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Effects of a structured teaching program for cancer patients undergoing head and neck radiation therapy on anorexia, nutritional status, functional status, treatment response and quality of life

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EFFECTS OF A STRUCTURED TEACHING PROGRAM FOR CANCER PATIENTS UNDERGOING HEAD AND NECK RADIATION THERAPY ON ANOREXIA, NUTRITIONAL STATUS, FUNCTIONAL STATUS, TREATMENT RESPONSE AND QUALITY OF LIFE

by

Marcia Moeller Grant

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The University of California, San Francisco

School of Nursing

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ABSTRACT

The patient with head and neck cancer undergoing radiation therapy is vulnerable to anorexia, defined as a decrease in appetite associated with a decrease in dietary intake, and potentially leading to nutritional depletion. Infrequently tested clinical interventions for anorexia include helping patients manage side effects, and learning about needed dietary intake.

Physical, psychological, and sociocultural factors interfering with food intake in cancer patients were identified from the literature. Using a multifactorial redundant model of food intake, a structured teaching program was designed to provide patients with ways to interrupt anorexia and to diminish nutritional depletion. The purpose of this study was to test the effects of this program on anorexia, nutritional status, functional status, treatment response, and quality of life.

The study sample consisted of 41 subjects undergoing radiation therapy for head and neck cancer and randomized to the structured teaching program (n=21) or the 'usual care' group (n=20). Age ranged from 24 to 84 with a mean of 56.

Despite randomization, two major variables differed significantly between groups. The experimental group reported greater weight loss prior to the onset of therapy (5.4 kg versus 2.5 kg, $p=0.05$) and received a higher dosage of radiation treatment to site 2 of the radiation field ($p=0.03$). Each of these factors had a potential to exascerbate weight loss during the treatment period.

Results showed significantly higher scores on nutrition knowledge for the experimental group at the end of the treatment period ($p=0.05$). Three important, but not statistically significant, trends occurred. The experimental group reported lower appetite scores, maintained a consistently higher caloric and protein intake, and lost weight at a rate no faster than the control group. No differences were found in relation to age, functional status, treatment response, or quality of life.

Findings provide evidence that a structured teaching program may reduce the expected decrease in dietary intake during radiation therapy in spite of decreased appetite. In addition, findings support the need to include both the subjective measurement of appetite and the objective measurement of dietary intake in descriptions of anorexia in cancer patients.

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CHAPTER 1

INTRODUCTION AND STATEMENT OF THE PROBLEM

Nutritional depletion occurs frequently in patients with cancer and is associated with both the course of the disease and with cancer treatment. Multiple factors, such as decreased dietary intake (DeWys, 1977), increased metabolic expenditure (Bozzetti, Pagnoni, & Del Vecchio, 1980), increased gluconeogenesis (Waterhouse, Jeanpretre, & Keilson, 1979) and increased tumor utilization of protein (Carmichael, Clague, Keir & Johnston, 1980) have been hypothesized as causes of this depletion (Dickerson, 1983).

Anorexia, or a decrease in appetite accompanied by a spontaneous decrease in food intake in cancer patients, may play a major role in nutritional depletion, predisposing the patient to infections and poor wound healing (Ruberg, 1984), and to cachexia, or body wasting which can be a cause of death in cancer patients (Morrison, 1976). In addition, anorexia and other eating problems impact negatively on the patient's quality of life (Padilla et al., 1983).

In the clinical setting, anorexia is a feeding disorder frequently encountered by the nurse in the daily care of cancer patients. It can occur during any stage of cancer and is associated with the natural course of the disease, with treatment, and with the emotional response of the individual to the illness (Dickerson, 1983). For example, some patients may report a decrease in appetite and/or a decrease in weight at the time of diagnosis even though no symptoms are present (Theologides, 1981). For patients undergoing surgical interventions and radiation therapy, anorexia and weight loss are common (Costa & Donaldson, 1980; Welch, 1980). In addition, many patients who die from cancer are anorectic, have suffered significant weight loss and are malnourished (Morrison, 1976).

The elderly cancer patient may be particularly vulnerable to anorexia and nutritional depletion because of nutritional changes associated with aging process. Changes in digestion from decreased absorption, motility and vascular perfusion contribute to poor nutrition in the elderly (Nasrallah & Iber, 1984). Other changes such as loss of teeth, of ability to swallow, of taste and smell sensitivity, and of saliva volume also predispose to poor dietary intake (Baum & Bodner, 1983). Problems related to changes in physical arrangements, strength, and loss of eating companions further enhance the risk of poor nutrition (Andrews, Haneman & Arnold, 1967; Baum, 1981A, 1981B; Eastwood, 1972; Goldman, 1979; Tonna, 1977).

The elderly comprise a substantial proportion of the cancer patient population. The risk of developing cancer is increased to more than 17% in women and more than 23% in men over the age of 65 as compared with less than 1.5% in men and women under the age of 40 (Seidman, Silverberg & Bodder, 1978). Head and neck cancer represents approximately 5% of all new cancers diagnosed, and that incidence increases with age (National Cancer Institute, 1979). Overall incidence rates are approximately 17/100,000 and increase to 45/100,000 in the 6th decade and 65/100,000 in the 7th and 8th decades (National Cancer Institute, 1979).

A common form of treatment for elderly cancer patients is radiation therapy, a cancer treatment given to approximately 60% of all cancer patients each year, and over half a million in 1983 alone (Brady, Markol & Fisher, 1986). Radiation therapy is especially important for elderly patients unable to tolerate surgery. However, the incidence and severity of negative sequelae of radiation therapy may be increased in the elderly patient. Aging also results in a decrease in the ability of the cells to repair themselves (Sinex, 1977). Thus, when radiation is given to elderly patients, a higher risk for the development of negative side effects, such as anorexia, weight loss, and nutritional depletion may be present.

Examination of factors influencing dietary intake and feeding behavior in health reveals a multifactorial, redundant model, composed of physiological, psychological and sociocultural factors (Novin & VanderWeele, 1977; Toates, 1981). Temporary interference with one of the factors may produce a temporary loss of dietary intake, while interference with several of the factors over a period of time could lead to a failure in the system, with a devastating nutritional result (Grijalva & Lindholm, 1982).

The head and neck cancer patient undergoing radiation therapy is vulnerable to many interferences with dietary intake (Daly et al., 1984; Donaldson, 1984; Johnston, Keane, & Prudo, 1982). The selection of approaches to the management of anorexia for the head and neck cancer population can be made and tested within the framework of a redundant food intake model. One approach possible is to assist the patient in maintaining an adequate dietary intake through an educational program designed to 1) identify an individualized nutritional goal, 2) explain why nutrition is important during therapy, 3) manage the common side effects which interfere with the ability to eat during radiation therapy, and 4) promote ways to deal with emotional distress and sociocultural changes.

Examination of previous studies of head and neck cancer patients undergoing radiation therapy reveals difficulties with instruments to measure anorexia: appetite scales and daily dietary intake measurements suffer from reliability and validity threats (Bassett & Dobie, 1983; Chencharick & Mossman, 1983; Daly, et al, 1984; Hamill, 1978; Johnston et al., 1982). Dietary counseling is difficult to evaluate because the specific content of the program as well as the patient's comprehension and use thereof have not been reported. Enteral support, via tube feeding, has shown positive results in decreasing weight loss during radiation therapy for head and neck cancer patients (Daly et al., 1984). The area not reported to date is whether or not the patient can maintain dietary intake of sufficient calories and protein orally without being subjected to insertion of a feeding tube.

It is the purpose of this study to test the effects of a structured teaching program based on supporting the redundant system for maintaining food intake and the effects of age on anorexia, nutritional status, functional status, treatment response and quality of life in a group of cancer patients undergoing radiation therapy for head and neck cancer.

CHAPTER 2

REVIEW OF LITERATURE

Maintaining Dietary Intake in Health

Physiological Perspective

Factors which promote dietary intake in health may be viewed from a physiological and/or psychosocial perspective. Various physiological theories have been proposed. The oldest systematic theory of the regulation of food intake is derived from work by Cannon & Washburn (1912). The theory proposes that the major stimulus to food intake is the occurrence of hunger pangs which result from contraction of the stomach. In turn, food intake stops when the stomach is quiet. This theory was useful from both empirical and common sense viewpoints. Then several incidences occurred to cause its decline. First, stomach surgery increased, and more and more patients experienced only temporary feeding disorders after either stomach dennervation or total gastrectomy. In addition, information for the development of another theory became available, and provided a more complete explanation of feeding behavior.

This second theory involves the glucostatic hypothalamic dual center hypothesis and is referred to as a centralist theory, as contrasted with the "peripheral" nature of Cannon's theory. Through a series of studies done by several investigators and replicated by others, two areas of the hypothalamus associated with feeding behavior were isolated. Using rat and mice models, experimentally placed lesions in the two areas produced changes in the animal feeding behavior. The lateral hypothalamic area became known as the feeding center since stimulation of the area activates feeding while lesions in this area interrupt feeding behavior, producing aphagia and adipsia. The ventromedial area of the hypothalamus became known as the satiety center since stimulation of the area inhibits eating while lesions in this area produce obesity (Stellar, 1954). It was proposed that these centers contain glucose receptors that respond to differing levels of blood glucose (Mayer, 1955). However, this theory fails to take into account other interconnected systems. In addition, other experiments demonstrated that feeding behavior could be recovered even after extensive damage to the hypothalamus (Teitelbaum & Epstein, 1962). A simple system of dual centers responding to changes in glucose metabolism does not adequately describe the experimental observations obtained. The focus has turned again to peripheral mechanisms whereby sensors in the oronasal, gastro-intestinal tract, and liver are examined.

Oronasal factors, such as taste, smell, texture, and sight of food are influential in feeding behavior (Peck, 1976; Rolls, 1981). Taste may be even more important than calories in maintaining an adequate oral intake. For example, rats were given various diets after being fed either ad lib or deprived of food. The deprived rats ate more food when saccharine was present than when quinine was present illustrating the importance of taste for ingestion to occur (Jacobs & Sharma, 1969).

The stomach as a major source of signals controlling feeding has again received attention. In studies by Davis and Campbell (1973), meals that rats had just eaten were removed from the stomach by suction. The animals did not show signs of satiety even after large amounts of food had been ingested. The authors concluded that stomach distention appeared to be a critical factor in regulating feeding. An alternate explanation, however, could be that satiety was never reached because sensors active in the suppression of hunger but located below the stomach were never activated. Also related are studies of the gastrointestinal hormone, cholecystokinin, which is released from the gastrointestinal tract in response to feeding and produces a period of lessened food intake. (Smith & Gibbs, 1976). Whether or not the gut is involved in signals that indicate adequate ingestion of food has been studied in experiments involving infusion via intra-duodenal cannula and by-passing the mouth and stomach (Rogers, Martin, VanderWeele, & Novin, 1977). It appears that there may be metabolic receptors in the gut that respond to ingested materials. The liver has been hypothesized to have receptors, probably glucostatic, that respond to blood glucose levels by suppressing eating until a meal is digested and absorbed (Novin, VanderWeele, & Rezek, 1973). The involvement of the liver in the regulation of feeding behavior appears particularly logical because of its function in glucose homeostasis; i.e. the liver stores glucose by synthesis of glycogen, releases glucose molecules by breaking down stored glycogen, and manufactures glucose via gluconeogenesis. Current research approaches involve the exploration of mechanisms involved in coordinating peripheral and central factors which impact on appetite. It appears that the drive for food and its ingestion is of high priority, and animals are generally in a "feeding mode." Both peripheral and central neural and hormonal signals appear to interrupt this feeding mode and lead to at least a temporary state of satiety (Morley & Levine, 1985).

As more sensors are identified and studied, the complexity of the system of ingestion of food has become evident. It is apparent that a system of multiple physiological factors is involved in the maintenance of feeding behavior. No hierarchy in this system is presently apparent (Grijalva & Lindholm, 1982; Novin & VanderWeele, 1977).

These mechanisms have been associated primarily with short term controls over feeding behavior. A different perspective of research is seen in the experiments involving mechanisms thought to be responsible for long term control over feeding behavior, as in the lipostatic theory. According to this theory when body fat reserves are depleted, the satiety signal is decreased and an increase in feeding is seen (Friedman & Stricker, 1976). This theory has been referred to as the "set-point" theory. Other long term control theories include the thermostatic theory wherein experiments on body temperature show that cold stressed animals eat more and engage in more activity in order to generate heat through increased metabolism (Spector, Brobeck & Hamilton, 1968). Another long term theory referred to as aminostatic hypothesis focuses on the relationship between levels of amino acids and food intake, In one study testing this hypothesis experimental animals reduced their intake of food when their diet was low or devoid of a single amino acid of if there was an excess of one amino acid (Mellinkoff, Franklin & Boyle, 1956). While location of receptors for detecting levels of amino acids has not been identified, one possible explanation may be found in the use of a specific amino acid such as tryptophan in the synthesis of the neurotransmitter serotonin. Derangements in serotonin have been hypothesized as one mechanism involved in the occurrence of anorexia in cancer patients (Theologides, 1981).

Psychosocial Perspective

Psychological and sociocultural factors are also influential in determination of dietary intake. However, these factors have not been studied as extensively as the physiological theories. Knowledge of psychological and social factors tends to be based more on observation than experimentation.

Psychological factors influential in maintaining dietary intake have been identified by observation of those factors which inhibit dietary intake. For example, emotional states such as depression and anxiety have been linked to a decreased interest and desire to maintain dietary intake (Beck, 1972). Schacter, Goldman & Gordon (1968) compared eating behavior of normal and obese individuals exposed to an anxiety producing situation (suggestions of receiving electric shock following the end of the tasting session). Normal subjects responded as predicted with a decrease in food intake. Obese subjects responded inconsistently with some increasing intake and some decreasing intake. These results were confirmed by McKenna (1972) who also produced a decreased food intake in normal individuals exposed to a higher anxiety producing situation.

Psychological factors are also influential in determining why eating is started. Both the appearance of appetizing food and the time of day (i.e. mealtime) may be more important than feelings of hunger in the initiation of eating behavior (Wooley et al., 1975).

Goldman, Jaaffa, and Schacter (1968) studied effects of time changes on eating patterns in Air France flying personnel. Findings demonstrated a consistent relationship between degree of weight deviation and spontaneous complaints about difficulties in adjusting to the discrepancy between local meal time and physiological state. Moreover people of normal weight as compared with those who were overweight had the greatest difficulty adjusting to different mealtimes. Palatability and pleasure influence food intake as well

(Wooley et al.,1975). Evidence of this stimulation for eating bombards us daily through television commercials, magazine advertisements, and food aromas. Few people are immune to the simple smell of fresh bread from the bakery.

Sociocultural factors are important determinants of dietary intake as well. Social facilitation of feeding has been demonstrated in studies on dogs. In a series of experiments, James & Gilbert (1953, 1956) demonstrated that dogs having a previous history of eating with other dogs, ate even when in a food-sated condition as long as other dogs were feeding. Food choice is also influenced by individually experienced factors such as familiarity and environment; and culturally transmitted factors such as ethnic foods specific to cultural subgroups (Wooley et al., 1975). Food represents security, status, identity and social acceptability in our society (Bayer, Bauers, & Kapp, 1983).

In summary, both central and peripheral physiological factors are influential in the development and maintenance of feeding behavior. Psychosocial factors are also associated with feeding behavior. There is strong evidence for a redundant and flexible system with multiple aspects, thus illustrating the need for an integrated approach to the explanation of feeding behavior (Toates, 1981). No model presently available appears to explain adequately the variety of signals and sites involved in the control of food intake (Kissileff & Van Itallie, 1982). Future clinical studies are likely to benefit from a broader approach integrating physiological, psychological and sociocultural factors.

Changes During Aging Which Influence Nutritional Status

The aging process is accompanied by changes that potentially interfere with appetite, dietary intake, and the maintenance of nutritional status. Digestive, oral, and psychosocial changes have been described.

Digestive Changes

Changes in digestion appear to be associated with altered structures of the mucosa and muscular wall. A decrease in acid secretion in the stomach has been reported. In a comparison of 20-49 year olds, with 50-60 year olds, and those over 60 years of age, basal and histolog-stimulated secretions decreased as age increased (Baron, 1963). These results were confirmed by Siurala, Isokoski & Varis (1968) who demonstrated impairment of gastric motility. Changes in intestinal secretions have been demonstrated as well. In a study of 29 patients aged 36 to 95, D-xylose tolerance tests were conducted to compare intestinal absorption of sugar across age groups. No differences were found from 36 to 69 years of age. However, after 69 years of age, xylose excretion decreased and was further decreased over the age of 80. In the 80 year old group, hourly values were lower, reached peak levels later, and blood disappearance rates were slower (Guth, 1968). Reduced amplitude of esophageal peristalsis (Hallis & Castell, 1974), impaired gastric motility (Andrews et al., 1967), and delayed evacuation time (Eastwood, 1972) are among other changes demonstrated in the aged population. These changes may be responsible for the decrease in digestion frequently described in the elderly (Nasrallah & Iber, 1984).

Hiatal hernia is common in the elderly. In persons under age 30 it occurs less than 10 percent of the time and increases to 60 percent in persons over the age of 60 (Stilson, Sanders, & Gardiner, 1969).

Oral Changes

Oral status in the elderly is generally reported in textbooks as emphasizing a series of negative changes such as decreased saliva, decreased oral motor function, and decreased taste sensitivity (Baum, 1981A). These changes, however, have been based on studies of populations that have frequently been small, institutionalized, and of questionable health status. In a longitudinal study of oral physiology in 175 individuals well distributed with respect to age and sex, multiple clinical, biochemical, psychological and sociological evaluations have been used to describe oral status and parameters likely to influence oral health (Baum & Bodner, 1983). The study subjects are community volunteers who are highly educated and come from upper and middle socioeconomic groups. Several findings are available in relation to oral factors that may influence appetite, dietary intake, and nutritional status. In relation to saliva production, healthy individuals did not show decreases in stimulated parotid saliva flow rate with increased age. However, when older individuals with likely medical pathology of some kind present were examined, salivary production was depressed. Because there is a lack of norms for salivary flow rates and salivary constituents, the physiological significance of this decrease is not known.

Oral motor functions were evaluated in the same study by resistance of the tongue to posterior displacement on firm manual pressure, history of snoring and the ability to maintain nasal respiration with the cheeks distended. Results have been reported on 86 subjects and reveal abnormalities in the group older than 50 years of age at a rate two and one half times the rate of the younger group. These abnormalities included decreased tongue positional stability and an inability to close the junction of the mouth and pharynx, leading to mouth breathing which could conceivably dry the oral mucosa (Baum, 1981A). Such oral motor changes could be important in the occurrence of dysphagia in the elderly, especially if esophageal motility is decreased. In a study of esophageal motility patterns, peristalic waves in ninety year olds were only 50 percent of swallows compared to 90-95 percent in a normal young age group (Soergel, Zboralshe, & Amberg, 1964). The lower esophageal sphincter failed to relax in over half of the swallows and there was a delay of esophageal emptying in the elderly. These findings accompanied by decreased oral motor functions in the elderly could lead to an increased occurrence of dysphagia in the healthy, elderly population.

The third oral change reported by the same investigators had to do with taste acuity and food enjoyment. Data from 162 volunteers were used. Participants were asked to provide a subjective assessment of their taste perception and enjoyment of food. Reports of diminished taste acuity increased with age, but were twice as high in the older group with questionable-status health history, as opposed to the older group of healthy subjects. When asked about food enjoyment compared to ten years previously, healthy participants reported that satisfaction was the same or better, while questionable-status health participants reported decreased food enjoyment (Baum, 1981B). In general these results point to some mild changes in oral status which accompany the aging process. Changes are apparently more frequent and severe when the population tested is of questionable health status.

Mild salt taste detection changes in the elderly have recently been reported in a study of 76 healthy adults age 23 to 92 (Grzegorczyk, Jones & Mistretta, 1979). Using a forced choice, staircase procedure with distilled water rinses between stimuli, an age related decrease in salt acuity was observed. However, the decrease was smaller than that reported in previous studies. These findings are contrary to the more extensive pathological changes in oral status reported by earlier researchers studying the process of aging (Meyer & Necheles, 1940; Nedelman & Bernick, 1978; Richman & Abarbanel, 1943). Differences may be related to the populations tested, since Baum's studies and the Grzegorczyk study have used healthy community volunteers.

An additional oral change that accompanies the aging process is the loss of teeth. This loss has been associated with a decreased enjoyment of food partly because of self imposed dietary restrictions that accompany it (Chauncey, Muench, Kapur, & Wayler, 1984).

Psychosocial Changes

Psychosocial changes in the elderly also impact on dietary intake. Advancing age is commonly associated with decreased economic status, social and support networks, authority, and loss of loved ones (Neugarten, 1979). The psychological response to the increased incidence of chronic diseases in the elderly may bring about changes in appetite and food intake (Finch & Hayflick, 1977). There may be changes in shopping habits and abilities, living conditions, and eating environments (Nasrallah & Iber, 1984). The recreational aspects of food and eating are particularly evident in institutions for the aged. Observations in the Hebrew Rehabilitation Center for the aged revealed that the residents focus their activities around mealtime, sitting in the hall for an hour or more before meals are served (Sherwood, 1973).

Income, as a social factor, also influences the adequacy of dietary intake. In a study of the relationship between nutritional adequacy and age, educational level, income, and size of household, 2 groups each containing 35 elderly citizens from Pennsylvania were interviewed (Guthrie, Black, & Madden, 1972). In Group 1, income was at the prevailing poverty level, while in Group 2, income and assets were too high to meet the poverty standard. The estimated food expenditures for Group 1 were significantly lower than in Group 2 ($p<0.02$). This difference held across both 1 person and 2 person households. Group 1 also had significantly less intake of protein, iron, and riboflavin than did Group 2 ($p<0.05$). Distribution of meals over the day showed that a high proportion of nutrients was taken at breakfast and a slightly lower proportion at the evening meal. Data on shopping habits showed that the poor rely a lot on either friends or relatives for transportation to the store and help in food purchasing. These findings illustrate the potential impact of social and cultural factors on dietary intake in the elderly.

Studies of changes during the aging process which influence nutritional status include digestive, oral and psychosocial factors. Studies on digestive factors have shown a number of abnormalities, but have not identified what specific impact these changes have on nutritional status. Studies on oral changes have traditionally identified changes in taste, smell, saliva, and oral motor functions. Recent well controlled studies have refuted findings from earlier studies, probably because healthy elderly, rather than unhealthy elderly, subjects have been followed. Psychosocial factors have been identified primarily through descriptions of eating patterns and include the need for adequate income, help with shopping and the importance of the recreational aspect of eating. These factors indicate that changes during the aging process have a potential impact on dietary intake. These factors, especially decreased oral motor function, could lead to earlier and more severe side effects for the elderly patient undergoing radiation therapy for head and neck cancer.

