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Assessing the impact of chemotherapy-induced nausea and vomiting on quality of life of patients with cancer

Rose G. Conde
San Jose State University

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**ASSESSING THE IMPACT OF CHEMOTHERAPY-INDUCED NAUSEA AND
VOMITING ON QUALITY OF LIFE OF PATIENTS WITH CANCER**

A Thesis

Presented to

**The Faculty of the School of Nursing
San Jose State University**

In Partial Fulfillment

**of the Requirements for the Degree
Master of Science**

by

Rose G. Conde

December, 1996

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ABSTRACT

ASSESSING THE IMPACT OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING ON QUALITY OF LIFE OF PATIENTS WITH CANCER

by Rose G. Conde

This descriptive study addressed the impact of chemotherapy-induced nausea and vomiting on quality of life and daily functioning of patients with cancer. Twenty outpatients receiving chemotherapy were studied ($N = 20$). Instruments utilized were: (a) the Functional Living Index-Cancer (FLIC), composed of five subscales which includes physical well-being, psychological well-being, social well-being, family situation, and nausea; (b) the Functional Living Index-Emesis (FLIE) which measures the impact of nausea and vomiting on daily functioning which includes physical activities, social and emotional functions, and ability to enjoy meals; and (c) a Demographic Data Form (DDF). Data were analyzed using descriptive statistics, means, and standard deviations.

The results of this study indicated that the participants perceived that they had both a moderate quality of life and moderate daily functioning. The results of this study suggested that nausea and vomiting as side effects of chemotherapy moderately affected the participants' quality of life and daily functioning.

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Chapter 1

INTRODUCTION

Cancer chemotherapy is associated with numerous toxicities such as nausea and vomiting (Tortorice & O'Connell, 1990). Nausea and vomiting following chemotherapy are often overlooked causes of impairment in cancer patients (Lindley et al., 1992). Nausea and vomiting can further debilitate patients in whom physical and psychological status is already compromised and may seriously diminish their quality of life (QOL). A number of nursing, psychological, and pharmacological measures can be employed to reduce these side effects. The physical distress may be such that some patients refuse further potentially curative treatment. The physical distress that patients experience provides a considerable challenge for the oncology nurse (Adams, 1993).

Background of the Problem

According to Grunberg and Hesketh (1993), patients receiving cancer chemotherapy perceived nausea and vomiting to be the most severe side effects. Indeed, some groups ranked nausea above vomiting. Despite current antiemetic therapy, up to 40% of patients endure nausea and vomiting (Adams, 1993). Even when vomiting has stopped, nausea may persist for several weeks (Stewart, 1990). Although bone marrow suppression and organ failure may be life threatening, patients rank nausea and vomiting as the most

severe and distressing side effects (Tortorice & O'Connell, 1990). "Complications of chemotherapy-induced emesis (CIE) include anorexia, weight loss, malaise, dehydration, esophagogastric junction tears, pathologic fractures, aspiration pneumonia, and anticipatory vomiting" (Tortorice & O'Connell, 1990, p. 129). Similarly, nausea and vomiting can decrease the cancer patient's nutritional status directly, and may also lead to food aversion and changes in taste and appetite, with resultant weight loss and decline in QOL (Adams, 1993). In addition, most patients experience a decreased energy level and difficulty maintaining day-to-day activities. Those patients who suffer from severe and prolonged nausea and vomiting may delay or discontinue subsequent chemotherapy. This response is unfortunate, since some regimens are highly effective and potentially curative (Tortorice & O'Connell, 1990).

Several practical non-pharmacological measures for supporting patients can be employed including dietary measures to maintain adequate nutritional status. Patients should be given frequent, small, but nourishing and appetizing meals. They should be encouraged to drink 3-4 liters of fluid daily to maintain fluid and electrolyte balance which can be impaired by repeated vomiting. Diversional therapy in the form of listening to music or watching television and videotapes provides useful

distraction. Relaxation therapy, guided imagery, and hypnosis by appropriately trained therapists can be employed to reduce anticipatory nausea and vomiting (Adams, 1993).

Coons (1987) studied 74 patients receiving chemotherapy who were divided into two groups. The first group of 37 patients was given instruction in, and practiced guided imagery; the second group of 37 patients did not. In guided imagery, patients are asked to imagine a scene that they find relaxing. The degree of progressive muscle relaxation was measured in both groups. The group practicing guided imagery demonstrated a greater degree of progressive muscle relaxation than did the second group. Progressive muscle relaxation (combined with guided imagery) resulted in a significant reduction in anxiety, and symptoms of nausea were less severe, less frequent, and of shorter duration.

Pharmacological measures for supporting patients receiving chemotherapy primarily rely on the standard antiemetics, the dopamine antagonists, such as metoclopramide, prochlorperazine, and dexamethasone. These drugs may also act by increasing gastrointestinal motility, thereby encouraging gastric emptying. The dopamine antagonists are by far the most effective and consequently the most widely used drugs for patients with highly emetogenic chemotherapy regimens (Adams, 1993).

In a study by Cassidy (1988), granisetron was found to be an effective and well-tolerated antiemetic in patients

receiving a variety of chemotherapeutic regimens. Of the 20 patients studied, 11 were completely protected from vomiting, and 9 had vomiting and mild to moderate nausea. Interesting, in 3 of the patients in whom granisetron was delayed until 4 to 6 hours after chemotherapy administration, vomiting had already begun but ceased immediately when granisetron was administered.

In a multi-center trial by Cuppisol (1990), granisetron was found to be highly effective as a prophylactic and intervention therapy. Over 90% of the patients experienced no vomiting and only mild nausea over a 24-hour period.

Chevallier (1990) reported that a prophylactic dose of granisetron (the study group) was as effective at controlling cisplatin-induced nausea and vomiting as high-dose metoclopramide plus dexamethasone (the comparative group). Seventy percent of patients in the granisetron group and 69% in the comparative group experienced no vomiting and only mild nausea. Furthermore, patients who received granisetron remained free of extrapyramidal effects, while these effects occurred in 6% of patients in the comparative group who were treated with high-dose metoclopramide and dexamethasone drugs (Tabona, 1990). The overall incidence of adverse effects was lower in granisetron treated patients and largely comprised of mild to moderate headache which resolved spontaneously or with simple analgesics (Smith, 1990).

Nausea and vomiting can present significant clinical management problems for nurses caring for cancer patients. The distress caused by nausea and vomiting can have negative consequences for patient compliance and QOL. Thus, control of acute symptoms is essential to improve the outcome for patients experiencing chemotherapy-induced nausea and vomiting and to reduce the risk of the complications of prolonged nausea and vomiting.

Purpose of the Study

The purpose of this study was to assess the impact of chemotherapy-induced nausea and vomiting on QOL in patients with cancer. Many of the patients received either continuous chemotherapy infusion in an inpatient unit or intermittent bolus chemotherapy regimen in an outpatient clinic. For convenience of study and to enhance accessibility, this study assessed the impact of chemotherapy-induced nausea and vomiting on QOL in patients with cancer in the outpatient setting.

Findings from this study may help expand the current body of knowledge generated by previous research on QOL and chemotherapy-induced nausea and vomiting. Information collected on the incidence and duration of nausea and vomiting following chemotherapy may lead to the development of more effective nursing measures to help cancer patients achieve an improved QOL.

Research Question

The research question for this study is: What is the impact of chemotherapy-induced nausea and vomiting on QOL of people with cancer? QOL includes physical functioning, psychological functioning, and social functioning.

Definition of Terms

For the purpose of this study, the following definitions are utilized:

1. Cancer is (a) "a malignant new growth anywhere in the body of a person or animal; malignant tumors are cancers that tend to metastasize (spread) locally or to distant parts of the body, and (b) any of various diseases characterized by the uncontrolled growth of new cells that disrupt body tissue, metabolism, etc." (Webster's New World Dictionary, 1988, p. 203).
2. Nausea is a "feeling of sickness at the stomach, with an impulse to vomit" (Webster's New World Dictionary, 1988, p. 904).
3. Vomiting is "the act or process of ejecting the contents of the stomach through the mouth" (Webster's New World Dictionary, 1988, p. 1497).
4. Quality of life (QOL) is the subjective reporting by a person of his or her sense of well-being, happiness, and satisfaction in three dimensions (physical, psychological, and social) (Payne, 1992; Winer, 1994).

Summary

This chapter described the background of the problem of chemotherapy-induced nausea and vomiting and presented the complications of CIE. This chapter also reviewed pharmacological and nonpharmacological measures for supporting patients experiencing chemotherapy-induced nausea and vomiting. Furthermore, it presented the purpose of the study, the research question posed in the study, and the terms and definitions utilized in the study. The author hopes that the study findings may help expand and develop better nursing measures to achieve an improved QOL for patients with cancer.

Chapter 2

CONCEPTUAL FRAMEWORK AND REVIEW OF THE LITERATURE

This chapter examines the concepts of QOL and chemotherapy-induced nausea and vomiting and the conceptual framework used in this study. A general review of the literature is also presented.

Conceptual Framework

The conceptual framework for this study is drawn from Bianchi's (1995) unpublished doctoral dissertation. In Bianchi's (1995) work, it is noted that there is no universally agreed upon definition of QOL. Many researchers who study QOL have used the World Health Organization's (WHO) definition of health as their basic operational definition of health (Stewart & Ware, 1992). The WHO (1948) defines health as a "state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (p. 29). The WHO's definition calls attention to the multidimensionality of health (Stewart, 1992). "The multiple dimensions include not only the physical, mental, and social dimensions specified by the WHO, but also multiple types of indicators of those dimensions such as functioning, symptoms, emotional status, and various diagnoses" (Stewart & Ware, 1992, p. 12). Definitions of QOL, the concept of QOL, and the three dimensions of QOL are described.

