.0
Combo 1 and 2	7	17.1	17.5
	1	2.4	Missing
Total	41	100.0	100.0
Valid cases	40	Missing cases	1

Table 18

Frequency Statistics for Purpose of Treatment Per M.D.

Purpose of Treatment	Frequency	Percent	Valid Percent
Cure	28	68.3	70.0
No Cure	12	29.3	30.0
	1	2.4	Missing
Total	41	100.0	100.0
Valid cases	40	Missing cases	1

Table 19

Frequency Statistics for Antiemetic Given Patient Prior to Chemotherapy

Antiemetic	Frequency	Percent	Valid Percent
Compazine (PO, IM, IV)	15	36.6	37.5
None	12	29.2	30.0
Decadron - Compazine	9	22.0	22.5
Compazine - Reglan	2	4.9	5.0
Compazine - Ativan	1	2.4	2.5
Compazine - Marjuana	1	2.4	2.5
	1	2.4	Missing
Total	41	100.0	100.0
Valid cases	40	Missing cases	1

Table 20

Frequency Statistics for Clarity of Chemotherapy Risk Explanation

How Clear Was Treatment Explanation	Frequency	Percent	Valid Percent
Not Too Clear	1	2.4	2.6
Adequate	2	4.9	5.3
Fairly Clear	12	29.3	31.6
Very Clear	23	56.1	60.5
	3	7.3	Missing
Total	41	100.0	100.0
Valid cases	38	Missing cases	3

Table 21

Frequency Statistics for Preferred Method of Learning

Method of Learning	Frequency	Percent	Valid Percent
Read a Book (1)	6	14.6	15.0
Talk to Expert (2)	4	9.8	10.0
Listen Expert - TV/Radio (3)	1	2.4	2.5
Do it and Learn By Mistake (4)	1	2.4	2.5
1 and 2	12	29.3	30.0
1 and 2 and 3	2	4.9	5.0
1 and 2 and 4	3	7.3	7.5
1 and 2 and 3 and 4	8	19.5	20.0
2 and 4	2	4.9	5.0
Other	1	2.4	2.5
	1	2.4	Missing
Total	41	100.0	100.0
Valid cases	40	Missing cases	1

Table 22

Frequency Statistics for Chemotherapy Treatment Total Sample

Drug Regimen	Frequency	Percent of Sample
CMF = Cytoxan, Methotrexate, 5FU	20	51.2
CAV = Cytoxan, Adriamycin, Vincristine	4	9.8
POC-VAM = Procarbazine, Vincristine, CCNU alternated with VP 16, Adriamycin, Methotrexate	2	4.9
M-BACOD = Methotrexate, Bleomycin, Adriamycin, Vincristine & Decadron	2	4.9
Adriamycin	2	4.9
CVP = Cytoxan, Vincristine, Prednisone	2	4.9
5FU-Mitomycin	2	4.9
MOPP = Nitrogen Mustard, Vincristine, Prednisone, Procarbazine	2	4.9
DTIC-CCNU	1	2.4
L-10M = Vincristine, Prednisone, Adriamycin, Ara-C, Cytoxan for Acute Leukemia	1	2.4
FAM = 5FU, Adriamycin, Mitomycin C	1	2.4
Adriamycin-Cytoxan	1	2.4

Techniques for Data Collection

The data were collected from October, 1984 to March, 1986 when a sample of 41 was obtained. The six offices were contacted by the investigator Monday through Friday to check if patients appropriate for the study would be seen that day. After the study was explained by the Medical Oncologist, the patients willing to participate met with the investigator prior to administration of chemotherapy. Each patient received an explanation of the study in more detail and were given the human subject's assurance. If they agreed to participate in the study the informed consent (Appendix K) was signed. Once consent was obtained, baseline data was collected (RINV, ASDS, and Demographics) and the patient was randomly assigned to either the experimental or the control group. The control group was given three sets of RINV and ASDS and instructed to complete these questionnaires 6-12 hours, 24 hours, and 36 hours after receiving chemotherapy. The experimental group received 30-90 (mean 60.7, standard deviation 19.1) minute intervention outlined in Appendix G. The patient was given specific drug information sheets and two booklets (Chemotherapy & You and Eating Hints). The experimental patients were given three sets of RINV and ASDS to be filled out 6-12 hours, 24 hours, and 36 hours after the chemotherapy injection. Experimental patients had a mean of one family member present during the session (standard deviation 1.4, range 0 to 5). Mean time between education session and actual chemotherapy treatment was 1.6 days (range from 0 to 14, standard deviation 2.9).

Instruments

Adapted Symptom Distress Scale

Ruth McCorkle used nausea as part of her Symptom Distress Scale (SDS) in 1981. Rhodes, et. al. adapted the SDS by modifying the language and scaling (added two vomiting scales) and developed the Adapted Symptom Distress Scale (ASDS) (Appendix L). Rhodes, et al. also established reliability and validity for this tool in their study reported in Cancer Nursing (Rhodes, Watson, Johnson, 1984). Modifications made by Rhodes et al. concentrated on modifying the language of the tool to be more easily understood by patients. This tool results in a measurement of total symptom distress. Rhodes, et al. found high correlation between RINV and ASDS when comparing the nausea and vomiting subscales (Spearman Correlation Coefficient .93 p = .0007 and .98 p = .001 respectively). This tool was chosen for this study on the basis of this high correlation and as a measure of symptom distress.

The ASDS is a 16 item, 5 point Likert-type paper and pencil tool that measures the degree of discomfort reported by patients in relation to their symptoms. The scale ranges from 0 ("I never feel this") to 4 ("I suffer from this all of the time"). The reliability of the ASDS was determined by using Cronbach's alpha. Two separate administrations of the ASDS to patients receiving chemotherapy yielded reliability estimates of 0.90 (N=40) and 0.96 (N=29). Construct validity of the ASDS was established by first comparing well citizens and chemotherapy patients (differences were significant p=0.009) and second item scores, total scores and subscale scores were compared for the ASDS given prior to chemotherapy and after

the next cycle of chemotherapy, correlations were expected to be moderate to low. Using the Spearman correlation coefficient for the total scale score r=0.54 (n=29, p=0.0027), item correlations between the two groups (pre and post chemotherapy) ranged from 0.30 to 0.76 (n=30, p=0.04 - 0.0001) and subscale correlations between same two groups ranged from 0.42 (pain) -0.84 (coughing and breathing) (p=0.02).

Rhodes Index of Nausea and Vomiting

Rhodes, et al. developed the Rhodes Index of nausea and vomiting in 1982. The Rhodes INV is a 5 item, 5 point Likert-type pencil and paper tool that measures the patient's perceived duration and frequency of nausea, vomiting and retching and amount of vomiting (Appendix M). The scale ranges from 0 "During last 12 hours I have not felt or experienced nausea or vomiting" to 4 "During last 12 hours I felt severe distress from nausea or vomiting". The frequency of nausea and vomiting tool was developed by Rhodes, Watson, and Johnson to reflect the vomiting patterns identified in the literature and through experience (Rhodes, et al., 1983). The RINV is a self report tool designed to be used primarily on outpatients to assist in more accurate data collection when direct observation is not possible. This tool was chosen for use in this study for two reasons: 1) it was demonstrated to have high reliability and validity, and 2) the patients referred to this study were expected to be and actually were outpatients (n=38).

The reliability was tested using a split-half procedure and Cronbach's Alpha, on a convenience sample of patients. Cronbach's Alpha reliability estimates ranged from .89 to .97 and the split half procedure yielded

reliability estimates of .83 to .99. The Concurrent validity and construct validity was established in three ways. Concurrent validity was tested over two courses of chemotherapy and using the Spearman Formula the correlations were r=.87 (n=18) and r=.83 (n=16), respectively. Construct validity was tested in three ways between groups likely to have a low symptom distress scale (well citizens N=72) and a group likely to have high symptom distress scale (chemotherapy patients N=32). Significant differences (p=.0003) were obtained in the ordinal measurements between these two groups using the Wilcoxon-Mann Whitney test. The ASDS nausea scale was compared to the nausea scale of the RINV and the vomiting scale of the ASDS was compared to the vomiting scale of RINV. The Spearman correlation coefficient was .93 (n=8, p=.0007) and .98 (n=8, p=.0001) respectively. Finally, the percent of agreement was determined between the self-report vomiting scales for frequency and amount on the RINV and the nurse recordings of the number of times and the specific measurement of emesis on the inpatient's I&O Sheet. A 77.7% agreement (n=18) was found. Rhodes et al. concluded the RINV form had acceptable reliability and validity.

Scoring of ASDS and RINV

For the purpose of scoring the ASDS and RINV the individual sub-scales were grouped as follows: ASDS Total Score (which represented the sum of 16 items on the scale), each sub-scale of the ASDS was scored separately (See Table 23), RINV Total Score (which represented the sum of 8 items on the scale), RINV Total Distress from Nausea and Vomiting (which represented the sum of items #2, 3, 5, on the RINV scale), RINV

Table 23

Scoring of ASDS

Variable Name	Low possible score	High possible score	Item number for each subscale
ASDS Total Score	0	64	1-16
ASDS Nausea Frequency	0	4	1
ASDS Vomiting Frequency	0	4	3
ASDS Nausea Distress	0	4	2
ASDS Vomiting Distress	0	4	4
ASDS Enjoy Food	0	4	5
ASDS Sleep	0	4	6
ASDS Pain Frequency	0	4	7
ASDS Pain Distress	0	4	8
ASDS Tired Frequency	0	4	9
ASDS Concentrating trouble	0	4	10
ASDS Appearance	0	4	11
ASDS Breathing trouble	0	4	12
ASDS Bowel movements	0	4	13
ASDS Worried	0	4	14
ASDS Fear	0	4	15
ASDS Cough	0	4	16

Table 24

Scoring of RINV

Variable Name	Low possible score	High possible score	Item number for each subscale
RINV Total Score	0	32	1-8
RINV Total Distress nausea & vomiting	0	12	2,3,5
RINV Pattern Nausea	0	12	4,5,7
RINV Pattern Vomiting	0	12	1,3,6
RINV Pattern Retching	0	8	2,8
RINV Distress Retching	0	4	2
RINV Distress Nausea	0	4	5
RINV Distress Vomiting	0	4	3
RINV Amount Vomiting	0	4	6
RINV Frequency Vomiting	0	4	1
RINV Length Nausea	0	4	4
RINV Frequency Nausea	0	4	7
RINV # Periods of Retching	0	4	8

Pattern of Nausea (which represented the sum of items #4, 5, 7 on the RINV scale), RINV Pattern of Vomiting (which represented the sum of items #1, 3, 6 on the RINV scale), RINV Pattern of Retching (which represented items #2 and 8 on the RINV scale), and all individual items were scored separately. (Summarized in Table 24). All variables were collected by patient self-report at the following time periods, Time one prior to first chemotherapy, Time two the evening after taking CT (approximately six hours after CT), Time three the morning after taking CT (approximately 18 hours after CT) and Time Four the evening 24 hours after taking chemotherapy (approximately 30 hours after CT).

Demographic data was collected in the following general areas: age, sex, race, schooling, occupation/profession, medical diagnosis other than cancer, cancer diagnosis (by patient), cancer prognosis (by patient and physician), purpose of treatment (by patient and physician), number of months since diagnosis, chemotherapeutic agents, additional medications taken, past experience with cancer in family and social contacts, preferred method of learning, and performance status (rated by physician and patient). The demographic data form was modified by the investigator from the demographic data form Dodd developed for her studies of self-care behavior of patients receiving treatment for cancer (Appendix N).

CHAPTER IV

Chapter IV consists of the results of the statistical analysis of the research hypothesis, descriptive analysis of the patient interviews, and presentation of results of exploratory finding incidental to the research hypothesis. Statistical analysis was performed using a computer with the Statistical Package of the Social Scientists (SPSS-X) Software. The investigator consulted with a bio-statistician to perform this analysis.

Statistical analysis using Multiple Regression analysis did not support the hypothesis that patients who received a patient education and support session combined with antiemetic therapy prior to receiving chemotherapy will experience a significant reduction in the duration, frequency, distress and amount of nausea and vomiting as compared to a randomly assigned control group. No statistical differences were found between the two groups. Because the diagnosis of breast cancer comprised 50% of the sample, an additional analysis looked at the patient's with only the diagnosis of breast cancer also found no statistical differences between the experimental and control groups. Preliminary analysis identified two co-variables that were included in the Multiple Regression equation. Several additional findings were found to be significant and will be described later in this chapter. Further description of the preliminary analysis and analysis of the hypothesis will follow. The frequency distribution for the scores of the ASDS and RINV for the sample (N=41) are outlined in the Appendices (ASDS Appendix O, RINV Appendix P).

Preliminary Analysis

The investigator, based on experience with the data, chose variables that may not have been balanced between the experimental and control

groups to be tested as possible co-variables. These variables included sex, secondary medical diagnosis, educational level, performance status rated by patient, prognosis (limited vs. advanced), purpose for treatment (cure vs. no cure), cancer diagnosis, chemotherapy treatment, and use of antiemetics. A Chi-square test was performed for each of these variables looking for significant differences between the experimental group and control group for these variables. On the basis of this test 2 variables, antiemetic use (p=.0137) and chemotherapy treatment (p=.0578), showed differences that were significant (Table 25 and Table 26) and 1 variable, cancer diagnosis (p=.1607) showed a trend towards significance (Table 27).

Next three variables (number of other meds, time since cancer diagnosis, performance status) were analyzed by Pearson correlation coefficient for correlation with selected dependent variables. The investigator selected 3 variables ASDS total score, RINV total score and RINV total distress from nausea and vomiting as the dependent variables most likely to show differences between the control and experimental groups. These 3 variables were tested each for Times 1, 2, 3 and 4 which were the data collection points. With a significant P value ($P \leq 0.05$), correlates were considered weak if the coefficient was less than .5, moderate if the coefficient was between .5-.7, and strong if the coefficient was greater than .7. Using this criteria strong correlations were found for ASDS Total Score Time 1 and ASDS Total Score Time 2, 3 and 4. Of interest is that ASDS Total Score Time 1 was not found significantly correlated with the RINV scores (Table 28).

Table 25

Comparisons of Antiemetic Use by Treatment Group

	Treatment Group		
Antiemetic*	1 (Experimental)	2 (Control)	Row Total
1	7	2	9
Decadron/Compazine	35.0	10.0	22.5
2	2	10	12
None	10.0	50.0	30.0
3	11	8	19
All Others	55.0	40.0	47.5
Column Total	20	20	40
Percentage	50.0	50.0	100.0

Chi-Square	D.F.	Significance	Min E. F	Cells with E. F < 5
8.58479	2	0.0137	4.500	2 of 6 (33.3%)

Number of missing observations = 1

* For the purpose of analysis antiemetics used were regrouped into Decadron and Compazine, None, all others.

Table 26

Comparisons of Chemotherapy Treatments

	Treatment Group		
Chemotherapy*	1 (Experimental)	2 (Control)	Row Total
1	7	13	20
CMF	35.0	65.0	50.0
2	13	7	20
All Other Chemo	65.0	35.0	50.0
Column	20	20	40
Total	50.0	50.0	100.0

Chi-square	D.F.	Significance	Min E. F	Cells with E. F < 5
2.50000	1	0.1138	10.000	None
3.60000	1	0.0578	(Before Yates Correction)	

Number of missing observations = 1

* For the purpose of analysis chemotherapy treatments were regrouped into Cytoxan, Methotrexate, and 5FU (CMF) and all other chemotherapy.