Changes During Cancer and Cancer Treatment which Influence Nutritional Status

Nutritional depletion results simply from a decreased intake, and increased metabolic need or a combination of both. Factors influencing nutritional depletion can thus be divided into either decreases in intake or increases in need (Table 2.1).

Decreases in Dietary Intake

Alterations in Appetite and Oral-Gustatory Factors

Alterations in appetite and oral gustatory factors have been examined in both cancer patient populations and in animal models. Abnormalities of taste and smell have been observed in a variety of cancer patient populations. DeWys and Walters (1975) studied 50 patients with metastatic cancer. Patient ages ranged from 16 to 79 with a median of 57 years. Subjective measurement of taste change was collected via a semi-structured interview. Objective measurements of detection and threshold levels of salt, sweet, bitter and sour tastes were collected using a 3 stimulus, forced choice technique. Decreases in taste were reported by 25 of the patients, and an aversion for meat was reported by 16 of the patients. Abnormalities included an elevation of sucrose recognition, and a lowered urea recognition. Patients who had abnormal taste, had an increased incidence of weight loss. Since the study included patients with a variety of tumor types and tumor burdens a comparison of taste and smell changes with tumor types was not possible.

Table 2.1

Factors Influencing Nutritional Depletion in Cancer Patients

I. Decreases in Intake
   A. Alterations in Appetite and Oral-Gustatory Factors
   B. Alterations in Digestion and Assimilation
   C. Psychosocial Factors Influencing Food Intake
II. Increases in Need
   A. Alterations in Energy Expenditure
   B. Alterations in Carbohydrate, Fat, and Protein Metabolism

A study of taste thresholds of patients with esophageal cancer did not reveal the same pattern of taste changes

(Kamath, Mams, Lad, Kohrs, & McGuire, 1983). In this study, taste threshold changes in 12 cancer patients were compared to a control group of subjects matched for age, smoking and alcohol consumption, and no differences were found. However, comparison with another control group of healthy nonsmokers showed marked differences.

Bernstein hypothesizes that tumor growth may suppress appetite indirectly by producing food aversions. These aversions are learned because they are associated with unpleasant internal symptoms and result in a decreased dietary intake (Bernstein, 1982). Evidence for this hypothesis was reported in Bernstein's studies of children and adults, followed by studies using an experimental animal model (Bernstein & Bernstein, 1981). In the study of children, subjects were randomly assigned to an experimental group which was offered an unusually flavored ice cream before their chemotherapy treatment. The control group was offered an equal period of time exposure to a toy. Another control group received neither exposure to the toy, nor the novel ice cream, and was receiving chemotherapy which was not associated with any gastrointestinal irritation. Testing for food aversions was done two to four weeks later by offering patients a choice between eating the ice cream or playing with a game. The results indicated that the patients in the control group were three times as likely to choose the ice cream as patients in the experimental group. It appears that the children developed aversions to the ice cream when it was consumed before treatment that induced gastrointestinal discomfort. The study was repeated in an adult population receiving chemotherapy with one experimental group receiving Maple Nut Ice Cream and the other receiving Hawaiian Delight Ice Cream. The control group received either no chemotherapy or intravenous vincristine only. Testing occurred approximately five weeks later when flavor preference tests were conducted. Results were similar to the first study, with a significantly lower percentage of experimental subjects preferring the flavor of ice cream consumed just prior to their chemotherapy treatment. Bernstein views these food aversions as one of the contributing factors to the occurrence of anorexia in cancer patients undergoing cancer treatment. (Bernstein, 1986)

In 1982, Johnston et al., reported on thirty-one patients receiving radiation therapy for localized head and neck cancers. Mean age was 58 years with a range of 40-79 years. Patients were interviewed before, during and up to 6 months post treatment. Patients rated each of the following symptoms on a separate 10 cm visual analogue scale weekly during therapy and at 3 months and 6 months post therapy: ability to smell, dysgeusia, dysphagia for solids/liquids, appetite, fatigue, xerostomia, mouth/throat pain, and skin irritation. Information on weight loss, anthropometric measurements and tumor characteristics was collected as well. Twenty of the 31 patients (68%) lost over 5% of their presenting weight within one month of completing treatment, and weight losses ranged from 5.4% to 18.9%. Some patients continued to lose weight up to 6 months post treatment. Findings revealed that the symptom scores were higher for patients who lost more than 5% of their pretreatment weight by the fourth week of radiation therapy. Xerostomia and dysphagia scores continued to rise up to the end of treatment and persisted for up to 6 months, while other symptoms decreased by the first follow up visit. All symptoms increased during the treatment period. Appetite changes were not reported in the original article, but correspondence from the investigators revealed that 73% of the subjects experienced a loss of appetite by the end of therapy. Correlations were done to determine whether any treatment or patient variables could be related to the occurrence of weight loss. The only correlating factor was the size of the radiation field, with weight loss most profound in patients with field size greater than 8 x 8 cm. While diet history was taken at the beginning of the study period, data on caloric intake during radiation therapy were incomplete and thus were not analyzed. Relationships between appetite and other variables were not identified. No description was presented on whether those patients who had more than 5% weight loss responded to treatment differently from those who did not. Impact on quality of life was not identified. No reliability or validity tests of the instruments used were reported.

Mossman and his associates have conducted a series of studies focusing on taste, smell, salivary, and appetite changes in patients undergoing radiation therapy. A study of 27 patients with various forms of head and neck cancer was composed of 2 groups (Mossman & Henkin, 1978). The first group consisted of 9 patients one year following completion of radiation therapy, and the second group consisted of 18 patients followed before, during and one month post radiation therapy. Four taste qualities were measured - salt, sweet, sour, and bitter. Anorexia was measured by "standard means," which Mossman (January 13, 1984) has since clarified in a personal communication. Patients were simply asked if they had experienced changes in appetite. In the first group, all patients were tested one year following completion of radiation therapy and all had persistent taste changes, 6 had anorexia, and 5 had xerostomia. In the second group of subjects, one of the 18 had taste changes prior to radiation therapy, and 3 of the 18 had anorexia prior to radiation therapy. During and after therapy, 12 of the 18 patients experienced taste loss and 9 of the 18 patients experienced anorexia. Not all patients with taste changes experienced anorexia, but all except one patient with anorexia experienced taste changes. The taste changes started 3 weeks after radiation therapy, the bitter and salt qualities showed the earliest and greatest impairment, and sweet quality the least. These findings are parallel to those reported earlier in the DeWys and Walter study (1975). There was little correlation between subjects' complaints of taste changes and active measurement of diseases prior to radiation therapy. For Group 1, patients with long term taste changes were treated with zinc. Although this aspect was an uncontrolled trial, it was useful in ameliorating taste changes in some patients.

In a follow up study of long term taste changes, 13 patients who received radiation therapy 1-7 years previously were tested for taste and salivary gland changes (Mossman, Shatzman, & Chencharick, 1982). Nine of the 13 patients had taste loss and every patient with radiation to the parotid glands had measurable salivary dysfunction. Only one of the subjects complained of anorexia. Results indicated that taste and salivary function could have maximum injury during curative radiation therapy, and could persist for a long period post therapy while anorexia was not a long term problem.

A third study of head and neck cancer patients undergoing radiation therapy was conducted in order to evaluate nutrition related complications (Chencharick & Mossman, 1983). The incidence of dry mouth, abnormal taste function, anorexia, altered food preferences, and dysphagia, was collected on 74 subjects from 3 institutions. Twenty percent of the patients complained of appetite loss prior to therapy. By the fourth week of therapy, 60% were aware that they had this problem. Appetite was measured subjectively: the investigators asked the patients what the status of their appetite was. Reliability of the measures used to evaluate appetite was not reported. Twenty five percent of the patients were aware of dry mouth prior to radiotherapy and by the fourth week 80% complained of this problem. Fourteen percent of the patients reported taste changes prior to radiotherapy and this increased sixfold by the fifth week of therapy. Thresholds for sweet increased during therapy, with patients tending to sweeten foods and fluids more as radiotherapy progressed. Use of salt seemed to remain constant. Forty percent of the patients complained of swallowing dysfunctions prior to radiotherapy and this problem increased to over seventy percent by the sixth week of treatment. Weight loss of at least 5 kg. was present in 15 (94%) of the patients prior to therapy. Additional weight loss during therapy did not occur and may have been related to the weekly nutritional counseling given when patients were weighed. Analysis of dietary intake was done on only 8 patients and revealed adequate caloric intake throughout the course of therapy. However, a decrease in protein and fat and an increase in carbohydrate (mostly as sugars) occurred as therapy progressed. How this group of eight was selected and how well they represented the rest of the subjects are not reported. Thus results related to analysis of dietary intake must be interpreted cautiously. In general, findings indicated that this group of head and neck cancer patients started radiation therapy with nutritionally related symptoms and a history of weight loss, and those followed were able to prevent further weight loss. Relationships of these findings to complications of therapy were not reported.

Another study reported on taste changes in sixty-two cancer patients with various stages of tumors in the upper gastrointestinal tract or lung. Subjects were classified as anorectic or non-anorectic based on scores obtained on a 5 point patient-rated appetite scale with the patients falling in the middle number classified as anorectic only if they expressed a desire for food but could not eat as much as usual because they were weak from surgery, nauseated from chemotherapy or had gastrointestinal obstruction (Trant, Serin, & Douglas, 1982). A 24 hour dietary recall was obtained within the seven day period prior to taste testing. Taste changes were obtained from five randomized taste samples with distilled water rinses between. Patients reported that the following symptoms were related to reduced or changed dietary intake: early satiety, nausea, pain, constant fullness, dysphagia, bitter taste in mouth, dryness in mouth, bloated feeling and changes in the taste of foods. While these symptoms were present in both anorectic and non-anorectic groups, they predominated in the anorectic group. Thus, the subjective self-rating scale for appetite appeared to discriminate between anorectic and non-anorectic groups. The nutritional status of the anorectic group was significantly worse than the non-anorectic patients as illustrated on percentage weight loss, percentage ideal body weight, arm muscle circumference, caloric intake as percentage of basal energy expenditure, and serum albumin. No taste abnormalities were identified among patients grouped by tumor site, therapy, or appetite. There was some preference for sweet stimuli in some anorectic patients. Anorectic patients rated their activity level as significantly lower than non-anorectic patients. In addition the anorectic patients had significantly fewer servings of sweet foods per day than the non-anorectic group. Ratings of hedonic response to taste revealed no pattern in relation to therapy, tumor site, or degree of anorexia, thus preventing any generalizations to the population at large except that individual responses may differ. Findings of this study differ from some of the other studies represented here, and may be a result of the mixed population of tumor types and stages in the population sampled as well as the different method of taste testing employed.

Studies of dietary intake have been conducted in order to identify the extent to which a lack of intake versus an increased need for intake can explain the weight losses observed. One hundred ninety-five ambulatory patients with a variety of cancers were compared to 205 matched controls in order to identify the relationship of anorexia as measured by dietary intake to weight loss (Costa, Bewley, Aragon & Siebold, 1981). Anorexia was defined as a spontaneous decrease in food consumption and was measured via 24 hour recall of dietary intake. The relationship of intake to weight loss was identified by classifying patients as losers or keepers dependent on whether or not they had lost within 60 days at least 5% of the weight present when first consulting a physician about cancer symptoms. Measurements included a medical and weight history, measurements of height, anthropometric parameters, and estimates of food intake by a three day diet and by 24-hour recall. Since no significant differences were found between the three day diet and the 24-hour recall, the latter was used in the analysis. Results revealed that average caloric consumption for male cancer patients (N=86) was 1894 and for male controls (N=76) was 2358 ($P<0.005$). For female cancer patients (N=113), average caloric consumption was 1556 as compared to 1612 for female controls (N=129) ($p<0.05$). Thus, male cancer patients in this study reported eating significantly less than their controls and these differences were not reported by the females studied.

One subset of male patients with lung cancer was sufficiently large enough to evaluate separately (N=61). In this subset, cancer patients reported eating less than controls, but there were no differences found when patients were classified as losers and keepers. Thus, decreased dietary intake did not appear to be a relevant factor in weight loss experienced in the subpopulation of lung cancer males. In this study, it appears that anorexia was not present in the female population studied, and, while present in the male population, did not account for the weight loss observed.

Difficulties in the sample and design of this study leave a number of unanswered questions. The sample of male subjects studied included 61 (71%) with lung cancer, in which cachexia is a profound, frequent, early, and potentially fatal complication. The nature of cachexia in the lung cancer population does not follow the pattern seen in other cancer populations (Morrison, 1981). At the same time, the diagnostic categories of the female subset are not described, and may include breast cancer patients. Female breast cancer patients are not prone to cachexia if not on therapy and if on adjuvant therapy are prone to weight gain (Knobf, Mullen, Xistris, & Moritz, 1983). Without knowing the percentage of breast cancer patients included, it is difficult to interpret the findings. Certainly male and female differences reported are confounded by the site of the cancer. A major difficulty with the design is the inclusion of a one time only measurement of dietary intake. While the 24-hour dietary recall can be a reliable measure for the assessment of dietary intake (Dwyer, 1979;Halpern, 1979), questions remain about the period of time used for recording. Was this 24-hour period a typical period? What was the stage of disease, the type of therapy, the length of the disease, and the psychological state of the patient during the 24-hour period of dietary recall? Such factors may have a profound influence on the dietary intake of the patient and may confound the results obtained.

In a multi-institutional study of anorexia in cancer patients, anorexia was studied as measured by decreases in dietary intake (DeWys, Costa & Henkin, 1981). Patients were enrolled in a multi-faceted protocol which included different sites and stages of cancer. Caloric intake was estimated by a computerized nutrient analysis of 3-day diet diaries. Basal energy expenditure was calculated using standard tables corrected for body surface area. For the 89 subjects studied, caloric intake ranged from 543 to 3905, with a median intake of 1831 calories. When compared to basal energy expenditures, 22 (25%) of the patients had caloric intake below their calculated energy expenditure, 40 (45%) had caloric intake between basal expenditure and 50% above that level, and 27 (30%) had caloric intake above 50% of the calculated energy expenditure. Since even a moderate amount of activity requires a caloric intake of about 50% above the basal energy requirements, findings from this study indicate that the great majority of the patients studied had inadequate dietary intake. Subjects were asked to identify symptoms they felt were interfering with their ability to eat. A variety of symptoms were reported. Fifty percent of the patients reported one or more symptoms with the most frequent symptoms including oronasal symptoms, gastrointestinal tract symptoms such as early satiety, and side effects of chemotherapy.

Findings in this study differ from the Costa et al study (1981). Differences may be related to the populations sampled, but since neither study identified specific diagnosis and stage of disease, comparisons across studies are difficult.

This group of studies on cancer patients experiencing decreased dietary intake suggest several factors that may be involved. These factors include changes in appetite as reported by patients, as observed in relation to dietary selections and oral gustatory problems such as changes in taste, smell, and ability to swallow. Findings across studies are not consistent. These inconsistencies may be related to mixed populations of cancer sites, stages, and the insensitivity of the instruments used to collect appetite change information and dietary intake. Animal studies have provided some solutions to these methodological difficulties, and are presented next.

Animal Studies Animal models of cancer anorexia and cachexia have been developed in order to examine the potential mechanisms involved. These models depend on the quantification of dietary intake as the main measurement for the development of anorexia. One example of this animal research involves a series of studies on the Wistar Rat (Mordes & Rossini, 1981). In the first study, rats implanted with Leydig cell tumor (known for its small size and associated with arrested weight gain) were compared to rats implanted with breast carcinosarcoma, a tumor not associated with weight loss. After 18 days, weight gain was arrested in the rats bearing Leydig tumor, and remained unaffected in the rats bearing the breast tumor tissue. Food intake was not measured in this first study. In the second study, food intake and reversal thereof were examined. The reduction in weight gain was again found after 18 days, and, following removal of the tumor tissue, was reversed within 3 days of the surgical tumor removal. Reimplantation of tumor again led to decreased dietary intake and weight loss. In the third study, three groups of parabiotic rats were compared, some with a partner with implanted Leydig tumor, some with a partner with breast tumor tissue, and some with sham implants. Measurement of dietary intake and weight at 46 days following implants showed no differences between breast tumor-bearing rats and sham implant rats but a significant decrease between the Leydig tumor-bearing rats and both other groups. These differences were apparent in both the partner containing the implant and the tumorless partner. These results indicate that the rat with an implanted Leydig tumor is a suitable model for the examination of cancer anorexia. This and other models have subsequently been used to examine potential mechanisms involved in anorexia and cachexia.

Bernstein & Sigmundi (1980) have also used a rat model to study anorexia and cachexia. The model used is a male Wistar-Furth rat implanted with PW-739 sarcoma. This tumor is associated with anorexia and cachexia as observed by a predictable decrease in dietary intake followed by profound nutritional depletion. Nutritional problems begin in 5 to 6 weeks and are lethal by 8 to 12 weeks. Using this model, Bernstein & Sigmundi studied the effects of learned food aversions during the course of cancer. Following a period of

10 days during which a specific American Institute of Nutrition (AIN) diet was fed to both experimental and control (non tumor bearing rats) groups, preference for the AIN diet was determined by offering a choice between the AIN diet and a novel diet. Results showed that during the 10 day period, mean diet intake of tumor bearing rats declined considerably and was significantly lower the last 2 days. In addition, tumor-bearing rats had a significantly lower preference for the AIN diet during the choice period. The tumor-bearing rats also increased their diet intake of novel diet during the choice period eating as much as the controls. A second study was conducted to determine whether the differences observed were due to tumor-induced changes in taste responsiveness versus taste aversion to the diet. Half of the animals in the experimental group and half in the control group received a modified AIN diet and the other half of each group a modified NIH (National Institutes of Health) diet for 21 days. Then the taste choice was offered on day 22. Results revealed that tumor-bearing animals had lower preferences for whichever diet was administered during the tumor growth period than did controls. Thus tumor growth had a significant effect on preference for the associated diet. In a third study, other diets were used to test the generality of tumor-associated aversions. Diets consisted of ground Purina monkey chow or a soy meal diet. Animals were exposed to the diet for 8 days and then were given the taste choice. The same results as previously obtained occurred,

with the tumor-bearing rats showing lower preference for the associated diet than the controls. These three studies show that in this animal model, tumor-bearing animals consume significantly less diet than controls, and show significantly lower preference for the diet consumed during the tumor growth period. This has been interpreted as a food aversion which develops during periods of tumor growth.

Questions that remain include whether these findings are applicable to other cancer models in animals, to human cancer populations, and whether such food aversions could be contributing to cancer anorexia.

Other animal studies were initiated to test whether food aversions occurred in response to the side effects of cancer treatment (e.g. nausea and vomiting associated with certain chemotherapeutic agents) or to aversive physiological effects of the tumor tissue (Bernstein & Bernstein, 1981). Using a cross-over design and two different pre-exposure diets, groups of tumor-bearing animals and control animals were assigned to one of two diets. On Day 22 they were given a preference test with a choice between the two diets for 24 hours. Tumor-bearing animals showed significantly lower preference for the pre-exposed diet than did the non tumor-bearing animals. It appears that aversions are specific to the diet being consumed during tumor growth. These results provide some evidence for the occurrence of anorexia in response to tumor growth alone.

Further work has been done comparing learned food aversions with two different experimental tumors (Bernstein & Fenner, 1983). The same design was implemented, this time with rats implanted with Leydig tumors and rats implanted with Walker-256 carcinosarcoma. The rats with Leydig tumors developed the strong aversions to the diet eaten just after tumor implant, while the rats with Walker-256 tumors did not develop diet aversions. While both these tumors have been used to demonstrate anorexia in tumor bearing animals, the mechanisms for development of the anorexia appear different, with one mechanism being the learned food aversions.

Another series of animal studies was undertaken to determine whether anorexia in tumor-bearing animals was related to abnormal serotonin metabolism (Krause, Humphrey, von Meyenfeldt, James, & Fischer, 1981). These studies relate to the hypothesis that when brain tryptophan levels increase, serotonin synthesis increases. It is known that high levels of brain serotonin cause anorexia (Krause et al., 1981). The first study involved a comparison of tumor-bearing Sprague-Dawley rats allowed free access to food and water, to a pair-fed non-tumor bearing group, and to a non tumor-bearing group with free access to food. The purpose of this design was to differentiate tumor specific effects on weight from reduced dietary intake effects on weight. Within 10 days the food intake in the tumor-bearing rats (and the pair-fed non tumor group) had fallen significantly behind that of the free-feeding rats.

Comparisons between tumor-bearing rats and the pair-fed group versus the non tumor bearing group showed significantly increased levels of brain tryptophan and increased brain serotonin turnover in the tumor bearing rats. These results suggest that the decreased food intake in the tumor bearing rats may have been secondary to increased central serotonin activity.

The second study was designed to test whether an increase in branched-chain amino acids in the diet could compete with tryptophan for entry across the blood-brain barrier. This study was based on knowledge that tryptophan must compete with the neutral amino acid group for penetration across the blood-brain barrier. It was hypothesized that if levels of neutral amino acids, or the branches chain amino acid groups could be increased, less tryptophan could penetrate the blood-brain barrier, and less serotonin could be synthesized. With decreased levels of serotonin, anorexia would not occur. Two groups of tumor bearing rats were compared, one tumor-bearing group was fed normal animal chow, the other tumor bearing group was fed a branched-chain amino acid enriched diet. Results suggested that anorexia was delayed in the group receiving the branched-chain amino acid.

In another study of tumor-bearing rats, increased brain tryptophan and serotonin as compared to tumor-free controls were demonstrated (Wesdorf, Krause, & Von Meyenfeldt, 1983; Chance, von Meyenfeldt & Fischer, 1983). These results have been confirmed by yet another team of investigators (Nichols, Maickel, & Yim, 1983). Decreases in plasma albumin, which accompany the increases in free tryptophan have also been observed in humans (Wesdorf et al., 1983). It is postulated that the derivation of the stimuli is the expanding tumor tissue, although correlations between tumor types, anorexia, and stage of disease are lacking.

Several other animal models have been developed and used to examine other factors that may be associated with cancer anorexia. For example, damage to the ventromedial hypothalamus usually produces hyperphagia and obesity in normal rats and mice while damage to the lateral hypothalamus usually produces acute aphagia and chronic residual feeding deficits. When either of these conditions is produced in tumor-bearing anorexia animal models, no alterations occur in the feeding control disturbances associated with the tumor growth (Morrison, 1981). These results suggest that the hypothalamic system is not involved in cancer anorexia. Morrison also studied whether the normal response to caloric dilution (increased intake) changed in the animal anorexia model (Morrison, 1981). Rats with implanted cancers were unable to compensate completely for caloric dilution within the first quarter of tumor growth as compared to a non tumor-bearing group. Other feeding controls, such as reduced environmental temperature and taste distortions have also been examined in animal models and show dietary intake impairments that occur during initial tumor growth periods

(Morrison, 1981). These findings in animal models suggest that tumor growth can successively delete a number of individual factors influencing dietary intake, and that initial compensation may be possible because of the redundancy of mechanisms involved in the feeding control system. However, as factors influencing dietary intake are successively lost, compensation is no longer possible, and control over dietary intake fails (Morrison, 1981).