General Definitions of QOL

Evaluation of physical, psychological, and social well-being has been termed "QOL" (Bianchi, 1995). QOL involves five types of functioning: (a) physical functioning (Stewart, 1992), (b) psychological functioning (Stewart, 1992), (c) mental functioning (Stewart & Ware, 1992), (d) social functioning (Stewart, 1992), and (e) social/role functioning (Stewart & Ware, 1992).

Payne (1992) states that QOL is operationalized as measurement of anxiety, depression, self-esteem, health locus of control, physical performance, and symptoms. Ferrans (1990) defines QOL as a person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him or her. In addition, QOL is conceptualized as a multidimensional concept consisting of four areas known as domains. "The domains are: (a) health and functioning domain, (b) socioeconomic status domain; (c) psychological/spiritual domain, and (d) family domain" (Ferrans, 1990, p. 15).

Dimensions of QOL

The three dimensions of QOL, namely, physical, psychological, and social dimensions, are adapted from the work of Bianchi (1995). In this study, only QOL concepts that fit into a problem-oriented approach are addressed; namely, physical, psychological, and social dimensions. Permission to use the QOL construct for physical,

psychological, and social dimensions was obtained from the author (see Appendix A).

Physical Dimension

The physical dimension construct of QOL is adapted from the work of Stewart (1992). "It has been classified into two concepts--physical functioning and physical clinical status" (Bianchi, 1995, p. 26). Definition of physical clinical status is not addressed because it is beyond the scope of this study; therefore, only the definition of physical functioning is addressed (see Figure 1).

Definitions of physical functioning. Physical functioning refers to performance of or the capacity to perform a variety of physical activities normal for people in good health (Stewart & Kamberg, 1992). It is the performance of activities of daily living, such as bathing, dressing, grooming, toileting, and feeding. More recent work in defining physical functioning has led to the development of three subconcepts; namely: (a) "self-care activities, which involve bathing, dressing, toileting, feeding, transferring, and grooming activities; (b) mobility activities, which are activities related to getting around indoors and outdoors and in the community; and (c) other physical activities, which include the ability to walk, run, use stairs, lift objects, and bend" (Bianchi, 1995, p. 28).

Figure 1. Conceptual Framework of the Physical Dimension Construct of Quality of Life by R. Bianchi, 1995. Adapted with permission of the author.

Psychological Dimension

For the purpose of this study, the author chose to examine the relationship between physical functioning and two psychological dimension concepts: intellectual/mental functioning and psychological clinical status. Other psychological dimension concepts and QOL concepts are beyond the scope of this study and are not addressed. The psychological dimension of QOL is adapted from the work of Stewart and Ware (1992). Psychological dimension concepts

are intellectual/mental functioning, psychological clinical status, and satisfaction with life. For this study, definitions of both intellectual/mental functioning and psychological clinical status are utilized (see Figure 2).

Figure 2. Conceptual Framework of the Psychological Dimension Construct of Quality of Life by R. Bianchi, 1995. Adapted with permission of the author.

Definition of intellectual/mental functioning. The category of mental functioning includes cognitive components, which are the most direct indicators of mental health (Stewart, 1992). Cognitive functioning pertains to memory, concentration, perception, psychomotor ability, attention span, confusion, comprehension, problem solving and judgment, and orientation in time and space (Stewart, 1992). Many people experience variations in confusion and forgetfulness that are important to daily functioning (DF) and well-being.

Definition of psychological clinical status. "In the psychological dimension of QOL, clinical status is defined as the presence and severity of mental impairment or disorder, or psychological distress symptoms. A mental impairment is a chronic or permanent defect resulting from disease, injury, or congenital malformation" (Bianchi, 1995, p. 31). A mental disorder or impairment is diagnosed based on information about a patient's signs, symptoms, functioning, and feelings (Stewart, 1992). Diagnosed cognitive disorders (e.g., Alzheimer's disease) are included in the clinical status category (Stewart, 1992). Psychological distress that is attributed specifically to health problems (e.g., worried about health) can be defined, in which case the distress may be indicative of physical health as well as mental health (Stewart, 1992). Psychological distress can be defined as positive or

negative states including anxiety, depression, behavioral-emotional control, loneliness, positive affect, and feelings of belonging (Stewart, 1992). Because life presents countless opportunities to feel appropriately anxious or depressed, the absence of anxiety and depression should not necessarily be a sign of mental health. However, psychological distress for whatever reason can lead people to seek help from the medical care system, and reduction of distress is one goal of health care (Stewart, 1992).

Social Dimension

"The social dimension of QOL is composed of four concepts; namely, social functioning, role functioning, social support, and social well-being" (Stewart, 1992). For this study, both social functioning and role functioning are utilized (see Figure 3). Social support and social well-being are beyond the scope of this study and are not utilized.

Definition of social functioning. Social functioning is a broad and general concept that can include all human behavior in social role and contexts (Stewart, 1992). More specifically, social functioning can be viewed in terms of a person's adjustment or adaptation to the normative expectations regarding behavior or social roles within the community (Sherbourne, 1992).

Social functioning is defined as the ability to develop, maintain, and nurture social relationships

Figure 3. Conceptual Framework of the Social Dimension Construct of Quality of Life by R. Bianchi, 1995. Adapted with permission of the author.

(Sherbourne, 1992). To the extent that a person's performance conforms to social expectations and responsibilities, the person is seen as functioning well (Sherbourne, 1992). Social functioning is comprised of two subconcepts: social interaction and family functioning (Sherbourne, 1992). Social interaction is "the quality and quantity of social activities or contacts made with family or friends, neighbors, and groups" (Bianchi, 1995, p. 33). Family functioning refers to the quality of interactions among family members. It is conceptualized in terms of cohesion within the family. However, there is a wide variety of other more specific family characteristics

including adaptability, the amount of communication and support, conflict, affection, expressiveness, and time spent together (Sherbourne & Kamberg, 1992).

Definition of role functioning. Role functioning refers to the degree to which an individual performs or has the capacity to perform activities typical for a specified age and social responsibility. Historically, the definition of role functioning has focused narrowly on job-related limitations, although many measures also include limitations in the performance of housework or schoolwork (Sherbourne, Stewart, & Wells, 1992). When broadly defined, the definition of role functioning includes: (a) work for pay, whether for financial or for other reasons, which is considered a main component of QOL; (b) work as a housewife, which typically refers to the ability to perform household tasks; and (c) being a student (Sherbourne et al., 1992).

Review of the Literature

Nausea and Vomiting

The mechanism responsible for nausea and vomiting varies according to etiology. For both radiation-induced and chemotherapy-induced nausea and vomiting, it is thought that neuroactive agents, such as 5-hydroxytryptamine, are released from the small intestine and travel via blood to the chemoreceptor trigger zone (CTZ) situated in the medulla oblongata of the brain (Adams, 1993). Circulating neurotransmitters from CTZ, which, in turn, activate the

vomiting center, are also activated by inputs from higher centers and by vagal and sympathetic afferents from the gastrointestinal system and liver. Nausea, retching, and vomiting ensue, along with a number of other associated phenomena (Adams, 1993; Craig & Powell, 1987).

The gravity of the nausea and vomiting relates primarily to the type of drug administered. Most forms of cancer chemotherapy produce nausea and vomiting, with cisplatin and dacarbazine representing the most severe end of the spectrum (Adams, 1993). The problem of CIE is often compounded by the combination of agents; the differing profile of emetic responses over time can combine to create a pattern of nausea and vomiting. Furthermore, the additive nature of the emetic effect can produce more marked nausea and vomiting when antiemetic drugs are used concomitantly; the frequency and severity of nausea and vomiting appear to be greater with the more acute dosing regimens (Adams, 1993; Stewart, 1990). The associative physical problems of nausea and vomiting include dehydration, anorexia, and fatigue. The loss of stomach contents can produce metabolic imbalances such as chloride and potassium depletion, leading to metabolic alkalosis and volume depletion which can exacerbate the nephrotoxicity of chemotherapeutic agents, especially that of cisplatin (Adams, 1993; Craig & Powell, 1987).

Acute nausea and vomiting start within 4 hours of treatment, reach a peak between 4 and 10 hours, and last for as long as 12 to 24 hours, although some symptoms can persist for days. There are, however, important exceptions to this pattern. Dacarbazine, for example, can cause rapid onset of nausea and vomiting (within 30 minutes), whereas cyclophosphamide produces peak symptoms between 12 and 24 hours (Triozi & Laszlo, 1987). With the more emetogenic compounds, such as cisplatin, patients may experience delayed nausea and vomiting after the initial 24-hour period. Often nausea and vomiting develop 7 days post-chemotherapy (Kris, Gralla, & Clark, 1990), but if the acute phase can be controlled, there is often an improvement in the frequency and severity of delayed nausea and vomiting (Whickham, 1989). The characteristics of patients receiving chemotherapy must also be taken into consideration. Younger patients tend to be more susceptible to emesis than older patients, and women more than men. In addition, a history of heavy alcohol consumption has been correlated with a reduced risk of emesis (Grunberg & Hesketh, 1993). The patient's experience of nausea and vomiting can, therefore, be determined by a number of factors, including anxiety, pathological status, and the nature of the emetic stimulus.

The sequelae of inadequate emesis control range from the obvious increase in patient discomfort, with its attendant negative psychosocial effects, to loss of patient

compliance and iatrogenic medical consequences (Craig & Powell, 1987). Severe nausea and vomiting, with their accompanying fatigue and anorexia, result in an increase in anxiety, depression, and the development of anticipatory emesis, which adversely impact on the patient's QOL and lead to major psychosocial problems (Craig & Powell, 1987).