Table 27

Comparisons of Cancer Diagnosis

	Treatment Group		
Cancer Diagnosis*	1 (Experimental)	2 (Control)	Row Total
1	8	13	21
Breast	40.0	61.9	51.2
2	12	8	20
All Other Cancer	60.0	38.1	48.8
Column	20	21	41
Total	48.8	51.2	100.0

Chi-square	D.F.	Significance	Min E. F	Cells with E. F < 5
1.18822	1	0.2757	9.756	None
1.96726	1	0.1607	(Before Yates Correction)	

*For the purpose of analysis cancer diagnosis was regrouped into breast cancer and all other cancers.

Table 28

Pearson Correlation Coefficients for Selected Dependent and Independent Variables

	ASDS Total Score Time 2	RINV Total Score Time 2	ASDS Total Score Time 3	RINV Total Score Time 3	ASDS Total Score Time 4	RINV Total Score Time 4	RINV Total Distress N/V Time 2	RINV Total Distress N/V Time 3	RINV Total Distress N/V Time 4
Number of other Meds	.2904 (39) p=.073	.0071 (39) p=.966	.2832 (40) p=.077	.1519 (40) p=.349	.3024 (40) p=.058	.0895 (40) p=.583	-.0116 (39) p=.944	.2340 (40) p=.146	.1151 (40) p=.480
Time Since Cancer Diagnosis	.1755 (39) p=.295	.2091 (39) p=.201	.1323 (40) p=.416	-.0464 (40) p=.776	.0459 (40) p=.778	-.1556 (40) p=.338	.0594 (39) p=.719	-.035 (40) p=.827	-.1655 (40) p=.307
Performance Status Rated by Patient	-.5955 (37) p=.000	-.2018 (37) p=.231	-.5896 (38) p=.000	-.3188 (38) p=.051	-.6486 (38) p=.000	-.2895 (38) p=.078	-.1267 (37) p=.455	-.3792 (38) p=.019	-.3255 (38) p=.046

(Table continued)

	ASDS Total Score Time 2	RINV Total Score Time 2	ASDS Total Score Time 3	RINV Total Score Time 3	ASDS Total Score Time 4	RINV Total Score Time 4	RINV Total Distress N/V Time 2	RINV Total Distress N/V Time 3	RINV Total Distress N/V Time 4
ASDS	.7897	.2043	.7650	.3347	.8505	.3595	.1843	.4081	.3765
Total Score	(39)	(39)	(40)	(40)	(40)	(40)	(39)	(40)	(40)
Time 1	p=.000	p=.212	p=.000	p=.035	p=.000	p=.023	p=.261	p=.009	p=.017
RINV	.4606	.2515	.3413	.1369	.3541	.3562	.1831	.1893	.3524
Total Score	(39)	(39)	(40)	(40)	(40)	(40)	(39)	(40)	(40)
Time 1	p=.003	p=.123	p=.031	p=.400	p=.025	p=.024	p=.264	p=.242	p=.026
RINV Total	.4803	.5333	.2454	.1040	.2923	.4573	.5736	.1877	.4329
Distress N/V	(39)	(39)	(40)	(40)	(40)	(40)	(39)	(40)	(40)
Time 1	p=.002	p=.000	p=.127	p=.523	p=.067	p=.003	p=.000	p=.246	p=.005

(Coefficient/(Cases)/2-Tailed Sig) "." Is printed if a coefficient cannot be computed.

Finally variables that could be divided into 2 groups were evaluated for significant variance by 2 sample T-Tests using the variables ASDS Total Score Time 2, 3 and 4, RINV Total Score Time 2, 3 and 4, and RINV Total Distress from Nausea and Vomiting Time 2, 3 and 4. Variables that were grouped in 3 or more categories had one way ANOVA analysis of the above dependent variables. Significant differences between the mean scores were found for ASDS Total Score Time 2, RINV Total Score Time 2, and RINV Total Distress from Nausea and Vomiting Time 2 by cancer diagnosis (Table 29). Significant differences were also found for ASDS Total Score Time 2, RINV Total Score Time 2, and RINV Total Distress from Nausea and Vomiting Time 2 by chemotherapy (Table 30). Additionally the two sample T-tests showed no differences between the experimental and control groups for the dependent variables ASDS Total Score Time 1 and RINV Total Score Time 1 (Table 31).

Table 29

2 Sample T-Test by Cancer Diagnosis Significant Findings

Variable	Group*	n	mean	Std dev	F value	2-tail prob	T value	Degrees of freedom	2-tail prob
ASDS	1	20	9.9	7.0					
(Total Score					2.41	.065	-3.22	37	0.002
Time 2)	2	19	19.4	10.9					
RINV	1	20	1.6	3.1					
(Total Score					8.04	0.000	-2.17	22.21	0.041
Time 2)	2	19	6.3	8.9					
RINV	1	20	0.35	.59					
(Total Distress					34.57	0.000	-2.25	18.99	0.036
Time 2)	2	19	2.2	3.4					

* Group 1 = Breast Cancer

Group 2 = All Other Cancers

Table 30

2 Sample T-Test by Chemotherapy Significant Findings

Variable	Group*	n	mean	Std dev	F value	2-tail prob	T value	Degrees of freedom	2-tail prob
ASDS	1	19	10.3	7.0					
(Total Score					2.55	0.052	-2.79	32.13	0.009
Time 2)	2	20	18.6	11.2					
RINV	1	19	1.7	3.2					
(Total Score					7.51	0.000	-2.05	24.20	0.051
Time 2)	2	20	6.0	8.8					
RINV (Total	1	19	0.4	0.6					
Distress Nausea/					32.3	0.000	-2.18	20.24	0.041
Vomiting	2	20	2.0	3.4					
Time 2)									

* Group 1 = CMF Chemotherapy

Group 2 = All Others

Table 31

2 Sample T-Tests for Time 1 Scores

Variable	Group*	n	mean	Std dev	F value	2-tail prob	T value	Degrees of freedom	2-tail prob
ASDS	1	20	15.9	9.3					
(Total Score					1.47	.411	0.03	38	.976
Time 1)	2	20	15.8	11.3					
RINV	1	20	.035	1.2					
(Total Score					2.28	0.08	-1.67	38	0.103
Time 1)	2	20	1.15	1.8					

*Group 1 = Experimental, Group 2 = Control

Using one way ANOVA the variable of antiemetic use was evaluated for its effect on the variables of interest. No significant differences were found. Therefore, based on this preliminary analysis the variables of cancer diagnosis and chemotherapy were identified as co-variables and used as predictors in the Multiple Regression equation.

Analysis of the Hypothesis

Multiple Regression was used to test the effects of predictor variables (Chemotherapy, Cancer Diagnosis, Treatment Group) on criterion or dependent variables chosen by the investigator, as the most likely to show significant variance, to test the hypothesis. Initial Multiple

Regression equations were created for these criterion variables of ASDS Total Score Time 2, 3, 4; RINV Total Score Time 2, 3, 4 and RINV Total Distress from Nausea and Vomiting Time 2, 3, and 4. The ASDS variables had the predictor variable of the ASDS Total Score Time 1 added to the multiple regression predictor equation, the RINV variables had RINV Total Score Time 1 added and RINV Total Distress from Nausea and Vomiting Time 1 added to the prediction equation. The Multiple Regression analysis was conducted in four steps; step one the time 1 predictor variable was entered, step two and three chemotherapy and cancer diagnosis predictor variables were entered and step four treatment group was entered. Results of the regression analysis equation are summarized in Tables 32, 33 and 34. The predictor variable of treatment group was found not to have significant predictive power for any of the nine criterion variables. On the basis of significant Beta weights the criterion variables of ASDS Total Score Time 2, 3 and 4, RINV Total Score Time 4, RINV Total Distress Nausea and Vomiting Time 2 and 4, were found to be the better predictors of the equation. On the basis of significant R^2 values the equations for ASDS Total Score Time 2, 3 and 4 were found to be the most predictive equation. Multiple Regression equations were performed for each of the other variables without significant findings in regards to the effects of treatment group on the dependent variable. Of note is that the scores on all subscales of the ASDS at time 1 were predictive of the scores at time 2, 3 and 4 ($p<.0001$). The scores of the subscales of the RINV at time 1 were not found to be predictive of scores at time 2, 3 and 4.

Table 32

Step One of Regression Analysis

Criterion of Dependent Variable	Time	Predictor of Independent Variable	Time	Beta† WT	R2ø	Correlation Coefficient
ASDS Total Score	2	ASDS Total Score	1	.789*	.623**	.790
ASDS Total Score	3	ASDS Total Score	1	.765*	.585**	.765
ASDS Total Score	4	ASDS Total Score	1	.850*	.723**	.851
RINV Total Score	2	RINV Total Score	1	.251	.063	.251
RINV Total Score	3	RINV Total Score	1	.137	.018	.137
RINV Total Score	4	RINV Total Score	1	.356+	.126++	.356
RINV Total Distress Nausea & Vomiting	2	RINV Total Distress Nausea & Vomiting	1	.573x	.329xx	.574
RINV Total Distress Nausea & Vomiting	3	RINV Total Distress Nausea & Vomiting	1	.187	.035	.188
RINV Total Distress Nausea & Vomiting	4	RINV Total Distress Nausea & Vomiting	1	.435∇	.187Δ	.433

(table continued)

† Beta weights are regression coefficients that would have been obtained assuming the various predictor variables have equal means and standard deviations. The higher the beta weight the better the predictor.

ϕ The R2 variables provides an index of the predictive power of the equation. If the value is high its highly predictive.

* Sig T = .0000 + = .0241 x = .0001 ∇ = .0053

**Sig F = .0000 ++ = .0241 xx = .0001 Δ = .0053

Table 33

Step Two and Three of Regression Analysis

Criterion or Dependent Variable	Time	Predictor of Independent Variable	Beta WT	$R2^{\emptyset}$	Correlation Coefficient
ASDS Total Score	2	Chemotherapy	-.147	.645	.413
		Cancer Diagnosis	.297	.645	.472
ASDS Total Score	3	Chemotherapy	-.284	.593	.181
		Cancer Diagnosis	.268	.593	.245
ASDS Total Score	4	Chemotherapy	.171	.731	.186
		Cancer Diagnosis	-.241	.731	.210
RINV Total Score	2	Chemotherapy	-.079	.164	.314
		Cancer Diagnosis	.393	.164	.343
RINV Total Score	3	Chemotherapy	-.308	.028	-.003
		Cancer Diagnosis	.307	.028	.030
RINV Total Score	4	Chemotherapy	-.292	.135	.012
		Cancer Diagnosis	.283	.135	.048
RINV Total Score	2	Chemotherapy	-.010	.394	.330
Nausea & Vomiting		Cancer Diagnosis	.268	.394	.355
RINV Total Score	3	Chemotherapy	-.223	.042	.052
Nausea & Vomiting		Cancer Diagnosis	.257	.042	.079
RINV Total Score	4	Chemotherapy	-.218	.200	.138
Nausea & Vomiting		Cancer Diagnosis	.301	.200	.172

Table 34

Step Four of Regression Analysis

Criterion Variables	Time	Predictor Variables	Beta WT	R2	Correlation Coefficient	Signif T
ASDS Total Score	2	Treatment Group	.021	.645	-.067	.8434
ASDS Total Score	3	Treatment Group	-.082	.599	-.059	.4749
ASDS Total Score	4	Treatment Group	-.037	.733	-.005	.6946
RINV Total Score	2	Treatment Group	-.062	.167	-.060	.7227
RINV Total Score	3	Treatment Group	-.277	.091	-.177	.1286
RINV Total Score	4	Treatment Group	-.223	.176	-.074	.1978
RINV Total Distress Nausea & Vomiting	2	Treatment Group	-.099	.402	-.048	.4933
RINV Total Distress Nausea & Vomiting	3	Treatment Group	-.185	.071	-.125	.3003
RINV Total Distress Nausea & Vomiting	4	Treatment Group	-.258	-.257	-1.59	.1111

Separate analysis was performed on the sub-group of patients with the diagnosis of cancer of the breast (n=21) using multiple regression analysis. The criterion variables tested were: ASDS Total Score Time 4, RINV Total Score Time 2, 3 and 4, RINV Total Distress from Nausea and Vomiting Time 2, 3 and 4. The score at time one for each dependent variable (ASDS Total Score, RINV Total Score, or RINV Total Distress from Nausea and Vomiting) and treatment group were stepped into the regression equations. No significant differences were found between the control and experimental group in analysis of the above mentioned dependent (criterion variables) (Table 35). Chemotherapy was not tested in the Multiple Regression equation because it was directly related to the diagnosis of breast cancer (CMF is the primary treatment used) and the small sample size dictated a more simple analysis.

Table 35

Multiple Regression Analysis for Breast Cancer

Criterion Variables	Time	Predictor Variables	Time	Beta WT	R2	Correlation Coefficient	Signif T
ASDS Total Score	4	ASDS Total Score	1	.947	.819	.905	.0000
		Treatment Group		-.117	.831	.225	
RINV Total Score	2	RINV Total Score	1	.323	.131	.363	.1162
		Treatment Group		.124	.145	.226	
RINV Total Score	3	RINV Total Score	1	-.153	.011	-.106	
		Treatment Group		.161	.035	.117	
RINV Total Score	4	RINV Total Score	1	.187	.047	.217	
		Treatment Group		.101	.056	.156	

(table continued)

Criterion Variables	Time	Predictor Variables	Time	Beta WT	R2	Correlation Coefficient	Signif T
RINV Total Distress Nausea & Vomiting	2	RINV Total Distress Nausea & Vomiting	1	.052	.007	.087	
		Treatment Group		.128	.022	.143	
RINV Total Distress Nausea & Vomiting	3	RINV Total Distress Nausea & Vomiting	1	-.118	.003	-.059	
		Treatment Group		.235	.055	.205	
RINV Total Distress Nausea & Vomiting	4	RINV Total Distress Nausea & Vomiting	1	.041	.003	.062	
		Treatment Group		.081	.010	.092	

Exploratory Findings (Additional Analysis)

This section will present the results of analyses of research questions posed after evaluation of data collected.

1. Is there a difference in the effectiveness and the use of antiemetics by the subjects?

2. Is there a difference in the severity of nausea and vomiting as measured by the RINV Total Score Time 4 by type of chemotherapy administered and site of interview?

3. Is there a difference between the rating of Karnofsky Status by M.D. and patient?

4. Was there a difference in the understanding by the patient of his/her prognosis and purpose for treatment in experimental group and control group?

5. Did the experimental group have a better understanding of the expected side effects from treatment?

6. Did the experimental group express that they had a clearer explanation of the risks of treatment then the control group expressed?

7. Descriptive analysis of subjects past experience with cancer and of subject questions during intervention interviews?

8. Was there a difference between the experimental and control group dosage of chemotherapy agents and route administration?

Effectiveness of antiemetics:

Antiemetic use was measured at Time 2, 3 and 4 for all subjects except those (n=4) collected as part of the pilot study. They were grouped into three categories by the investigator, 1) Decadron and Compazine,

2) Compazine alone, and 3) no antiemetic used. A one way ANOVA was used to analyze the variance of scores by the three groups on the RINV Total Score Time 4. The score ranges were analysed by the TUKEY-HSD Procedure for multiple ranges looking for differences at the .050 level. Variances were also tested for homogeneity by use of the Cochrans C and Bartlett-Box F tests. Results showed a significant difference at Time 4 with the compazine alone group showing significantly more nausea and vomiting ($p \leq .05$) then the Decadron and Compazine group and the no antiemetic used group (Table 36). Also, as already reported the patients in the experimental group took antiemetics at time 1 significantly more often than the control groups ($p=0.0137$). This trend continued through times 2, 3 and 4.