An additional factor potentially influencing dietary intake is motor ability, and this has also been studied in the animal model (Morrison, 1981). In cancer patients, asthenia or loss and absence of strength, may account for inability to maintain dietary intake. Asthenia may be more of a consequence of nutritional depletion, rather than a factor initiating decreased dietary intake. It represents still another dimension of factors influencing dietary intake. The animal analogue of asthenia is decreased motor activity. Morrison (1981) studied four animal tumor systems in relation to depression of motor activity. Findings indicated that all four models showed a decreased dietary intake, but only three of the systems revealed progressive decrease in motor activity. It appears that asthenia is a frequent, but not an inevitable occurrence in the development of anorexia and cachexia.

These animal studies have revealed several factors that may be influential in the occurrence of cancer anorexia. Diet or food aversions, increased brain serotonin, inability to adjust to caloric dilution, reduced environmental temperature, and decreased motor activity have been examined. None of these appears to be universal across tumor types. Findings suggest a non unitary nature of causation for anorexia in cancer patients, and the need for continued and varied research approaches to discovering clinically relevant approaches for alleviation.

Alterations in Digestion and Assimilation Diminished dietary intake in cancer patients may also be related to abnormalities in the gastrointestinal tract with decreases in digestion and absorption. Two processes are possible. The first involve tumors which impinge directly on the gastrointestinal tract and accessory organs such as the liver, thus interfering with the movement of food through the gastrointestinal tract as well as the digestion of food and absorption of digestive end products. The second involves changes within the gastrointestinal tract associated with a malnourished state. Both these processes can lead to nutritional depletion in the cancer patient.

Tumors which arise in or impinge upon the gastro-intestinal tract may directly affect nutritional status by interfering with the ingestion, digestion and/or absorption of food. Tumors located at different areas affect nutritional status differently. For example, tumors of the head and neck, the difficulty resulting is primarily one of mechanical interference with a resulting decrease in ingestion (Lawrence, 1979). Prevalence and characteristics of nutritional problems at the time of diagnosis for this population of patients was studied by Bassett and Dobie (1983). Fifty patients admitted to the University of Washington for diagnosis of previously untreated upper digestive tract malignancies were studied. Subjects varied as to length of time since first symptoms occurred and stage of disease. Data included demographic characteristics, tumor characteristics, physical examination measurements, and selected laboratory tests. Of the 39 men and 11 women participating, 42% had oral cancer, 21% had laryngeal cancer, 19% had oropharyngeal cancer, and 17% had cancer of the hypopharynx. Results revealed that only 40% of the patients were in a good state of nutrition, while 20% were classified as fair, and 40% were classified as poor. The classification system for nutritional status was based on the method used by Copeland, Daly, and Dudrick (1979).

Tumors of the stomach may impact on nutritional status from mechanical interference and through intragastric losses of blood and protein rich fluid (Lawrence, 1979). Gastrectomy is the treatment of choice for most of the gastric cancers. Following gastrectomy, carbohydrate and protein digestion remain intact, but malabsorption of fat can occur (Lawrence, 1979).

Primary tumors of the small intestine are rare, but may include metastases from other sites. Mechanical obstruction can occur. Loss of blood and protein rich fluids into the intestinal lumin result in nutritional debilitation in the patient (Dickerson, 1983). Lymphatic involvement of the small intestine can produce steatorrhea and fat malabsorption (Dickerson, 1983).

Tumors of the liver and the pancreas produce deficiencies in the production of digestive enzymes, resulting in malabsorption of fat, protein, carbohydrate, vitamins and mineral (Dickerson, 1983). Anorexia is frequent in pancreatic cancer and leads to a progressive weight loss (Lawrence, 1979).

When the malnourished state is present for a period of time sufficiently long enough to cause changes in the small intestinal lining, a vicious cycle of further depletion may occur. The migrating cells of the intestinal villi are shed into the intestinal lining, carrying with them enzymes used in the digestion of food (Moog, 1981). When a malnourished state persists, changes in this lining occur decreasing the villi and resulting in a reduction of intestinal enzymes. Malabsorption results (Dickerson, 1983).

In summary, when tumors involve the gastrointestinal tract and accessory organs, interference with the mechanical aspects of digestion, with the absorption of end products occurs and can lead to nutritional depletion. Alterations in digestion and assimilation are also related to the occurrence of a malnourished state which may occur in both patients whose cancers involve digestive organs and those whose cancer does not involve digestive organs.

Psychosocial Factors Influencing Food Intake Decreases in intake may also be reflected in the psychosocial dimension. Observations of psychosocial factors that influence the intake of food in cancer patients have been identified primarily through clinical experience and descriptive studies. In the work reported by Holland, Rowland, and Plumb (1977), 3 general areas of anorexia have been identified: anorexia which is transient and related to the initial diagnosis, recurrence of disease, and period of pain and discouragement; anorexia related to cancer treatment; and anorexia related to the disease. In only the transient anorexia are psychosocial factors primarily involved in the onset and occurrence of anorexia. For the other two areas, physiological factors are far more important. However, psychological interventions are encouraged at all stages and with all patients. Treatments recommended include appetite-stimulating drugs for which clinical trial information in cancer patients is not readily available, and behavioral techniques that help stimulate eating. These techniques include supplementing intake with highly nutritious and appetizing between meal snacks, providing socialization for patients at mealtimes, and individualizing the diet according to any changes that have occurred in the patient's taste and smell.

The increased occurrence of depression in cancer patients may be related potentially to the onset or exacerbation of anorexia. In a descriptive study of fifty patients undergoing curative radiation therapy on a variety of anatomical sites, Peck and Boland (1977) conducted psychiatric interviews before and after therapy focusing on patient attitude toward treatment and illness. Sixty percent of the patients showed a significant degree of anxiety before treatment and eighty percent did so after completion of treatment. Patients were poorly informed on the expected side effects, had many questions about radiation therapy, and did not expect the therapy to help. Nonetheless no patient dropped out of therapy. This study illustrates the emotional environment that can be present during and following radiation therapy. This emotional environment could compound appetite and ingestive losses during and following radiation therapy. Other reports of psychosocial factors affecting appetite are primarily of case studies (Peteet, Medeiros, Slavin, & Walsh-Burke, 1981) and clinical recommendations (Gormican, 1980).

Increases in Metabolic Needs

If decreases in food intake alone account for the nutritional depletion observed in cancer patients, the provision of excess calories should reverse the depletion. While such an approach is successful in some patients, a large portion of cancer patients lose weight out of proportion to their intake history. Provision of adequate calories by oral, enteral or parenteral routes does not change median survival rates of patients with advanced cancer

(Heber, Byerley, Chi et al., 1986; Heber, Chlebowski, Meguid, & McAndrew, 1986). Abnormalities in energy expenditure, glucose, fat, and protein metabolism illustrate additional factors which influence nutritional depletion in cancer patients (Heber, Chlebowski, Meguid and McAndrew, 1986).

Alterations in Energy Expenditure Nutritional depletion in cancer patients can also be related to increases in metabolic need (Table 2.1). The improvement in ability to measure energy expenditure in hospitalized patients has made it possible to study whether metabolic rate in cancer patients is different from that predicted in normal individuals (Appendix A). If a high basal energy expenditure could be demonstrated in cancer patients, it could help in explaining the observed weight loss. However, studies that have examined energy expenditure in cancer patients have not yielded consistent results. In some studies increases in metabolic rate have been reported. Warnold, Lundholm, and Schersten (1978) reported on the energy balance for 10 cancer patient with various types of malignant tumors. Energy expenditure was calculated using oxygen consumption, heart rate, and the Weir formula (1949). Results revealed that both the daily energy expenditure and the resting metabolic rate were significantly greater in the cancer patients than they were in a control group of healthy subjects of the same age range. These results were confirmed by Bozzette, Pagnoni, and Del Vecchio (1980) who reported on 65 patients with locally advanced or disseminated cancer. Resting metabolic expenditure measurements were obtained using indirect calorimetry. Sixty percent of the subjects had resting metabolic expenditure rates that were 20 percent above normal. Strong correlations were obtained between resting metabolic expenditure and weight loss and between resting metabolic expenditure and serum transferrin. No relationship was observed between resting metabolic expenditure and creatinine-height index. These results suggest that increased resting metabolic rates may play an important role in the weight loss of cancer patients. However, the small sample size in the Warnold et al., study (1978) and the heterogeneity of cancer types in both studies make interpretation difficult.

Two additional studies have revealed findings that do not correspond with those of Warnold et al., (1978) and Bozzette et al, (1980). In a study of 200 hospitalized cancer patients, Knox et al (1983) measured resting energy expenditure (REE-M) using bedside indirect calorimetry and compared it to the predicted resting energy expenditure using the Harris-Benedict formula (REE-P). The population studied included 77 males and 123 females with the following distribution for types of cancers: 44% had gastrointestinal malignancy, 29% had gynecologic malignancy, and 19% had a malignancy of genitourinary origin. Classification of patients into hypometabolic, normometabolic, and hypermetabolic categories was done.

Normal standards were based on the Boothby, Berkson and Dunn studies (1936) at the Mayo Clinic, where they showed that 95% of normal individuals have a measured resting energy expenditure within 10% of that predicted by the Harris-Benedict formula (1936). In the Knox et al study (1983), subjects who fell below 90% of that predicted by the Harris-Benedict formula were classified as hypometabolic, and those who fell above 110% of that predicted by the Harris-Benedict formula were defined as hypermetabolic. Of the 200 subjects: 33% were hypometabolic, 41% were normometabolic, and 26% were hypermetabolic. A series of statistical analyses were conducted to discover whether hypothesized variables influenced the occurrence of the metabolic state. Classifications did not appear to be related to percentage of weight lost, visceral protein status, age, height, weight, sex, tumor burden, or presence of liver metastasis. It was concluded that cancer patients may exhibit metabolic aberrations, but they are not uniformly hypermetabolic.

The same group of investigators conducted a second study patterned after the first but focused on a more homogenous population of gastrointestinal cancer patients (Dempsey, et al, 1984). The purposes of the study were to characterize the frequency and severity of aberrations in resting energy expenditure and to identify any host/tumor characteristics that might be used to explain the differences found. The sample consisted of 173 clinically stable patients with biopsy proven carcinoma of the gastrointestinal tract (esophagus, stomach, small intestine, colon, rectum, liver, bile ducts or pancreas). Data included height, weight, triceps skin fold, albumin, total iron binding capacity, resting energy expenditure (REE-M) as measured by indirect calorimetry using the Weir formula for calculations, and predicted energy expenditure (REE-P) using the Harris-Benedict formula. Additional information was also collected on tumor site and tumor burden. Findings revealed the following distribution of subjects into the three metabolic states: 36% were hypometabolic, 42% were normometabolic, and 22% were hypermetabolic. Hypometabolic was defined as REE-M below 90% of REE-P, while hypermetabolic was defined as REE-M more than 110% of REE-P. This definition is the same as that used in the Knox et al study (1983). Comparisons across these three groups were then made on nutritional status as measured by percent ideal body weight, percent usual body weight, albumin, total iron binding capacity, and dietary intake in calories. No differences were revealed. It appears that each group was similarly malnourished, as illustrated by a comparable percent of mean body weight loss (14% versus 11% versus 11%). Groups were also compared on tumor characteristics. While no significant differences in tumor burden, disease duration, or percentage of patients with liver metastases occurred, a significant distribution difference was revealed by tumor site. Patients with esophageal and colorectal cancer tended to be normometabolic, patients with pancreatic and hepatobiliary tumors tended to be hypometabolic, and patients with gastric cancer tended toward hypermetabolism. However each tumor site had at least one patient in each of the metabolic groups.

While improvements in measurement of energy expenditure have occurred, difficulties remain that produce major methodological problems for researchers in this area. One of the problems is the selection of an appropriate control group. Both nutritionally well cancer patient controls (Holroyde, Gabuzda, & Putnam, 1975) and patients without malignant disease who are matched to the cancer subjects for comparable weight losses (Waterhouse, Jeanpretre & Keilson, 1979) have been used. Comparisons of findings become difficult across such studies. Additionally, other factors known to affect the resting energy expenditure are frequently not controlled during the study period. These factors and the direction in which they influence energy expenditure are important intervening variables.

For example, the clinical course of cancer includes irregularly occurring complications that may impact on energy expenditure, e.g. infections, fever, and hemorrhage (Waterhouse, 1981). Age, as well, has a predicable impact on energy expenditure. The infant has the highest energy expenditure, and this gradually decreases through young adulthood, middle age and into old age (Young, 1977). The age variable is included in the Harris-Benedict formulas.

Studies using other methods need to continue to analyze age as a potential intervening variable.

The nutritional status of the individual patient has an impact on energy expenditure, although the measurement of this influence continues to be a problem.

Undernutrition generally reduces BMR to a greater degree than it influences body weight (Young, 1977). This decrease is rapidly restored to normal during feeding. By the same token, overfeeding does not always result in the expected weight gain. This occurs even when physical activity is not increased (Young, 1977). Difficulties in evaluating nutritional status, in identifying nutritional history, and differences in measuring energy expenditure promote further difficulties in the interpretation of energy expenditure studies in cancer patients.

In summary, measurements of energy expenditure in cancer patients have been done in order to determine whether or not increases in metabolic expenditure could account for weight losses observed. Both heterogeneous and homogenous populations of cancer patients have been studied and results have been equivocal. Some patients appear to be hypermetabolic, some within normal limits, and some are hypometabolic. Comparisons with factors such as location of disease, extent of disease, and age have not revealed significant differences between these groups. Other potentially intervening variable such as baseline nutritional status continue to present measurement difficulties.

Alterations in Carbohydrate, Fat, and Protein Metabolism

The second area of nutritional depletion related to metabolic need concerns changes in carbohydrate, fat, and protein metabolism as observed in cancer patients. Marked changes have been demonstrated in the metabolism of cancer patients. These changes can be interpreted in relation to fuel sources used to provide energy for daily tissue activity in normals, and in unstressed and stressed starvation (Table 2.2). (See Appendix B for a description of fuel source changes during starvation.)

The presence of some types of cancer appear to alter the metabolic patterns. One of the changes identified is an increased occurrence of amino acid derived glucose production via gluconeogenesis. Several studies reveal evidence of this alteration. Brennan (1977) reported a case study of a patient with diffuse lymphoma who was not hypermetabolic from increased stress, exercise or infection. The basal metabolic rate was minimally elevated at 115% above the predicted normal level. Even when 3000 to 4000 calories of parenteral nutrition were administered daily, no weight gain was obtained. Brennan concluded that the tumor bearing host appeared unable to conserve lean tissue and body protein even when starvation was reversed. Using a tracer technique for the conversion of alanine to glucose, Waterhouse et al., (1979) compared 7 control subjects to 8 cancer patients in the advanced stages of disease, and with a history of more than 20% loss of their normal body weight. The purposes of

Table 2.2

Fuel Sources and Lean Body Mass Changes

During Stages of Starvation

	Fuel Sources	Total Muscle Mass Lost 10 Days	20 Days
Starvation	Glucose	15%	30%
Starvation Adaptation	Ketones		2%
Stressed Starvation	Glucose	23%	

this study were: 1) to study the conversion of the carbon skeleton of alanine to glucose using radioactive tracer techniques, and 2) to describe whether glucose administration would result in suppression of gluconeogenesis. Results indicated that over twice as much carbon from alanine was converted to glucose in the group with malignant disease as was found in the control group. It appears that there is an increased demand for glucose in the tumor bearing host, and this demand results in increased cycling of alanine. However, the suppression of gluconeogenesis by administration of small amounts of glucose occurred in both groups, indicating that gluconeogenesis in the cancer patient may be interrupted. Mechanisms involved in the change were not postulated, and may, in fact, differ among cancer and non cancer patients.

Another alteration found in cancer patients is an increased cycling of energy-expensive lactate to glucose via the Cori cycle (Stein, 1978). In this metabolic pathway, glucose is converted to lactic acid by glycolysis and then reconverted to glucose in the liver. This cycle is used during anaerobic metabolism. While it is useful in conditions where oxygen is lacking, and energy from glucose is needed immediately, it is an energy expensive pathway since it results in the expenditure of 6 moles of ATP instead of the production of 30 moles of ATP which would result if the 2 moles of lactate were metabolized via the Kreb Cycle. In a study of 20 patients with metastatic colorectal cancer increased rates of lactate production were observed via an isotope-tracer technique (Holroyde & Reichard, 1981). Even though the population was homogeneous with respect to cancer diagnosis, neither the tumor burden nor other clinical and biochemical determinants were correlated with the extent of lactate production. Thus even in a fairly homogeneous population, heterogeneity with respect to lactate metabolism was present (Holroyde & Reichard, 1981).

A third derangement in carbohydrate metabolism seen in cancer patients is a slower decrease in blood glucose levels during glucose tolerance tests. This is consistent with the data on impaired glucose tolerance, or insulin resistance (Smith, Kisner, & Schein, 1980). Several studies reveal this derangement. In a comparison of 10 cancer patients and 11 controls, insulin resistance was studied by administration of insulin challenge, and an intravenous glucose tolerance test. Results revealed that the cancer patients had a smaller glucose response to insulin than the non cancer patient, indicating a decreased insulin sensitivity. In another study by Smith et al., (1980), 7 cancer patients were compared to 10 normal controls. Glucose tolerance curves demonstrated a markedly higher curve for the cancer patients with a mean two hour blood glucose concentration in excess of 160 mg/100ml after a standard oral glucose dose. These findings are consistent with the clinical picture of insulin resistance. Other studies by Lundholm, Edstrom, Ekman, Karlberg, and Schersten (1981) reveal further evidence of insulin resistance in the cancer bearing host. Exact mechanisms and causes for these derangements are not yet evident and many investigations are underway to further define these alterations (Chlebowski & Heber, 1986).

In summary, alterations in carbohydrate metabolism occur in cancer patients and may play a part in the occurrence of nutritional depletion during the course of cancer and cancer treatment.

Alterations in fat metabolism during the clinical course of cancer have also been observed. Tumor bearing rats and mice lose more fat than their controls (Lundholm et al., 1981). This pattern, however, has not been illustrated consistently in humans. Warnold, et al., (1978) studied a convenience sample of cancer patients, and found that some of them had fat stores that were of the same size as in healthy controls. Nevertheless, a profound wasting of body fat in cachectic persons occurs (Smith, et al., 1980). A potential cause for this wasting is the production by the tumor tissue of lipolytic substances which increase mobilization of fat. Some evidence for this activity is found in animal studies (Liebelt, Liebelt, & Johnston, 1971). Other investigators have measured the level of plasma free fatty acid as an indirect measurement of mobilization of fat stores in cancer patients. Conflicting results have been obtained. For example, Mueller and Watkin (1961) showed an increase in free fatty acids that appeared to be related to the activity of the underlying tumor tissue. However, control over dietary intake and nutritional status of study subjects was not maintained, and could have confounded the analysis of the study. Smith et al., (1980) also measured levels of free fatty acids in cancer patients. They found slightly higher levels in cancer patients, but these levels were not significantly different from levels found in an unspecified control group. Thus, evidence is not clear on the relationship of free fatty acid levels as a measurement of mobilization of fat stores or as an indication of an alteration of fat metabolism in cancer patients.

Additional work is found in studies on the inability of the cancer patient to adapt to chronic starvation by the use of fat stores (McAndrew, 1986). Continued gluconeogenesis from amino acids sources as discussed above provides evidence that this switch to fat-derived fuel sources does not occur consistently in cancer patients. However, studies of body composition also give an indication of the extent of depletion in fat stores that is eventually observed. Moore et al., (1963) conducted extensive body composition studies on one lymphoma patient, and found that the total body water was 77.5%, suggesting that there was literally no body fat present. Similar results were achieved by Warnold, et al., (1978) and revealed that cancer patients when contrasted to controls exhibited a diminished body fat in the presence of a relatively expanded extracellular water.

In summary, alterations in fat metabolism have been demonstrated in cancer patients and may be related to the nutritional depletion that occurs.

Studies on altered protein metabolism in cancer patients have used a variety of methods to measure protein metabolism (Appendix C). The study by Waterhouse, et al., (1979) described above under glucose metabolism is an example of a study of protein metabolism as well. Using a tracer technique with radioactive alanine, these investigators demonstrated increased glucose-to-alanine conversion, increased alanine levels, and increased flux of alanine from the circulation. These findings are consistent with the conversion of alanine to glucose via gluconeogenesis, and illustrate the patients inability during starvation to spare protein derived glucose as fuel. The amount of uncontrolled gluconeogenesis from alanine was not significant in terms of energy expenditure, but results do illustrate the presence of abnormal protein metabolism in the cancer patients studied.

Another study revealed a pattern which can be described as a remodeling of body protein (Carmichael, Clague, Keir &

Johnston, 1980). This study described whole body protein turnover, synthesis and breakdown in 11 patients with differing stages of colorectal carcinoma and with a uniform dietary intake. The method used to measure whole body protein turnover was isotope dilution using radioactive labeled leucine. Subjects were classified as anorectic or non-anorectic (anorexia scale was not indicated in the publication), and when divided according to nutritional status using anthropometric measurements, the majority of the patients were moderately to severely depleted, and the anorectic subjects were more depleted than the non-anorectic ones. State of disease was evaluated using Dukes classification. Results indicated that protein turnover increased with advancement of disease, but was lower in anorectic patients, indicating some adaptation to starvation. Increased body protein synthesis was also demonstrated. Since muscle wasting and body weight loss were present, the increase in body protein synthesis appeared to be related to increased tumor utilization of protein. Such an interpretation is based on animal studies which reveal that even though the tumor contains less than 6 percent of the body's nitrogen, it accounts for about 25 percent of the total body protein synthesis (Stein, et al, 1976). Finally, results indicated that while all patients were in positive nitrogen balance, anthropometric measurements indicated a loss of host protein. The explanation offered for this finding was that there may be a translocation of protein from body muscle to more active sites of protein synthesis such as in the tumor tissue itself. These derangements in protein metabolism appear to be a remodeling of protein metabolism in the cancer patient.

Another recent study illustrating the alteration in protein metabolism in cancer is a study of the effects of total parenteral nutrition on whole body protein metabolism (Burt, Stein, Schwade, & Brennan, 1984). Eleven patients with a history of weight loss and with localized squamous cell carcinoma of the distal esophagus were studied in the postabsorptive state and then again 2 weeks following total parenteral nutrition. Whole body radioactive potassium scanning was used to measure lean body mass. Whole body protein kinetics were measured by radioactive glycine infusions. Results indicated that a favorable change of protein metabolism occurred following two weeks of total parenteral nutrition. This favorable change was indicated by a significantly increased body weight, positive nitrogen balance, decreased urinary excretion of 3-methylhistidine (used to indicate nitrogen output) and increased whole body protein flux. Changes were accentuated in the subgroup of patients whose whole serum insulin levels were between 40 and 120 u/ml, which suggests that an ideal level of serum insulin is needed for adequate protein synthesis. The body weight increase may have been related to a gain in body water. However total body potassium was increased, although insignificantly, during the two week period, and gave some indication that the increase in body weight represented a combination of increased body lipid, water, or both. The stability of lean tissue mass during the total parenteral nutrition period indicates that the loss of tissue mass which was occurring prior to TPN was interrupted. This study illustrates that nutritional support given to patients malnourished as a result of cancer and cancer treatment, may be repleted and alterations in metabolism, specifically protein metabolism may be interrupted. Impact on morbidity and mortality was not addressed.