Poor control of nausea and vomiting with previous chemotherapy may lead patients to develop anticipatory nausea and vomiting, which occurs in approximately 25% to 30% of all previously treated patients and has been shown to occur in 65% of patients receiving cisplatin despite antiemetic therapy (Coons, 1987). It is suggested that anticipatory nausea and vomiting are a respondent learning process (Redd & Andrykowski, 1982), analogous to the classical conditioning described by Pavlov in the 1920s. Repeated exposure to sensory stimuli, such as sights, sounds, and odors associated with the administration of chemotherapy, gradually provokes nausea and vomiting (Adams, 1993). Anticipatory nausea and vomiting may also occur during or after chemotherapy. They may confound the assessment of acute or delayed symptoms.

Anxiety has also been shown to be a significant factor in the development of anticipatory nausea and vomiting. As a conditioned response, anticipatory nausea and vomiting are particularly resistant to antiemetic therapy. Management with behavioral techniques may have to be attempted. It is

important to make all attempts to avoid anticipatory nausea and vomiting, by the effective control of acute nausea and vomiting from the initial course of chemotherapy onwards (Adams, 1993; Craig & Powell, 1987).

Patients have reported that nausea and vomiting are their first concern while receiving chemotherapy (Lindley et al., 1992). In a recently reported study, nausea was reported by 50% and vomiting by 27% of cancer patients on the day of chemotherapy administration. Nausea persisted for 5 days in 14% of patients, and vomiting persisted for 5 days in 3% of patients. As expected, the incidence and the duration of CIE were significantly influenced by the emetogenicity of chemotherapy and antiemetic therapy administered (Lindley et al., 1992).

Penta, Poster, and Bruno (1993) found that 85% of a group of physicians who treated patients with cancer reported that 10% to 15% of their patients refused chemotherapy at some point because of nausea and vomiting. Similarly, Laszlo (1993) estimated that 30% of patients refused chemotherapy because of nausea and vomiting, and an additional 20% of patients delayed treatment or missed clinic appointments because of fear of nausea and vomiting. For individuals that may be cured or significantly benefitted by treatment, premature cessation of therapy may allow the disease to progress, resulting in significant

increases in morbidity and mortality (Craig & Powell, 1987; Lindley et al., 1992).

Kris et al. (1990) noted that 60% to 80% of patients who received high-dose cisplatin experienced some nausea and vomiting commencing 24 or more hours after chemotherapy and lasting up to 120 hours. These effects were present in a significant number of patients who experienced no nausea and no vomiting during the initial 24 hours following cisplatin administration (Kris et al., 1990). Nausea and vomiting occurring up to 7 days following chemotherapy (delayed nausea and vomiting) were also described. Doxorubicin and cyclophosphamide were the chemotherapeutic agents associated with delayed nausea and vomiting (Lindley, Bernard, & Fields, 1989).

Lindley et al. (1989) studied the incidence and duration of chemotherapy-induced nausea and vomiting. They followed 138 patients over a 12-week period at two teaching hospitals (6 weeks in each institution). Anticipatory nausea and vomiting were reported by 9% and 7% of patients, respectively. On the day chemotherapy was administered (day 1: acute nausea and vomiting phase), 50% and 27% of patients reported nausea and vomiting, respectively. Percentages fell to 22% and 11% by day 3 and 14% and 3% on day 5. Of the patients who reported nausea and vomiting during the 5-day period, 52% and 33% experienced nausea and vomiting, respectively, during the delayed period (day 2-5).

The authors concluded that the emetogenicity of the administered chemotherapy regimen influences the occurrence of both acute and delayed nausea and vomiting. Therefore, patients who received moderately to strongly emetogenic chemotherapy regimes should receive antiemetic therapy for a minimum of 3 days following chemotherapy (Lindley et al., 1989).

Strum, McDermed, Pileggi, Reich, and Whitaker (1990) tested the safety and efficacy of intravenous metoclopramide in the prevention of chemotherapy-induced nausea and vomiting. They followed 50 patients including hospitalized patients receiving their initial treatment with potent, emetogenic non-cisplatin-containing regimens; and outpatients receiving both their initial and maintenance non-cisplatin-containing chemotherapy. All fifty patients received metoclopramide with one or more of three intravenous metoclopramide dosage schedules, based on whether they received their chemotherapy on an inpatient or outpatient basis. Metoclopramide was administered as an intravenous piggyback (IVPB) over a 15-minute period with one of the following dosage schedules: (a) Schedule A: 20 mg IVPB for 6 doses beginning 30 minutes before chemotherapy, and again at 1.5, 3.5, 6.5, 9.5, and 12.5 hours after chemotherapy was initiated; (b) Schedule B: 0.75 mg/kg IVPB for 6 doses 30 minutes before chemotherapy with the same frequency as with Schedule A; and (c) Schedule C: 0.75 mg/kg IVPB for 3 doses

30 minutes before chemotherapy, and again at 1.5, 3.5, 6.5, 9.5, and 12.5 hours after chemotherapy was initiated.

Strum et al. (1990) found that of the patients treated, 39 (78%) achieved total protection (no emesis), and 9 (18%) attained antiemetic protection (one or two emeses) when all dosage schedules of metoclopramide were combined, i.e., when patients received a combination of Schedules A, B, or C; or B-C based on whether they received their chemotherapy on an inpatient or outpatient basis. Therefore, total or major antiemetic protection was observed in 48 (96%) patients receiving a broad range of potentially emetogenic chemotherapy, i.e., nitrogen mustard and cyclophosphamide, or dactinomycin and dacarbazine. Strum et al. (1990) concluded that the intravenous metoclopramide possessed significant antiemetic activity in patients receiving potent, non-cisplatin-containing chemotherapy. The dosage and scheduling required to provide total protection against nausea and vomiting appeared to be dependent on the inherent emetic potency of the chemotherapy used.

Quality of Life

Lindley et al. (1992) followed 122 patients over an 8-week time period to examine the changes in QOL of cancer patients for 3 days immediately following each chemotherapy administration. Approximately 56% of 122 patients reported CIE. Of the patients who experienced CIE, 23% were unable to go to work due to emesis; 22% reported they were unable

to prepare meals due to emesis; 12% reported that emesis made them unable to care for themselves; and 12% reported that they were unable to take prescribed medications on at least one occasion during the 3-day period immediately following chemotherapy due to emesis. The authors concluded that CIE patients perceived that vomiting, and to a slightly lesser extent, nausea, substantively influenced their ability to complete household tasks, enjoy meals, spend time with their family and friends, and maintain DF and recreation.

Campora et al. (1992) studied the impact of chemotherapy on the QOL of breast cancer patients. They studied 137 breast cancer patients. Of the 137 patients, 102 received adjuvant chemotherapy and 35 received palliative chemotherapy for metastatic disease. Both groups responded to a 37-item QOL questionnaire to evaluate the impact of the disease and treatment on physical, psychological, and social well-being.

Campora et al. (1992) found that physical and social activities were reported as unaltered or normal by 64% to 70% of the adjuvant chemotherapy group and 52% to 67% of the palliative chemotherapy group. Psychological status was judged normal by 39% to 45% of the patients in both groups. In addition, weight gain was reported by 86% of patients undergoing palliative chemotherapy. The majority of patients in both groups (84%) judged that their relationship

with their partner and/or family was good. Moreover, moderate and/or severe anxiety was reported in approximately 25% of patients in both groups. Severe anxiety was reported by 19% of the adjuvant group and 22% of the palliative group. Moderate and/or severe depression was reported by approximately 25% of the adjuvant group. Severe depression was infrequently reported by 4% of the adjuvant group and 4% of the palliative group. The authors concluded that the study indicated that the majority of breast cancer patients responded normally to the stresses of both adjuvant and palliative chemotherapy and that QOL did not appear to improve with the termination of chemotherapy (Campora et al., 1992).

Winer (1994) studied QOL of women with breast cancer. QOL was conceptualized as a measure of self-esteem, degree of anxiety, and perceived meaningfulness. In this study of 128 women with breast cancer, he found that all of the patients feared the possibility of cancer recurrence, were concerned about mortality, had difficulty with body image and sexuality, and were distressed over the loss of a breast or both breasts. He concluded that detailed QOL assessment could provide a comprehensive description of potential side effects from the patient's point of view. In addition, QOL assessment could be helpful in weighing the risks and benefits of treatment options, particularly when differences in survival among the options were small or nonexistent.

"QOL assessment not only provides needed information for patients and their health care providers, but may also be of importance in assessing treatment outcomes as policy makers critically evaluate the cost-effectiveness of cancer treatments" (Winer, 1994, p. 410).

Summary

These studies demonstrate the occurrence and impact of nausea and vomiting following chemotherapy on the QOL of patients with cancer. CIE remains a common problem with significant consequences despite the advances in antiemetic therapy that have occurred over the past 5 years. The studies' findings strongly indicated that symptoms of nausea and vomiting impact on the patient's ability to maintain normal function, and create in his/her perspective hardships on both himself/herself and his/her family. Reasons for and consequences of CIE and its impact on QOL in cancer patients merits further investigation.

Chapter 3

RESEARCH DESIGN AND METHODOLOGY

This chapter presents the methodology of the research study. It describes the population, setting, instruments, and manner in which data were collected and analyzed.

Research Design

This study utilized a descriptive, quantitative research design. It assessed the impact of chemotherapy-induced nausea and vomiting on QOL in patients with cancer.

Sample

A convenience sample of 20 cancer patients who were receiving intermittent bolus chemotherapy regimens in an outpatient setting were studied. In this study, malignancies of four histological types were included: "(a) carcinomas (any of several kinds of cancerous growths deriving from epithelial cells); (b) sarcomas (any of various malignant tumors arising from muscle, bone, fat, and other connective tissue); (c) lymphomas (arising from lymphoid tissue); and (d) leukemias (cancers of the hematological system)" (Donehower, 1985, p. 2). The patients were required to meet the following criteria to be eligible for the study. The patient was eligible if he or she was: (a) at least 18 years of age; (b) diagnosed with carcinomas of the breast or colon, or leukemias that were progressing at the time of the patient's participation in the study and not in the state of remission; (c) able to

read, write, and speak English; and (d) willing to respond to the questionnaires verbally or in writing. The researcher read the questionnaires to the participant and/or marked stated responses if the participant was physically unable. Spouses, family, and/or friends were not allowed to answer the questions.