Table 36

Effectiveness of antiemetics

Variable	Time	Group	n	mean	Std Dev	Cochrans C	Bartlett-Box	Significant Tukey
ANTIEMETIC TIME 1								
RINV		1*	9	.555	1.67			
Total Score	1	2*	18	.444	1.04	p=.172	p=.052	NS*
		3*	12	1.417	2.02			
RINV		1	9	3.22	5.91			
Total Score	4	2	18	4.78	7.30	p=.471	p=.603	NS
		3	12	5.75	5.63			
ANTIEMETIC TIME 2								
RINV		1	5	.400	.89			
Total Score	1	2	14	.428	1.09	p=.039	p=1.40	NS
		3	20	.850	1.69			
RINV		1	5	2.80	3.70			
Total Score	4	2	14	3.43	5.11	p=.052	p=.175	NS
		3	20	5.45	7.38			
ANTIEMETIC TIME 3								
RINV		1	2	.000	.000			
Total Score	1	2	9	.556	1.13	p=.008	p=.301	NS
		3	27	.74	1.56			

(Table continued)

Variable	Time	Group	n	mean	Std Dev	Cochrans C	Bartlett-Box	Significant Tukey
RINV		1	2	1.00	1.41			
Total Score	4	2	9	6.22	9.65	p=.000	p=.027	NS
		3	27	3.85	4.99			
ANTIEMETIC TIME 4								
RINV		1	2	.000	.000			
Total Score	1	2	9	.556	1.13	p=.010	p=.293	NS
		3	26	.692	1.57			
RINV		1	2	1.00	1.41			Group 2 is
Total Score	4	2	9	8.78	9.39			signif diff
		3	26	2.77	4.30			group 3 or 1
								$p \leq .05$

*Group 1 = Decadron and Compazine

Group 2 = Compazine alone

Group 3 = No antiemetic used

NS* = Non significant

Emetic potential of different chemotherapy agents:

For the purpose of identifying the emetic effect of differing chemotherapy regimens chemotherapy regimens were grouped as follows; 1) CMF (n=20), 2) Adriamycin containing regimens (n=8), 3) other (n=5)

comparing the mean scores of RINV Total Score Time 1 and 4. No significant differences were found between mean scores by chemotherapy regimen (Table 37).

Table 37

Emetic potential of different chemotherapeutic agents

Variable	Group	n	mean	F	Signif F
RINV	1 CMF*	20	4.65		F
Total Score	2 Adriamycin*	8	6.63		
Time 4	3 Other*	5	3.80		
Main Effects				0.050	0.951
Drug					

*CMF = Cytoxan, Methotrexate, 5FU

Adriamycin = Regimens containing Adriamycin

Other = All other chemotherapy

Karnofsky status:

Patients and physicians were asked to rate the Karnofsky status pretreatment using the scale in Figure 1. Physicians rated patients higher on this scale then the patients rated themselves. This was found to be significant as measured by a two sample t-test ($p \leq .0001$) (Table 38).

Figure 1. Karnofsky Status Question.

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26. Your performance status at the time of the interview:

____ 90-100 Full active, able to carry on all predisease performance without restriction.

____ 70-89 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sendentary nature, e.g., light housework, office work.

____ 50-69 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.

____ 30-49 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

____ 10-29 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

Table 38

Karnofsky Status Rated by Patient and M.D.

Variable	n	mean	Standard Deviation	T Value	Degrees of Freedom	2-Tail Prob
Performance rated by M.D.	38	90.6	2.3	5.95	37	0.000
Performance rated by Patient		81.0	2.7			

Significant differences were also noted when the experimental subjects and control subjects were analyzed separately (Appendix Q and R).

Site of interview:

T-test analysis was performed on the site of interview for the experimental group. Three patients were interviewed in a hospital, two at their place of work and fifteen at home. Analysis using RINV Total Score Time 4 as the dependent variable showed a significant difference between the means of the two groups (interviewed at home and interviewed away from home) p=.018 with the "at home" group having the higher mean scores (Table 39) indicating more nausea and vomiting at time 4.

Table 39

Two Tail T-Test Site of Intervention

Group	n	Mean RINV Total Score Time 4	F Value	2-Tail Prob	T Value	Degrees of Freedom	2-Tail Prob
Away from Home	5	0.8000	58.89	.001	-2.64	15.32	0.018
Home	15	6.6667					

However, a one way ANOVA failed to show a significant difference in variation between the two groups associated with interview site.

Understanding of prognosis:

Subjects were asked to name stage of disease and purpose of treatment (Figure 2).

Figure 2. Question 12 and 19 Stage of Disease and Purpose for Treatment.

12. Stage of disease (a) limited _____ (b) advanced _____.

19. Is the purpose of your receiving treatment to cure the disease?

Yes _____ No _____ Not sure _____

To shrink the tumor? Yes _____ No _____ Not sure _____.

A cross tabulation table was formed comparing the understanding of prognosis and purpose for treatment by patients controlling for treatment group and the physician's statement of prognosis and purpose for

treatment. In the experiment group (N=17) 8/9 patients or 88% correctly identified a limited prognosis, 7/8 or 87% correctly identified an advanced prognosis. In the control group (N=19) 9/12 or 75% correctly identified a limited prognosis and 5/7 or 71% correctly identified an advanced prognosis. This difference between the control and experimental group was significant (p=.05). When asked to identify the purpose of treatment 7/7 100% accurately identified cure as the purpose of treatment and 4/6 or 67% correctly identified no cure or control as the purpose of treatment in the experimental group. In the control group 11/13 or 85% correctly identified cure as the purpose of treatment and 2/3 or 67% identified no cure correctly. The difference between the 2 groups identifying cure as the purpose of treatment was significant (p= 0.5). Seven patient in the experimental group and four patients in the control group were unsure of purpose of treatment. These findings were in contrast to the findings of the Dodd and Mood study who found patients correctly identified their prognosis if it was limited and the purpose for treatment was cure, however, patients were less accurate in identifying a prognosis that was advanced and a purpose for treatment of palliation.

Knowledge of side effects:

Patients were asked to list chemotherapy drug side effects that they expected or were told by their physician. (Figure 3).

Figure 3. Question 18 Side Effects Expected by Patient.

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18. At the time your physician explained the chemotherapy program to you he/she probably mentioned that some people experience side effects when taking this (these) drugs. Please list the side effects you expect to experience. (You may use the list attached to choose from).

This list was compared to the actual list of side effects the physician and/or nurse attributed to the chemotherapy drugs. Using a two-tailed T-test the ability of the experimental verses control group to accurately name side effects was compared. A difference in means were found, however, it was not found to be significant (p=.376) (Table 40).

Table 40

Two Tail T-Test Analysis of Knowledge of Side Effects

Group	n	mean	Std Dev	Standard Error	T Value	Degrees of Freedom	2-Tail Prob
Experimental	20	39.0	31.6				
				7.1	.9	37	.376
Control	19	30.6	26.5				

Eight patients of the total sample answered the question concerning side effects expected that they expected no side effects. These patients were compared to the rest of the sample (n=32) for their score on the RINV Total Score Time 4. The mean score for the expected no side effects group was lower than the rest of the sample but this was not found significant by 2 sample t-test (p=.235) (Table 41).

Table 41

Two Tail T-Test Analysis of Nausea and Vomiting in Patients That Expect No Side Effects.

Group	n	mean	Std Dev	Standard Error	T Value	Degrees of Freedom	2-Tail Prob
Expect no side effects	8	2.25	6.4	2.2			
					-1.21	38	0.235
Expect side effects	32	5.34	6.5	1.1			

Clarity of side effects explanation:

When asked to rate the clarity of the side effects (Figure 4) explanation most patients in the sample (n=23) rated the explanation as very clear (a score of 4 or 5). No significant difference using Chi-square was found in the rating of the clarity of the treatment explanation. This finding was also seen in the Dodd & Mood study and seems to indicate that patients believe they have been well informed even when they have limited understanding of the treatment.

Figure 4. Question 20 Rate Clarity of Side Effects Explanation.

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20. Before you start your chemotherapy how clearly have the purpose and risks of your chemotherapy been explained to you? Here is a five point scale ranging from "I did not understand at all" to "Very clear." Please indicate by a number how clear that explanation was.

1	2	3	4	5
I did not understand it at all	Not too clearly	Adequate	Fairly Clear	Very Clear

---

Table 42

Chi-Square Analysis of Total Sample Rating of Side Effects Explanation (Question 20).

Rating	Experimental	Control	Row Total
Not very clear (1, 2, 3)	8	7	15 39.5
Very clear (4, 5)	12	11	23 60.5
Column Total	20 52.6	18 47.4	
Chi-square	D.F.	Significance	
0.0	1	1.0000	

Past experience with cancer:

The entire sample (N=41) was asked a series of questions concerning their experience with cancer in their family and close friends (Figure 5).

Figure 5. Patient's experience with cancer.

Has anyone in your family or close friends had cancer? _____

If yes, 1) Who? _____

2) Type of cancer? _____

3) Type of treatment used? _____

4) How are they now? _____

Most subjects (n=34) answered yes to the first question (experimental subjects n=20; control subjects n=14). There were five subjects who had not had previous experience with cancer all were in the control group. Two control patients did not answer the question. A crosstabulation table and chi-square showed the difference between the groups to be significant ($p<.02$) (Table 43) with experimental group having more experience with cancer than the control group.

Table 43

Chi-Square Analysis of Differences Between Experimental and Control Group Experience with Cancer.

Cancer in Family	Experimental	Control	Row Total
Yes	20	14	34
	(100.0%)	(73.7%)	(87.2%)
No	0	5	5
	(0%)	(26.3%)	(12.8%)
Column Total	20 (51.3%)	19 (48.7%)	39 (100.0%)
Chi-square	D.F.	Significance	
6.21	1	0.02	

Subjects responded to the question of who in their families had cancer with multiple answers. Some subjects listed up to 4 persons in their family who had cancer. It is an interesting finding that when asked to list type of treatment received, 46.2% of the sample responded, "none" (Table 46). Descriptive tables of the entire sample's response to the who, type, treatment and status questions follows (Tables 44, 45, 46 and 47).

Table 44

Who has Cancer in Family or Friends

Category Label	Frequency	PCT of Responses	PCT of Cases
Parent, Sibling, Inlaw, Grandparent	30	52.6	88.2
Friends	10	19.3	32.4
Niece, Cousin, Aunt, Uncle	11	19.3	32.4
Spouse	4	7.0	11.8
Child	1	1.8	2.9
Total Responses	57	100.0	167.6

Missing cases 7 Valid Cases 34

Table 45

Type of Cancer in Family or Friends

Category Label	Frequency	PCT of Responses	PCT of Cases
Breast	17	31.5	51.5
Lung	9	16.7	27.3
Colon	5	9.3	15.2
Leukemia	4	7.4	12.1
Uterus-Cervix	4	7.4	12.1
Lymphoma	3	5.6	9.1
Bladder	2	3.7	6.1
Liver	2	3.7	6.1
Gastric	1	1.9	3.0
Head & Neck	1	1.9	3.0
Hodgkins	1	1.9	3.0
Kidney	1	1.9	3.0
Ovarian	1	1.9	3.0
Prostate	1	1.9	3.0
Pancreas	1	1.9	3.0
Unknown	1	1.9	3.0
Total Responses	54	100.0	163.6

Missing cases 8 Valid Cases 33

Table 46

Treatment Family or Friends Used

Category Label	Frequency	PCT of Responses	PCT of Cases
None	43	46.2	126.5
Chemotherapy	14	15.1	41.2
Surgery	13	14.0	38.2
Don't Know	7	7.5	20.6
CT-RT	5	5.4	14.7
Surg-CT	3	3.2	8.8
Surg-CT-RT	3	3.2	8.8
Surg-RT	3	3.2	8.8
Radiation Treatment	2	2.2	5.9
Total Responses	93	100.0	273.5

Missing cases 7 Valid Cases 34

Table 47

Status of Family Member of Friend Now

Cancer in Family	Experimental	Control	Row Total
Cured-Fine	7	7	14
	(26.0)	(38.9)	
Dead	20	11	31
	(74.0)	61.1)	
Column	27	18	45

Descriptive analysis of subject's questions during interviews:

A short narrative was written after each experimental group interview conducted by the investigator. A descriptive analysis of these notes and contents is contained in Table 48.

Table 48

Experimental Group Questions and Concerns During Interview

	N
Patient expressed concern over getting AIDS from transfusion	20
Questions about drugs, side effects and treatment schedule	12
Patient demonstrated increase anxiety/pain	10
Questions about disease and prognosis	9
Family cancer experience negative	7
Questions about self care behavior	7
Patient expressed that he/she expected N/V	6
Qeustions about diet, vitamins and exercise	4
Patient expressed positive attitude	3
Family cancer experience positive	2
Patient expressed financial concerns	1

Dosage of chemotherapy agents:

A comparative analysis was performed examing the dosages of chemotherapy per meter squared for the subjects in the experimental and control groups. This anslysis examined the patients with the diagnosis of breast cancer, oat cell lung cancer and lymphoma which comprised the majority of diagnoses seen in this study. Similar treatment protocols by diagnosis were used for treatment in patients in the experimental and

control groups and these were compared by dosage of Cytoxan and Adriamycin per meter squared. Table 49 presents this comparison. The size of the individual cells were too small to perform parametric statistics.

Table 49

Dosage of Chemotherapy Agents

Diagnosis	N	Treatment Protocal	Experimental Group n	RINV Mean Total Score* 2	4	Control Group n	RINV Mean Total Score 2	4
Breast Cancer	19	CMF (IV CTX 600mgm/M^2)	1	2.0	0.0	5	2.2	4.4
		CMF (po CTX 100mgm/M^2x14d)	4	4.0	6.7	5	2.7	6.0
		CMFVP (po CTX 70mgm/M^2/Dx9mo)	2	0.0	0.0	3	4.3	1.0
Oat Cell Lung Cancer		CAV (IV CTX 1000mgm/M^2 & Adriamycin 50mgm/M^2)	4	8.0	3.7	1	0.0	0.0
		POC (IV CTX 600mgm/M^2)	1	8.0	1.8	0	--	--
Lymphoma		MBACOD (IV CTX 600mgm/M^2 & Adriamycin 40mgm/M^2)	1	1.7	0.0	1	0.2	0.0
		CVP (IV CTX 750mgm/M^2)	1	0.5	1.0	1	0.0	0.0

*Lower the score, lower the N/V.

CHAPTER V

Chapter V will discuss the significance of the results of this research study, the limitations found in interpreting the results, the implications for nursing practice, the problems in the study design, and proposals for future research.

Results of Research Study

The purpose of this study was to discover the effects of pre-chemotherapy patient education on the post-chemotherapy pattern of nausea and vomiting. In order to be successful in answering this question the research design must control for several variables that also have influence on the post-chemotherapy nausea and vomiting experienced by patients. These variables include antiemetics, chemotherapy regimen, cancer diagnosis and experience of staff administering chemotherapy. The results of this study will be discussed in the light of the control or lack of control over these variables. Several points of interest have been proposed in the literature review of the emetogenic effects of chemotherapy these include:

1. Patients react individually and demonstrate variability in frequency and duration of vomiting, as well as in their response to antiemetics (Zook & Yasko, 1983; Kennedy, et al., 1981).