As the ability to measure various aspects of metabolism has increased, investigators are beginning to conduct more complex studies that combine a number of measurements. Two recent examples are presented to summarize the present state of research on metabolic factors and their relationship to nutritional depletion in cancer patients. In the first study, a comparison of glucose dynamics, energy metabolism, and nitrogen balance were studied in eight malnourished cancer patients and seven malnourished patients without cancer (Eden, Edstrom, Bennegard, Schersten, & Lundholm, 1984). The purpose of the study was to evaluate the role of elevated overall flux of glucose as a metabolic pathway of energy drain on cancer patients. Subjects in the cancer group had a history of weight loss, generalized disease from several possible cancer primary sites (one testicular carcinoma, and one colon carcinoma), and had clinical signs of malnutrition and cachexia, but were not totally bedridden.

The non cancer patients were also malnourished, but had no signs of active disease when studied (one chronic malnutrition due to gastric resection, one had chronic pancreatitis, one had senile depression due to generalized arteriosclerosis, one had previous bile fistula without extrarenal losses and two had senile depression). Measurements of glucose flux via injection of labeled glucose and energy expenditure via indirect calorimetry were carried out at baseline and following two weeks of an enteral nutrition refeeding protocol. Results indicated that blood glucose concentration rose 25 to 30% and lactate concentration rose approximately 40% in both cancer and non-cancer patients during the feeding period. Insulin levels rose as well, but were significantly lower in cancer patients as compared to control patients. Resting and total energy expenditure did not differ significantly between groups, and both groups changed from a negative to a positive energy balance, and to positive nitrogen balance during enteral nutrition. Results indicated that cancer patients had an increase glucose flux when fasting which corresponded to 42% of their spontaneous daily intake of glucose. These findings appear to indicate that the cancer patients studied had an increased glucose demand, which contributed to the weight loss experienced during disease. Thus an energy drain on the cancer patient is present. However the energy drain per 30 day period was calculated to be only 0.9 kg of body fat. Thus it probably plays only one small part in the multi-faceted problem of cachexia and weight loss in cancer patients.

In the second study, changes in energy metabolism, substrate use, and hormone profiles were examined in 31 cancer patients before and after receiving either 4 weeks of total parenteral nutrition, or 4 weeks of continuing to ingest a self-regulated oral diet (Russell, et al, 1984). All patients had small cell lung cancer. Actual resting energy expenditure was measured via indirect calorimetry, and predicted energy expenditure was calculated from the Harris-Benedict formula. Results indicated that the actual resting expenditure was 31% higher than the predicted resting energy expenditure as determined by the Harris-Benedict measurement. In addition, caloric intake was clearly insufficient to meet caloric need. Thus weight loss was a result of hypermetabolism and relative anorexia. Total parenteral nutrition resulted in a significant and positive energy balance, but this balance was not maintained post feeding in anorectic patients. The dominant fuel source for the patients was fat and this was not reversed during total parenteral nutrition. Weight gain associated with total parenteral nutrition was coupled with increased anorexia, leading to further weight loss when the nutritional support was discontinued. The major impact on catabolism was tumor response - those patients whose tumors responded to the chemotherapy protocol did better. Thus it appears that one way metabolic alterations are reversed is through tumor response to therapy.

In summary, one major group of studies being conducted to examine why nutritional depletion occurs in cancer patients involves alterations in energy expenditure, in carbohydrate, fat, and protein metabolism (Kurzer & Meguid, 1986; Lundholm, 1986). Findings illustrate abnormalities but patterns are not consistent and the degree of abnormality demonstrated does not account for the extent of weight loss which occurs in most patients (Kaempfer & Lindsey, 1986). It appears that while alterations in energy expenditure, carbohydrate, fat and protein metabolism may account for some of the nutritional depletion seen in cancer patients, decreases in dietary intake may play a major role in the continued and profound weight loss observed.

Consequences of Anorexia in Cancer Patients

The significance of anorexia and nutritional depletion in cancer patients is related to the potential impact on morbidity, mortality and quality of life. Recognizing stages before these final consequences would be of particular significance to the clinician responsible for identifying anorexia and for initiating appropriate interventions.

Weight Loss

Weight loss and a resulting nutritional depletion are also consequences of anorexia and result directly from the decrease in food intake below metabolic need and/or alterations in host metabolism. In many patients, the occurrence of weight loss may be the patient's and the clinician's first clue to the existence of anorexia. Weight loss is an important clinical indicator: a weight loss of more than 5% in four weeks or more than 10% in 6 months is considered severe (Blackburn & Harvey, 1980). While such a severe weight loss may not in and of itself be dangerous, when coupled with any other major stress, such as trauma, surgery, or infection, complications can occur that would have been unlikely without the weight loss (Blackburn & Harvey, 1980).

Decreased Immune Status

Anorexia, with an accompanying nutritional depletion, can lead to a depressed immune status via decreased macrophage mobilization, depressed lymphocyte function, and impaired phagocytosis (Shils, 1979). In such a compromised state, the patient is vulnerable to infections that may be life threatening. When the nutritional state is reversed, the immune state is also reversed, altering the patient's response to disease and therapy (Kaminski, Nasr, Moss, Berger, & Sriran, 1982).

Decreased Treatment Tolerance

Another consequence of anorexia is a decreased tolerance to cancer treatment (Costa & Donaldson, 1979). If anorexia and a resulting malnutrition occur during cancer therapy, the effect may be disabling and may even interrupt the therapy. For example, radiation therapy for patients who lose significant amounts of weight may be discontinued before an adequate tumor dose of radiation is administered (Copeland, Souchon, MacFadyen, Rapp, & Dudrick, 1977). Surgical patients who have had a history of severe weight loss may have impaired capacity for wound healing (Ruberg, 1984). If the surgery involves resection of a great deal of soft tissue, as done with a radical neck dissection, the wound may not heal (Copeland, MacFadyen, MacComb, Guillamondegui, Jesse, & Dudrick, 1975). For patients receiving chemotherapy, anorexia is frequently associated with other side effects such as nausea, vomiting, and mucosal ulcerations. A combination of these toxic effects can be dose limiting, decreasing the amount of chemotherapy administered to levels below usual doses (Costa & Donaldson, 1979).

Cachexia

One devastating consequence of anorexia is cachexia, a profound systemic abnormality in host metabolism characterized by weakness, wasting, depletion, redistribution of host components, hormonal aberrations and a progressive failure in vital function (Costa, 1977; Lindsey, Piper, & Stotts, 1982). Cachexia is a major occurrence in progressive malignancy and is seen in as many as two thirds of the terminally ill patients (Morrison, 1976). Anorexia does not always lead to cachexia, but most patients with cachexia are anorexic at some time during the course of the disease and its treatment (Garattini et al., 1980). Cachexia may, in turn, increase anorexia.

Decreased quality of life

Food intake and eating are important aspects used to define quality of life. In a study of 1000 30-year olds, 1000 50-year olds, and 1000 70-year olds, 6500 critical incidents were submitted in response to questions about what incidents had a significant effect either positive or negative, on their overall quality of life (Flanagan, 1982). A total of 15 factors, identified by several independent judges, included virtually all of the 6500 incidents. Eating was identified under the factor material comforts--desirable home, food, conveniences, and security. This factor was rated as important or very important by 80 per cent of the 30 year olds, 87 per cent of the 50 year olds, and 87 per cent of the 70 year olds.

In a report on the development of a quality of life index for cancer patients, quality of life for 39 radiation therapy patients was compared to 48 chemotherapy inpatients, 43 chemotherapy outpatients, and 38 non patients (Padilla et al., 1983). Appetite was one item on a 14 item linear analogue scale designed to rate four aspects of quality of life among groups: psychological well being, physical well being, symptom control, and general quality of life. Linear analogue scales included pain, nausea, vomiting, strength, appetite, work, eat, sex, sleep, general quality of life, satisfaction, useful, and worry about cost. On a 100 millimeter scale, the average appetite score for radiation outpatients was 54 with only ability to work and sex having more depressed scores. Ability to eat was also low for radiation outpatients with a mean of 62 and only 5 items ranked below it. These results indicate that the problems of appetite and eating occur in cancer patients undergoing radiation therapy and impact negatively on quality of life. Anorexia results in several consequences that indirectly affect quality of life. Fatigue and asthenia may result from nutritional depletion and in turn perpetuate an inadequate intake. Fatigue is a common symptom in cancer patients (McCorkle & Young 1978), and is a major factor impacting on the quality of life of the cancer patient (Grant, Padilla, Presant, Lipsett, & Runa, 1984).

Cancer Mortality

Nutritional depletion appears to play a major role in cancer mortality. One of the first studies to focus on this role was that of Warren (1932), who examined the laboratory findings in 500 cases of carcinoma from four Eastern hospitals. Clinical records and the post-mortem protocol of each patient were examined. The cases were selected at random but excluded sarcoma, lymphoblastoma, and leukemia. While no childhood cases were included, age distribution was not specified except that the age level was high. Percentage distributions by site included 11% buccal cavity; 11% stomach and liver; 18% peritoneum, intestine, and rectum; 20% female genitals; 17.4% breast; 4.6% skin; and 18% unspecified. It was Warren's opinion that the distribution of cancer sites in the study group was a representative sample of the fatal cases of cancer for that area of the country. Warren reported that cachexia was the most frequent single cause of death and accounted for more than 22% of the deaths. Cachexia was defined as progressive wasting and weakness accompanied by increasing anemia. Various pulmonary disorders were also identified as causing death, and when grouped together accounted for an additional 24% of the deaths. The pulmonary disorders included pneumonia; pulmonary insufficiency, and pulmonary embolus. Renal insufficiency accounted for 13% of the deaths, peritonitis accounted for 11.2% of the deaths, hemorrhage, hepatic insufficiency and intestinal obstruction for 4% of the deaths each, and the remaining 17.8% by other causes.

Reporting of cachexia as the cause of death in cancer patients has not been done consistently following publication of Warren's (1932) findings. In fact, although there is a general association between the occurrence of cachexia and death in cancer patients, the mechanisms involved in death from nutritional depletion have not been identified. Death from starvation in non cancer patients has not revealed specific mechanism either (Lawson, Richmond, Nixon, & Rudman, 1982). Autopsies of Irish prisoners who died during hunger strikes have uncovered no single cause of death. The organs of the body just stopped functioning (Graf, 1981). Major progress in cancer research since Warren's study has focused on the causes of cancer and methods of treatment. Only recently has attention been turned to the nutritional aspects of care. Two studies emphasize the frequency of nutritional problems for today's cancer patients.

The first study reports the incidence of protein-calorie undernutrition in hospitalized cancer patients (Nixon, et al 1980). In phase one of this study a convenience sample of 54 consecutively admitted subjects from the Emory University Hospital Medical Oncology Ward during the summer of 1977 was studied. The average age was 57 with a range of 42 to 73. Data collected included percentage of ideal body weight, mid arm muscle circumference, 24-hour urine creatinine-height index, serum albumin, type of cancer, duration of cancer, history of treatment, clinical symptoms, location of metastases, and length of survival. Percentage distributions by site of cancer included 39% colon, 11% breast, 7% melanoma, 6% each for stomach, head/neck, testicular, and unknown, 3.7% each for lung and renal cell, and 1.8 % each for pancreas, sarcoma, lymphoma, astrocytoma, cholangiocarcinoma, adrenal and vaginal. Findings revealed an almost universal prevalence of protein-calorie undernutrition as illustrated by loss of adipose tissue, visceral, and skeletal muscle which varied unpredictably from patient to patient. The most sensitive index to protein-calorie undernutrition was the creatinine-height index which fell below 80 percent of standard in 88 percent of patients. In phase 2, another thirty subjects with diagnosed protein-calorie undernutrition were studied on the Clinical Research Unit for underlying mechanisms potentially affecting nutritional status. Additional data collected on this group included vitamin levels, caloric intake, basal metabolic rate, and stool fat content. Basal metabolic rate and voluntary oral intake of calories did not differ significantly from rates for normal sedentary subjects. While no significant linear associations were identified between the protein-calorie undernutrition and type of cancer, duration of disease, location of metastases or past surgical and radiation treatment, the degree of malnutrition was significantly correlated with survival. Thus it appears that there is a nutritional threshold below which survival is jeopardized. Findings were not reported for specific age groups. However, the control group for comparisons was matched for age and sex to the phase 1 subjects. Results are potentially confounded by the heterogeneity of the cancer diagnoses, some of which are more likely to be associated with nutritional problems than others. The linear associations based on a sample of 1 or 2 cases of specific types of cancer may be erroneous. The study also involved a convenience sample and bias in sample selection may have occurred.

A second study which describes the nutritional problems in today's cancer patients focuses on the frequency of weight loss in a variety of tumor types and the prognostic importance of weight loss prior to chemotherapy (DeWays et al 1980). Data for this study were derived from 3047 patients enrolled in 12 chemotherapy protocols of the Eastern Cooperative Oncology Group. Weight loss was collected by patient interview and defined as a percent loss compared to the patient's weight before illness and as a loss within the previous six months. It should be noted that this is quite different from a comparison of weight as a percentage of ideal body weight. Such a definition could result in grouping patients who were overweight before illness with patients whose weight was within normal range or underweight before illness. These three groups may respond quite differently to a major weight loss, with the underweight group tolerating a much smaller weight loss. Performance status was measured on a 5 point scale from fully active to completely bedridden. Age distribution data were not identified. Results revealed that 46% of the patients experienced no weight loss, 22% had between 1 and 5% weight loss, 17% experienced between 5 and 10% weight loss, and 15% experienced over 10% weight loss. For nine of the twelve chemotherapy protocol groups, survival was significantly shorter in patients who had experienced weight loss. In addition when compared to performance status, weight loss was associated with an unfavorable performance status category. This suggests that weight loss and performance status may be interrelated or have a common basis. Explanations include the possibility that the weight loss in these cancer patients resulted from loss of the muscle compartment, and thus performance status was effected. Subjects with pancreatic and gastric cancer, however, did not demonstrate the correlation between weight loss and performance status. It was postulated that in this group of patients, weight loss may have reflected a simple starvation, with most of the weight loss being associated with loss of body fat, and therefore having less impact on performance status. While the numbers of patients involved in this study were substantial, the variety of tumor types and stages make interpretation of the results difficult. In summary, results illustrate the potential value of weight loss as a prognostic factor in survival of cancer patients. Since the weight loss did not necessarily result in losses which placed patients in weight loss categories below ideal body weight, the actual occurrence of weight loss appears to be the essential factor rather than whether or not the patient dropped significantly below ideal body weight.

In summary, consequences of anorexia and nutritional depletion in cancer patients include cachexia, weight loss, decreased treatment tolerance, decreased immune status, decreased quality of life and death. Nutritional depletion continues to be found in today's cancer population. The occurrence of weight loss can be used to predict response to chemotherapy, with those having no weight losses responding more favorably to chemotherapy. The consequences of anorexia identify it as a significant problem for today's cancer patient.

Measurement of Anorexia

The concept of anorexia is a dynamic one, as illustrated by the expanded definition used today. Anorexia is defined simply in the medical dictionary as a diminished appetite or aversion to food (Stedman, 1982). When examining anorexia in cancer patients, researchers and clinicians have expanded this definition to include observations of decreased food intake as well. For example, DeWys (1977) defines anorexia as a reduced appetite which includes both physiological and psychological components influencing food intake. Costa's (1977) definition includes a loss of appetite and a poor intake of food.

This expanded definition is accepted by researchers using animal models to examine cancer anorexia and cachexia. Morrison (1981) states that the expanded definition is essential if the problem is to be studied at the animal level. With animal research, it is possible to manipulate tumor factors, treatment factors, and other social factors, and observe their impact on the intake of food, thereby providing some essential descriptions of the mechanism that may be involved in the phenomena of cancer anorexia (Morrison, 1981).

Measurement of anorexia with its expanded definition needs to include both the subjective perception of appetite loss and the more objective measurement of dietary intake. Subjective aspects are obviously not measurable in animal models. However, even in human anorexia studies, reliability and validity threats to subjective measurement are present. Dietary intake, on the other hand, can be carefully measured in animal studies by controlling the diet, carefully measuring the intake, and calculating changes from day to day. With the human, these measurements are possible as well, but are again vulnerable to reliability threats, since a glass of milk to one subject may contain a different amount than that for another subject. In addition, although many sophisticated studies on the caloric and nutrient value of specific foods have been conducted, the science is still imperfect. Food values can change in response to the environment in which the food was grown, and the methods used in processing. Thus even the objective measurement of anorexia by dietary intake has potential reliability and validity threats. In examining previous studies on anorexia, attention to the way measurements were done is an important aspect of critique.

In summary, the concept of anorexia is defined presently as a decrease in appetite accompanied by a spontaneous decrease in dietary intake. Initial studies of anorexia in both cancer patients and cancer animal models have been conducted, and have begun to explain some aspects of the phenomena involved. Anorexia is an important concept in present day nursing practice. However, measurement of anorexia, in both its subjective and objective parameters, remains a challenge.

Anorexia in Head and Neck Cancer Patients

From this literature review the concept of anorexia has been developed from the broad perspective of nutritional depletion in cancer patients by examining known factors related to dietary intake in health, relevant nutritional changes that occur during the aging process, factors which influence nutritional depletion in cancer patients and the consequences of anorexia and nutritional depletion. In order to develop relevant questions for clinical research within this broad framework of knowledge, anorexia in a specific population of cancer patients has been selected as a focus. This perspective includes a critical evaluation of studies on anorexia and nutritional depletion during radiation therapy for head and neck cancer. From this more specific perspective, gaps in the knowledge are identified, and a conceptual framework for the present study is discussed.

Six studies have focused on the problems of head and neck cancer patients undergoing radiation therapy (Table 2.3). Discussion of these studies includes the characteristics of the population, the design, what measurements were made of anorexia, nutritional status, morbidity, treatment responses, quality of life, and study findings. Areas in which information is lacking or results are equivocal are discussed.

The first study on head and neck patients undergoing radiation therapy is a quasi-experimental study comparing the effects of an individualized intervention on nutritional assessment and counseling in an experimental group of 9 patients, with a concurrent control group of 9 patients, and a retrospective control group of 16 patients (Hamill, 1978).

Table 2.3

Studies on Head and Neck Cancer Patients undergoing Radiation Therapy

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
Hamill, P., 1978 Master's Thesis University of Rochester, School of Nursing Purpose: To document the effectiveness of a nursing intervention of individualized patient instruction and counseling regarding nutritional requirements	Independent Nursing intervention of individualized patient instruction and counseling on nutrition over a 6 week period of radiation therapy Dependent Changes in weight, triceps skin folds, arm muscle circumference, laboratory values, dietary intake, and level of function	Nutritional assessment questionnaire 24-Hour diet intake Scale, Skin calipers Laboratory tests	9 Experimental 9 Concurrent Controls 16 Retrospective Controls	Six-weeks Weight loss average Experimental -2# Concurrent Controls-6# Retrospective Controls-6.5# No differences in hematocrit across groups Other laboratory tests not available in control groups No differences in functional level across groups Other data incomplete and not analyzed

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
Johnston, Keane & Prudo, 1982 *Journal of Parenteral and Enteral Nutrition*	Weekly symptoms: smell, dysgeusia, dysphagia solids/ liquids, xero- stomia, mouth/ throat pain, skin irritation, appetite, fatigue.	10 cm Linear analogue scales	31 head and neck patients under going radiation therapy	68% lost 5% of usual weight within a month following completion of radiation therapy
Purpose: To determine the relationship between weight loss and 1) pre- treatment characteristics, 2) volume and site of tumor irradiated, and 3) various symptoms Dietary counseling throughout			Convenience sample	Average loss of weight was 10% with a range of 5.4 - 18.9%
			Curative intent	
	Weight, height Triceps skinfolds,	Scale, Skin calipers		Only correlation significant to weight loss was field size of 8 x 8 cm or greater
	WBC, Absolute Lymphocyte Count Albumin, Creatinine, Creatinine-Height Index.	Laboratory tests		if weight loss was high, symptom distress on line scale was high

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
Bassett, & Dobie 1983 <u>Otolaryngology, Head and Neck Surgery</u>	Weight loss history Oral intake Anorexia, Dysphagia via historical assessment	Nutritional questionnaire Physical exam Laboratory test	50 consecutively admitted head and neck cancer patients No previous treatment	32% had weight loss of 15# with reference to stated norm. 42% unable to eat 3 meals a day 48% difficulty swallowing 90% could ambulate 42% anergic responses
<u>Purpose</u>: To document the suspected prevalence of suboptimal nutrition, to characterize the type of impairment present, to identify clinical variables associated with the nutritional deficits, and to assess the cost and practicability of one method of assessment.	Height, weight %IBW, triceps skinfolds, midarm muscle circumference, ability to ambulate, Hemoglobin, albumin, transferrin, lymphocytes, creatinine height index (CHI), skin tests for cell mediated immunocompetance			Nutritional status via Copeland's schedule 40% good 20% fair 40% poor 52% no diet change 35% soft foods only 12% liquids only 2% cannot swallow Clinical parameter that was most indicative of nutritional score was history of most recent diet. No relationship between stage of tumor and nutritional status CHI most sensitive laboratory test.