Setting

The setting for this study was an outpatient chemotherapy clinic in an urban hospital in Northern California. During the study, the number of patients seen in this clinic was 80 to 120 patients per day.

A written proposal was submitted outlining the purpose, background, methodology, setting, and use of human subjects to the Hospital's Institutional Review Board for the Protection of Human Subjects. Approval for conducting this research study at the study site was obtained from the Hospital's Institutional Review Board (see Appendix B).

Protection of Human Subjects

Approval of the study design and protection of patient rights were ensured by the following means. The research study was approved by the San Jose State University Committee on Protection of Human Subjects. The proposal was submitted in writing and met the requirements set forth by San Jose State University (see Appendix C).

Data Collection

A total of 20 patients were approached and invited to participate in the research study. The researcher approached patients receiving intermittent bolus chemotherapy (chemo push) for 1 to 5 days in the outpatient chemotherapy clinic while they were in the clinic for treatment. Participation was invited through face-to-face contact only. The researcher explained the general purpose of the study, the form of involvement required, and the time commitment required. If the patient agreed to participate, written consent was obtained (see Appendix D). On day 1, participants were asked to complete: (a) Informed Consent, (b) Demographic Data Form (DDF) (see Appendix E), and (c) The Functional Living Index-Cancer (FLIC) questionnaire (see Appendix F). On day 4, the researcher returned to the outpatient chemotherapy clinic to ask the participants to fill out the last questionnaire; namely, The Functional Living Index-Emesis (FLIE) questionnaire (see Appendix G). This contact was the researcher's last contact with the patient. Only gratitude and heartfelt thanks were expressed to the participants. Participants did not receive any other form of compensation.

The researcher reviewed each research packet collected for completeness. The researcher maintained a confidential master list of all patients asked to participate, along with their responses. This process prevented asking the same

patient to participate more than once. The names of patients who agreed to participate were listed on a separate, confidential master list. A code number was assigned to each name. The coding ensured accurate assembly of the packet during and after data analysis. The coding also ensured the patient's name was not known to the statistician during data analysis.

Instruments

Two standardized instruments used in this study were: (a) The Functional Living Index-Cancer (FLIC) questionnaire, an existing multidimensional QOL evaluative scale (Schipper, Clinch, McMurray, & Levitt, 1984); and (b) The Functional Living Index-Emesis (FLIE) questionnaire, modeled after the FLIC, but specifically addressing the impact of chemotherapy-induced nausea and vomiting on the patient's daily functioning (Lindley et al., 1992). The Demographic Data Form (DDF) was developed specifically for this research study.

Demographic Data Form

Demographic data were collected to describe the patient population characteristics and define the nature of the study population. Knowledge about the types of participants was helpful in data interpretation and analysis (Haber, 1986). The Demographic Data Form was formulated by the researcher based upon a review of literature on QOL. The researcher chose demographic variables which were believed

to be both descriptive of the population and easily obtained, and which helped interpret the basic question posed in this study.

Each participant was requested to complete the following demographic information: (a) age, (b) sex, (c) marital status, (d) race/ethnicity, (e) highest grade level completed, (f) income level, (g) number of cycles of chemotherapy, (h) type of cancer, (i) when cancer was diagnosed, and (j) name, dose, and frequency of antiemetic regimen. The information was solicited in writing and verbally by the researcher. Participants were assured that the information was to be kept confidential.

The Functional Living Index-Cancer Scale (FLIC Scale)

The FLIC scale was utilized to measure the patient's QOL. The instrument consists of 22 questions (items) which represent five factors (subscales) related to a cancer patient's QOL (physical well-being and physical ability, psychological well-being, social well-being, hardship due to cancer, and nausea). Below each question was a line, called a linear analogue scale, which was divided into seven equal parts. There were three aspects of the answer scales that must be understood in order to make sure that the patient answered the question appropriately. These were: (a) the natural direction of the scale; (b) whether the high end was on the right or left side of the page; and (c) whether or not the high end represented good QOL.

Schipper et al. (1984) stated that there were four combinations of left/right and good/bad QOL possible in the scale. They were:

1. The scale had its high end on the right, and this end represented good QOL. For example, question 2 asked how well a person was coping with everyday stress. The high end of the scale was "very well," which was on the right-hand side of the page. Coping very well with stress represented good QOL.

2. The scale had its high end on the right but this represented poor QOL. For example, question 1 asked how often a person felt depressed. The high end of the scale was "continually," which was on the right-hand side of the page. Continually feeling depressed represented poor QOL.

3. The scale had its low end on the right and this represented good QOL. For example, question 3 asked how much time a person spent thinking about his/her illness. The high end of the scale was "constantly," which was on the left-hand side of the page; the low end of the scale was "never," which was on the right-hand side of the page. In this case, the low end of the scale, which means never thinking about illness, represented good QOL.

4. The scale had its low end on the right but this represented poor QOL. Question 4 asked a person to rate his/her ability to continue with usual leisure activities. The high end of the scale was "able," which was on the left

hand of the page while the low end of the scale was "unable," which was on the right-hand side of the page. In this case, the low end of the scale, which meant being unable to continue with usual leisure activities, represented poor QOL.

The scale was used like a ruler to measure how much an answer applied to the participant. A total score was created by summing the responses to the 22 questions. The range of total scores possible was between 22 (all "1" responses on each scale) and 154 (all "7" responses on each scale). A higher score corresponded to a higher quality of life.

The FLIC has been validated through its use with 837 patients in two cities over a 3-year period. Criteria for validity include "stability of factor analysis, concurrent validation studies against the Karnofsky, Beck Depression, Spielberger State Trait Anxiety, and Katz Activities of Daily Living Scales, as well as the scaled version of the General Health Questionnaire and The McGill/Melzack Pain Index" (Schipper et al., 1984, p. 472). Cronbach's alpha for the FLIC was above .90 for the before and after administration of the questionnaire.

The statistical methods used to establish validity for all the concurrent validation studies were factor analysis, correlation coefficients, and comparison of means (Schipper

et al., 1984). Schipper et al. (1984) performed a factor analysis on data from the FLIC to determine if the factors underlying the FLIC were similar to those factors underlying the FLIC in prior trials. In this study, Cronbach's alpha for the FLIC was also above .90 before and after administration. Thus, the reliability of the FLIC was augmented. Permission to utilize the instrument was obtained from the author (see Appendix H).

The Functional Living Index-Emesis

The FLIE questions were created and modeled after the FLIC questions, but specifically addressed the impact of nausea and vomiting on physical activities, social and emotional functions, and ability to enjoy meals. It is a visual analogue scale. This 18-item instrument contains 9 items for nausea and 9 items for vomiting and is similar in length and format to the FLIC. At the end of the scale (line) were words describing extremes moving from "none" or "not at all" (score of 1) to "a great deal" (score of 7). Caution was given to the participants to look at the responses closely and to answer the questions appropriately. The possible score range is 18 to 126 with the lower scores indicating a more negative impact from nausea and vomiting on the patient's DF.

The validity and reliability of the FLIE were tested using Pearson product moment correlations and Cronbach alpha coefficients. As an assessment of the validity of the FLIE

to measure the impact of nausea on a patient's DF, the FLIE score was correlated with patient-reported measures of vomiting frequency and nausea severity. Pearson correlation between FLIE scores (after treatment) and patient-reported nausea and vomiting were $-.65$ and $-.68$, respectively. The correlations were of the direction expected (increased nausea and vomiting creates a negative impact on patient's DF) (Lindley et al., 1992). Reliability of the FLIE was assessed using Cronbach's alpha, a measure of inter-item correlation or consistency of response within an instrument. The calculated alpha was $.90$ for the responses given in the before and after administrations of the FLIE (Lindley et al., 1992). Permission to use the instrument was obtained from the author (see Appendix I).

Analysis of the Data

The demographic data were analyzed in the following ways. The mean, standard deviation, and range were calculated for the demographic variable of age. Frequencies and percentages were calculated for the following demographic variables: (a) sex, (b) age, (c) marital status, (d) race/ethnicity, (e) highest grade level, (f) income level, and (g) antiemetic regimen. The percent, frequency, and mean were calculated for the demographic variable of cycles of chemotherapy. Frequencies and percents were calculated for the demographic variable of type of cancer. The remaining demographic variable of

month/year of cancer diagnosis was analyzed utilizing percent and frequency.

Means and standard deviations were calculated for each item of the FLIC scale and FLIE scale and subscales of FLIC and FLIE. Overall FLIC and FLIE scores were calculated for each respondent using the author's instructions.

Chapter 4

ANALYSIS AND INTERPRETATION OF DATA

This study described the impact of chemotherapy-induced nausea and vomiting on QOL and on DF of patients ($N = 20$) with cancer. It examined the relationship between the specific subscale of nausea and vomiting and perception of QOL and DF in cancer patients treated in an outpatient clinic.

Description of the Sample

Table 1 describes the demographic variables of the sample: (a) sex, (b) age, (c) race/ethnicity, (d) marital status, (e) highest grade level of school completed, and (f) income level. There were an equal number of male participants ($n = 10$, 50%) and female participants ($n = 10$, 50%). The participants' ages were between 38-68 years of age with a mean age of 52 years and a standard deviation of 9.7 years.

Participants were predominantly Caucasian ($n = 13$, 65%). The next most frequently reported ethnicity was Asian ($n = 5$, 25%). The smallest reported ethnicity was Hispanic ($n = 2$, 10%).