2. Patients generally come to treatment with preconceived notions from sources commonly called "well meaning friends". Negative past perceptions have a positive correlation for increased nausea and vomiting (Zook & Yasko, 1983).

3. Antiemetics should be given prophylactically prior to the start of chemotherapy (See-Lasley & Ignoffo, 1981).

4. Social conditioning by friends, family, medical staff and media increases emotional distress and, therefore, exacerbate psychologic factors present and leads to increased nausea and vomiting (Chang, 1981; Andrykowski, et al., 1983).

5. Kennedy et al. (1981) suggested that nurse-initiated interventions for nausea and vomiting should focus in the time period before and immediately following treatment because this was reported by 40% of the patients as the time of occurrence of nausea and vomiting. Fourty-seven percent of patients in Kennedy's study reported the duration of vomiting as 12 hours or less.

6. Patients can be found in differing phases and systems of care depending on their stage of disease and perceptions of disease. Teaching should be geared to the patients' need in each phase (i.e. Phase I teaching should be simple and concise and Phase II teaching should be more complex) (Watson, 1982). These points of interest from the literature will also be included in the discussion of the results of this study in order to formulate a plan for further research in the area.

It is clear that the results of this study did not support the hypothesis offered: Randomly assigned cancer patients who received a patient education and support session and antiemetic therapy prior to receiving chemotherapy will experience a significant reduction in the duration, frequency, distress and amount of nausea and vomiting as compared to a control group of cancer patients receiving chemotherapy for the first time. No significant statistical differences ($p \leq .05$) were found between the control and experimental group for any of the many dependent variables

tested. Results approaching significance indicated a trend towards the control group having less nausea and vomiting. This result was in contrast to the investigator's clinical (4 year) experience with the intervention. Designing a fair test of this intervention presented many problems, some of which, may explain the discrepancy in results.

It is interesting that the control group experienced so many refusals (n=8) by patients eligible to participate as research subjects. This speaks to, however it was not measured, the highly anxious and stressful time that patients face prior to taking chemotherapy. It could also indicate that patients who refused were still in Phase I of their disease and illness and were unable to commit the time to complete questionnaires without more support from the investigator. It makes it very difficult to perform a study with a truely randomized group of subjects and presents a unique form of selection bias. The investigator's experience with accrual for this study was that the highly anxious patients offered the experimental intervention benefited from this extra support and rarely refused to be a part of the study and consequently the "sickest" patients initially prior to chemotherapy were included in the experimental group. The corresponding patients in the control group refused to participate in the study. It is also important to note that these groups did not show any difference in the pattern of nausea and vomiting and therefore, patients receiving information about side effects will not have more nausea and vomiting.

Control of the variables of setting, cancer diagnosis, chemotherapy drugs and antiemetics present another problem. The investigator did not work in any of the settings from which patients were randomized. This

made it very difficult to maintain a constant accrual rate with control over the variables mentioned. In order to statistically test this intervention each variable would need to be represented by a n=10 and a much larger study may result in significant findings. However, the differences between the experimental and control groups for these 4 variables when tested was found to be nonsignificant.

Preliminary analysis of variables in the study did reveal some differences when considering diagnosis and chemotherapy. Twenty-one of forty-one patients were diagnosed with breast cancer and it appears that the nausea, vomiting and symptom distress experienced by these patients at certain time periods was less than patients with other diagnoses. Also 19 of breast cancer patients received CMF chemotherapy and showed significantly less nausea and vomiting and symptom distress at Time Two. This may reflect that the patients had not started the Cytoxan (if taken P.O.) until the day after receiving 5FU and Methotrexate. However, some patients in the sample received I.V. Cytoxan on day one of the cycle. The pattern of nausea and vomiting in breast cancer patients receiving CMF chemotherapy warrants further research.

The use and effectiveness of antiemetics by patients in this study is a very important finding. Significant results were found for these variables. Patients in the experimental group were more likely to take antiemetics prior to taking chemotherapy than the patients in the control group. Single agent antiemetics were less effective at 30 hours after taking chemotherapy then taking multiple antiemetics or no antiemetic at all. This finding has implications for the support of patient self-care and

effectiveness of single agent antiemetics.

Orem described a role for nurses in patient education effecting an increased ability for self-care. This was supported by this study. The experiment group demonstrated self-care behavior by their use of antiemetics at times 1 through 4. See-Lasley and Ignoffo (1981) strongly felt that patients needed to take antiemetics regularly in order to insure their effectiveness. However, despite the tendency for the experimental group to use antiemetics there was not a significant difference in the pattern of nausea and vomiting in this group.

The understanding of the effectiveness of antiemetics has been very frustrating and confusing to researchers, as is evidenced by a review of the literature. It appears from this study's finding that patients who take no antiemetics 30 hours after taking chemotherapy have significantly less nausea and vomiting than the patients who use compazine alone, that use of antiemetics after taking chemotherapy needs to be examined closely. Analysis of this finding seems to indicate that at time 4 or 30 hours after receiving chemotherapy there are some patients who do not need antiemetics because their nausea and vomiting has resolved. This supports Kennedy's findings. However, the patients who still have nausea and vomiting at this time need more than single agent antiemetic support. These patients may benefit from individually prescribed combination antiemetics as proposed by See-Lasley and Ignoffo. This concept will warrant further study.

Much confusion is noted in the literature surrounding the emetogenic effects of chemotherapy. This confusion is also seen in clinical practice as

practitioners share conflicting opinions about the emetogenic potential of certain chemotherapy drugs and, therefore, give differing antiemetics for these drugs. This finding was supported in this study. No differences in the pattern of nausea and vomiting were found between C.M.F., Adriamycin containing regimens and "highly" emetogenic drugs (Nitrogen Mustard, DTIC and Mitomycin). Perhaps it is wise not to generalize the effects of these drugs for the patient but to individualize the treatment of side effects based on patient's individual reaction to these drugs.

A patient personality type seemed to emerge in this study that warrants further study. Some patients seem to possess a positive attitude about treatment and life in general. These patients tended to report having fewer overall side effects. An attempt was made retrospectively to identify these patients by looking at the pattern of nausea and vomiting in patients who stated they expected no side effects from chemotherapy. However, this does not accurately measure the scores of all of these patients because some of them gave very complete lists of the side effects attributed to the drugs they were to receive. Further research into the differences between these patients who do far better than expected while taking chemotherapy would be interesting.

Also, this study provided evidence of strong past experience and negative perceptions of chemotherapy. Most of the sample (n=32) reported that someone in their family had had cancer. Often subjects reported multiple family members and peers with cancer. A significant number of the patients in the experimental group had a negative experience with their family and peers with cancer and treatment. Taking into consideration the

findings of Zook and Yasko it may be wise to stratify this variable in future studies.

A significant additional finding of this study was the rating of Karnofsky Status by patients and physicians. Many treatment decisions are made based on the Karnofsky Status and often the dosage of drugs is reduced based on this rating. It appears based on the highly significant finding that patients rated the Karnofsky Status an average of 10 points lower than the physician. Indicating that there needs to be improved communication between these two groups. The nurse's rating of Karnofsky Status was not included in this study but may be a significant variable in further studies. Using the Karnofsky Status as a patient self-report tool would seem to be indicated by these findings.

Limitations

The limitations of this study have been discussed throughout this paper and need only to be listed here:

1. Multiple Diagnoses
2. Multiple Chemotherapy Drugs Protocols
3. Variable Use of Antiemetics
4. Small Sample Size

A discussion of the difficulties with accrual is important here. It is difficult to foresee the difficulties at the outset of a research study that are found when the study is actually conducted. Rhodes, who developed the ASDS and RINV, also expressed frustration with accural while attempting to limit her research with these tools to specific disease sites (Personal communication, 1986). It is extremely difficult to access

subjects from outside treatment settings. This author would recommend that if this study were to be replicated it would need to be done in a major treatment setting with a large referral base for specific disease groups. Breast cancer seems the most likely choice based on the accrual pattern of this study. However, in other settings lymphoma, leukemia or oat cell lung cancer may be appropriate choices. It is of utmost importance that further research in chemotherapy induced nausea and vomiting be done controlling and stratifying for disease site and chemotherapy.

The tools used to measure nausea, vomiting and symptom distress performed well in this study. There were some areas of disagreement with the results of Rhodes et al. Rhodes reported that the ASDS Nausea and Vomiting scales were highly correlated with the RINV. This correlation was not supported by the results of this study. Further the ASDS was collected by the investigator at time 1, 2, 3 and 4. The results of correlations between the ASDS Total Score and subscale scores for times 1, 2, 3, and 4 were highly correlated. This finding suggests that the ASDS could be collected at time 1 only or time 1 and 4 with equivalent results. This would reduce the demands for self report data made on the patient and also reduce the extent of statistical analysis necessary.

Dodd's (1982) findings that patients who were given pre-treament teaching were more knowledgeable about side effects also was not supported by the findings of this study. This may reflect the difficulty encountered in accurately measuring the number of side-effects attributed to the drug by physician and nurse and then measurement of the accuracy of the patient's self report. This could be further complicated by the

patients who reported they expected no side effects in response to the question about what side effects they expected to happen while taking chemotherapy. Careful rewording of this question may change these results. Also it is important to be able to record the side effects explanation that is given patients in both experimental and control groups by nurses and physicians.

Significance of Nursing Theory, Practice, Service and Education

This study was designed to support the important role of nurses in the management of symptoms and education of patients receiving chemotherapy for the first time. The high rate of patients who refused to participate in this study seems to support the concept that the period of cancer diagnosis and start of cancer treatment is a very stressful time for patients. Dodd's studies (1982, 1981) have found that the education given to patients as a function of the informed consent by the physician alone is not retained by patients. This is further supported by Watson (1982) who reports that this information must be reinforced.

Despite the lack of significant findings by this study, the development of a complete educational package will benefit nursing practice. The delivery of patient education is a role that is firmly entrenched in nursing practice. Content analysis of the 20 patient interviews revealed a wealth of information that patients sought after education by their physician. This clearly identifies a role for further education by Oncology Nurses during the period of time between the explanation by the physician and start of treatment.

Helping the patient resume self-care behaviors is a role of nursing

practice identified by Orem. The finding of increased antiemetic use by the group who met with investigator indicates that nurses can effect self-care behaviors in patients. The experience of cancer diagnosis and the start of treatment is a time of perceived loss of control for the patient. Interventions that help return that control to the patient may have a significant effect on patient welfare. This will warrant further research.

Finally, this study lends support to the concept of multifaceted patient response to chemotherapy and the need for combination antiemetic support of patients. Two patients in the experimental group had their antiemetic regimens changed based on the results of the measurement by this investigator. One patient receiving CMF had not been given any antiemetic support for her first course of therapy. She experienced significant nausea and vomiting. The physician provided antiemetic support and she had better control of nausea and vomiting. A second patient experienced refractory nausea and vomiting with the use of Compazine alone and required hospitalization. The physician changed the patient to Decadron and Compazine with resolution of the patient's nausea and vomiting. The patient was treated as an outpatient with minimal side effects after the first course of treatment. The nurses role in identification of symptom distress and side effects management is supported by this study. There is an ethical consideration when designing a study of nausea and vomiting secondary to chemotherapy that both groups are getting adequately prescribed antiemetics.

Future Recommendations

It is important that future nursing research continues in the area of management of side effects from chemotherapy, especially the side effect of nausea and vomiting. Studies should concentrate on specific disease sites, chemotherapy and antiemetic agents. This investigator recommends that further research in this area be done either in treatment centers with a larger referral base or in cooperation with large community based clinical trials groups. Research is still needed to clarify existing knowledge of the emetogenic effects of chemotherapy, effectivenss of antiemetics, the use of prophylactic and combined antiemetics, the effects of patient education, and behavioral methods for the control of nausea and vomiting. Studies should be done in cooperation with other investigators to ensure high accrual and adequate sample size to facilitate statistical analysis.

In addition to further study of nausea and vomiting this study suggests other areas needing further research. Research into the use and accuracy of the Karnofsky rating scale certainly is indicated. Further research of the effects of pre-chemotherapy patient education as a role of nursing will be important also. Further research into the effects of negative past perceptions of cancer and the significance of information received from well meaning friends on the patient is indicated by the findings in this study.

Conclusion

The variability of chemotherapy induced nausea and vomiting is a significant problem facing patients and their caregivers. Nurses must take

a leading role as symptom managers and promoters of patient self-care behaviors. While the results of this study did not support the hypothesis, they do support the need to continue research in this area. Also insight has been provided into the many difficulties that the study of chemotherapy induced emesis presents. This information will serve to understand the problems encountered with a study designed to study nausea and vomiting induced by chemotherapy.

The ability to give chemotherapy for the effective treatment of cancer and at the same time effectively manage side effects is something everyone involved in cancer treatment would like to achieve. Nursing will play a significant role in management of side effects. The use of patient education to give patients accurate expectations of side effects, self-care interventions and the treatment plan is well outlined as a nursing role by this study. Research into the multifaceted nature of the problem of chemotherapy induced nausea and vomiting and development of multifaceted therapy approaches continues to be a significant research problem. The ultimate control of this side effect will improve the quality of life for patients receiving treatment for cancer, as well as, improve the results of that therapy, which must remain a major focus of medical and nursing research.