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
Chencharick & Mossman, 1983 <u>Cancer</u>	Tumor characteristics, Radiation, Dietary habits	Chart data assessment-good, fair, poor	74 head and neck cancer patients undergoing radiation therapy	At 1 month post-therapy only 4 patients had remaining tumor
<u>Purpose</u>: To assess the subjective frequency of dry mouth, abnormal taste function, anorexia, altered food preference, and dysphagia prior to and during radiotherapy for head and neck cancer; to correlate these findings with objective changes of nutritional status as measured by body weight and dietary history	Weekly ratings of mouth dryness taste, dysphagia appetite, food preferences	Semi-structured questionnaire	Curative intent	20% taste loss and oral symptoms prior to therapy
	Body weight	Scale for weight		80% had oral and nutritional problems at end of therapy
	24-hour diet history	24-hour diet history	8 patients participated in diet history portion	Weight loss average 5kg before therapy, no further loss during therapy
	Dietary counseling throughout			Diet history showed caloric deficiency at start of therapy = 1746 and a decrease by end of therapy = 1698 (N=8 patients)
				Changes start--end Taste 17% 80% Foods 18% 80% taste bad Sugar added 1% 32% Salt added 12% 8%
				Abnormal tasting food including high protein foods, fruits and vegetables, breads, cereals, coffee

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
Daly, JM, Hearne, B, Dunaj, J, et al, 1984, American Journal of Surgery Purpose: To compare intensive nasogastric feeding with optional oral nutrition in patients with advanced head and neck cancer while they were receiving radiation therapy.	Independent Subjects randomized to 1) optional oral nutrition were counselled on calories & protein intake, needs, diet pattern needed, nutritional supplements, seen 2x/week by dietitian & study team, 2) nasogastric feeding group were counselled on calorie & protein intake needs, and nutritional supplements plus proper techniques of tube feeding, preparation of formulas, and administration of the procedure, care of the tube, of equipment. Formula used was Isocal.		40 accrued of which 5 were lost (1 ineligible due to tumor site, 1 died before RT, one withdrew after gastrectomy that interrupted RT, 2 randomized to T.F. converted to oral because of noncompliance and 2 on oral converted to T.F. because of accelerated weight loss during 2 week of RT). Data summarized for 18 T.F. and 17 oral, but which 35 used, not indicated. Study Period Baseline - 8 weeks of therapy for a weekly-biweekly visit, and 1 month post treatment follow-up.	TF group significantly higher mean caloric intake (39 Kcal, range=33-42) than oral group (30Kcal, range=28-32). TF group significantly higher protein intake (1.4g/kg r 1.2-1.5) than oral group (1.1/kg range=6-1.3 Both groups, especially TF group, had severe toxicities during with RT with extent and duration greater for TF group Significant decreases in serum albumin in both groups, with faster recovery of TF group by 1 month post.

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
	Dependent			
	1. Median caloric intake weekly during RT.	24 hour dietary recall for baseline, 3 day for weekly.		No significant initial differences between groups on MAMC, but oral group showed a significant decrease during RT.
	2. Median protein intake weekly during RT.			
	3. Nutritional assessment MAMC weight albumin 1+4 week, end of therapy, 1 month post.	 Lange calipers scale Lab tests		Patients with TF had significantly less weight loss (0.6% loss) as compared to oral feeding (6.1% loss).
	4. Functional status quality of life	Karnofsky scale		
	5. Toxicities (dysphagia, xerostomia, mucositis, nausea, vomiting, diarrhea, constipation)	6 point self-rating scale		No differences across groups in tumor response to treatment.
	6. Taste changes	Subjective scale		
	7. Various demographic variables			
	8. Survival			No difference across groups in terms of survival time.

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
Enig, Winther & Hessov, 1985 Nutrition and Cancer	Independent: Period 1=no dietary ad-vise Period 2= dietary instruction by a dietitian	Dietary intake	41 subjects either pharyngeal (13) or laryngeal (28)	No significant difference in energy and protein intake before and during RT
Purpose: Effects of RT on energy and protein intake and nutritional status	Dependent: Changes in wt skinfold thickness (biceps, triceps, sub-scapular, and suprailiac. Upper arm circumference	Harpenden skinfold calipers Durnin and Wormersley's bodyfat tables	Each group followed for a period of 5 months	Changes in wt albumin, and transferring all normal for patients with laryngeal cancer Significant loss of wt serum albumin for patients with pharyngeal cancer during study period
	Serum albumin and transferrin Adverse effects: pain when swallowing, dryness of oral mucosa, nausea	Four point scale -1= none, 4 = severe for adverse effects		Small and significant increase in adverse effects for groups both diagnostic during therapy but no correlation of this change to energy intake or nutrition status
	Food intake 4 days	Nutrient analysis by computer		Nutrition status of laryngeal patients maintained by an average protein of of 1 g/kg/day and an average energy intake of 135% of BMR. Nutrition status of pharyngeal patients not maintained by mean protein intake of 0.9 g/kg/day and mean energy intake of 121% of BMR.

Author, Source Purpose	Variables	Instruments	Subjects and Time Period	Pertinent Findings
				No significant difference in Period I and II of food intake as a result of dietitian's instructions.

The independent variable, an individualized nutritional assessment and counseling, was carried out by the investigator over the six week period of radiation therapy. Dependent variables included changes in weight, triceps skin fold, arm muscle circumference, changes in laboratory values, changes in dietary intake, and changes in level of function.

Findings revealed a mean decrease of 2 pounds between the first and sixth week of therapy for the experimental group, and this change was not significant. For the concurrent control group, mean weight loss was 6 pounds and this change from 1st to 6th week was significant. For the retrospective control group, mean weight loss was 6.5 pounds and was significantly different from week 1 to week 6. Differences between the weight changes in the experimental, concurrent control, and retrospective control were not significantly different. Thus changes in weight were significantly decreased in the two control groups, but this decrease was not significant across groups. Findings on triceps skin fold measurements and arm muscle circumference were not analyzed because of errors in collection. Laboratory values for hematocrit showed no significant changes either within or between groups. Albumin and total protein measurements were available for the experimental group only, and thus comparisons across groups were not possible. Data on 24-hour dietary intake were not analyzed because of incompleteness in data collection. The measurement for functional status showed no significant differences across experimental and control groups.

Major problems occurred in the implementation of this study and resulted in a lack of data for analysis. The independent variable, an individualized nutritional assessment and counseling program, was defined according to individual patient needs as determined by the investigator. It is, thus, not possible to replicate such a variable in other populations. In addition, no data were reported on what the patient actually learned during the nutritional assessment and counseling sessions. Patients in the experimental group, however, utilized a protein and calorie supplement and this was not done in the control groups. Thus, nutritional supplementation may have been the major factor influencing the weight change differences observed. Nonetheless, without knowing what the independent variable included and what dietary intake occurred, it is not possible to interpret the results confidently. Data were not collected for several of the dependent variables and thus findings were limited. This occurred for triceps skin folds, mid arm muscle circumference, albumin, total protein, and 24-hour diet intake. Additional variables that would have added useful data to the study are treatment responses, radiation effects, and information on quality of life.

The second study cited in Table 2.3 on head and neck cancer patients undergoing radiation therapy was a descriptive time series study, following patients from the initiation of therapy to 6 months post treatment completion

(Johnston et al., 1982). A convenience sample of 31 head and neck cancer patients was followed in order to determine the relationship between weight loss and pre-treatment characteristics, volume and site of tumor irradiated and various symptoms. Nutritional counseling was given throughout the treatment period and included an introduction to the conventional supplements used. Two patients received enteral nutrition via tube during the last week of therapy. No patients received parenteral nutrition. The patients rated the following symptoms weekly on a 10 cm visual analogue scale: smell, dysgeusia, dysphagia solids/liquids, xerostomia, mouth/throat pain, skin irritation, appetite, and fatigue. Other measurements included height, weight, triceps skin folds, mid arm muscle circumference, white blood count, absolute lymphocyte count, albumin, creatinine, 24-hour creatinine height index, and evaluation of dietary habits as good, fair, or poor.

Findings showed a weight loss of 5% or more in 20 of the 31 subjects (68%). The mean loss was 10% for this group with a range of 5.4% to 18.9%. The loss began after one week of treatment, peaked 3 months post treatment, and continued for the vast majority until 6 months post treatment. Weight loss was not correlated with actual weight, any laboratory findings, dietary habits, or dental extraction history. It did correlate with size of radiation field, with the weight loss higher in all patients with field sizes greater than 8 x 8 cm. As weight loss increased, so did scores on symptoms.

For example, scores for xerostomia, dysphagia, mouth/throat pain, and dysguesia were higher in patients who lost more than 5% of their pre-treatment weight at 1 month. Data on ability to smell, appetite, fatigue, and skin irritation were similar to the other symptoms. Dysphagia and xerostomia peaked at the end of therapy and persisted up to 6 months. Appetite decrease peaked at the end of therapy, but had not returned to pre-treatment levels by 6 months post treatment.

These findings illustrate the weight loss problem in head and neck cancer patients undergoing radiation therapy. Lacking in the available data is an indication of the dietary intake, and whether or not weight losses were associated with actual decreases in dietary intake. The persistence of symptoms, some up to 6 months post treatment, indicates a need to identify what impact on quality of life this treatment regimen produces. A quality of life instrument would have been a valuable addition. An explanation of the nature of the nutritional counseling done would have been helpful, especially in applying the findings to different settings, and identifying helpful recommendations to other institutions. Findings do suggest that patients need nutritional counseling throughout and following treatment, and need symptom relief from problems of xerostomia and mouth/throat pain. Interventions with artificial saliva and topical analgesics for the mouth need testing. Further clarification of changes in dietary intake is needed.

The third study cited in Table 2.3 by Bassett and Dobie (1983) involved 50 consecutively admitted head and neck cancer patients (1983). The purpose of this descriptive study was to document the suspected prevalence of suboptimal nutrition, to characterize the type of impairment present, to identify clinical variables associated with usual nutritional deficits, and to assess the cost and practicality of one proposed method of assessment. Measurements included a questionnaire to identify the history of weight loss, decreased oral intake, anorexia, and dysphagia. Additional data included height, weight, percentage ideal body weight, triceps skin fold, mid arm muscle circumference, and ability to ambulate. Laboratory tests included hemoglobin, albumin, transferrin, total lymphocyte count, creatinine height index, and skin tests for cell mediated immunocompetence.

The sample was composed of 39 males and 11 females. Head and neck tumors were in various stages and sites. A weight loss of 15 pounds with reference to a stated norm occurred in 32% of the subjects. When asked to characterize their recent diet, 52% said there had been no diet changes, 34% were taking only soft foods, 12% were taking liquids only, and 2% were unable to swallow at all. Composite nutritional scores were made using Copeland, Daly and Dudrick's (1979) schedule. Results showed 40% were in good nutritional status, 20% were in fair nutritional status, and 40% were in poor nutritional status. The clinical parameter most indicative of the nutritional status was the patient's description of the most recent diet. No correlations were found between nutritional status and stage of tumor or site of tumor. Among the laboratory tests used, creatinine height index was the most sensitive, with nearly the entire population falling below the lower limit of normal.

Findings of this descriptive study indicate that nutritional problems are frequently present at the time the patient initially seeks medical care. Interventions for early nutritional repletion need to be identified and tested.

The fourth study cited in Table 2.3 on head and neck cancer patients undergoing radiation therapy has as its purpose to assess the subjective frequency of dry mouth, abnormal taste function, anorexia, altered food preference, and dysphagia prior to and during radiation therapy, and to correlate the changes revealed with objective changes of nutritional status as measured by body weight and dietary history (Chencharick & Mossman, 1983). A sample of 74 head and neck cancer patients undergoing radiation therapy was followed in this descriptive study. Measurements of subjective responses were made weekly via a structured questionnaire. A 24-hour diet intake was obtained in 8 patients at the beginning and end of therapy. Body weight changes were recorded weekly.

Findings revealed that taste changes increased throughout radiation therapy, starting with approximately 17% of the patients being affected at the beginning of the study and ending with approximately 80% of the subjects. When asked whether foods tasted bad, 18% responded yes at the beginning of therapy, and 80% responded yes at the end of therapy. When asked whether sugar needed to be added to food, 1% said yes at the start of therapy, and 32% said yes at the end of therapy. When asked whether salt was added, 12% said yes at the beginning of therapy and 8% said yes at the end of therapy. Foods that were classified by patients as tasting abnormal included high protein foods, fruits and vegetables, sweets, breads and cereals, and coffee. Patients tended to sweeten foods, and had few changes in salt use. Prior to therapy, 40% of the subjects experienced dysphagia and by the end, 70% were experiencing it. Prior to therapy 20% of the subjects were experiencing appetite loss, while at the end of therapy, 60% were experiencing it. For weight loss, 90% of the subject had a 5kg loss prior to beginning radiation, and weight stayed the same across the group throughout the course of therapy. Dietary intake on the 8 patients who recorded it revealed that carbohydrate increased significantly and this increase occurred primarily in simple sugars. The average caloric intake at the beginning of therapy was 1746, while by the end of therapy it dropped to 1698.

Findings were in contrast to those found in other studies. For example, no weight loss during the radiation therapy period for this study contrasts with the average of 2 pounds, 6 pounds, and 6.5 pounds in Hamill's study (1978), and the average of 5% in the Johnston, et al. study (1982).

Like the other studies, this study does not identify what the dietary counseling sessions included, and thus replication of this aspect is not possible. Findings are not correlated with tumor site, stage, radiation therapy field size and dose, other radiation problems such as skin breakdown or any quality of life issues.

The fifth study cited in Table 2.3 used a quasi-experimental design to compare the effects of enteral tube feeding versus oral only feeding on a group of patients undergoing radiation therapy for head and neck cancer (Daly et al., 1984). A convenience sample of forty patients was randomized to the enteral group versus the oral group. However, this randomization did not determine final group assignment, since two patients initially randomized to oral feeding were converted to tube feeding because weight loss accelerated during the first 2 weeks of radiation therapy. Also two patients initially randomized to tube feeding were converted to oral feeding because of noncompliance with the tube feeding regimen during the first week. These changes threaten the validity of the randomization.

The distribution of nasopharynx versus other head and neck cancers among the groups revealed that the enteral group had nasopharyngeal cancer and 13 other cancers, while the oral group had 6 nasopharyngeal cancers and 12 other cancers. Six patients in each group had Stage I or II cancers, while the enteral group contained 16 patients with Stage IV cancer and the oral group had 12 patients with Stage IV cancer.

While males predominated in each group, distribution of sex across groups was equivalent. Twelve of the subjects in the enteral group had difficulty swallowing and 10 did not, while in the oral group only 6 patients had difficulty swallowing and 12 did not.

Five of the original forty subjects were dropped after randomization: one was ineligible because of tumor site, one died during preradiation chemotherapy, one needed partial gastrectomy and was withdrawn from the study, and two received radiation elsewhere. Thus, final analysis was done on 18 enteral patients and 17 orally fed patients.

The two values of the independent variable were operationalized as follows. For the orally fed group, nutritional assessment and dietetic counseling were carried out in order to maximize oral intake, with the initial goal for oral intake of 40 kcal/kg of body weight per day, and 1 to 1.5 grams of protein/kg body weight per day. If weight gain did not occur, recommendations for oral intake were increased by 5 kcal/kg per day each week. Recommendations included the inclusion of dietary supplements, and subjects were given choices from Sustacal, Ensure, Citrotein, and Promix. Artificial saliva was used as well. For the enterally tube fed group, dietary counseling was similar with daily goals of 40 kcal/kg body weight and between 1 and 1.5 grams of protein/kg body weight ordered. The formula used was Isocal. If weight gain did not occur, caloric intake was increased by 5 kcal/kg per day. Patients were encouraged to eat orally when possible. Instructions included procedures needed for enteral tube feeding.

Dependent variables included baseline and weekly nutritional assessment of weight, mid arm muscle circumference, serum albumin, Karnofsky rating of functional status, side effect toxicities (dysphagia, xerostomia, mucosistis, nausea, vomiting, constipation, and diarrhea) as assessed by dietitians following patient interview, and caloric and protein intake via weekly 3 day food intake records. Dietitians were available to see the patients on a day to day basis to ensure compliance with the regimen. The family was included in nutritional counseling sessions as well.

Comparisons of the two groups initially indicated no significant differences in sex, age, or weight loss. The patients in the enteral group had a larger percentage (55%) of abnormal swallowing as compared with the oral group (33%). The tube fed group maintained a higher mean caloric intake (39 kcal/kg, range 33 to 42) as compared to the oral group (30 kcal/kg, range 28 to 32). Toxicities began for both groups during the second week, and the tube fed group had significantly greater severely rated toxicities than the oral group. Whether these were related to the tube was not indicated. No significant differences in albumin levels were present at baseline, and both groups had significant decreases by the fourth week. Tube fed subjects recovered to normal albumin levels sooner at the end of radiation therapy and at one month post follow up. No significant differences were found in mid arm muscle circumference at the onset of the study. During therapy the tube fed group tended to maintain median mid arm muscle circumference, while a significant decrease occurred in the oral group. No significant differences in body weight loss were present between groups for subjects with primary nasopharyngeal carcinoma. Patients with all other head and neck cancers had significantly less mean body weight loss with tube feeding (0.90), as compared with oral feeding (6.1%).

Radiation dosage was higher but not significantly so in the tube group versus the oral group. No difference in survival patterns across groups was found by 20 months post treatment. Tumor response to radiation therapy did not differ across groups.

Further questions about the nutritional support needed for patients undergoing radiation therapy for head and neck cancer have resulted from this study. The issue of age was not addressed, both groups being approximately equal and no stratification done for the older group of patients included in the study. The nature of the nutritional counseling emphasized the amount of calories and protein needed, and recipes that are useful in providing these requirements were discussed with patients in the oral group. No evidence is presented that the patients were instructed on any other factors which influence feeding behavior, such as management of oral gustatory and general symptoms, psychological support and the social environment for eating. Thus the question of what led to the inability of the orally fed group to ingest sufficient calories as compared to the enterally fed group has not been addressed.

In addition, patient comprehension of the nutritional counseling material was not reported, thus it is not known whether the patients in the oral intake group comprehend the daily caloric and protein intake necessary. Learning to take in sufficient food to meet a daily specific amount of caloric and protein is probably more difficult for most people than learning to administer several cans of tube feeding formula a day. Toxicities (dysphagia, xerostomia, mucositis, nausea, vomiting, constipation, and diarrhea) were significantly greater for the tube fed group. These findings contrast with those of Hamill's (1978) who felt that the nutritional counseling when individualized, produced less weight loss than in a control group who did not have such counseling, and with those of Chencharick and Mossman (1983) who attributed no significant weight loss during radiation therapy to the nutritional counseling that was available.

The sixth study used a quasi-experimental design to examine changes in food intake and nutrition status in patients with laryngeal or pharyngeal cancer receiving radiation therapy (Enig, Winther & Hessov, 1985). A convenience sample of 41 patients was studied over a 10 month time frame. In the first 5 months (Period I), 22 patients (14 laryngeal cancer, 8 pharyngeal cancer) were followed while receiving the usual care. During the second 5 months (Period II), 19 patients (14 laryngeal cancer, 5 pharyngeal cancer) received dietary instruction from a dietitian.

Data included a diet intake recorded for four days using a specified food-intake questionnaire and analyzed for nutrient content using a computerized program; basal metabolic rate calculated from height, weight, age, sex, and compared with the normal value tables of Fleisch; nutritional status via weight height, skinfold thickness (biceps, triceps, subscapular, and suprailiac); upper arm circumference; serum albumin and serum transferrin. Calculated scores for nutrition included (1) fat-free body weight calculated by subtracting the body fat content (identified by comparing skinfold scores on tables by Durnin and Womersley, 1974) from body weight and (2) arm muscle circumference calculated as upper arm circumference - 0.314 x triceps skinfold thickness in mm. Food intake instructions were individualized for each patient in Period II based on their dietary history and estimates of their nutritional needs. Adverse effects recorded included ratings of 1=none to 4=severe for pain when swallowing, dryness of the oral mucosa, and nausea.

Results indicated that mean scores for energy and protein intake for all patients before and during radiation therapy were no different in subjects from Period 1 versus Period 2. However, if patients were grouped according to diagnosis (pharyngeal versus laryngeal cancer) disregarding

Period assignment, intakes of pharyngeal cancer patients were significantly lower (119% of BMR). A small number from each diagnostic category also had protein intake below 0.8 g/kg body weight/day. Nutrition assessment revealed no significant difference except loss of body weight, body fat and fat free body mass in the pharyngeal cancer patients only during treatment (mean weight loss = 5.0 kg). A small but significant drop in serum albumin occurred in the same group. For both diagnostic groups, significant increases in adverse effects occurred.

Results revealed that a mean energy intake of 121% of BMR and a mean protein intake of 0.9g/kg of body weight is insufficient to maintain weight during radiation therapy. No evidence was found that the food instructions made any impact on food intake during therapy.

The lack of impact of dietary counseling is difficult to analyze because 1) the content varied for each patient and so no standard instructional package can be examined for potential problems, 2) no data were presented to illustrate whether or not the patient learned anything from the dietary instruction, and 3) there was no indication if weekly instructional sessions took into account the analysis of the patient's reported dietary intake. These results contrast with Hamills (1978) and those of Chencharick and Mossman (1983) who felt nutritional counseling had high value.

Another problem with the study involves the high proportion of laryngeal cancer patients and the very low number of pharyngeal patients. One does not expect much nutritional depletion in laryngeal cancer patients. The radiation field is generally very small and few adverse effects result. However, in this study, dropping the patients with laryngeal cancer would have left only 8 patients in Period I and 5 patients in Period II. While this would be the population predicted to benefit most from nutritional counseling, the number of subjects is too small to have confidence in the findings. No instruments were identified for measurement of anorexia or subjective symptom distress.

By combining the findings of each of these studies, some recommendations for the present study can be made. Instrumentation is a problem in almost all of the studies, reliability and validity of research tools are not reported. In addition the tools, are not described in enough detail to be useful in replicating or extending findings. A major variable in all the studies has to do with the quality of dietary intake. Dietary intake measurements were a problem, and the content of the dietary counseling was not reported. While dietary counseling appeared to be effective in some of the studies, comprehension of the patient of the dietary content, and application of the patient in terms of self care were not specified. Thus it is difficult to identify just how dietary counseling was effective. Length of follow up differed across studies, and did not include the post treatment time reported in the Johnston et al. study (1982).

Thus, comparisons were not possible and confirmation of the continued weight losses observed by Johnston, et al, could not be validated in the other studies.

While it seem obvious that some sort of nutrition support for this population of patients is needed, reports of the value of nutritional counseling for oral intake, versus enteral nutrition, versus parenteral nutrition have been from individual anecdotal experience, with only a few prospective studies reported. Proponents of parenteral nutrition have lauded its values (Copeland et al, 1975). The value of enteral nutrition appears positive as well (Daly, et al, 1984). An overriding question is whether the cost of such nutritional support is justified in relation to patient's response.

If it is possible to maintain the needed calorie and protein intake by tube feeding, it should be possible to maintain the needed dietary intake orally given a patient with sufficient motivation, with the physical ability to eat, and with an understanding of the nature of dietary intake needed. The redundant model of feeding behavior, with its biopsychosocial components, would predict that the patients with the most interruption to the factors which promote feeding behavior would have the most difficult time in overcoming anorexia, while those with minimal interruption would have the easiest time. If this prediction is upheld, it could be used in future studies to identify those patients most likely to need nutritional support by invasive techniques, and those patients who could be educated, motivated, and persuaded to maintain adequate oral dietary intake during radiation therapy for head and neck cancer.