Over half of the study participants were married ($n = 11$, 55%). The remainder were divorced ($n = 7$, 35%) or widowed ($n = 2$, 10%).

Over half of the participants were educated at the college level ($n = 11$, 55%), while the remainder completed

Table 1.

Demographic Variables (N = 20)

	Frequency	Percent
<u>Sex</u>		
Male	10	50
Female	10	50
<u>Age</u>		
31-40 years	2	10
41-50 years	8	40
51-60 years	4	20
61-70 years	6	30
<u>M</u> = 52.25 years		
<u>SD</u> = 9.70 years		
<u>Race/Ethnicity</u>		
Caucasian	13	65
Asian	5	25
Hispanic	2	10
<u>Marital Status</u>		
Married	11	55
Divorced	7	35
Widowed	2	10
<u>Highest Grade Level of School Completed</u>		
12th grade	9	45
College graduate	11	55
<u>Income Level</u>		
\$25,001-\$35,000/yr	5	25
\$35,001-\$45,000/yr	9	45
\$45,001-\$55,000/yr	6	30

12th grade level ($\underline{n} = 9, 45\%$). Over one third of the population ($\underline{n} = 9, 45\%$) had an income level between \$35,000 and \$45,000 per year. The second most frequently reported income level was between \$45,000 and \$55,000 per year ($\underline{n} = 6, 30\%$).

Table 2 displays the oncology related diagnoses and treatment data for the sample. Participants' primary cancer sites were: (a) breast ($\underline{n} = 9, 45\%$), (b) colon ($\underline{n} = 7, 35\%$), and (c) leukemia ($\underline{n} = 4, 25\%$).

The study data were collected during the first 3 months of 1996. Between January and March, 1996, over half the sample participants ($\underline{n} = 11, 55\%$) were diagnosed with cancer and began a course of chemotherapy. Six (30%) participants had been diagnosed with cancer in January-December 1995, while the remainder of the participants ($\underline{n} = 3, 15\%$) had been living with the diagnosed cancer for a period of 22-24 months at the time of the study.

Over half of the participants ($\underline{n} = 11, 55\%$) were in cycle 3 of chemotherapy. The next most frequently reported cycle of chemotherapy was cycle 4 ($\underline{n} = 5, 25\%$), followed by cycle 5 ($\underline{n} = 3, 15\%$) and cycle 2 ($\underline{n} = 1, 5\%$). Mean number of cycles of chemotherapy was 3.5.

Over one third of the population ($\underline{n} = 9, 45\%$) was on a moderate antiemetic regimen. The second most reported potency of antiemetic regime was strong ($\underline{n} = 7, 35\%$), followed by weak antiemetic regime ($\underline{n} = 4, 20\%$).

Table 2.

Oncology Related Diagnoses and Treatment (N = 20)

	Frequency	Percent
<u>Primary Site of Cancer</u>		
Breast	9	45
Colon	7	30
Leukemia	4	20
<u>Month/Year of Cancer Diagnosis</u>		
January-March 1996	11	55
January-December 1995	6	30
December 1994-January 1995	3	15
<u>Number of Cycles</u>		
2	1	5
3	11	55
4	5	25
5	3	15
<u>Antiemetic Regimen Potency</u>		
Weak	4	20
Moderate	9	45
Strong	7	35

Functional Living Index-Cancer

The Functional Living Index-Cancer (FLIC) consisted of 22 questions (items) which represent five factors (subscales) related to a cancer patient's QOL: (a) physical well-being and ability, (b) psychological well-being, (c) social well-being, (d) family situation, and (e) nausea. Each item ranking was reported by mean and standard deviation (see Table 3). The raw data were analyzed by how the participant responded to the questions related to his/her activities and well-being.

Physical Well-Being Subscale

The physical well-being subscale represented the largest grouping of items thought to contribute to QOL for cancer patients. Questions 4, 6, 7, 10, 11, 13, 15, 20, and 22 described the physical well-being subscale. Analysis of the physical well-being subscale demonstrated a mean rank score of 4.20, indicating a moderate QOL, and a standard deviation of 0.25.

Psychological Well-Being Subscale

The second group of questions represented the participant's psychological well-being. Questions 1, 2, 3, 9, 18, and 21 represented the psychological well-being subscale. Analysis of the psychological well-being subscale items demonstrated a mean rank score of 4.30, indicating a moderate QOL, and a standard deviation of 0.25.

Table 3.

Functional Living Index-Cancer (FLIC) Scales Data (N = 20)

	M	SD
1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.	4.45	1.05
2. How well are you coping with your everyday stress?	4.60	1.14
3. How much time do you spend thinking about your illness?	4.30	1.34
4. Rate your ability to maintain your usual recreation or leisure activities.	4.35	1.42
5. Has nausea affected your daily functioning?	3.95	1.27
6. How well do you feel today?	4.75	1.07
7. Do you feel well enough to make a meal or do minor household repairs today?	4.40	1.27
8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past two weeks.	4.27	0.96
9. Rate how often you feel discouraged about your life.	3.95	1.09
10. Rate your satisfaction with your work and your jobs around the house in the past month.	4.20	0.83
11. How uncomfortable do you feel today?	3.90	1.02

(table continues)

Table 3 (continued).

Functional Living Index-Cancer (FLIC) Scales Data (N = 20)

	M	SD
12. Rate in your opinion how disruptive your cancer has been to those closest to you in the past two weeks.	3.90	0.85
13. How much is pain or discomfort interfering with your daily activities?	4.35	1.18
14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past two weeks.	4.10	0.91
15. How much of your usual household tasks are you able to complete?	3.85	1.08
16. Rate how willing you were to see and spend time with those closest to you in the past two weeks.	4.15	1.04
17. How much nausea have you had in the past two weeks?	3.50	1.10
18. Rate the degree to which you are frightened of the future.	4.05	1.09
19. Rate how willing you were to see and spend time with friends in the past two weeks.	3.65	0.87
20. How much of your pain or discomfort over the past two weeks was related to your cancer?	3.80	1.10
21. Rate your confidence in your prescribed course of treatment.	4.55	1.05
22. How well do you appear today?	4.45	0.99

Family Situation

The third group of questions represented the family situation subscale. Questions 8, 12, and 14 described the hardship and disruption caused by cancer. Analysis of the family situation subscale demonstrated a mean score of 4.10, indicating a moderate QOL, and a standard deviation of 0.12.

Social Well-Being Subscale

The fourth group of questions described the social well-being subscale. Questions 16 and 19 described the questions related to social activities. Analysis of the data demonstrated a mean rank score of 3.90, indicating a moderate QOL, and a standard deviation of 0.28.

Nausea Subscale

The last group of questions described the nausea subscale. Questions 5 and 7 represented the nausea subscale. Analysis of the data demonstrated a mean rank score of 4.20, indicating a moderate QOL, and a standard deviation of 0.22.

FLIC Total Score

The total FLIC score demonstrated a mean score of 91.00 and a standard deviation score of 17.00. Analysis of the data indicated that the sample population reported a moderate QOL when considered in the context of living with and being treated for cancer.

Functional Living Index-Emesis

The Functional Living Index-Emesis (FLIE) addressed the impact of nausea and vomiting on DF which included physical activities, social and emotional functions, and ability to enjoy meals. The FLIE contained nine items (subscale) for nausea and nine items (subscale) for vomiting and was similar in length and format to the FLIC. Each item ranking was reported by means and standard deviations (see Table 4). The raw data were analyzed by measuring how much impact nausea and vomiting had on DF which included physical activities, social and emotional functions, and ability to enjoy meals.

Nausea Subscale

Questions 1-9 described the nausea subscale. Analysis of the data demonstrated a mean rank score of 4.00, indicating moderate DF, and a standard deviation of 0.07. Three of the nine nausea item questions (1, 3, and 7) related to physical activities demonstrated a mean rank score of 4.00, indicating moderate DF. Four of the nine nausea item questions (2, 6, 8, and 9) related to social and emotional functions demonstrated a mean rank score of 3.90, indicating a moderate DF. The remaining two of the nausea item questions (4 and 5) related to ability to enjoy meals demonstrated a mean rank score of 4.00, indicating moderate DF.

Table 4.

Functional Living Index-Emesis (FLIE) Scales Data (N = 20)

	M	SD
1. How much nausea have you had in the past 3 days?	3.65	0.93
2. Has nausea affected your ability to maintain usual recreation or leisure activities in the past 3 days?	3.55	0.99
3. Has nausea affected your ability to make a meal or do minor household repairs during the past 3 days?	4.50	1.14
4. How much has nausea affected your ability to enjoy a meal in the past 3 days?	4.00	1.12
5. How much has nausea affected your ability to enjoy liquid refreshment in the past 3 days?	4.05	0.99
6. How much has nausea affected your willingness to see and spend time with family and friends in the past 3 days?	4.20	1.43
7. Has nausea affected your daily functioning in the past 3 days?	3.95	1.09
8. Rate the degree to which your nausea has imposed a hardship on you (personally) in the past 3 days.	3.80	1.00
9. Rate the degree to which your nausea has imposed a hardship on those closest to you in the past 3 days.	3.90	1.07
10. How much vomiting have you had in the past 3 days?	3.55	1.09

(table continues)

Table 4 (continued).