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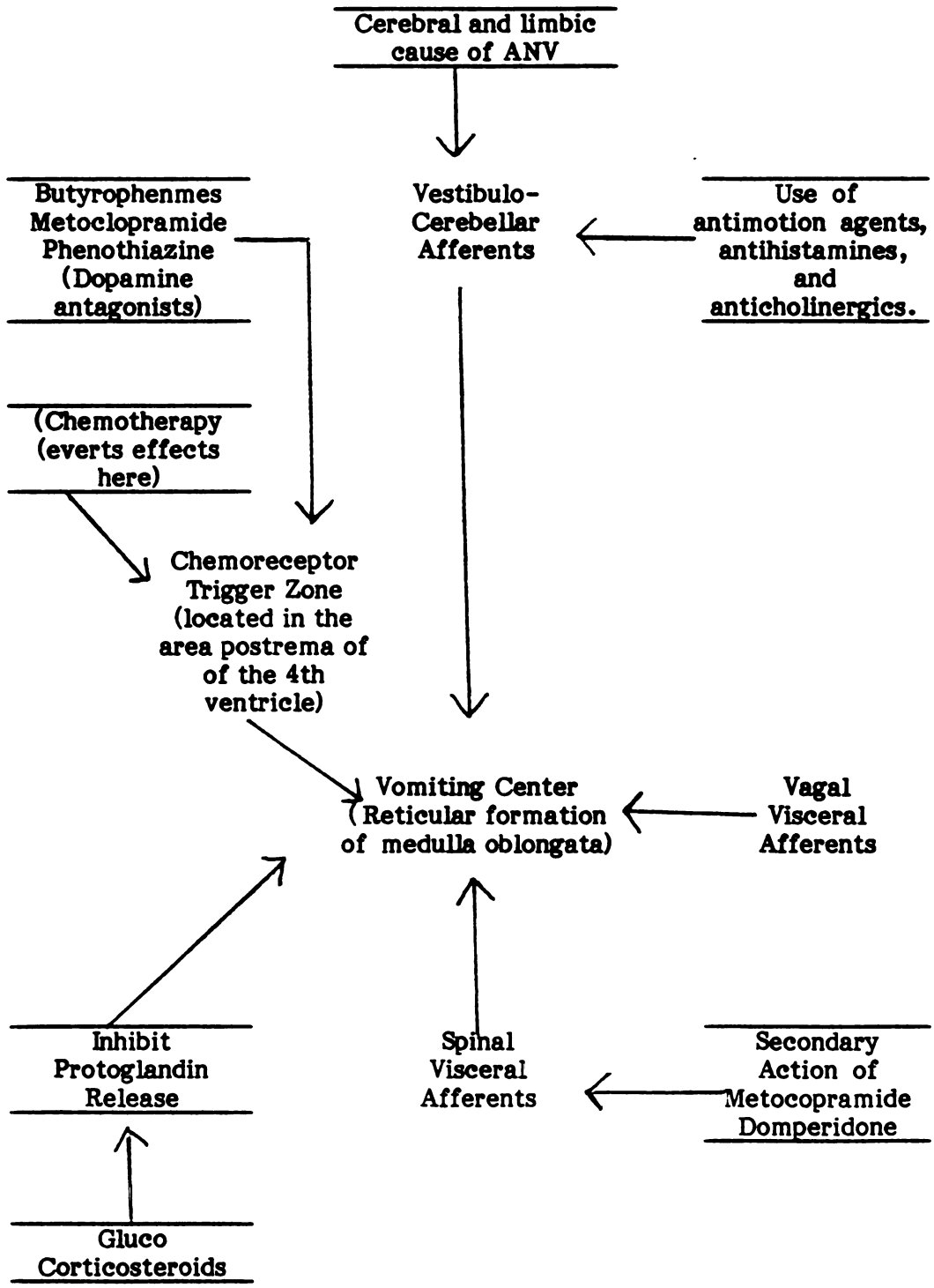
APPENDICES

APPENDIX A

Mechanisms of Nausea and Vomiting



APPENDIX B

Antiemetic Comparative Mechanisms of Action, Toxicities, and Therapeutic Effects

Drug	Site	Antiemetic Potency	Toxicities		
			Sedative effects	Extra pyramidal effects	Hypotensive effects
Phenothiazines					
Piperazine compounds					
Prochlorperazine (Compazine)	CTZ (VC)*	High	Moderate	High	Low
Thiethylperazine (Torecan)	CTZ (VC)	High	Low	Moderate	Moderate
Aliphatic coumpounds					
Chlorpromazine (Thorazine)	CTZ (VC)	Moderate	High	Moderate	High
Promethazine (Phenergan)	Labyrinth + CTZ	Low	Moderate	Low	Low
Antihistamines					
Cyclizine (Marezine)	Labyrinth, CTZ (VC)	Low	Moderate	None	None
Butyrophenones					
Haloperidol (Haldol)	CTZ (VC)	High	Low	High	Moderate
Droperidol (Inapsine)	CTZ	Moderate	Low	High	Moderate
Miscellaneous					
Trimethobenzamide (Tigan)	CTZ	Low/Moderate	Low	Low	None
Benzquinamide (EmeteCon)	CTZ (VC)	High/None	Moderate	None	Low/None
+Delta-9-tetrahydrocannabinol	Not known	High	Low	None	Low
+Metoclopramide (Reglan)	CTZ (VC)	High	Low	Low	Low
+Dexamethasone (Decadron)	Normalizes abberant gut mobility Unknown ?	High/Moderate inihibition of prostaglandins			

*CTZ, chemoreceptor trigger zone; VC; vomiting center

+Investigational.

Note: Adapted from Manual of Oncology Therapeutics (p. 337-8), K. See-Lasley and R. Ignoffo, 1981, St. Louis: C.V. Mosby Company. Copyright 1981 C.V. Mosby Company. Adapted with permission.

APPENDIX C

Time Frames of Onset and Duration of Vomiting From Antineoplastic Drugs (Intravenous Administration)

Name	Onset After Administration	Duration
Actinomycin D	1-5 hrs	24 hrs
Adriamycin	1-3 hrs	24 hrs
Ara-C	15 minutes	Several hrs
BCNU	2 hrs	24 hrs
CCNU	4-6 hrs	24 hrs
CisPlatinum	1 hr	8-12 hrs
Cytoxan	6 hrs	10 hrs
Daunamycin	1-3 hrs	24 hrs
DTIC	1-3 hrs	1-12 hrs
L Asparaginase	15 minutes	—
Methyl CCNU	1-6 hrs	6-8 hrs
Mithramycin	6 hrs	12-24 hrs
Mitomycin	1-2 hrs	4-72 hrs
Nitrogen Mustard	½-2 hrs	24 hrs
Streptozotocin	1-4 hrs	—

(Carter 1977; Knopf 1979)

*This is a partial list of drugs known to cause vomiting in most patients. Drugs not listed here cause none to moderate nausea and vomiting and time frames are not listed in literature.

APPENDIX D

Emetogenic Potential of Cancer Chemotherapy Agents

Most Severe	Somewhat Severe	Least Severe
Cisplatin	Cyclophosphamide	Vincristine
Adriamycin	Cytosine Arabinoside	Vinblastine
DTIC	Methotrexate	5-Fluorouracil
Nitrogen Mustard	Mitomycin	Bleomycin
Actinomycin	Nitrosoureas Procarbazine	6-Mercaptopurine

(John Penta, Ph.D., 1983)

APPENDIX E

Definition of key terms of Orem's Self-Care Model

Self-Care is a deliberate goal seeking action that individuals initiate and perform on their own behalf in maintaining life, health and well-being.

Dependent-Care is self-care performed by others when the individual is unable (i.e., the care of an adult for a child).

Therapeutic self-care demands are the totality of self-care actions to be performed to meet known self-care requisites.

Self-care requisites describes the purposes to be obtained by self-care. Three types identified:

1. Universal, which focuses on life processes and the maintenance of human structure and function.
2. Developmental, which focuses on human developmental processes and events during the life cycle.
3. Health-deviation requisites arise from disabilities, deviations or defects in human structure and function, and from medical diagnosis and treatment of pathologic conditions.

Self-care agency or dependent-care agency is the ability for engaging in self-care, developed in the course of day to day living through the spontaneous process of learning.

Self-care deficit or dependent-care deficit, is the qualitative or quantitative inadequacy of the self-care agency to meet self-care demands.

Nursing agency—the ability to nurse. The characteristic that qualifies persons to fill the status of nurse in social groups.

Nursing systems stands for all actions and interactions of nurses and patients in nursing practice situations. There are three types:

1. Wholly compensatory is selected when a patient cannot or should not perform any self-care actions, thus the nurse must perform them.
2. Partially compensatory is selected when the patient can perform a few, but not all, self-care actions.
3. Supportive-educative nursing system is selected when the patient can and should perform all self-care actions.

APPENDIX F

Partially Compensatory Nursing System

A. Outcomes

1. Nurse action

   a. performs some self-care measures for the patient,

   b. compensates for self-care limitations of the patient,

   c. assists the patient as required, and

   d. regulates self-care agency.

2. Patient action

   a. performs some self-care measures,

   b. regulates self-care agency, and

   c. accepts care and assistance from the nurse.

B. Subtype one

1. Patient performs universal measures of self-care; nurse performs medically prescribed measures and some universal self-care measures.

2. Methods of helping

   a. acting for or doing for the patient,

   b. guiding the patient,

   c. supporting the patient,

   d. providing a developmental environment,

   e. teaching the patient.

C. Subtype two

1. Patient learns to perform some new care measures.

2. Methods of helping

a. acting for or doing for the patient,

b. guiding the patient,

c. supporting the patient,

d. providing a developmental environment,

e. teaching the patient.

Adapted from Orem, D.E.: Nursing: Concepts of practice (2nd ed.). New York: McGraw Hill, 1980, pp. 96-101.

APPENDIX G

Outline of Patient Education Session

I. Introductions

II. Overview of purposes of chemotherapy

A. Cellular interaction of chemotherapeutic agents with bodily function.

1. In relation to normal cells

a. Hair

b. Mucus membranes in mouth and G.I. tract

c. Blood cells

2. In relation to malignant cells

B. Overview of general side effects

1. Alopecia

2. Diarrhea and/or constipation

3. Stomatitis

4. Myelosuppression

5. Nausea and vomiting

III. Specific explanation of patient's chemotherapy program.

A. Review of all chemotherapy drugs patient will be taking.

B. Explanation of specific potential side effects based on chemotherapeutic agent; explanation of benefits of medicine.

C. Guidelines for self-care intervention of side effects. Side effects management techniques information tool.

IV. Patient questions and answers.

To reinforce the above teaching, written information is provided to patients. See following bibliography for a sample of some materials.

V. Bibliography

A. Adria Labs: Chemotherapy and You; Adria Labs, 1978. Drug information sheets for specific chemotherapy agents.

B. Dodd, M. (1981); Enhancing self-care behaviors through informational interventions in Patients with cancer who are receiving chemotherapy; Doctorial dissertation. Michigan.

C. Greater Sacramento Cancer Council (1981); Can We Help?; packet of resources and pamphlets.

D. U.S. Department of Health and Human Services (1980); Chemotherapy and You; National Institute of Health, November.

E. U.S. Department of Health and Human Services (1980) Eating Hints, National Institute of Health, August.

APPENDIX H

Self-Care Measures to Control Nausea and Vomiting

Description

Your chemotherapy may cause you to experience slight nausea to severe episodes of vomiting. Whether you experience nausea and vomiting or not, it is not an indication that the drug is or is not destroying cancer cells.

Duration

Nausea and vomiting usually disappear within one week after you stop your daily regime of chemotherapy. If you are prescribed weekly chemotherapy, you are likely to experience the nausea and vomiting only after (several hours to twenty-four hours) you receive the drugs. If your nausea and vomiting are severe, your chemotherapy may be discontinued and another drug will be used to treat your disease.

Self-Care Measures

1. Ask for an anti-nausea pill, suppository, or shot before (30-60 minutes) each treatment and take your pill or suppository every four hours if you require the medicine. Marijuana may be prescribed by the physician in some states. The use of marijuana in the reduction of nausea is included in the following publication: Using Marijuana in the Reduction of Nausea Associated with Chemotherapy, by R. Raffman, Murray Publishing Co., 1979, Seattle. Available from Murray Publishing Co., 2312 3rd Avenue, Seattle, Washington 98121, $1.95.

2. Eat small snacks (5-6 times a day). Sweet or salty foods may be tolerated.

3. Rest after meals. Activity can aggravate the nausea. If you recline after meals, make sure your head is 4 inches higher than your feet.

4. Drink liquids frequently (but not with meals), if you are able (Ginger-ale, 7-Up, Coke, Pepsi). It is essential that fluids with salt be given when vomiting is severe or prolonged to make up for the body's loss of water and salt. The fluids listed contain salt and water.

5. Avoid hot foods. There orders sometime aggravate nausea. Try cold meat and fruit plates with cottage cheese, small sandwiches of bland food.

6. Take a pain pill if you are in pain before the pain gets too bad.

7. Eat crackers when nausea occurs. This may prevent dry heaves.

8. Take only fluids for several hours after the treatment. It may be helpful to eat a light snack before the treatment.

9. Try and distract yourself when nauseated from this sensation by doing activities you particularly enjoy, e.g., music, sleeping, talking about other things, self hypnosis, slow mouth breathing.

10. Avoid greasy foods because they take longer to leave the stomach, while carbohydrate-containing food leaves the stomach much quicker. The volume of food in the stomach can be reduced by avoiding liquids at mealtime and taking them 1 hour before or after eating.

11. Keep an estimate of the intake of fluids and output of urine to assess possible dehydration. The signs and symptoms of dehydration are dryness of the skin and mouth, decreased urine volume and sunken eyes.

12. Talk with your physician about scheduling the treatment later in the day. The effects of nausea and vomiting may cause you to lose the

evening meal, but you may regain some appetite by morning. Keep track of your sickness patterns, record the onset and duration. By knowing your particular pattern of sickness you can determine better when to do the self-care measures.

13. Clean your mouth well before meals and brush your teeth soon after eating.

14. Rinse your mouth with a mouth wash following a vomiting episode.

15. Avoid doing your own cooking if the odor makes you nauseated. Sit in another room or take a walk while the food is being cooked.

16. Eat slowly so that only small amounts of food enter your stomach at one time.

17. Chew your food well so it can be digested more easily.

18. Do not make yourself eat more than you can possibly manage.

Consult Physician or Nurse if:

1. You have been vomiting and have not been able to keep anything down for twenty-four hours and/or you are experiencing the signs and symptoms of dehydration.

2. You are bloated, having pain or a swollen stomach before an episode of vomiting and these symptoms are relieved by vomiting.

Taken with permission from Dodd, M. (in press). Handbook for Managing the Side Effects of Chemotherapy and Radiation Therapy. Norwalk Conn, Appleton Century and Crofts Pubs.

APPENDIX I

Chemotherapy Drug Information Sheets

ADRIAMYCIN

ır Oncologist, the Cancer Specialist who is consulting on your illness, ; recommended that you be treated with chemotherapy (chemicals or drugs ;d to treat cancer). After careful evaluation and based on previous ›erience with situations similar to yours he recommends the use of the ıg Adriamycin.

:e you will find listed some of the side effects that you may experience ile taking this drug and some of the things you can do to help tolerate ;m better.

JSEA, VOMITING AND DIARRHEA

ı may experience this for a few days following treatment. You will be :ered medication to help control the nausea. If you do have diarrhea ı may be more comfortable if you take fluids or soft, bland foods, ›ecially foods such as boiled milk and cheese. Should the area around ; anus become sore, try using Vitamin A & D ointment. This is available drug stores without a prescription. Your doctor should be informed of ;se side effects at your next visit.

OPECIA (loss of hair)

most all patients lose their hair while taking Adriamycin. This is be- use the hair cells are very fast growing, as are the cancer cells, and nce Adriamycin is aimed at the fast growing cancer cells, it also affects .e hair cells. This may include all body hair. The hair will grow back ter you have received your full course of the drug. When it grows back . might be slightly different in texture and color. You may wish to have wig or hair piece selected within two weeks of your first treatment.

'OMATITIS (sores in the mouth)

ıtients experience this in varying degrees; some have redness in their)uths and some have sores like fever blisters. It is very important that)u maintain good mouth care in order to prevent infections. If you have :omatitis this should be reported to the doctor before you take your next)se of medicine. If the soreness causes difficulty eating the doctor can :escribe a medication to take some of the discomfort away during meals.)ft, bland foods at medium temperatures may make eating more pleasant. ıe following is suggested for oral care:

1. Brush teeth after each meal with a soft bristle brush.
2. Use mouth wash with each brushing and before bed. You may use one of the following:
   a. Commercial mouth wash
   b. Salt water
   c. A mixture of 1 part hydrogen peroxide to 4 parts salt water. For salt water mixture use 1 tsp. salt to 1 qt. boiled water.

)MOR PAIN

)u may notice pain in the area of your tumor following your injection.

)NE MARROW SUPPRESSION

)ur bone marrow produces your blood cells. Adriamycin can temporarily)wer the number of cells produced for fighting infection (the white lood cells or WBCs) and for clotting the blood (platelets). Should you ave unusual bleeding or bruising or have a fever, cough, urine burning, sore that is not healing, or any other sign of infection, notify your)ctor immediately. It is of the utmost importance that treatment of hese problems start right away. Your doctor will order blood tests as eeded to chekc your blood cells.