The value of an educational approach for assisting patients in maintaining adequate oral intake during radiation therapy is related to studies which describe severe lack of knowledge among cancer patients in general regarding cancer treatment, side effects and self-care approaches (Dodd, 1982A; Dodd, 1982B; Dodd, 1983; Dodd, 1984; Dodd, 1987; Dodd & Mood, 1981). This knowledge deficit occurs even though oncology nurses have defined patient education about cancer, cancer treatment, side effects, and self care as a primary theme in the standards needed for quality patient care (American Nurses Association, 1979). What few studies have beencompleted reveal that cognitive information interventions are of value in both laboratory and clinical settings for improving patients' compliance with self care, the improvement of self care ability and the improvement of emotional stability (Dodd and Mood, 1981; Israel and Mood, 1982; Johnson, 1973; Johnson, Rice, Fuller and Endress, 1978; Mood, 1984; Padilla et al., 1981). In relation to knowledge needed to prevent nutrition depletion in patients who are supported primarily through oral intake, the most frequent approach used has been the educational approach of dietary counseling (Chencharick & Mossman, 1983; Daly et al., 1984; Hamill, 1978; Johnston et al., 1982). Nutrition education and counseling are essential parts of the cancer patients' care plan (Dwyer, 1986).

An individual characteristic of potential importance in testing a cognitive educational approach to maintaining nutrition status in cancer patients undergoing treatment is the construct of locus of control (Rock, Meyerwitz, Maisto, & Wallston, 1987). This construct refers to a person's expectancies of personal control over life events. Scales used in locus of control studies generally classify subjects as internal wherein a person attributes changes in life events to his own activities and beliefs versus external wherein life events result as a matter of luck or chance (Padilla, et al., 1981). This construct has been used in research on teaching approaches for management of distress (Padilla, et al., 1981). It is a construct that appears to have some usefulness in predicting success in the treatment of obesity. A specific scale, the weight locus of control scale (WLOC) has been developed as a measure useful in obesity research (Saltzer, 1982). This scale has been used to examine the relationship between perceptions of control over weight and success in achieving weight loss (Saltzer, 1982). The WLOC scale provides a way to operationalize the construct of locus of control in regard to weight. Locus of control has not been reported in studies of cancer patients when the focus is on minimizing weight loss. Exploration of this construct in patients whose objective is to maintain weight or minimize weight loss may provide information of importance in predicting those individuals who are most likely to benefit from an educational program on self help measures.

Summary and Conceptual Framework

The conceptual framework for this study combines knowledge of normal feeding behavior, proposed factors influencing anorexia in cancer patients and consequences of anorexia in cancer patients. The system which controls ingestion of food in health includes physiological, psychological, and sociocultural factors (Figure 2.1). An essential component is the existence of a functional gastrointestinal tract. Physiological factors include central and peripheral components. The central components are located in the central nervous system and function as a central integrating and ingestion controlling center (DeWys, Costa & Henkin, 1981). For example, the glucostatic hypothalamic dual center hypothesis is a central component and is composed of two centers, one referred to as the feeding center since stimulation of the area activates feeding, and the other referred to as the satiety center since stimulation of this area inhibits feeding behavior. It has been hypothesized that the source of stimulation for these centers is the blood glucose level. Peripheral factors include a system of sensors for taste and smell in the oronasal region, a system of sensors which are primarily volumetric in the upper gastrointestinal tract, and a system of sensors, for example in the liver, which are responsive to changes in metabolites and hormones in the blood (DeWys et al., 1981). Long term controls over feeding behavior include the lipostatic theory, also known as the set point theory;

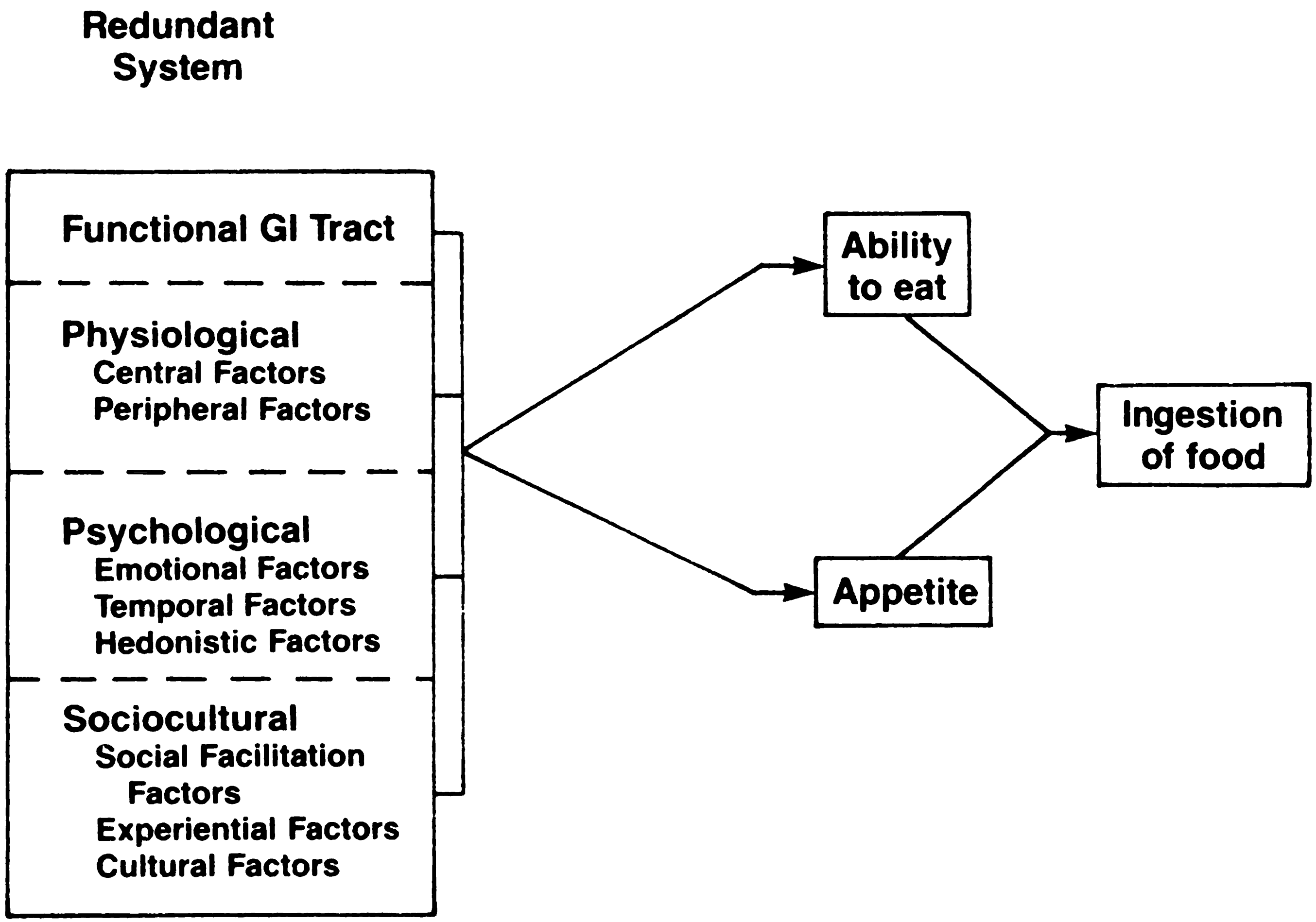

Figure 2:1. Food Intake Model

the thermostatic theory; and the animostatic hypothesis. Experimental studies have been conducted to test these physiological factors of the system for maintaining dietary intake, but specific relationships between factors are not yet known. The system appears to be a multifactor system, with no hierarchy yet described.

Psychological factors are influential in control of dietary intake as well. Emotional states, such as depression and anxiety, have been known to decrease dietary intake, while other factors such as time of day have been associated with the initiation of feeding activity. Hedonistic factors include the pleasure of a good meal enjoyed in an ambient atmosphere. Sociocultural factors are influential in determining the environment for eating, the companions with whom one eats, and the specific types of foods selected and eaten. For example, a change in the environment for eating and a change in eating companions potentially may affect the quality and quantity of foods ingested. The psychological and sociocultural factors influencing dietary intake have not been studied as extensively as the physiological factors. The extent of their potential impact on feeding behavior is not yet known nor is the influence of the combination of physiological, psychological and sociocultural factors.

In summary, the system for maintaining dietary intake appears to be one with built in redundancy, illustrating the advantages of an integrated approach to studying the phenomenon of eating disorders such as anorexia in cancer patients. This redundant system leads to ingestion of food by maintaining the ability to eat and the appetite. The result of maintaining food intake is a normal nutritional status (Figure 2.2). While the well organism eats to stay alive and functional, for humans ingestion of food is heavily intertwined with social and pleasurable events. Thus ingestion of food is not only necessary for normal human growth and development, but provides pleasure and quality of life.

Several nutritional changes which may impact on dietary intake have been demonstrated to occur during the aging process (Figure 2.3). Decreases in gastric motility, gastric acid, and intestinal absorption have been described. An increased occurrence of hiatal hernia has been identified. Oral changes include some decrease in salivary production, decreased oral motor functions, and some diminished taste acuity. These digestive and oral changes have been identified through descriptive studies. Their relationship to the occurrence of anorexia in the elderly cancer patient is unknown. Changes in psychosocial factors influencing dietary intake in the aging patient include loss of food enjoyment in the ill elderly, depression, decreased economic status, loss of usual meal companions, and difficulties in shopping for food. The identification of these psychosocial factors has occurred in a less precise way than the physical factors identified above. However, both sets of factors could be influential in the occurrence of anorexia in older

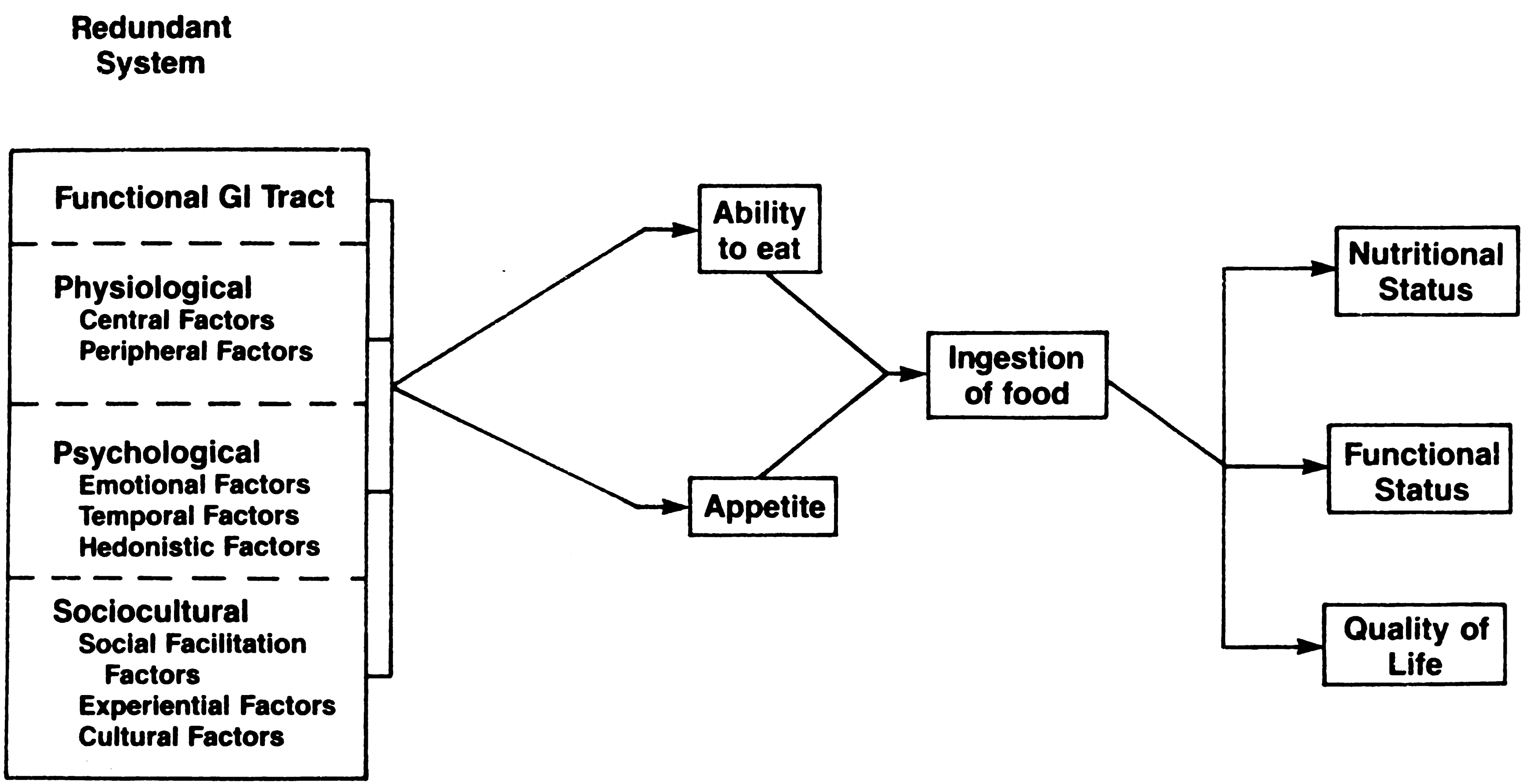

Figure 2:2. Impact of Food Intake

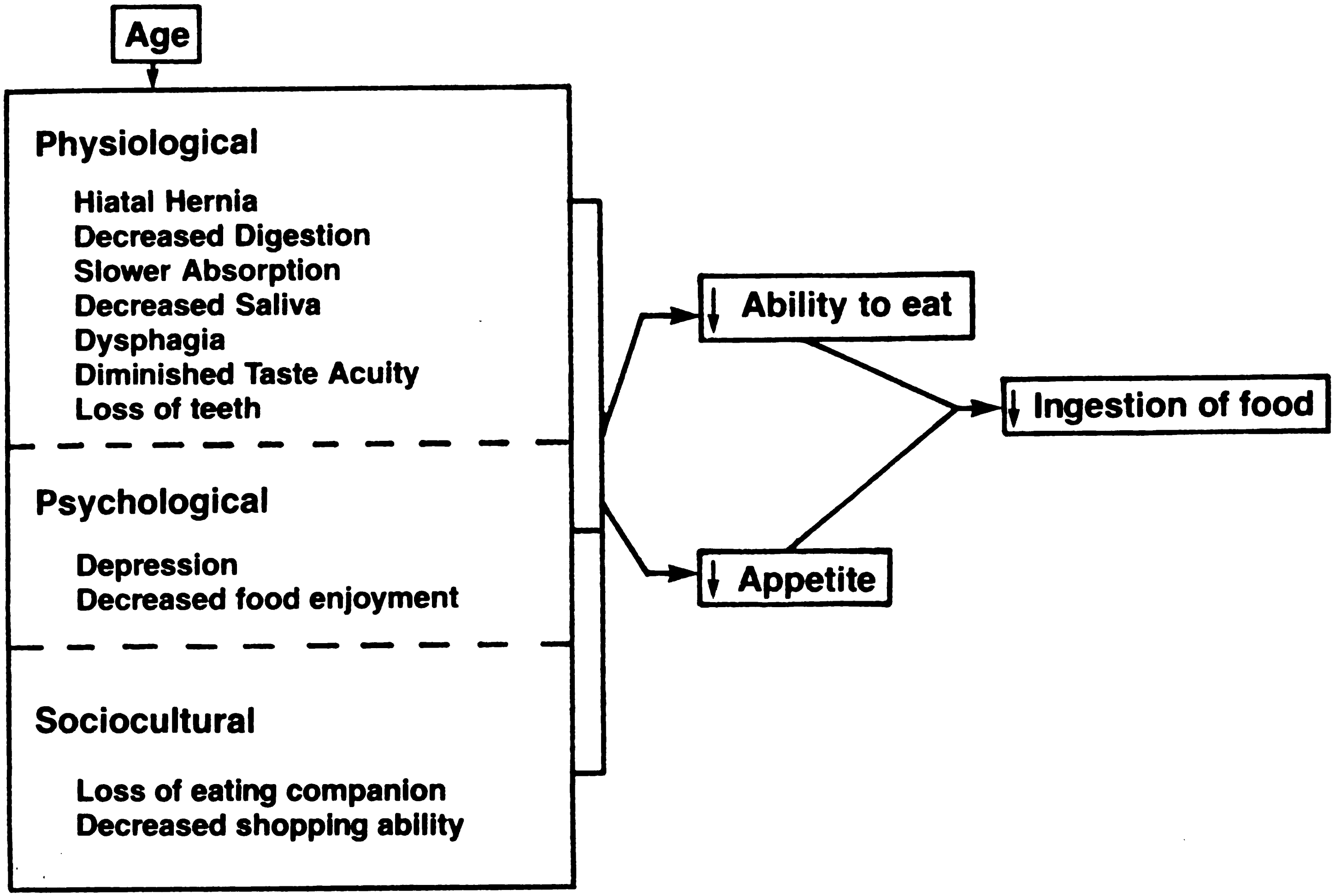

Figure 2:3. Changes in Food Intake Associated with Aging

cancer patients. The relationship between the extent of anorexia and the age of the patient has not yet been described.

Influences on the occurrence of nutritional depletion in cancer patients can be divided into factors leading to a decreased dietary intake, and factors leading to an increase in dietary need. Factors which lead to a decrease in dietary intake in cancer patients include physiological, psychological, and sociocultural problems (Figure 2.4). Studies using human subjects have focused primarily on oral-gustatory problems and nutritional impact of therapy. Reports include studies on taste and smell changes, food aversions, patterns of weight loss in specific therapies, and dietary intake differences in mixed cancer populations. Findings, however, are not consistent. Methodological difficulties, such as mixed populations of cancer patients, mixed stages of cancer, and differences in instruments used to measure appetite may have produced these inconsistencies.

Animal studies have been designed to elucidate the factors involved and have indicated that decreases in dietary intake in anorexic tumor models appear to be related to aversions that develop for specific foods ingested during periods of tumor growth. However, these findings are not consistent across different animal tumor models, and suggest that different factors may be relevant in different types of tumors. One factor examined in animal models is that of abnormal serotonin metabolism. Increases in both brain

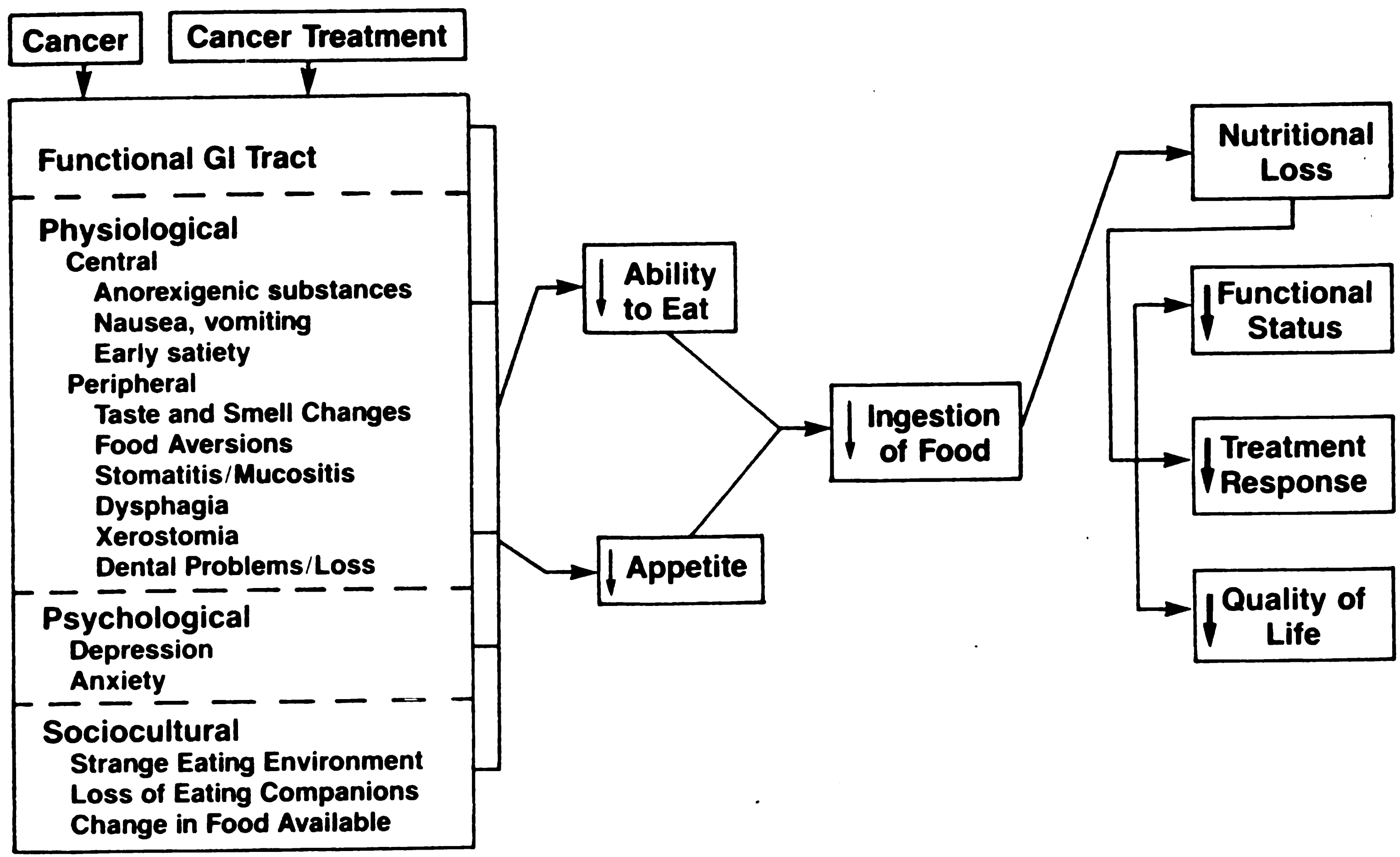

Figure 2:4. Changes in Food Intake During Cancer and Cancer Treatment

tryptophan and serotonin turnover have been demonstrated in pair-fed rat studies. Similar increases in serotonin have been associated with the occurrence of anorexia in non cancer patients, and may be associated with anorexia in cancer patients as well. The derivation of the tryptophan which apparently leads to the greater serotonin turnover has not been identified. It is possible that it may be secreted by tumor tissue, but that fact has not yet been demonstrated.

Other animal studies suggest that the normal response to caloric dilution (i.e. increased dietary intake), is lacking. Still another factor which may be involved is the decrease in motor activity which accompanies a depleted nutritional state. This asthenia has been demonstrated in some anorexia animal tumor systems, but not in others. Nutritional depletion may occur because the asthenic animal is too weak to maintain needed feeding behavior.

In summary, the animal studies reveal a number of factors that appear to be related to the development of anorexia in a cancer system: diet aversions, increased brain serotonin, inability to adjust to caloric dilution, and decreased motor activity. None of these factors appear to be universal across tumor systems. Anorexia appears to be a multidimensional phenomenon. Using the framework of a multifactor redundant system for the maintenance of dietary intake, one can hypothesize that as more factors stimulating dietary intake are deleted, compensation fails, and the downward spiral of nutritional depletion occurs.

Decreases in dietary intake are also related to the inability of the patient to ingest and move material through the digestive tract because of the obstruction by tumor tissue, damage to the gastrointestinal tract via treatment side effects, and nutritional depletion. The changes in the digestive system that occur compromise the ability of the body to eat, digest and assimilate food.