Functional Living Index-Emesis (FLIE) Scales Data (N = 20)

	M	SD
11. Has vomiting affected your ability to maintain usual recreation or leisure activities in the past 3 days?	4.10	1.11
12. Has vomiting affected your ability to complete your usual household tasks during the past 3 days?	3.90	0.96
13. How much has vomiting affected your ability to enjoy a meal in the past 3 days?	4.05	1.09
14. How much has vomiting affected your ability to enjoy liquid refreshment in the past 3 days?	4.30	1.03
15. How much has vomiting affected your willingness to see and spend time with friends in the past 3 days?	3.85	1.38
16. Has vomiting affected your daily functioning during the past 3 days?	4.10	1.02
17. Rate the degree to which your vomiting has imposed a hardship on you (personally) in the past 3 days.	4.15	1.13
18. Rate the degree to which your vomiting has imposed a hardship on those closest to you in the past 3 days.	4.05	1.23

Vomiting Subscale

Questions 10-18 described the vomiting subscale as it related to physical activities, social and emotional functions, and ability to enjoy meals. Analysis of the data demonstrated a mean rank score of 4.00, indicating moderate DF, and a standard deviation of 0.15. Three of the nine vomiting item questions (10, 12, and 14) related to physical activities demonstrated a mean rank score of 3.90, indicating moderate DF. Four of the nine vomiting item questions (11, 15, 17, and 18) related to social and emotional functions demonstrated a mean rank score of 4.00, indicating moderate DF. The remaining two of the vomiting item questions (13 and 14) related to ability to enjoy meals demonstrated a mean rank score of 4.20, indicating moderate DF. The data revealed that, generally, vomiting and nausea both had a mean rank score of 4.00.

FLIE Total Scale

The total FLIE score demonstrated a mean score of 71.00, with a standard deviation of 8.50. Analysis of the data indicated that the sample population reported moderate DF when considered in the context of living with and being treated for cancer.

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

This chapter presents conclusions drawn from the data analysis presented in this study. Recommendations for patient care are discussed. QOL and DF issues are becoming more important in health care and in society. QOL and DF indicators merit further research.

Summary

QOL is thought to be an inherent phenomena developed over time in each individual. DF is an important aspect of QOL. QOL influences health actions, behaviors, and choices. The saying goes, "when you have your health, you have everything." As such, then, what affects health affects QOL. Surgery, radiation therapy, chemotherapy, immunotherapy, and hormonal therapy constitute the treatment modalities of cancer therapy and are used alone or in combination with one another. Treatment-related difficulties or toxicities vary depending on the specific modalities that are used.

Detailed QOL and DF assessment can provide a comprehensive description of potential side effects from the patient's point of view. Furthermore, QOL and DF assessment can be helpful in weighing the risks and benefits of treatment options, particularly when differences in survival among the options are small or nonexistent. QOL and DF assessments not only provide needed information for patients and their health care providers, but may also be of

importance in assessing treatment outcomes as policy makers critically evaluate cost-effectiveness of cancer treatments. With a broader understanding of the problems that patients confront, physicians, nurses, and other health care providers can work together to develop new treatments to minimize the adverse effects of cancer therapy. It is hoped that QOL and DF research will lead not only to increased understanding, but also to improvement in the care of patients with cancer.

Limitations

A number of limitations affected this study and its findings. One factor was the outpatient convenience sample. Using a convenience sample rather than a random sample was a limitation. Using only outpatient chemotherapy patients did not represent the general population of cancer patients undergoing cancer treatment. Therefore, the findings are not generalizable to the cancer population. Findings can only be applied to this sample. Broadening the population base to include both outpatient and inpatient cancer patients undergoing radiation therapy, surgery, or immunotherapy would have increased the generalizability of the results and may have changed the findings considerably.

Second, the sample size is a limitation. The sample size was too small. Cohen (1977) suggests that the larger the sample size, the more significant the results.

Therefore, having a larger sample would have yielded more significant findings.

Third, the sensitivity of the FLIC instrument in reflecting the experience of living with cancer was felt to be inadequate for the purpose of the study. Another instrument specific to cancer and treatment for cancer or an option such as a semistructured interview designed to detect individual interpretations may have been a better choice.

Lastly, there was the possibility that QOL and DF orientation was different in each subject prior to the diagnosis of the cancer. The study findings indicated that serial measurement of QOL and DF orientation, as patients progress through cancer diagnosis and treatment, could yield more pertinent data than a one-time assessment of QOL.

Discussion of Findings

This study sample was described as middle-aged, well educated, middle class, and mainly Caucasian. The demographics of the sample were not representative of the community from which it was drawn. Future research in this arena could include more detailed exploration of the effects of age, gender, ethnicity, income level, and educational level on the variations in QOL and DF orientation.

In this study, the primary types of cancer site occurrence of the participants were: (a) breast, (b) colon, and (c) leukemia of the bone marrow. These sites were for both genders and not listed in descending order of

frequency. In the geographical region from which the study sample was drawn, as well as in the State of California and the nation, the four most common types of cancer site occurrence are: (a) prostate, (b) female breast, (c) lung, and (d) colorectal (Bay Area Cancer Registry, 1991). Thus the types of cancer site occurrence for the study participants were not representative of the general population. Future research in this area should include cancer sites that are representative of those sites most commonly found in the general population.

Functional Living Index-Cancer

The study participants reported that they perceived overall moderate QOL. In the physical well-being subscale, the data indicated that the sample participants were functioning satisfactorily related to their disease. Considering the participant was living with and being treated for cancer, analysis of the psychological well-being subscale data demonstrated that the participant spent a reasonable amount of time thinking about his/her illness and the outcome of the cancer treatment.

In the family situation subscale, the data revealed that the participants perceived that cancer posed moderate hardship and disruption in his/her life personally and to those individuals closest to him/her. In the social well-being subscale of the FLIC, the data indicated that the participant was willing to see and spend

moderate time with friends and those individuals closest to him/her.

The nausea subscale was the last subscale of the FLIC. In the nausea subscale, analysis of the data showed that nausea, as one of the side effects of cancer treatment, had a moderate affect on the participant's DF.

In a sample of this size, it was unlikely that the majority of the participants were functioning without any problems related to their disease. Both cancer and chemotherapy treatments caused symptoms and side effects, which adversely affected QOL and DF.

Several explanations for the study findings were possible. First, 85% of the sample population had been diagnosed with cancer sometime between January 1995 and March 1996. It might have been that the chronicity of living with cancer had not yet made a significant impact on the lives of the participants.

Secondly, all the participants were receiving chemotherapy treatment as outpatients. They were able to remain in their own environment after their treatment and continue their lives with some degree of normalcy. Factors such as home, family, and neighborhood that influenced the experience of QOL for the individual were still present.

Third, the timing of data collection during the course of chemotherapy treatment could have influenced the participant's responses. Chemotherapy was generally given

for a total of six cycles. Side effects were nonexistent or minimal for the first few cycles. Some symptoms, such as pain, may have improved for the first few weeks. It would be interesting to investigate whether symptom occurrence and length of time under treatment affected participant's feelings regarding his/her QOL.

Functional Living Index-Emesis

Generally, the participants reported that vomiting had the same effect on DF as nausea. The fact that the mean scores on both the nausea and vomiting scales were at the midpoint of the scale indicated a moderate impact from these side effects, which have often been considered as having little importance by health professionals. FLIE scores indicated that CIE participants perceived that vomiting and nausea influenced their ability to complete household tasks, enjoy meals, spend time with family and friends, and maintain DF and recreation. The results of the findings indicated that FLIE was a sensitive tool for assessing specific effects of CIE on QOL and DF.

Comparison of Findings to Literature

Craig and Powell (1987) found that inadequate emesis control ranged from an increase in patient discomfort with its attendant negative psychosocial effects to loss of patient compliance. Moreover, Coons (1987) found that nausea and vomiting with its accompanying fatigue and anorexia resulted in an increase in anxiety, depression, and

the development of anticipatory emesis, which adversely impacted on the patient's QOL and led to major psychosocial problems.

This study found that participants had a moderate QOL. Also, this study found that the antiemetic regimen, if taken before and after chemotherapy treatment as prescribed by doctors, decreased the likelihood that nausea and occasional vomiting would occur.

In a separate study, Lindley et al. (1992) found that patients who experienced CIE perceived that vomiting influenced their ability to spend time with their family and friends, maintain DF and recreation, complete household tasks, and enjoy meals with family and friends. In a similar study, Campora et al. (1992) found that cancer patients reported no negative impact of their disease and treatment on their physical, psychological, and social well-being. They found that patients judged their relationship with their partner and/or family to be good and infrequently rated their anxiety as moderate or severe. The current study found that patients who experienced CIE perceived that vomiting and nausea moderately influenced their QOL and DF.

The range of side effects included in the FLIC and FLIE could be extended to include effects of sedation, perceptions of anxiety, and perhaps other commonly encountered toxicities of antiemetic therapy. These

additions might expand the FLIC's and the FLIE's ability to assess both the impact of chemotherapy-associated events and antiemetic toxicity on DF and QOL.

Recommendations

There are several recommendations for patient care that emerged as a result of this study. First, in order to utilize nursing intervention based on the knowledge of QOL and DF orientation, such orientation would need to be assessed. Baseline QOL and DF assessment would help the health care provider determine how patients view life and what would be important in their lives to maintain QOL and DF. Broader understanding of this orientation could lead to improvement in nursing care rendered to cancer patients.

More QOL and DF research is warranted. One recommendation for future research is to use the same QOL (FLIC) tool and DF (FLIE) tool to determine if they accurately reflect the nature of the cancer experience and the effects of cancer treatment. Another recommendation for future research is to use a large random sample of patients with the three most common types of cancer who are receiving chemotherapy in both inpatient and outpatient facilities.

Longitudinal research should be conducted to assess for changes in perceived QOL and DF over time. As treatment side effects occur and resolve, perceptions may change. In addition, if the disease progresses and the goal of

treatment changes from curative to palliative, perceptions of QOL and DF may change. Comparison of the results could yield valuable information regarding perceived QOL and DF.

Despite the reports of excellent emetic control obtained from the previous research, the state of the art in emesis control in cancer patients remains inadequate. Reasons for and consequences of CIE in cancer patients merits further investigation.