YOCARDIAL (HEART) DAMAGE

ne of the possible side effects of Adriamycin after prolonged use is eart muscle damage. After much study and experience, it has been shown hat chances of heart damage are small if the total amount of drug taken oes not exceed a certain amount. This total amount is calculated for each ndividual based on his height and weight. Careful records are kept so hat this total is not exceeded. In order to keep careful watch, the octor will have you get an EKG (tracing of your heartbeat) every few onths. This way he will be alerted for changes. You should be aware hat this heart damage may not show up until after the treatment has een stopped. Remember that the chance of this damage is small if the otal dose calculated for you is not exceeded. Should you have questions oncerning this, please ask the Oncologist.

)ARKENING OF SKIN EXPOSED TO RADIATION

f you have received radiation therapy you may notice darkening and in-reased sensitivity of the area treated. You may also notice that your kin is very sensitive to the sun and that you sunburn easily.

RED URINE

Your urine will turn red briefly after receiving the drug. It is caused)y eliminating the drug, which is red, from the body. It is not harmful.

SORES AROUND VEINS

If this drug leaks outside the vein, a sore area may develop. The nurse will use maximum caution to try to prevent this, but with fragile veins it may sometimes still occur. Please notify the doctor promptly if a sore area develops.

BLEOMYCIN

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he has recommended the use of the drug Bleomycin.

Here you will find listed some of the side effects you may experience while taking this drug, and some of the things you can do to tolerate them better.

STOMATITIS (Sores in the mouth)

Patients experience this in varying degrees. Some have redness in their mouth and some have sores like fever blisters. It is very important that you maintain good mouth care in order to prevent infections. If you have stomatitis this should be reported to the physician before you take your next dose of medicine. If the soreness causes difficulty in eating, the physician can prescribe a medication to take some of the discomfort away during meals. Soft, bland foods at medium temperatures may make eating more pleasant. The following is suggested for oral care:

1. Brush teeth after each meal with a soft bristle brush.

2. Use mouth wash with each brushing and before bed. You may use one of the following:
   a. Commercial mouth wash.
   b. Salt water. (For salt water mixture use 1 tsp. salt to 1 qt. boiled water).
   c. A mixture of 1 part hydrogen peroxide to 4 parts salt water.

FEVER AND FLU-LIKE SYMPTOMS

These may occur a few hours after your treatment. You will be given two tablets of Tylenol at the time of the injection to help you tolerate this better. You then may take the Tylenol every four hours as long as the symptoms persist. If your fever is greater than 100^{o} and the Tylenol does not bring it down, you should then notify the physician.

ALOPECIA (Loss of hair)

Some patients experience a thinning of their hair while taking Bleomycin. This is because the hair cells are very fast growing, as are the cancer cells, and since Bleomycin is aimed at the fast growing cancer cells, it also affects some of the hair cells. This hair will grow back after you have received your full course of the drug. When it grows back, it might be slightly different in texture and color.

TUMOR PAIN

You may notice pain in the area of your tumor following your injection.

SKIN AND NAIL CHANGES

With time, you may notice thickening of the palms of your hands or knuckes, or soreness of tongue and lips.

NAUSEA AND VOMITING

These rarely occur. You will be offered medication if necessary to help reduce these symptoms.

PULMONARY (LUNG) COMPLICATIONS

One of the side effects that some patients experience with Bleomycin is lung damage. Damage occurs usually after taking a large amount of this drug over a period of months. Your physician will add up your doses in order to keep the total amount below a certain level. He will check X-rays and possibly take breathing tests from time to time.

SPECIAL PRECAUTIONS

Patients with Lymphomas (cancer of lymph gland cells) may be especially sensitive to the side effects of this drug. Two small test doses will be given if you have this type of disease and you will be checked carefully for the side effects.

CYCLOPHOSPHAMIDE (CYTOXAN)

ur Oncologist, the Cancer Specialist who is consulting on your illness, s recommended that you be treated with chemotherapy (chemicals or drugs ed to treat cancer). After careful evaluation and based on previous perience with situations similar to yours he recommends the use of the ug Cytoxan.

re you will find listed some of the side effects that you may experience ile taking this drug and some of the things you can do to help tolerate em better.

AUSEA AND VOMITING

ou may experience this for a few days following treatment. It is usually layed from 3-18 hours after treatment. You will be offered medication help prevent this.

OPECIA (hair loss)

me patients lose their hair while taking Cytoxan. This is experienced approximately 50% of the patients taking this drug. This is because e hair cells are very fast growing, as are the cancer cells, and since toxan is aimed at the fast growing cancer cells, it also affects the air cells. This may include all body hair. The hair will grow back fter you have received your full course of the drug. When it grows back t might be slightly different in texture and color. You may wish to ave a wig or hair piece selected within two weeks of your first treatment.

LOOD IN THE URINE

his is not an infection. Cytoxan is eliminated through your bladder 24-8 hours after you receive your treatment. Cytoxan can cause irritation o your bladder while this is happening. You may prevent this by drinking ore water or other fluids for a few hours before receiving the drug, and or 24-48 hours after it. This will help wash the drug out of your system. e sure to try to urinate frequently. If you find blood in your urine, otify your doctor.

ONE MARROW SUPPRESSION

our bone marrow produces your blood cells. Cytoxan can temporarily lower he number of cells produced for fighting infections (the white blood cells r WBCs) and for clotting the blood(platelets). Should you have unusual leeding or bruising or have a fever, cough, urine burning, a sore that s not healing, or any other sign of infection, notify your doctor imme-diately. It is of the utmost importance that treatment of these problems tart right away. Your doctor will order blood tests as needed to check your blood cells.

CCNU

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug CCNU.

Here you will find listed some of the side effects that you may experience while taking this drug, and some of the things that you can do to help tolerate them better.

NAUSEA AND VOMITING

You may experience one or both of these for a few days following treatment. You will be offered medication that is generally effective to help control the nausea. It may help to take antinausea medicine and CCNU at bedtime, so that you may sleep through the nausea period.

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. CCNU can temporarily lower the number of cells produced for fighting infections (white blood cells or WBC's) and clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your physician immediately. It is of the utmost importance that treatment of these problems start right away. Your physician will order blood tests as needed to check your blood cells.

NOTE: The effects of CCNU on the blood cells are delayed to about 4-6 weeks.

DTIC

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug DTIC.

Here you will find some of the side effects that you may experience while taking this drug and some of the things you can do to help tolerate them better.

NAUSEA AND VOMITING, LOSS OF APPETITE

About one to three hours after you receive your injections you may experience nausea and vomiting. You will be offered medication to help prevent or reduce this. This usually only lasts one to twelve hours. Some loss of appetite may persist for up to two weeks.

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. DTIC can temporarily lower the number of cells produced for fighting infections (white blood cells or WBC's) and clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your physician immediately. It is of the utmost importance that treatment of these problems start right away. Your physician will order blood tests as needed to check your blood cells.

FLU-LIKE SYMPTOMS

After a few treatments you may feel like you have the "flu" by experiencing muscle aches and fever. This may last up to ten days after treatment.

ALOPECIA (loss of hair)

Patients rarely experience this.

METALLIC TASTE

Some patients experience this. In order to make meals more pleasant, practice good mouth care frequently and before and after meals. Experiment with different seasonings to see which makes food most palatable.

ETOPOSIDE (VP16)

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours he recommends the use of the drug VP16.

Here you will find listed some of the side effects that you may experience while taking this drug, and some of the things you can do to help tolerate them better.

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. VP16 can temporarily lower the number of cells produced for fighting infections (the white blood cells or WBC'S) and for clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your doctor immediately. It is of the utmost importance that treatment of these problems start right away. Your doctor will order blood tests as needed to check your blood cells.

NAUSEA AND VOMITING, LOSS OF APPETITE

About one to three hours after you receive your injections you may experience nausea and vomiting. You will be offered medication to help prevent or reduce this. This usually only lasts one to twelve hours. Some loss of appetite may persist for up to two weeks.

ALOPECIA (loss of hair)

Some patients lose their hair while taking VP16. This is because the hair cells are very fast growing, as are the cancer cells, and since VP16 is aimed at the fast growing cancer cells, it also affects the hair cells. This may include all body hair. The hair will grow back after you have received your full course of the drug. When it grows back, it might be slightly different in texture and color. You may wish to have a wig or hair piece selected within two weeks of your first treatment.

IRRITATION TO VEINS

Sometimes VP16 can cause an irritation or soreness in the vein it is injected into. This medicine is diluted and given slowly to prevent this. If your arm becomes sore or if you develop a reddened area at the site of the injection report this to your doctor or nurse.

NERVOUS SYSTEM

Rarely VP16 will affect your nervous system. If you notice any tingling or numbness in your arms or legs or any weakness, this should be reported to the physician. These symptoms usually go away after stopping the medication.

5-FLUOROURACIL (5FU)

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug 5-Fluorouracil (5FU).

Here you will find listed some of the side effects that you may experience while taking this drug, and some of the things you can do to tolerate them better.

FATIGUE

May occur during the first 24 hours after your first treatment. You may need to plan extra rest periods during this time.

ANOREXIA (Decrease or lack of appetite)

While receiving 5FU you may experience a decrease in appetite, You should make every effort to maintain good nutrition. This is both to help you feel stronger and to help the drugs work better for you. Your diet should be high in calories and protein. Good sources of protein are meat (beef, chicken, fish), cheese, beans and nuts. Eating smaller meals more frequently may also help. If you have any questions or need help in meal planning, refer to the "Eating Hints" booklet.

NAUSEA

You may experience this for a few days following treatment. You will be offered medication that is generally effective to help control the nausea.

DIARRHEA

If you do have diarrhea, you may be more comfortable if you take fluids or soft, bland foods, especially foods such as boiled milk and cheese. Should the area around the anus become sore, try using vitamin A & D Ointment. This is available in drug stores without a prescription. Your physician's office should be informed if this side effect is severe or lasts longer than a few days.

SOMATITIS (Sores in the mouth)

Patients experience this in varying degrees: Some have redness in their mouths and some have sores like fever blisters. It is very important that you maintain good mouth care in order to prevent infections. If you have stomatitis, this should be reported to the physician before you take your next dose of medicine. If the soreness causes difficulty in eating, the physician can prescribe a medication to take some of the discomfort away during meals. Soft, bland foods at medium temperatures may make eating more pleasant.

The following is suggested for oral care:

1. Brush teeth after each meal with a soft bristle brush.
2. Use mouth wash with each brushing and before bed. You may use one of the following:
   a. Commercial mouth wash.
   b. Salt water.
   c. A mixture of 1 part hydrogen peroxide to 4 parts salt water. (For salt water, use 1 tst. salt to 1 quart boiled water).

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. 5FU can temporarily lower the number of cells produced for fighting infections (the white blood cells or WBC's) and for clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your physician immediately. It is of the utmost importance that treatment of these problems start right away. Your physician will order blood tests as needed to check your blood cells.

METHOTREXATE

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug Methotrexate.

Here you will find lsited some of the side effects that you may experience while taking this drug and some of the things you can do to help tolerate them better.

NAUSEA AND VOMITING AND DIARRHEA

You may experience one or more of the above for a few days following treatment. If they occur, the physician should be phoned; he will prescribe medication to relieve them.

STOMATITIS (Sore areas in the mouth)

The physician should be phoned if this occurs. Medication is available to reduce the discomfort. Soft, bland foods at medium temperatures may make eating more pleasant. It is very important that you maintain good mouth care in order to prevent infections. The following is suggested for oral care:

1. Brush teeth after each meal with a soft bristle brush.
2. Use mouth wash with each brushing and before bed. You may use one of the following:
   a. Commercial mouth wash.
   b. Salt water.
   c. A mixture of 1 part hydrogen peroxide to 4 parts salt water. (For salt water use 1 tsp. salt to 1 quart boiled water).

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. Methotrexate can temporarily lower the number of cells produced for fighting infections (the white blood cells or WBC's) and clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your physician immediately. It is of the utmost importance that treatment of these problems start right away. Your physician will order blood tests as needed to check your blood cells.

CAUTION: Use of certain medications can interfere with the effectiveness of Methotrexate; therefore, do not take any medication without asking your physician. This includes even vitamins (especially the "B" vitamins).

MUTAMYCIN (MITOMYCIN)

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug Mutamycin (Mitomycin).

Here you will find listed some of the side effects that you may experience while taking this drug, and some of the things you can do to help tolerate them better.

NAUSEA AND VOMITING AND DIARRHEA

You may experience this for a few days following treatment. You will be offered medication that is generally effective to help control the nausea. If you do have diarrhea, you may be more comfortable if you take fluids of soft, bland foods, especially foods such as boiled milk and cheese. Should the area around the anus become sore, try using vitamin A & D ointment. This is available in drug stores without a prescription. Your physician's office should be informed if either of these side effects are severe or last longer than a few days.

ANOREXIA (Decrease or lack of appetite)

While receiving Mitomycin you may experience a decrease in appetite. You should make every effort to maintain good nutrition. This is both to help you feel stronger and to help the drugs work better for you. Your diet should be high in protein. Good sources of protein are meat, cheese, beans and nuts. Eating smaller meals more frequently may also help. If you have any questions or need help in meal planning, we have resource material available to you.

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. Mitomycin can temporarily lower the number of cells produced for fighting infections (the white blood cells or WBC's) and for clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your physician immediately. It is of the utmost importance that treatment of these problems start right away. Your physician will order blood tests as needed to check your blood cells.

ALOPECIA (loss of hair)

Some patients lose their hair while taking Mitomycin. This is because the hair cells are very fast growing, as are the cancer cells, and since Mitomycin is aimed at the fast growing cancer cells, it also affects the hair cells. This may include all body

hair. The hair will grow back after you have received your full course of the drug. When it grows back, it might be slightly different in texture and color. You may wish to have a wig or hair piece selected within two weeks of your first treatment.

STOMATITIS (sores in the mouth)

Patients experience this in varying degrees: Some have redness in their mouths and some have sores like fever blisters. It is very important that you maintain good mouth care in order to prevent infections. If you have stomatitis, this should be reported to the physician before you take your next dose of medicine. If the soreness causes difficulty in eating, the physician can prescribe a medication to take some of the discomfort away during meals. Soft, bland foods at medium temperatures may make eating more pleasant. The following is suggested for oral care:

1. Brush teeth after each meal with a soft bristle brush.
2. Use mouth wash with each brushing and before bed. You may use one of the following:
   a. Commercial mouth wash
   b. Salt water
   c. A mixture of 1 part hydrogen peroxide to 4 parts salt water. (For salt water mixture use 1 tsp. salt to 1 quart boiled water).

SORES AROUND VEINS

If this drug leaks outside the vein, a sore area may develop. The nurse will use maximum caution to try to prevent this, but with fragile veins it may sometimes still occur. Please notify the physician promptly if a sore area develops.

FEVER AND FATIGUE

May occur within a few days of your first treatment. You may take Tylenol to help control these symptoms. You are asked not to take aspirin because this may cause further decrease in blood clotting (platelets).

NITROGEN MUSTARD

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug Nitrogen Mustard.

Here you will find listed some of the side effects you may experience while taking this drug, and some of the things you can do to help tolerate them better.

NAUSEA AND VOMITING

You may experience this immediately when receiving your treatment. You will be offered medication to help control this. It may be necessary for you to take this medication one half hour before you receive your treatment. Vomiting usually stops within eight hours but nausea and lack of appetite may persist for twenty-four hours. Caution: After taking most nausea medications you should not drive a car. If you take this medication before your treatment, be sure to have someone else drive you to the office.