Psychosocial factors have been associated with anorexia of a transitory nature. Periods of anorexia may occur during the initial diagnosis, during recurrence of the disease, and during periods of pain and gastrointestinal symptoms such as nausea and vomiting. Schmale (1979) proposed that a profound withdrawal state occurs in some cancer patients who are extremely depressed. This state is accompanied by a radical decrease in dietary intake, and resulting weight loss. Few studies have been done that identify the impact of psychological factors on the occurrence of anorexia.

Social factors found in cancer patients include cultural food changes during hospitalization, loss of usual eating companions, and loss of ability to eat usual foods (for example, if the normal diet includes spicy, highly seasoned foods, and the patient is undergoing treatment which leads to a sore, inflamed mouth, these foods are no longer tolerated). A number of general symptoms occur in cancer patients that influence the occurrence of anorexia. Nausea, vomiting, and diarrhea are not uncommon symptoms during cancer treatment, and during growth of gastrointestinal tumors. These general symptoms depress the normal appetite sensations leading to anorexia. Fatigue is another symptom commonly found in cancer patients. Fatigue may lead to anorexia when a patient has insufficient strength to eat, or becomes too fatigued after a few bites to continue eating.

Increases in dietary need have been related to the occurrence of nutritional depletion in cancer patients also. Alterations in energy expenditure have been demonstrated, and include both hypometabolic states and hypermetabolic states. Relationships of these states to the kind and extent of tumor present have not revealed any predictable patterns. Changes in carbohydrate, fat and protein metabolism have been demonstrated and include increased gluconeogenesis, increased lactate production, insulin resistance, and possible increased tumor utilization of protein. That these derangements have not been consistently demonstrated may be related to a lack of sensitive instruments or other measurement problems. Findings on changes in energy expenditure and metabolism do not account for the extent of nutritional depletion that have been observed in some cancer patients. In summary it appears that combinations of decreased intake and increased need are likely to be occurring in the cancer patients experiencing nutritional depletion.

The consequences of decreased food ingestion in cancer patients if prolonged, include weight loss, cachexia, decreased treatment response, and decreased quality of life

(Figure 2.4). The extent to which decreased food ingestion contributes to cancer mortality is not clear. However, nutritional depletion certainly plays a major role in death from cancer. Weight loss has been demonstrated to be of some prognostic value in patients undergoing chemotherapy, with survival significantly shorter in patients experiencing weight loss, as opposed to those who had not experienced significant weight loss. For patients undergoing radiation therapy, nutritional problems are common before the onset of therapy, during therapy, and immediately following therapy. While study results and anecdotal reports indicate that nutritional support given to radiation therapy patients is helpful in decreasing nutritional problems it has not been demonstrated that nutritional support is beneficial in increasing response to radiation therapy, tolerance to therapy, or survival rates.

The concept of anorexia is defined as a decrease in appetite associated with a spontaneous decrease in dietary intake (Figure 2.5). This definition has been used in both animal and human research on anorexia. Anorexia is a concept relevant to nursing, since helping patients eat enough of the right kinds of foods is a clinical challenge nurses encounter frequently. Measurement of anorexia has been carried out in two ways. In animal studies, analysis of dietary intake in relation to calories, protein, carbohydrate, and fat is used to identify when anorexia begins and what factors influence its occurrence. Subjective measurement of appetite in

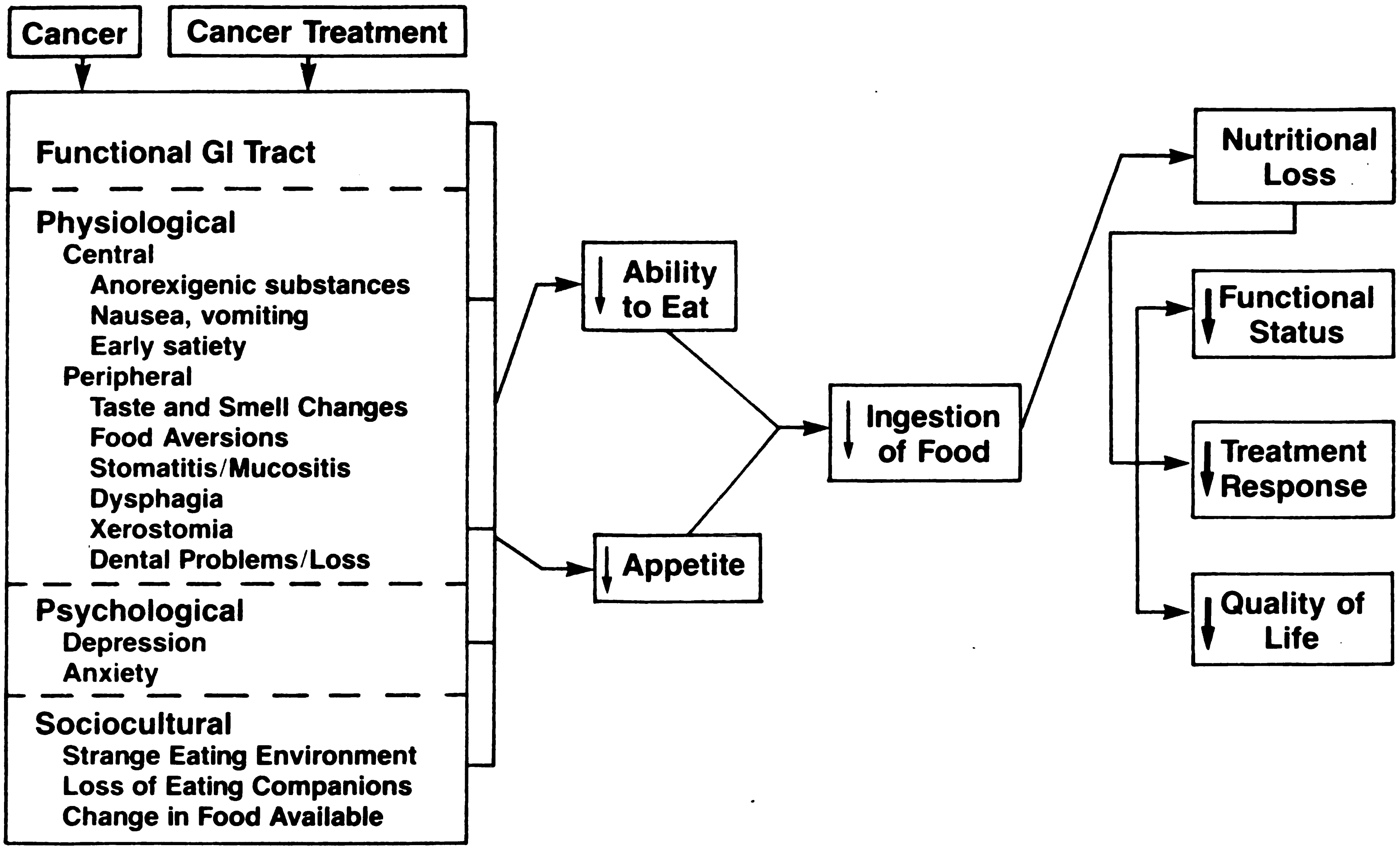

Figure 2:4. Changes in Food Intake During Cancer and Cancer Treatment

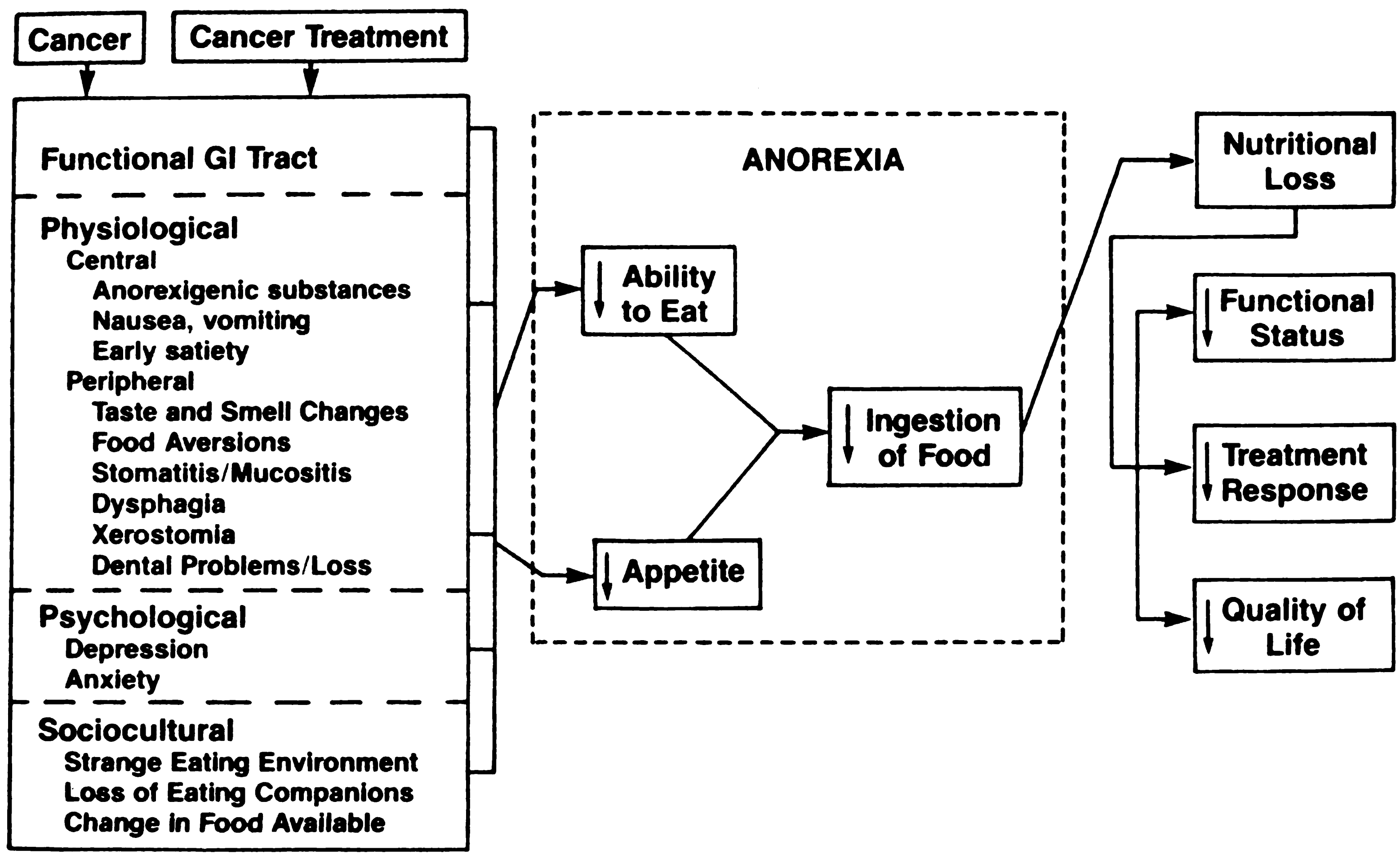

Figure 2:5. Anorexia During Cancer and Cancer Treatment

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animals is not possible. In human studies, both the objective dietary intake measurements and subjective measurements of appetite are possible. Dietary intake has been measured by dietary recall. The amount of calories and specific nutrients of dietary intake is computed by using standardized tables of the nutrient composition of foods. Computerized packages for such nutrient analysis are available to assist with this aspect of dietary intake. Subject measurement of anorexia, via appetite estimates is less precise. Some attempts to scale appetite have been made using semi-structured interview and linear analogue scale approaches. While these appear to be useful approaches, information on reliability and validity of these instruments is not available. Initial studies of anorexia in cancer patients and cancer animal models have been conducted, and have begun to explain some aspects of the phenomena involved. However, measurement of anorexia, in both its subjective and objective parameters remains a challenge.

Examination of the studies of anorexia in patients with head and neck cancer reveals a beginning description of the patterns that occur in this population. While problems with instrumentation are apparent in all of the studies, findings reveal that weight loss occurs either before or during radiation therapy and may involve from 32 to 68% of the patients. Reported weight loss across studies ranges from two pounds to fifteen pounds during the 6-8 week period of therapy. Dietary intake recordings are very limited in the studies reviewed. Taste changes and difficulty swallowing are common. The effects of nutritional counseling have been examined in two studies, but the counseling content was not reported specifically and the level of knowledge gained by the subjects was not identified (Daly et al., 1984; Hamill, 1978). A comparison of enteral tube feeding and oral feeding with nutritional counseling revealed that enteral tube feeding appeared to decrease undesired nutritional consequences, as seen in higher mean caloric intake, higher mean protein intake, and lower mean body weight loss (Daly et al., 1984). Tumor response and survival patterns did not vary across groups. In summary, a few studies have begun to describe anorexia in head and neck cancer patients. Appetite changes and oral gustatory changes, such as taste changes, have been described. Dietary intake information is available on only a few patients. Studies which report that dietary counseling has been carried out appear to have positive results, in terms of decreased weight loss. However, the lack of specification of the dietary counseling and the lack of validation of what the patient learns or does in terms of dietary intake makes interpretation of results most difficult.

Overriding questions that remain are 1) what happens to dietary intake during and following radiation therapy? 2) what happens to the subjective perception of appetite during and following radiation therapy? 3) what is the relationship between subjective perception of appetite and the objective measurement of dietary intake? 4) what impact does nutritional counseling have on both appetite and dietary intake during radiation therapy? 5) to what extent are psychosocial factors that have impact on food intake present in the head and neck cancer population undergoing radiation therapy? 6) how does the occurrence of anorexia in head and neck cancer patients undergoing radiation therapy relate to changes in nutritional status, functional status, treatment response, and quality of life? 7) are there differences in responses to nutritional counseling of elderly versus younger head and neck cancer patients? 8) is response to nutritional counseling related to the construct of locus of control?

Radiation therapy is a common and important therapy for cancer patients, especially the older cancer patient. However, it can be accompanied by severe side effects, not the least of which is anorexia and nutritional depletion. The need for and value of nutritional counseling in interrupting anorexia and nutritional depletion has not been adequately tested.

When a nurse cares for a cancer patient in the clinical setting, a primary responsibility is patient assessment, with a major part of that assessment focusing on potential nutrition problems. To identify the occurrence and extent of anorexia, the nurse notes the amount and kind of foods eaten. If the quality and quantity of dietary intake is decreased sufficiently, the problem of anorexia is present. Interventions generally planned include helping patients eat, encouraging intake of nourishing foods, managing symptoms which disrupt the ability to eat, and counseling the patient on needed dietary intake (Grant, 1985; Grant, 1986B; Kelly, 1986). A major gap in the research on anorexia in cancer patients is a lack of information on the effects of these interventions on the occurrence and persistence of anorexia. For the cancer patient suffering from potential interferences to normal feeding behavior, an intervention to be tested is a dietary counseling approach that focuses on maintaining normal feeding behavior, despite potential interferences. This program would include 1) persuading the patient to eat despite loss of appetite, 2) decreasing oral gustatory symptoms that potentially interfere with the ability to eat, 3) decreasing general symptoms such as nausea, vomiting, and fatigue, 4) promoting psychological well-being, and 5) promoting social factors which enhance intake (Figure 2.6). The effects of this intervention could be tested on the degree of anorexia, the patient's nutritional status before, during, and after a period of cancer treatment, functional status, treatment response, and quality of life. Other factors potentially influencing whether or not the intervention is effective include the patient's age, knowledge of the teaching program, locus of control, and the extent to which factors interfering with normal dietary intake are present.

This conceptual framework forms the foundation for the primary research questions posed: 1) Is a structured

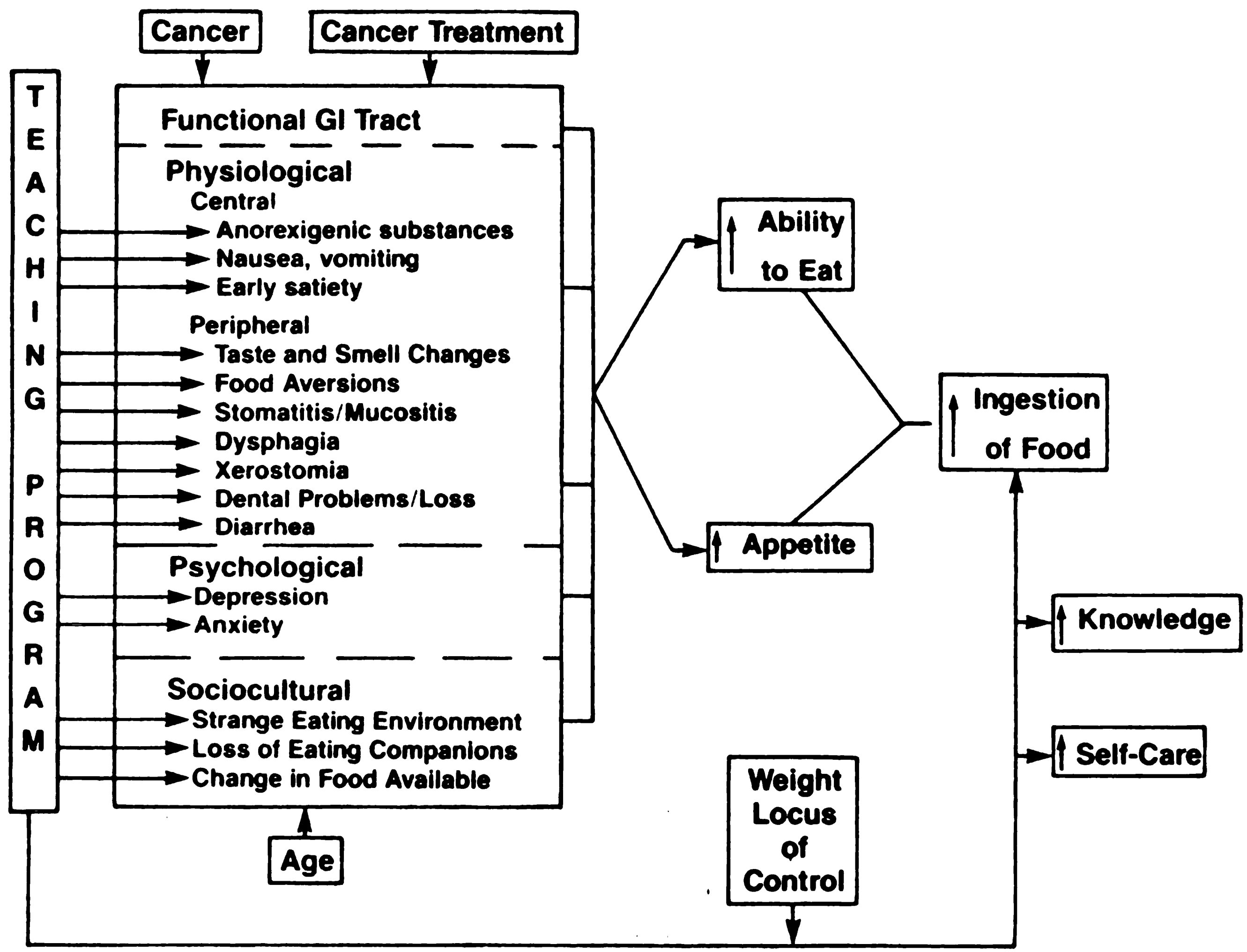


Figure 2:6. Teaching Program for Patients with Head and Neck Cancer Undergoing Radiation Therapy

nutrition teaching approach based on supporting the redundant system for maintaining feeding behavior effective in decreasing anorexia in cancer patients undergoing head and neck radiation therapy and 2) what are the effects of this approach on nutritional status, functional status, treatment response, and quality of life in patients undergoing radiation therapy for head and neck cancer.

Theoretical Conclusions and Hypotheses

The findings of the studies reviewed here lead to a number of theoretical conclusions that form the basis for the research questions. These conclusions are that:

1) Dietary intake is maintained by a redundant system influenced by biopsychosocial factors.

2) Prolonged alteration in factors that maintain dietary intake can lead to failure of the system to compensate, resulting in a decreased dietary intake.

3) Aging is associated with alterations in the factors that maintain dietary intake.

4) Cancer patients suffer from a number of biopsychosocial problems that can interfere with normal dietary intake.

5) Anorexia in cancer patients is a decrease in appetite associated with a spontaneous decrease in dietary intake.

6) Prolonged anorexia in cancer patients undergoing cancer treatment may lead to nutritional depletion, decreased

functional status, decreased treatment response, and decreased quality of life.

7) Responses to an educational approach to maintaining dietary intake may be related to locus of control.

These conclusions form the foundation for the research questions posed: 1) Is a structured nutrition teaching approach based on supporting the redundant system for maintaining food intake effective in decreasing anorexia in cancer patients undergoing head and neck radiation therapy and 2) what are the effects of this approach on nutritional status, treatment response, functional ability, and quality of life in cancer patients undergoing radiation therapy for head and neck cancer.

The specific hypotheses of this study are as follows (Figure 7):

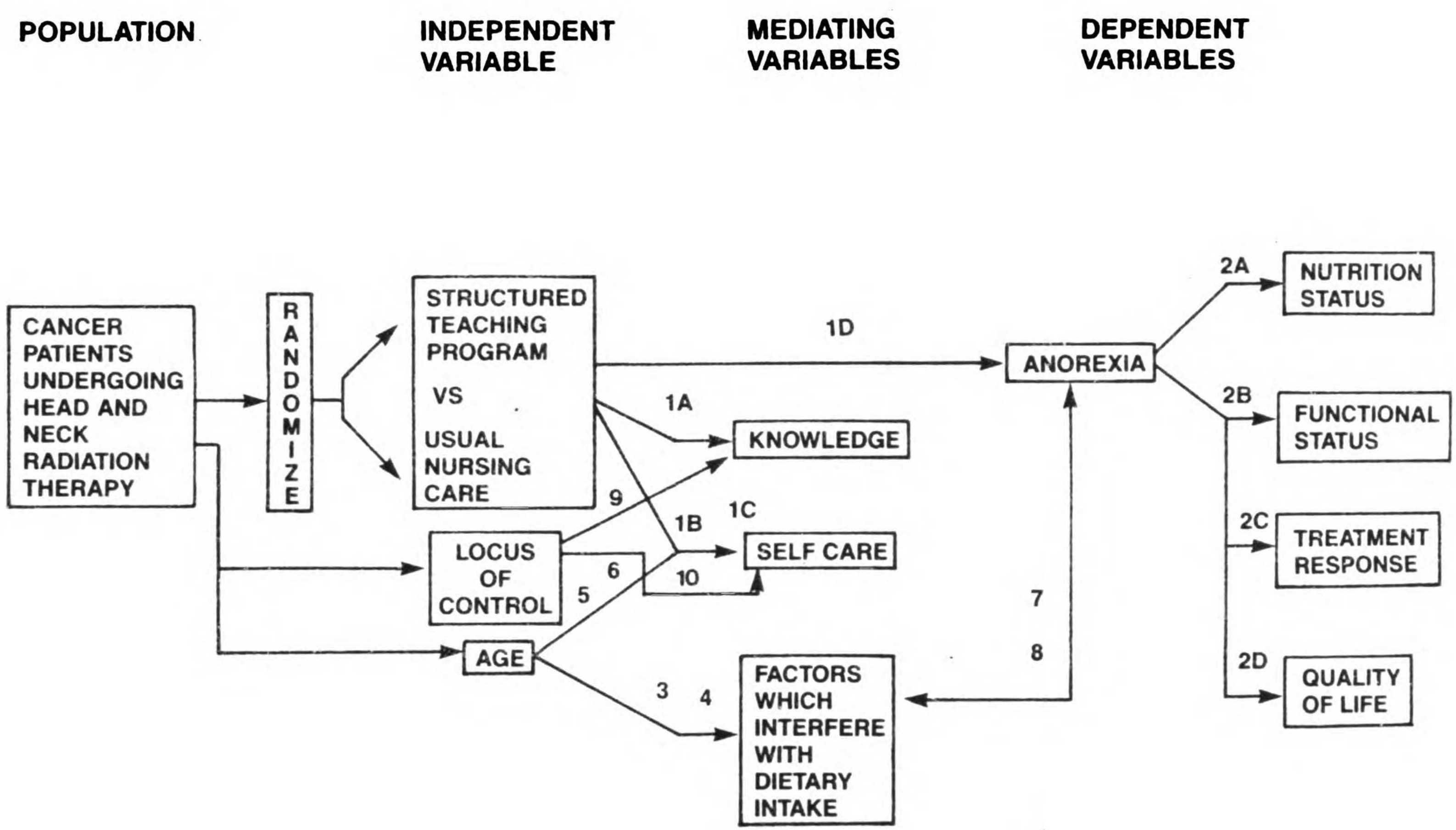
1) Patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will:

a) have greater knowledge on how to maintain dietary intake than patients who receive the usual nursing care.

b) demonstrate increased self care activity aimed at maintaining dietary intake than patients who receive the usual nursing care.

c) demonstrate better overall management of side effects than patients who receive the usual nursing care.

d) experience less anorexia than patients who receive the usual nursing care.