REFERENCES

References

Adams, L. (1993). Managing chemotherapy-induced nausea and vomiting. Professional Nurse, 92, 91-94.

Bay Area Cancer Registry Report. (1991). Community use of region one cancer registry. Belmont, CA: Northern California Cancer Center.

Bianchi, R. A. (1995). Development and testing of a conceptual framework of quality of life for people with HIV/AIDS. Unpublished doctoral dissertation, University of California, San Francisco.

Campora, E., Naso, C., Vitullo, M. T., Guidici, S., Camoirano, A., Repetto, L., & Rosso, R. (1992). The impact of chemotherapy on the quality of life of breast cancer patients. Journal of Chemotherapy, 4(1), 59-63.

Cassidy, J. (1988). Pharmacokinetics and anti-emetic efficacy of BRL43694. British Journal of Cancer, 58, 651-653.

Chevallier, B. (1990). Efficacy and safety of granisetron. European Journal of Cancer, 26(1), 33-36.

Cohen, J., (1977). Statistical power analysis for the behavioral sciences. New York: Academic Press.

Coons, H. L. (1987). Anticipatory nausea and emotional distress in patients receiving cisplatin-based chemotherapy. Oncology Nursing Forum, 14(3), 31-35.

Craig, R., & Powell, B. (1987). Management of nausea and vomiting in the cancer patient. American Journal of Medical Sciences, 293, 34-42.

Cuppisol, D. (1990). The efficacy of granisetron as a prophylactic anti-emetic and intervention agents. European Journal of Cancer, 26(1), 23-27.

Donehower, M. G. (1985). The behavior of malignancies. In B. L. Johnson & J. Gross (Eds.), Handbook of oncology nursing (pp. 1-20). New York: Wiley.

Ferrans, C. E. (1990). Development of quality of life index for patients with cancer. Oncology Nursing Forum, 17, 15-19.

Grunberg, S. M., & Hesketh, P. J. (1993). Control of chemotherapy-induced emesis. New England Journal of Medicine, 329, 1790-1796.

Haber, J. (1986). Sampling. In G. LoBiondo-Wood & J. Haber (Eds.), Nursing research: Critical appraisal and utilization (pp. 203-222). St Louis, MO: Mosby.

Kris, M. G., Gralla, R. J., & Clark, R. A. (1990). Incidence, course, and severity of delayed nausea and vomiting following the administration of high-dose cisplatin. Journal of Clinical Oncology, 3, 1379-1384.

Laszlo, J. (1993). Nausea and vomiting as major complications of cancer chemotherapy. Drugs, 25(1), 1-7.

Lindley, C. M., Bernard, S., & Fields, S. M. (1989). Incidence and duration of chemotherapy-induced nausea and vomiting in the outpatient oncology population. Journal of Clinical Oncology, 7, 1142-1149.

Lindley, C. M., Hirsch, J. D., O'Neill, C. V., Transau, M. C., Gilbert, C. S., & Osterhaus, J. T. (1992). Quality of life consequences of chemotherapy-induced emesis. Quality of Life Research, 1, 331-340.

Payne, S. A. (1992). A study of quality life in cancer patients receiving palliative chemotherapy. Social Science and Medicine, 35, 1505-1509.

Penta, J., Poster, D., & Bruno, S. (1993). The pharmacologic treatment of nausea and vomiting caused by cancer chemotherapy: A review. In J. Laszlo (Ed.), Antiemetic and cancer chemotherapy (pp. 53-92). Baltimore: Williams & Wilkins.

Redd, W. H., & Andrykowski, M. A. (1982). Behavioral intervention in cancer treatment. Journal Consultation in Clinical Psychology, 50, 1018-1029.

Schipper, H., Clinch, J., McMurray, A., & Levitt, H. J. (1984). Measuring the quality of life of cancer patients: The Functional Living Index-Cancer: Development and validation. Journal of Clinical Oncology, 2, 472-483.

Sherbourne, C. D. (1992). Social functioning: Social activity limitations measure. In A. L. Stewart & J. E. Ware (Eds.), Measuring functioning and well-being: The medical outcomes study approach (pp. 173-181). Durham, NC: Duke University Press.

Sherbourne, C. D., & Kamberg, C. J. (1992). Social functioning: Family and marital functioning measures. In A. L. Stewart & J. E. Ware (Eds.), Measuring functioning and well-being: The medical outcomes study approach (pp. 182-193). Durham, NC: Duke University Press.

Sherbourne, C. D., Stewart, A. L., & Wells, K. B. (1992). Role functioning measures. In A. L. Stewart & J. E. Ware (Eds.), Measuring functioning and well-being: The medical outcomes study approach (pp. 205-219). Durham, NC: Duke University Press.

Smith, I. E. (1990). A dose-finding study of granisetron in moderately emetogenic cytostatic chemotherapy. European Journal of Cancer, 26(1), 19-23.

Stewart, A. L. (1992). The medical outcomes study framework of health indicators. In A. L. Stewart & J. E. Ware (Eds.), Measuring functioning and well-being: The medical outcomes study approach (pp. 12-24). Durham, NC: Duke University Press.

Stewart, A. L., & Kamberg, C. J. (1992). Physical functioning measures. In A. L. Stewart & J. E. Ware (Eds.), Measuring functioning and well-being: The medical outcomes study approach (pp. 86-101). Durham, NC: Duke University Press.

Stewart, A. L., & Ware, J. E. (Eds). (1992). Measuring functioning and well-being: The medical outcomes study approach (pp. 11-23), Durham, NC: Duke University Press.

Stewart, D. J. (1990). Cancer therapy, vomiting, and anti-emetics. Cancer Journal of Physiology Pharmacology, 68, 304-313.

Strum, S. B., McDermed, J. E., Pileggi, J., Reich, L. P., & Whitaker, H. (1990). Intravenous metoclopramide: Prevention of chemotherapy-induced nausea and vomiting. Cancer, 53, 1432-1439.

Tabona, M. V. (1990). An overview on the use of granisetron in the treatment of emesis. European Journal of Cancer, 26(1), 38-42.

Tortorice, P. V., & O'Connell, M. B. (1990). Management of chemotherapy-induced nausea and vomiting. Pharmacology, 10, 129-145.

Triozzi, P. L., & Laszlo, Jr. (1987). Optimum management of nausea and vomiting in cancer chemotherapy. Drugs, 34, 136-149.

Webster's new world dictionary (3rd ed.). (1988). New York: Simon & Schuster.

Whickham, R. (1989). Managing chemotherapy-related nausea and vomiting: The state of the art. Oncology Nursing Forum, 16, 563-574.

Winer, E. P. (1994). Quality-of-life research in patients with breast cancer. Cancer, 74, 410-415.

World Health Organization. (1948). "World Health Organization constitution." In basic documents. Geneva: Author.

APPENDIX A
Author Consent Letter

SAN JOSE STATE UNIVERSITY
SCHOOL OF NURSING
SAN JOSE, CALIFORNIA 95192

May 4, 1995

Rose Conde
213 Galano Plaza
Union City, California 94587

Dear Ms. Conde,

This letter is to verify in writing that I have given you permission to utilize my quality of life conceptual framework as developed in my dissertation - Development and Testing of a Conceptual Framework of Quality of Life for People with AIDS. You may only use this conceptual framework for your thesis project.

I will be quite interested to hear from you regarding how well my quality of life conceptual framework worked in a sample of cancer patients undergoing chemotherapy. I wish you the best in your research pursuit.

Sincerely,

A handwritten signature in cursive script that reads "Rose Bianchi".

Rose Bianchi, DNSc., R.N.

APPENDIX B
Facility Consent Letter

EL CAMINO MEDICAL STAFF

2500 Grant Road, Mountain View, California 94040 (415) 940-7040 Facsimile (415) 966-9263

December 12, 1995

Rose Conde, RN
213 Galano Plaza
Union City, California 94587

RE: ASSESS THE IMPACT OF CHEMOTHERAPY-INDUCED NAUSEA AND
VOMITING ON QUALITY OF LIFE IN PATIENTS WITH CANCER

Dear Ms. Conde:

The above-noted study was approved following expedited review . In order to make the study more complete, I recommend that you consult your advisor and reconsider the design of the study with regard to the statistical analysis. You may wish to consider paired, non-parametric analysis.

This approval is contingent upon the following:

1. Your use of the approved consent form.
2. Your compliance with the approved investigational plan.
3. Your commitment to notify the Board of any unforeseen risks or complications that might reasonably have an effect on the Board's continued approval of the study.

The Board has scheduled this study for re-evaluation in one year or at the conclusion of the study, whichever occurs first.

Sincerely,

Michael S. Greenfield, M.D.
Chairman, Institutional Review Board

MSG/ae

Enc.

F:\MEDSTAFF\IRB\EXPD RVU

APPENDIX C

San Jose State University Approval Letter

A campus of The California State University

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408/924-2480

TO: Rose G. Conde
213 Galano Plaza
Union City, CA 94587

FROM: Serena W. Stanford
AAVP, Graduate Studies & Research

DATE: January 8, 1996

The Human Subjects-Institutional Review Board has approved your request to use human subjects in the study entitled:

"Assess the Impact of Chemotherapy-Induced Nausea
and Vomiting on Quality of Life in Patients with
Cancer"

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity when they participate in your research project, and with regard to any and all data that may be collected from the subjects. The Board's approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Serena Stanford, Ph.D., immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised that each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate, or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact me at (408) 924-2480.

APPENDIX D
Participant Consent Letter

Camino Healthcare
Consent To Be A Research Subject

APPROVED
12/13/95
DATE
Michael S. Crawford, M.D.
INSTITUTIONAL REVIEW BOARD
CHAMBERLAIN

Title of study: A descriptive study to assess the impact of chemotherapy-induced nausea and vomiting on quality of life in patients with cancer.