BONE MARROW SUPRESSION

Your bone marrow produces your blood cells. Nitrogen Mustard can temporarily lower the number of the cells produced for fighting infections (the white blood cells or WBC's), and clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your doctor immediately. It is of the utmost importance that treatment of these problems start right away. Your doctor will order blood tests as needed to check your blood cells.

SORES AROUND VEINS

If this drug leaks outside the vein, a sore area may develop. The nurse will use maximum caution to try to prevent this, but with fragile veins, it may sometimes still occur. Please notify the doctor promptly if a sore area develops.

PREDNISONE

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug Prednisone.

Here you will find listed some of the side effects that you may experience while taking this drug, and some of the things you can do to help tolerate them better.

SHORT TERM SIDE EFFECTS:

STOMACH IRRITATION OR INDIGESTION

While taking Prednisone you may experience stomach irritation or indigestion. It is very important that Prednisone be taken with medication to help counteract this. Your physician will also ask you to take Mylanta, Maalox or a similar medication to help prevent indigestion. If despite this, you still experience indigestion or "heartburn" while taking Prednisone, this should be reported to your physician.

INCREASE IN APPETITE

You may experience an increase in your appetite while taking Prednisone

FLUID RETENTION OR SWELLING

Prednisone can cause you to retain salt which may lead to fluid retention and swelling. It is because of this that you should limit the amount of salt in your diet. Your physician will give you guidelines to follow.

INCREASED SUSCEPTIBILITY TO INFECTION

Prednisone can reduce your resistance to infection. Should you have a fever, cough, urine burning, a sore that is not healing or any other sign of infection, notify your physician. It is important to start treatment right away.

EUPHORIA

You may experience an increased sense of well being while taking Prednisone. It may also make you nervous.

LONG TERM SIDE EFFECTS:

INCREASED FAT DEPOSITS ON BODY AND FACE

After taking Prednisone for a prolonged period of time, this drug can cause your body to have increased fat deposits. You may especially notice this in your face which will take on a rounded appearance or "moon face." You may also notice an increase in the size of your abdomen. Weight gain may occur. This is all reversible when the medication is stopped.

EASY BRUISING AND THINNING OF THE SKIN

Prednisone can cause the skin to lose a substance called collagen. Your skin may become somewhat thinner and you may bruise more easily.

SUGAR DIABETES

Prolonged use of Prednisone can cause you to develop sugar diabetes. This will go away when you stop taking the drug. Your physician will check for this at intervals and treat if necessary.

NOTE: MOST OF THESE SIDE EFFECTS ARE EXPERIENCED AFTER PROLONGED USE OF PREDNISONE. THEY ARE ALL REVERSIBLE AFTER YOU STOP TAKING THE MEDICATION.

PROCARBAZINE

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours, he recommends the use of the drug Procarbazine.

Here you will find listed some of the side effects that you may experience while taking this drug and some of the things you can do to help tolerate them better.

NAUSEA AND VOMITING AND DIARRHEA

You may experience these while taking Procarbazine. You will be offered medication that can help reduce these symptoms. The amount of nausea often decreases after a time, even while continuing to take the drug. Diarrhea is less common; if it is bothersome notify the physician.

BONE MARROW SUPPRESSION

Your bone marrow produces your blood cells. Procarbazine can temporarily lower the number of cells produced for fighting infections (the white blood cells or WBC's) and clotting the blood (platelets). Should you have unusual bleeding or bruising or have a fever, cough, urine burning, a sore that is not healing, or any other sign of infection, notify your physician immediately. It is of the utmost importance that treatment of these problems start right away. Your physician will order blood tests as needed to check your blood cells.

NERVOUS SYSTEM DAMAGE

Rarely Procarbazine will affect your nervous system. If you notice any tingling or numbness in your arms or legs or any weakness, this should be reported to the physician. These symptoms usually go away after stopping the medication.

NOTE: While taking this medicine the following foods should be avoided: Beer, yogurt, Brewer's yeast, wine, aged cheese, pickled herring, chicken livers and bananas. These foods can cause a reaction with this medicine.

VINCRISTINE

Your Oncologist, the Cancer Specialist who is consulting on your illness, has recommended that you be treated with chemotherapy (chemicals or drugs used to treat cancer). After careful evaluation and based on previous experience with situations similar to yours he recommends the use of the drug Vincristine.

Here you will find listed some of the side effects that you may experience while taking this drug, and some of the things you can do to help tolerate them better.

NERVOUS SYSTEM CHANGES

If you experience any of the following, report them to your doctor's office for further instructions before you receive your next injection: Change in sensation, tingling, muscle weakness, jaw pain, loss of coordination, unsteady gait, severe constipation. These are usually reversible. Note: Most patients taking this drug have some degree of constipation. You can usually control this by eating a diet high in roughage and using stool softeners and laxatives. Ask your doctor which of these to use and how often.

ALOPECIA (Loss of hair)

Some patients lose their hair while taking Vincristine. This is because the hair cells are very fast growing, as are the cancer cells, and since Vincristine is aimed at the fast growing cancer cells, it also effects the hair cells. The hair will grow back after the drug is stopped but it may be a slightly different texture or color. You may wish to select a wig or hairpiece if your hair should start to fall out.

NAUSEA AND VOMITING

Rarely occurs. You will be offered medication to help prevent this if it occurs.

MENTAL DEPRESSION

Some patients do experience some depression, but do not realize it is an effect of the drug. If you are aware of the cause, the depression may not be so disturbing.

STOMATITIS (Sores in the mouth)

This rarely occurs. You should report this to the doctor's office if it does occur and you will be offered medicine to make you more comfortable.

SORES AROUND VEINS

If this drug leaks outside the vein, a sore area may develop. The nurse will use maximum caution to try to prevent this, but with fragile veins it may sometimes still occur. Please notify the doctor promptly if a sore area develops.

hair. The hair will grow back after you have received your full course of the drug. When it grows back, it might be slightly different in texture and color. You may wish to have a wig or hair piece selected within two weeks of your first treatment.

STOMATITIS (sores in the mouth)

Patients experience this in varying degrees: Some have redness in their mouths and some have sores like fever blisters. It is very important that you maintain good mouth care in order to prevent infections. If you have stomatitis, this should be reported to the physician before you take your next dose of medicine. If the soreness causes difficulty in eating, the physician can prescribe a medication to take some of the discomfort away during meals. Soft, bland foods at medium temperatures may make eating more pleasant. The following is suggested for oral care:

1. Brush teeth after each meal with a soft bristle brush.
2. Use mouth wash with each brushing and before bed. You may use one of the following:
   a. Commercial mouth wash
   b. Salt water
   c. A mixture of 1 part hydrogen peroxide to 4 parts salt water. (For salt water mixture use 1 tsp. salt to 1 quart boiled water).

SORES AROUND VEINS

If this drug leaks outside the vein, a sore area may develop. The nurse will use maximum caution to try to prevent this, but with fragile veins it may sometimes still occur. Please notify the physician promptly if a sore area develops.

FEVER AND FATIGUE

May occur within a few days of your first treatment. You may take Tylenol to help control these symptoms. You are asked not to take aspirin because this may cause further decrease in blood clotting (platelets).

APPENDIX J

Script of Patient Education

SCRIPT FOR PATIENT EDUCATION STUDY

Hello, Mr./Mrs. _____, my name is Patti Palmer. I'm a nurse who is in graduate school at the University of California in San Francisco. Do you have any questions about the information sheet you've just read or the study that I could answer now?

You have been selected to be a part of the group who will be receiving the informational session with me prior to receiving your chemotherapy. I would like to tape this session for you to have to take home if that is ok with you.

Before starting I'd like to explain the primary reason I am involved in this study. Chemotherapy can cause side effects in some people. Sometimes there is nothing that can be done to prevent these from happening. After many years of working with patients taking chemotherapy for the first time I have come to know that nausea and vomiting is one of the most expected and feared side effects. It is also because of my experience that I have discovered that this side effect can be prevented or controlled with the use of medicines and information about the chemotherapy. I have designed this study to formally espouse that link.

The purpose of this session is threefold: 1) to teach you in general how chemotherapy works and how side effects happen, 2) to give you specific self care measures to help control nausea and vomiting, and 3) to answer any questions you might have about chemotherapy and cancer. I have found

through experience that it is difficult for patients to retain information given to them during this period of time and that much of what you are told needs to be repeated many times. That's ok. Your nurse here in the office will be happy to review this with you and I will be sending written information home with you as well as the tape. So if you find you don't understand something after you get home, don't hesitate to call your nurse here, your physician, or myself.

First I would like to explain how generally most chemotherapy medicines work. The word chemotherapy simply means chemicals to treat cancer. These chemicals are most often given in the form of shots in the vein, but can also be given in shots in the muscle or pills. A chemical that just treats cancer has not been invented yet so they use the next best thing, a chemical that interacts to decrease the growth of rapidly growing cells. Most chemotherapy drugs work this way. There are many normal cells in your body that are also rapidly growing such as, your hair, the membrane inside your mouth--this membrane also goes down your throat, into your stomach, through your intestines, and out your rectum--and most important are the blood cells. The blood cells are made in your bone marrow, which is located in the center of your bones. We are concerned about three blood cells: the red blood cell, which carries oxygen and nourishes your body, the white blood cells which fight infection, and the platelet cells which help clot the blood. Your doctor will be watching these cells

very closely with blood tests and it will be based on these blood tests that your chemotherapy is given every 3-4 weeks. This effect on the blood cells starts to happen 10-14 days after you have your chemotherapy and your body generally replaces the cells by 3-4 weeks after the date you took your chemotherapy. This is why your chemotherapy is spaced 3-4 weeks apart.

I would like to review the specific side effects of the medicines you will be receiving. Everyone who is about to receive chemotherapy expects 2 side effects: to lose their hair and to vomit. The truth is that not all chemotherapy drugs cause these side effects and there are interventions that can be done to minimize or control these. Very rarely are people so sick from these drugs that they cannot continue therapy and their normal activities. In fact, I've known of several people who are able to take these medications and go right back to work or about their normal activities without feeling nauseated. I'd like you to look at the two drug information sheets I've given you and will go through them together. Review Adriamycin and Cytoxan drug information sheets and self care for nausea and vomiting.

Answer any questions. Review data collection tools.

APPENDIX K

Informed Consent for Study

My name is Kim Thompson / Patti Palmer and I am a nurse doing graduate work at the University of California, San Francisco. I am conducting a study with patients who are receiving chemotherapy for the first time. Your doctor has given me permission to ask you to participate but the decision to participate is entirely yours. I do not work for the doctors so they will not know if you decide to participate of not. May I tell you more about my project?

This study is to determine the effect that an education and support session with me prior to chemotherapy has on the side effects you experience after taking chemotherapy. This study is important so that adjustments can be made in the information patients receive prior to chemotherapy in the future.

If you agree to participate in this study, I will ask you to complete a questionnaire that will take about 15 minutes. Then you will be randomly assigned to one of two groups. One group will be asked to fill out a questionnaire the evening after the chemotherapy is given, 12 hours after that and 12 hours after that, for a total of 3 times. It will take about 5 minutes each time to fill out this questionnaire. If you are in the second group you will receive a 30-45 minute education session prior to chemotherapy and then you'll be asked to fill out the questionnaire as in the first group. This is the only difference between the two groups. Each group will receive the medical and nursing care that all other patients

receive in your doctor's office.

Your responses on the questionnaire will be confidential and your anonymity will be protected. Your name will not appear on the questionnaire. You may refuse to answer any questions you do now wish to answer. No one on the office staff, including your doctors, will know your specific answers. When I report the results of the study to them, I will summarize all of the responses I get from all the patients who participate so that no individual can be identified.

As I mentioned earlier, you are free to decide to participate or not and may withdraw your consent to participate at any time without explanation. Whether you participate or not will not affect the care you receive from your physician or nurses. Your participation will not interfere with your doctor's appointment or when the doctor's nurse meets with you again. If your doctor is ready to see you before you finish the questionnaire, you may complete the questionnaire after your appointment or you may withdraw from this study.

There are no known risks to you for participating in this study, and the information you provide may be of great importance to improving the kind of health care provided to patients like yourself.

Do you have any questions?

Are you willing to participate? (If Yes) You may begin the questionnaire and after you have completed it I will tell you what group you have been assigned to.

APPENDIX L

Adapted Symptom Distress Scale

Adapted Symptom Distress Scale Form 1

Directions: Draw a circle around the sentence in each row that best describes how you feel.

Date_____

Time_____

I.D. Number_____

	Degrees of Distress			
I never feel any nausea or sickness at my stomach.	I seldom feel any nausea or sickness at my stomach.	I am frequently nauseous or sick at my stomach.	I am nauseous or sick at my stomach most of the time.	I suffer from nausea or sickness at my stomach all the time.
I never feel sick at my stomach.	When I am sick at my stomach, it is slightly severe.	When I am sick at my stomach, it is moderately severe.	When I am sick at my stomach, it is very severe.	When I am sick at my stomach, I am as nauseated as I can be.
I never throw up.	I seldom throw up.	I throw up frequently - several times a week.	I throw up at least once almost every day.	I throw up several times almost every day.
I have not felt any distress from throwing up.	When I throw up it is with slight distress.	When I throw up it is with moderate distress.	When I throw up it is with great distress.	I throw up with as severe distress as can be.
I cannot stand the thought of food.	I have to force myself to eat my food.	I don't enjoy my food.	I sometimes do not enjoy my food.	I enjoy my food.
I sleep well.	I occasionally have trouble sleeping.	I frequently have trouble sleeping.	I have trouble sleeping most of the time.	I cannot sleep.
I never have pain.	I have pain once in a while.	I frequently have pain - several times a week.	I am in some degree of pain most of the time.	I am in some degree of pain all of the time.
I never have pain.	The pain I have is not intense.	The pain I have is moderately intense.	The pain I have is very intense.	The pain I have is most unbearable.

Turn page over - continue on back

Adapted Symptom Distress Scale Form 1 (continued)

Degrees of Distress				
I am very tired all of the time.	I am tired most of the time.	I am frequently tired.	I am occasionally a little tired.	I feel rested.
I can concentrate.	I sometimes have trouble concentrating.	I frequently have trouble concentrating.	I have trouble concentrating most of the time.	I just can't seem to concentrate at all.
I am extremely upset about my appearance.	I am very upset about my appearance.	I am moderately upset about my appearance.	I am a little upset about my appearance.	I feel good about my appearance.
I breathe easily and without difficulty.	I occasionally have difficulty breathing.	I often have difficulty breathing.	I have difficulty breathing most of the time.	I can never breathe without difficulty.
I have no distress from my bowel movements.	My bowel movements cause me slight distress.	My bowel movements cause me moderate distress.	My bowel movements cause me great distress.	My bowel movements cause me as severe distress as can be.
I am not worried about things.	I am a little worried about things.	I am moderately worried about things.	I am very worried about things.	I am as worried as I can be.
I am as afraid as I can be.	I am very afraid about things.	I am moderately afraid of things.	I am a little fearful of things.	I am not fearful of things.
I never cough.	I have an occasional cough.	I have coughing spells.	I frequently have coughing spells.	I have persistent and severe coughing spells.

APPENDIX M

Rhodes Index of Nausea and Vomiting

INV-FORM 2

Directions: Draw a circle around the sentence in each row that most clearly corresponds to your experience. Please make one mark on each line.

I.D. Number_____ Date_____

Time_____ Time of C.T._____

I threw up seven or more times during the last 12 hours.	I threw up five-six times during the last 12 hours.	I threw up three-four times during the last 12 hours.	I threw up one-two times during the last 12 hours.	I did not throw up during the last 12 hours.
During the last 12 hours I have not felt any distress from retching or dry heaves.	During the last 12 hours I have felt great distress from retching or dry heaves.	During the last 12 hours I have felt moderate distress from retching or dry heaves.	During the last 12 hours I have felt mild distress from retching or dry heaves.	During the last 12 hours I have felt as severe distress from retching or dry heaves as can be.
During the last 12 hours I have felt as severe distress from vomiting as can be.	During the last 12 hours I have felt great distress from vomiting.	During the last 12 hours I have felt moderate distress from vomiting.	During the last 12 hours I have felt mild distress from vomiting.	During the last 12 hours I have not felt any distress from vomiting.
I have not felt nauseated or sick at my stomach during the last 12 hours.	I have felt nauseated or sick at my stomach for one hour or less during the last 12 hours.	I have felt nauseated or sick at my stomach for two-three of the last 12 hours.	I have felt nauseated or sick at my stomach four to six of the last 12 hours.	I have felt nauseated or sick at my stomach more than six of the last 12 hours.
During the last 12 hours I have not felt any distress from nausea/sickness as can be.	During the last 12 hours I have felt mild distress from nausea or sick at my stomach.	During the last 12 hours I have felt moderate distress from nausea or sick at my stomach.	During the last 12 hours I have felt great distress from nausea or sick at my stomach.	During the last 12 hours I have felt as severe distress from nausea or sick at my stomach.
During the last 12 hours I produced a very large (3 cups or more) amount each time I threw up.	During the last 12 hours I produced a large (2-3 cups) amount each time I threw up.	During the last 12 hours I produced a moderate (½-2 cup) amount each time I threw up.	During the last 12 hours I produced a small (up to ½ cup) amount each time I threw up.	During the last 12 hours I did not throw up.
I felt nauseated or sick at my stomach 7 or more times during the last 12 hours.	I felt nauseated or sick at my stomach 5-6 different times during the last 12 hrs.	I felt nauseated or sick at my stomach 3-4 different times during the last 12 hrs.	I felt nauseated or sick at my stomach 1-2 different times during the last 12 hrs.	I did not feel nauseated or sick at my stomach during the last 12 hours.
During the last 12 hours I have had NO periods of retching or dry heaves without bringing anything up.	During the last 12 hours I have had 1-2 periods of retching or dry heaves without bringing anything up	During the last 12 hours I have had 3-4 periods of retching or dry heaves without bringing anything up.	During the last 12 hours I have had 5-6 periods of retching or dry heaves without bringing anything up.	During the last 12 hours I have had 7 or more periods of retching or dry heaves without bringing anything up.

APPENDIX N

Demographic Data Collection Forms

QUESTIONNAIRE FOR PRE-CHEMOTHERAPY
PATIENT EDUCATION STUDY

1. Subject code number _____

2. Office _____

3. Age _____ 4. Sex _____

5. Birthdate _____/_____/_____
Month Day Year

6. Marital Status

_____ (1) Single, never married

_____ (2) Married

_____ (3) Divorced or separated

_____ (4) Widowed

7. Living arrangement

_____ (1) Alone

_____ (2) With spouse/partner

_____ (3) With family

_____ (4) Other

8. Highest grade in school completed

_____ (1) Up to 8th grade

_____ (2) Some high school

_____ (3) High school graduate

_____ (4) Some college

_____ (5) College graduate

_____ (6) Other, please specify _____

9. Occupation (if retired, former occupation) _____

10. Date of cancer diagnosis _____

11. Specific cancer diagnosis _____

12. Stage of disease (a) limited_____ (b) advanced_____

13. Medical diagnosis other than cancer_____

_____

14. Date chemotherapy due to start _____

15. Type(s) and date(s) of previous or current chemotherapy (include name of drugs, routes of administration) _____

_____

_____

16. Type(s) and date(s) of previous or current surgery for this illness _____

_____

17. Type(s) and date(s) of previous or current radiation therapy ___

_____

_____

18. Other medications (excluding chemotherapy) you are taking _____

_____

_____

19. Is the purpose of your receiving treatment to cure the disease?

Yes_____ No_____ Not sure _____

To shrink the tumor? Yes_____ No_____ Not sure_____

20. Before you start your chemotherapy how clearly have the purpose and risks of your chemotherapy been explained to you? Here is a five point scale ranging from "I did not understand at all" to "Very clear." Please indicate by a number how clear that explanation was.

1	2	3	4	5
I did not understand it at all	Not too clearly	Adequate	Fairly Clear	Very Clear

21. At the time your physician explained the chemotherapy program to you, he/she probably mentioned that some people experience side effects when taking this (these) drugs. Please list the side effects you expect to experience. (You may use the list attached to choose from). _____

_____

_____

22. Also you may have received information about side effects from other sources (i.e. friends, family, American Cancer Society). Please list below which side effects, if any, you have been told you may experience and who gave you that information. _____

_____

_____

23. Has anyone in your family or close friends had cancer?_____

24. If yes, 1) who? _____

2) Type of cancer? _____

3) Type of treatment used? _____

4) How are they now? _____

25. If you wanted to learn something new, like how to plant an herb garden, how would you go about learning how to do it?

_____ Read a book

_____ Talk to an expert

_____ Listen to an expert on T.V. or radio

_____ Do the activity and learn by my mistakes

_____ I do not like to learn new things

SIDE EFFECTS LIST

Anemia-decreased red blood cells

Appetite-decreased (anorexia)

Bleeding-decreased platelet cells (thrombocytopenia)

Blood in urine-(hematuria)

Blood pressure elevated (hypertension)

Blood pressure decreased (hypotension)

Constipation

Diarrhea

Feminization in men

Fever-caused by chemotherapy

Flu-like syndrome

Hair, increased (Hirsutism)

Hair, decreased (Alopecia)

Headache

Heart damage-cardiac toxicity

Infection-decreased white blood cells (Leukopenia)

Kidney damage-renal toxicity

Light sensitivity (Photophobia)

Liver damage-liver toxicity

Menstrual irregularities

Mood changes

Mouth sores (Stomatitis)

Muscle weakness

Nausea

Nervousness, irritability, insomnia

Numbness-tingling in hand and feet (Peripheral neuropathies)

Pain-at injection site or at the site of your tumor occurring when you are receiving your chemotherapy

Pain-abdominal

Pigmentation-increased coloring of skin under the nails

Red colored urine

Ringing sensation in your ears (Tinnitis)

Shortness of breathing-Dyspnia (Pulmonary Fibrosis)

Skin-changes in areas that have been previously treated with radiation therapy

Skin-hot flashes

Skin-rash, itching, peeling, hives (Dermatitis)

Skin-acne

Stomach irritation and ulcers (Gastric Ulcers)

Taste and smell changes

Urinary retention-unable to urinate all the urine that is in the bladder

Vomiting, mild (1-2 times daily)

Vomiting, severe (5 or more times daily)

Weakening of the bones (Osteo-porosis)

Weight-increase with fluid retention (Edema)

Weight-increase with fat deposits

26. Your performance status at the time of the interview:

___ 90-100 Full active, able to carry on all predisease performance without restriction.

___ 70-89 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.

___ 50-69 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.

___ 30-49 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

___ 10-29 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

INVESTIGATOR ABSTRACTING FORM

1. Subject code number _____

2. Office _____

3. Age _____ 4. Sex _____

5. Cancer diagnosis and date _____

_____

_____

6. Medical diagnosis other than cancer _____

_____

_____

7. Stage of disease _____

_____

_____

8. Types of previous and current chemotherapy, radiation therapy and surgery. _____

_____

_____

9. Other medications _____

_____

_____

10. Purpose for treatment _____

_____

_____

11. Performance status as rated by patient physician

1. 90-100 Full active, able to carry on all predisease performance without restriction.

2. 70-89 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature e.g., light housework, office work.

Performance status as rated by patient physician (Continued)

3. 50-69 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.

4. 30-49 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

5. 10-29 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

Other information.

APPENDIX O

Frequency Statistics for ASDS Subscales

Mean	Std Dev	Min	Max	* Valid N	Label
ASDS Total Score					
15.850	10.209	0	43	40	time 1
14.538	10.223	0	47	39	time 2
14.575	10.761	1	40	40	time 3
14.950	10.874	1	50	40	time 4
ASDS Nausea Frequency					
.825	.675	0	2	40	time 1
.897	1.119	0	4	39	time 2
1.025	1.187	0	4	40	time 3
.900	1.150	0	4	40	time 4
ASDS Vomiting Frequency					
.700	.564	0	2	40	time 1
.744	1.163	0	4	49	time 2
.875	1.324	0	4	40	time 3
.700	1.091	0	4	40	time 4
ASDS Nausea Distress					
1.025	1.074	0	4	40	time 1
.821	1.097	0	4	39	time 2
.900	1.150	0	4	40	time 3
.900	1.081	0	4	40	time 4

(Table continued)

Mean	Std Dev	Min	Max	* Valid N	Label
ASDS Vomiting Distress					
.875	1.114	0	4	40	time 1
.667	1.132	0	4	39	time 2
.850	1.292	0	4	40	time 3
.675	1.095	0	4	40	time 4
ASDS Enjoy Food					
.625	1.055	0	4	40	time 1
.949	1.468	0	4	39	time 2
1.075	1.347	0	4	40	time 3
1.075	1.269	0	4	40	time 4
ASDS Sleep					
.825	.874	0	3	40	time 1
.692	.977	0	4	39	time 2
.750	.977	0	4	40	time 3
.600	.744	0	3	40	time 4
ASDS Pain Frequency					
1.400	1.317	0	4	40	time 1
1.308	1.280	0	4	39	time 2
1.250	1.296	0	4	40	time 3
1.225	1.230	0	4	40	time 4

(Table continued)

Mean	Std Dev	Min	Max	* Valid N	Label
ASDS Pain Distress					
1.375	1.213	0	4	40	time 1
1.051	.944	0	3	39	time 2
1.100	1.057	0	3	40	time 3
1.075	.971	0	3	40	time 4
ASDS Tired Frequency					
1.800	1.043	0	4	40	time 1
1.692	1.239	0	4	39	time 2
1.825	1.196	0	4	40	time 3
1.875	1.223	0	4	40	time 4
ASDS Concentration					
.600	.709	0	2	40	time 1
.744	.910	0	4	39	time 2
.600	.744	0	3	40	time 3
.575	.636	0	2	40	time 4
ASDS Appearance					
.675	.829	0	3	40	time 1
.744	.928	0	3	39	time 2
.775	.862	0	3	40	time 3
.725	.905	0	3	40	time 4

(Table continued)

Mean	Std Dev	Min	Max	* Valid N	Label
ASDS Breathing					
.575	.781	0	3	40	time 1
.513	.854	0	3	39	time 2
.500	.751	0	3	40	time 3
.575	.093	0	4	40	time 4
ASDS Bowel Movement					
.750	.972	0	3	40	time 1
.667	.955	0	3	39	time 2
.600	.900	0	3	40	time 3
.700	.853	0	3	40	time 4
ASDS Worried					
1.750	1.335	0	4	40	time 1
1.256	1.019	0	3	39	time 2
1.150	1.057	0	3	40	time 3
1.225	1.000	0	4	40	time 4
ASDS Fear					
1.100	.928	0	4	40	time 1
1.000	.946	0	4	39	time 2
.950	.932	0	4	40	time 3
1.050	.986	0	4	40	time 4

(Table continued)

	Mean	Std Dev	Min	Max	* Valid N	Label
ASDS Cough						
	1.075	1.095	0	4	40	time 1
	.923	.870	0	3	40	time 2
	.875	.822	0	3	40	time 3
	.975	.947	0	4	40	time 4

APPENDIX P

Frequency Statistics for RINV Subscales

Mean	Std Dev	Min	Max	N	Label
RINV Total Score					
.750	1.548	0	6	40	time 1
3.897	6.965	0	29	38	time 2
5.325	8.135	0	29	40	time 3
4.725	6.520	0	27	40	time 4
RINV Total Distress					
.175	.446	0	2	40	N & V time 1
1.231	2.580	0	12	39	N & V time 2
1.825	3.434	0	12	40	N & V time 3
1.575	2.385	0	10	40	N & V time 4
RINV Pattern Nausea					
.600	1.429	0	6	40	time 1
2.282	3.332	0	12	39	time 2
2.850	3.752	0	12	40	time 3
2.900	3.608	0	12	40	time 4
RINV Pattern Vomiting					
.000	.000	0	0	40	time 1
1.205	3.019	0	12	39	time 2
1.600	3.241	0	11	40	time 3
1.025	2.044	0	8	40	time 4

(Table continued)

Mean	Std Dev	Min	Max	N	Label
RINV Pattern of Retching					
.050	.316	0	2	40	time 1
.487	1.315	0	7	39	time 2
.975	2.142	0	7	40	time 3
.775	1.593	0	7	40	time 4
RINV Distress Retching					
.125	.563	0	3	40	time 1
.308	.863	0	4	39	time 2
.500	1.132	0	4	40	time 3
.475	.933	0	4	40	time 4
RINV Distress Nausea					
.175	.385	0	1	40	time 1
.615	.935	0	4	39	time 2
.775	1.050	0	4	40	time 3
.775	.974	0	4	40	time 4
INV Distress Vomiting					
.000	.000	0	0	40	time 1
.333	.898	0	4	39	time 2
.600	1.236	0	4	40	time 3
.350	.736	0	3	40	time 4

(Table continued)

Mean	Std Dev	Min	Max	N	Label
RINV Amount Vomiting					
.000	.000	0	0	40	time 1
.333	869	0	4	39	time 2
.500	.961	0	3	40	time 3
.350	.893	0	4	40	time 4
RINV Frequency Vomiting					
.000	.000	0	0	40	time 1
.487	1.211	0	4	39	time 2
.575	1.217	0	4	40	time 3
.350	.700	0	3	40	time 4
RINV Length Nausea					
.250	.588	0	2	40	time 1
.795	1.196	0	4	39	time 2
1.000	1.340	0	4	40	time 3
1.100	1.429	0	4	40	time 4
RINV Frequency Nausea					
.200	.564	0	3	40	time 1
.872	1.341	0	4	39	time 2
1.050	1.431	0	4	40	time 3
1.025	1.349	0	4	40	time 4

(Table continued)

Mean	Std Dev	Min	Max	N	Label
RINV Periods of Retching					
.050	3.15	0	2	40	time 1
.179	.556	0	3	39	time 2
.500	1.198	0	4	40	time 3
.300	.823	0	4	40	time 4

APPENDIX Q

Experiment Group Karnofsky Status

Variable	n	mean	Standard Deviation	T Value	Degrees of Freedom	2-Tail Prob
Karnofsky Status						
Rated by M.D.		92.9	2.7			
	19			3.74	18	0.002
Rated by Patient		83.1	4.0			

APPENDIX R

Control Group Karnofsky Status

Variable	n	mean	Standard Deviation	T Value	Degrees of Freedom	2-Tail Prob
Karnofsky Status						
Rated by M.D.	19	88.4	3.8	4.78	18	0.000
Rated by Patient		78.9	3.6			

FOR REFERENCE

NOT TO BE TAKEN FROM THE ROOM

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