Principal Investigator: Rose G. Conde, R.N.
213 Galano Plaza
Union City, CA 94587
(510) 471-4559

Purpose of the study: You are invited to participate in a study. The purpose of the study is to assess the impact of chemotherapy-induced nausea and vomiting on quality of life in patients with cancer in the outpatient setting. Patients receiving intermittent bolus chemotherapy (chemo push) for 1 thru 5 days will be eligible for the study. We hope to learn how nausea and vomiting impact patients' daily living function and their overall quality of life. You were selected as a possible participant because of what you may be able to contribute to the study.

Study Procedure: If you decide to participate in this study you will be asked to fill out 3 separate questionnaires. On day 1, you will be asked to fill out (a) Informed consent, if you decide to participate in the study, (b) Demographic Data Form (DDF), and (c) The Functional Living Index- Cancer (FLIC). Then on day 4, you will be asked to fill out the last questionnaire namely The Functional Living Index- Emesis (FLIE). Your time involvement will be about 20 minutes.

Risks/Discomforts: The questionnaires do have some items which may bring forth emotional responses, both positive and perhaps negative, related to the experience of living with cancer. Unforeseeable risks could occur.

Possible benefits: The possible benefits of this study are contributions to the improvement of nursing care for yourself and others. The study may serve as a first step towards research to improve quality of life. But on the other hand, we do not promise any benefits from the study.

Confidentiality: Any information obtained during this study which could identify you will remain confidential. Summary information obtained in this study may be published in scientific journals or presented at scientific meetings. Furthermore, information obtained during this study will be placed in a locked cabinet and only the principal investigator will have access to it.

Withdrawal from study: Participation in this study is voluntary. Your decision whether or not to participate will not prejudice or harm your future relations with Camino Healthcare.

If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

Payment for Injury: There will be no payment for participating in this study. Any injury or condition incurred as a member of Camino Healthcare and as a consequence of being in this study will be treated in accordance with the members health plan coverage.

Questions: If you have questions, we want and expect you ask them. If you think of any questions later, Rose Conde, R.N., telephone (510) 471-4559 will be happy to answer them. Questions, comments or complaints about the study may be presented to the Institutional Review Board for the Protection of Human Subjects, Camino Healthcare 2500 Grant Road, Mountain View, CA. 94040, telephone (415) 940-7040, or Serena Stanford, Ph.D. Associate Academic Vice President/Graduate Studies and Research, San Jose State University, One Washington Square, San Jose, CA. 95192-0025, telephone (408) 924-2480.

I have read the above and am satisfied with my understanding of the study, its possible benefits, risks, and alternatives. My questions about the study have been answered. I hereby voluntarily consent to participate in the research study as described. I have been offered copies of this consent form and of the "Experimental Subjects Bill of Rights."

Signature of Participant

Date

Name of participant-printed

Witness

APPENDIX E

Demographic Data Form (DDF) Questionnaire

Demographic Data Form (DDF)

Code Number: _____ Marital Status _____

Age: _____

Highest Grade Level of School
Completed:Sex: M _____
F _____8th Grade: _____
12th Grade: _____
College Graduate: _____

Race/Ethnicity:

Caucasian _____
Black _____
Asian _____
Hispanic _____
Other _____

Income level:

Less than \$15,000/yr _____
\$15,001-\$25,000/yr _____
\$25,001-\$35,000/yr _____
\$35,001-\$45,000/yr _____
\$45,001-\$55,000/yr _____
More than \$55,000/yr _____

Cycles of Chemotherapy:

1 2 3 4 5 6

Type of Cancers: _____

Month/year of cancer diagnosis _____

Describe antiemetic regimen

Name of antiemetic drug: _____
Dose of antiemetic drug: _____
Frequency of drug: _____

APPENDIX F

Functional Living Index-Cancer (FLIC) Questionnaire

Functional Living Index-Cancer

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1-----2-----3-----4-----5-----6-----7
Never Continually

2. How well are you coping with your everyday stress?

1-----2-----3-----4-----5-----6-----7
Not well Very Well

3. How much time do you spend thinking about your illness?

1-----2-----3-----4-----5-----6-----7
Constantly Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1-----2-----3-----4-----5-----6-----7
Able Unable

5. Has nausea affected your daily functioning?

1-----2-----3-----4-----5-----6-----7
Not at all A Great Deal

6. How well do you feel today?

1-----2-----3-----4-----5-----6-----7
Extremely Extremely
Poor Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1-----2-----3-----4-----5-----6-----7
Very able Not Able

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past two weeks.

9. Rate how often you feel discouraged about your life.

10. Rate your satisfaction with your work and your jobs around the house in the past month.

11. How uncomfortable do you feel today?

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past two weeks.

13. How much is pain or discomfort interfering with your daily activities?

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past two weeks.

15. How much of your usual household tasks are you able to complete?

16. Rate how willing you were to see and spend time with those closest with you, in the past two weeks.

17. How much nausea have you had in the past two weeks?

18. Rate the degree to which you are frightened of the future.

19. Rate how willing you were to see and spend time with friends, in the past two weeks.

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

20. How much of your pain or discomfort over the past two weeks was related to your cancer?

1 2 3 4 5 6 7
None All

21. Rate your confidence in your prescribed course of treatment.

1 2 3 4 5 6 7

No Confidence Very Confident

22. How well do you appear today?

1 2 3 4 5 6 7

Extremely Poor Extremly Well

APPENDIX G

Functional Living Index-Emesis (FLIE) Questionnaire

Functional Living Index-Emesis

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

1. How much nausea have you had in the past 3 days?

1 2 3 4 5 6 7

None A Great Deal

2. Has nausea affected your ability to maintain useful recreation or leisure activities in the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

3. Has nausea affected your ability to make a meal or do minor household repairs during the past 3 days?

1-----2-----3-----4-----5-----6-----7
A Great Deal Not at all

4. How much has nausea affected your ability to enjoy a meal in the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

5. How much has nausea affected your ability to enjoy liquid refreshment in the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

6. How much has nausea affected your willingness to see and spend time with family and friends, in the past 3 days?

1 2 3 4 5 6 7
A Great Deal Not at all

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

7. Has nausea affected your daily functioning in the past 3 days?

1-----2-----3-----4-----5-----6-----7
Not at all A Great Deal

8. Rate the degree to which your nausea has imposed a hardship on you (personally) in the past 3 days.

1 2 3 4 5 6 7
Not at all A Great Deal

9. Rate the degree to which your nausea has imposed a hardship on those closest to you in the past 3 days.

1 2 3 4 5 6 7
Not at all A Great Deal

10. How much vomiting have you had in the past 3 days?

1 2 3 4 5 6 7

None A Great Deal

11. Has vomiting affected your ability to maintain usual recreation or leisure activities during the past 3 days?

1-----2-----3-----4-----5-----6-----7
A Great Deal Not at all

12. Has vomiting affected your ability to complete your usual household tasks during the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

Unless otherwise indicated, please respond to the following questions as they relate to your activities and well-being during the last two weeks.

13. How much has vomiting affected your ability to enjoy a meal in the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

14. How much has vomiting affected your ability to enjoy liquid refreshment in the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

15. How much has vomiting affected your willingness to see and spend time with friends in the past 3 days?

1-----2-----3-----4-----5-----6-----7
A Great Deal Not at all

16. Has vomiting affected your daily functioning during the past 3 days?

1 2 3 4 5 6 7
Not at all A Great Deal

17. Rate the degree to which your vomiting has imposed a hardship on you (personally) in the past 3 days.

1 2 3 4 5 6 7
Not at all A Great Deal

18. Rate the degree to which your vomiting has imposed a hardship on those closest to you in the past 3 days.

1-----2-----3-----4-----5-----6-----7
A Great Deal Not at all

APPENDIX H
Author Consent Letter (FLIC)

**World Health Organization Collaborating Centre for
Quality of Life in Cancer Care**

St. Boniface General Hospital Research Centre
351 Tache Avenue, Winnipeg, Manitoba, Canada R2H 2A6
Phone: (204) 235-3580 Fax: (204) 235-1231

June 1, 1995

Ms Rose Conde, R.N.
213 Galano Plaza
Union City, CA
94587
U.S.A.

Dear Ms Conde:

Thank you for your letter of May 10, 1995 requesting permission to use the FLIC scale. I have enclosed a copy of the FLIC, its scoring procedure, some information as to its administration as well as some general information.

We are always interested in knowing in what manner people use the FLIC, and would very much like to receive a copy of your thesis abstract for our information.

I wish you luck in your studies. Should you have any questions, or require any further information, please do not hesitate to contact our office.

Sincerely,

Leanne Matthes, B.A. (Hons.), M.A.
Research Associate

Centre de recherche
à l'Hôpital général

St-Boniface

General Hospital
Research Centre

St-Boniface General Hospital and
Research Centre

APPENDIX I
Author Consent Letter (FLIE)

THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

School of Pharmacy

Campus Box 7360, Beard Hall
The University of North Carolina at Chapel Hill
Chapel Hill, N.C. 27599-7360
(919) 966-1121
FAX Number (919) 966-6919

August 7, 1995

Rose G. Conde, R.N.
213 Galano Plaza
Union City, CA 94587

Dear Ms. Conde:

Thank you for your letter describing your Master's thesis which will focus on research that investigates the impact of chemotherapy-induced nausea and vomiting on quality of life in patients with cancer. Certainly this is an important area of study.

Yes, you are quite welcome to use my FLIE scale from my journal article "Quality of life consequences of chemotherapy-induced emesis."

I wish you well in your graduate program at San Jose State.

Cordially,

A handwritten signature in cursive script, appearing to read "C.M. Lindley".

C.M. Lindley, MS, PharmD, FCCP, FASHP, BCPS
Associate Professor of Pharmacy and Medicine

CML/er