Numbers refer to the number of the related hypothesis.

Figure 2:7. Study Variables and Hypotheses

2) Patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will:

a) demonstrate less nutritional depletion than patients who receive the usual nursing care.

b) demonstrate less decrease in functional status than patients who receive the usual nursing care.

c) demonstrate greater treatment response than patients who receive the usual nursing care.

d) experience less decrease in quality of life than patients who receive the usual nursing care.

3) Older head and neck cancer patients undergoing radiation therapy have a greater number of factors interfering with normal dietary intake than younger head and neck cancer patients undergoing radiation therapy.

4) Older head and neck cancer patients undergoing radiation therapy experience factors interfering with food intake and appetite to a greater extent than younger head and neck cancer patients undergoing radiation therapy.

5) Younger head and neck cancer patients undergoing radiation therapy report more self care activity aimed at alleviating side effects than older head and neck cancer patients undergoing radiation therapy.

6) Younger head and neck cancer patients undergoing radiation therapy report better overall management of side effects than older head and neck cancer patients undergoing radiation therapy.

7) There is a relationship between the number of factors interfering with normal dietary intake and anorexia.

8) There is a relationship between the extent of factors interfering with normal dietary intake and anorexia.

9) There is a relationship between the expectancies for control over weight and knowledge on how to maintain dietary intake in head and neck cancer patients undergoing radiation therapy.

10) There is a relationship between the expectancies for control over weight and self care aimed at maintaining dietary intake in head and neck cancer patients undergoing radiation therapy.

CHAPTER 3

METHODS

Purpose

The purpose of this study was to determine the effects of a structured program for maintaining dietary intake in a group of cancer patients undergoing head and neck radiation therapy on anorexia, nutritional status, functional status, treatment response, and quality of life as compared to a control group receiving the standard nursing care during radiation therapy. Two additional variables, age and locus of control, were identified and tested as independent variables because of their potential effect on responses to a structured teaching approach on self care during radiation therapy. Variables expected to mediate these effects were the knowledge of nutrition, the number and extent of factors which can interfere with dietary intake, and self care aimed at maintaining dietary intake. (Figure 3:1).

Definitions

1) Structured teaching program for cancer patients undergoing head and neck radiation therapy was an audiovisual program aimed at maintaining dietary intake and based on the redundant food intake model of biopsychosocial factors.

2) Knowledge of nutrition included patients' knowledge of nutritional needs (calories and protein) and knowledge of ways to maintain dietary intake to meet these nutritional needs.

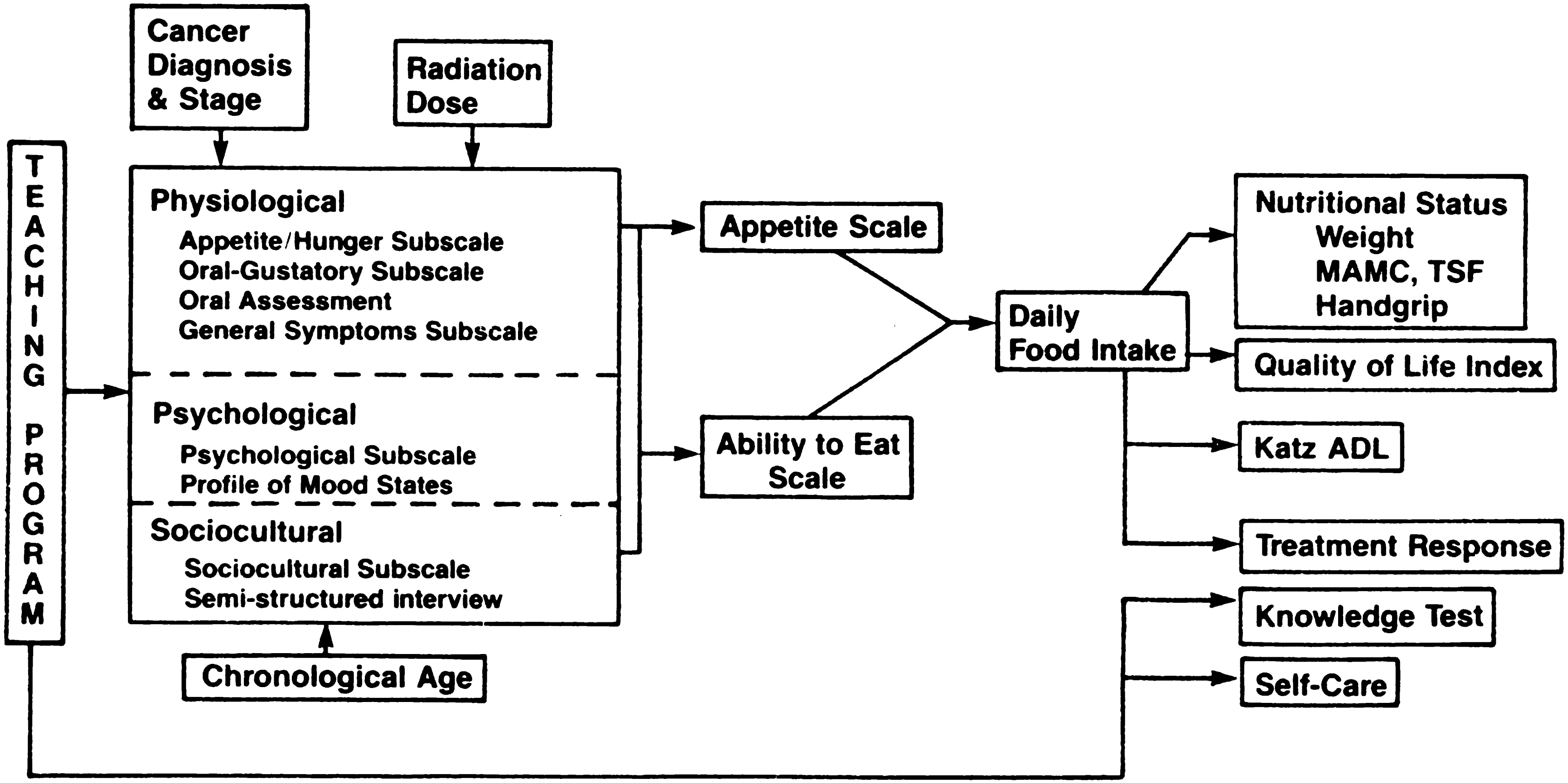


Figure 3:1. Measuring the Effects of the Teaching Program

3) Self Care referred to the self care patients use to manage factors which interfere with dietary intake.

4) Factors which interfere with patients' dietary intake included appetite-hunger problems, oral-gustatory problems, general symptoms, psychological problems, and sociocultural problems as related to dietary intake.

5) Anorexia was defined as a patient's decrease in appetite associated with a spontaneous decrease in dietary intake. It includes both the subjective dimension of appetite and the objective dimension of dietary intake.

6) Nutritional status of patients referred to the degree of malnutrition present.

7) Treatment response of patients referred to the response of the tumor to the treatment prescribed. In this study it referred to the response of the head and neck tumor to radiation therapy.

8) Quality of life of patients was a multidimensional construct composed of physical well-being, psychological well-being, symptom control, and general quality of life.

9) Functional status of patients referred to the ability to carry out daily activities.

10) Age of patients was defined as chronological age.

11) Perception of control of patients was defined as Locus of Control with respect to weight.

Design

A quasi-experimental pre-test/post-test design was used with consenting subjects randomized to either a structured program on maintaining dietary intake or the standard approach to nutritional care. Measurements of the effects of the program on anorexia, nutritional status, functional status, treatment response, and quality of life, were made at the beginning of radiation therapy, at various times during therapy (6-8 weeks), and at the post therapy follow-up visit (Table 3:1).

Sample

Criteria for inclusion in the study were: 1) no previous radiation therapy; 2) ability to speak and read English; 3) no concurrent metabolic conditions such as chronic renal failure, diabetes, or short bowel syndrome; and 4) functional gastrointestinal tract.

Sample size was determined on the basis of changes in weight reported in two previous studies, Hamill (1978) and Donaldson (1977). The average weight loss in the Hamill study was 4 pounds, and for the Donaldson study, 8 pounds. Sample size for alpha=.05 and beta=.8 was calculated for a 6 pound weight estimate, identifying a need for at least 27 subjects in each group. Thus a sample of 54 subjects, with 27 per group was planned.

Table 3:1

Study Design

Quasi Experimental Pre-Test Post-Test Design
Independent Variable
Structured Teaching Program
Versus Usual Nursing Care
Age
Weight Locus of Control
Mediating Variables
Knowledge of Nutrition
Self Care
Factors which Interfere with Dietary Intake
Dependent Variables
Anorexia
Nutrition Status
Functional Status
Treatment Response
Quality of Life

Subject accrual began in November of 1985 at one institution with three more institutions added in January, 1986. Because of low number of potential subjects, another facility was added in June of 1986. By November of 1986, 75 potential subjects had been processed, and accrual of new subjects stopped. Of these 75 potential subjects, 59 were approached to participate in the study. The other 16 were ineligible for a number of reasons (Table 3.2). Of the eligible 59, 15 patients refused for a variety of reasons (Table 3.3). The remaining 44 subjects were randomized to the study, and three of these dropped, one because the participation was too time consuming and the other two because they became too ill to continue. Thus, a convenience sample of 41 consenting adults, 18 years and older, and who were treated with radiation therapy for head and neck cancer participated in the study.

Subjects were randomly assigned to one of two groups. The experimental group received the structured teaching program and the control group was treated in the usual manner.

Table 3.2

Reasons for Ineligibility

Reason	Number
Prior radiation therapy	6
Too ill to approach	4
Non English speaking	3
Under 18 years of age	2
Approached too late into treatment	1
Total	16

Table 3.3

Reasons for Refusal to Participate

Reason	Number
No extra time	3
Too tired or too ill	3
Too anxious	2
Just did not want to	2
Transportation problems	1
Cultural food differences	1
Unknown	1
Total	15

Independent Variables

Two manipulations of the primary independent variable occurred. Group A received a structured audio-visual teaching program on nutrition for head and neck cancer patients. This program included 1) individualized information on the amount of calories and protein needed per day, 2) information on what kinds of foods are commonly used to increase caloric and protein intake, 3) information on the common interferences with dietary intake, and general approaches that can be used to manage these interferences given via an audio-visual program and a written hand out, and 4) weekly analysis of dietary intake, showing the number of calories and amount of protein ingested. The content of this program is found in Appendix E. Group B received the standard approach to nutrition care, which consisted primarily of information about nutrition given in response to the occurrence of a major problem such as the patient's inability to swallow or a loss of several pounds in one week. Group B did not view the audio-visual tape, receive the typed handout, or have dietary intake analyzed.

Two additional variables were used as independent variables in the analysis. Age was defined as chronological age. Locus of control was defined as a score on the weight locus of control scale (WLOC) (Saltzer, 1982, Saltzer and Golden, 1985). This scale was administered once at the beginning of therapy. The scale consists of four items, two internally worded items and two externally worded items. The scale has been used in several studies and has a test-retest reliability of 0.67 when used in a population of normal volunteers, and a Cronbach's alpha of 0.67 (Saltzer, 1982). Validation studies have illustrated the value of the WLOC in predicting behaviors in relation to weight locus of control and weight loss (Saltzer, 1982). The original scale was scored in a 6-point a Likert format and summed across the four items, with the internally worded items reversed scored. A possible range of scores was 4 - 24, with 4 being extremely internally oriented and 24 being extremely externally oriented. The format was changed to a series of four 100 mm linear analogue scales in the present study in keeping with the format of the other rating scales patients were asked to complete. Scoring of the linear format included reverse scoring of the internally oriented items and conversion of the final score to a 100 point scale by dividing by four. Thus, in the present study zero represents the most extremely internally oriented score and 100 represents the most extremely externally oriented score.

Mediating Variables

Several mediating variables were measured in order to provide information on the relationship between what was learned and the outcomes predicted.

Knowledge of Nutritional Needs and Ways to Maintain Nutrition was a check on the content of the independent variable manipulation, structured teaching program, and was operationalized as a paper and pencil knowledge test

(Appendix F). Content for this test was derived from the content of the structured teaching program. This test was given to both the experimental and control groups at the end of the first week of therapy and at the end of therapy. The test items were derived from the content of the audio-visual program and pilot tested in five patients prior to study implementation. Items were revised based on patients' recommendations. A total score of 51 was possible.

Self-Care of Problems Interfering with Dietary Intake was a check on the independent variable manipulation, structured teaching program, and was operationalized as self care ratios derived from Dodd's Self Care Behaviors Log (Appendix G). The log was filled out and summarized weekly. Four ratios were calculated for each week: 1) selected self-care activity defined as selected self-care behaviors divided by the total number of experienced side effects, 2) total self-care activity defined as the total number of self-care behaviors divided by the total number of experienced side effects, 3) self-care behavior efficacy defined as the total effectiveness of each self-care behavior divided by the total number of self-care behaviors, and 4) overall management of side effects, defined as the total "final" effectiveness rating of self-care behaviors for each side effect divided by the total number of experienced side effects. The self care tool has been used in a number of studies of patterns of self care in cancer patients (Dodd, 1982A; Dodd, 1982B; Dodd, 1983; Dodd, 1984; Dodd 1987).

Content validity of the self care tool was established though expert panels. Correlations of r=0.88 and r=0.97 were obtained respectively between performance scores and the average number of self care behaviors for pre and post intervention interviews (Dodd, 1982A; Dodd, 1983).

Factors Interfering with Dietary Intake was defined as those problems that occur in cancer patients that potentially influence appetite and dietary intake. They were operationalized as the 5 subscales of an anorexia tool (Appendix H, items 4-25). The tool was administered weekly during therapy and at the follow up visit. Each item in the subscales was a 100 mm linear analogue scale anchored at each end by extremes. Items on each of the subscales were as follows. The appetite-hunger sensations subscale was composed of 4 items: an interest in eating; hunger pains; feeling the desire to eat; and feeling hungry. The oral-gustatory subscale was composed of 6 items: taste changes; pain in the mouth; sore tongue; dry, cracked lips; difficulty swallowing solids; and dry mouth. The general symptoms subscale was composed of 4 items: nausea any time; nausea after eating; vomiting; and early satiety. The psychological subscale was composed of 4 items: feeling sad; feeling depressed; feeling tense or anxious; and feeling tired. The social factors subscale was composed of 4 items: eating alone; embarrassed to eat with others; difficulty preparing food; and changes in the time for eating. The reliability of each subscale was established with a pilot study of 51 cancer patients tested once either before, during or after radiation therapy for head and neck cancer (Grant, 1986A). The alpha reliability coefficient for each subscale was appetite-hunger= 0.84, oral-gustatory= 0.84, general symptoms=0.77, psychological factors=0.92, and social factors=0.65.

The validity of the scale was established in several ways. Content validity was established via a panel of experts composed of 7 registered nurses who work clinically with head and neck cancer patients, 3 dietitians who also work with head and neck cancer patients, 1 doctorally prepared researcher who, among other responsibilities, has a taste and smell clinic, and 1 physician who specializes in radiation therapy for patients with head and neck cancer. Concurrent validity of some of the subscales was conducted in the present study in several ways. Concurrent validity of the oral-gustatory subscale was done through comparisons with a weekly oral assessment carried out by a nurse (Appendix I). The instrument used for oral assessment had a reliability coefficient of 0.82, and was developed during a study of thirty-one bone marrow transplant patients (Grant, Sutliff, & Sortman, 1985). With that population the instrument was sensitive to the oral changes expected during the first few weeks following preparation for transplant, discriminating between chemotherapy routines and methods of radiation administration. The instrument was easy to use and score. The concurrent validity of the psychological subscale was carried out by having subjects fill out the Profile Moods

States (McNair, Lorr, & Droppleman, 1971) at the beginning and end of therapy (Appendix J). The tool measures tension-anxiety, anger-hostility, depression-dejection, vigor, fatigue, and confusion-bewilderment. Internal consistency reliabilities on the subscales range from .87 to .95 (McNair, Lorr, & Droppleman, 1971). It is simple to administer and score. The tension-anxiety and depression-dejection subscales were used to identify concurrent validity of the psychological subscale of the anorexia instrument.

The concurrent validity of the social factors subscale was carried out during a semi-structured interview conducted at the beginning and the end of therapy and designed to answer a number of question related to sociocultural aspects of eating and eating behavior (Appendix K).

<u>Age</u> was defined as chronological age. It was used to determine whether or not an even distribution of ages occurred in each group following randomization. Analysis of variance revealed no significant difference between the experimental and control groups ($p \leq 0.05$). Thus it was not necessary to use age as a covariate for analysis.

<u>Locus of Control</u> was defined as the score on the weight locus of control scale (WLOC). On a scale of 0 to 100, 0 represented the most extremely internally oriented score and 100 represented the most extremely externally oriented score. Analysis of variance revealed no significant differences between the experimental and control groups mean scores on the WLOC ($p \leq 0.05$).

Dependent Variables

Anorexia was defined as a decrease in appetite associated with a spontaneous decrease in dietary intake. It was operationalized in two ways. The subjective aspect of anorexia was defined as two 100 mm linear analogue scales measuring appetite and ability to eat. (Appendix H). The scales were administered at the onset of therapy, weekly throughout therapy, and at the follow up appointment.

The objective aspect of anorexia was defined as daily dietary intake. This was operationalized as the amount of calories and protein ingested daily derived from a mean daily score of a 3-day dietary intake filled out by the patient and verified by the investigator (Appendix L). Verification involved having the investigator or data collector go over items on the dietary intake sheets with the patients to make sure all intake was reported, e.g. butter added to food, between meal snacks, etc. A computer program, The Food Processor, was used to convert amounts and types of food ingested into caloric and protein equivalent (Geltz & Geltz, 1984). Dietary intake was calculated once each week during therapy and at the follow up appointment post therapy. Caloric and protein intake was compared for each subject with that amount individually recommended. These recommendations were calculated using the formula recommended by Daly (1984): 40 kcal/kg per day and 1 to 1.5 g of protein per kilogram per day. Using the basal energy expenditure formula plus a factor of 1.5 for the additional energy needed during radiation therapy, daily kcal need was calculated (Harris & Benedict, 1919).

Nutritional status was defined by several factors: history of weight loss, weight loss during radiation therapy, triceps skinfold changes during radiation therapy, mid arm muscle circumference changes during radiation therapy, and hand strength changes during radiation therapy (Appendix M).

History of weight loss was used to identify those patients vulnerable to nutritional problems during radiation therapy. The formula used was derived from Blackburn, Bistrian, Maini, & Schlamm (1977) and is as follows:

$$\frac{\text{Usual weight} - \text{actual weight}}{\text{usual weight}} \times 100$$

The significance in terms of severity was scaled with the following chart derived from Blackburn et al. (1977).

Time	Significant Weight Lost	Severe Weight Loss
1 week	1-2%	more than 2%
1 month	5%	more than 5%
3 months	7.5%	more than 7.5%
6 months	10%	more than 10%

Patients were identified as having a history of no weight loss, significant weight loss, or severe weight loss at the onset of radiation therapy. Reliability of patient recall of weight loss has been reported by Morgan, Path, Hill and Burkinshaw (1980), and indicated that a 3.6 kg error can occur. Validity of history of weight loss as a measure of nutritional status is based on reports of the prognostic value of weight loss in relation to increasing susceptibility to infection (Donaldson and Lenon, 1979), and on incidence of complications due to therapy (Johnston et al., 1982). Usefulness of history of weight loss is high since it is a measurement most people have made on themselves, and they can estimate how much they have lost within the recent past.

During radiation therapy, weight was evaluated in two ways. Weight for height was evaluated with frame size using Metropolitan Life Insurance charts (Build and Blood Pressure Study, 1959). Weight and height were actually measured, as well as wrist circumference. Weight was evaluated as follows:

Above or within IBW - adequate
5% below IBW - mild depletion
$>$ 5% below IBW - severe depletion

In addition, the actual number of pounds lost during radiation therapy was recorded weekly, and at the post follow up visit. In order to maintain maximum reliability for weekly weight evaluations several factors were controlled. The scale was the same, the time of day weight was measured was approximately the same, and the amount of clothing the patient had on was similar. For example, a patient was weighed with no coat and no shoes each time in order to have some standardization of clothing.

Validity of ideal body weight as a basis for evaluating nutritional status is frought with difficulty. Knapp (1983) identified multiple problems in the Metropolitan Tables (Build and Blood Pressure, 1959) the Framington Massachusetts Study results (Sorlie, Gordon, Kannel, 1980), and the American Cancer Society study (Lew & Garfinkel, 1979). Mortality rates were identified from potentially invalid criteria as is seen in the use of number of deaths by number of insurance policies in the Metropolitan Tables. The quality of data suffered as well; for example in the American Cancer Society study subjects were not actually weighed but reported their own weight. In the Hanes survey (Weight by Height and Age of Adults 18-74 Years, 1979) subjects wore the same clothing (foam rubber slippers and a disposable paper examination uniform), but the population included has been criticized because it was heavily weighted with minorities (Murray, 1981). Thus, data were initially compared using the Metropolitan tables but other norms were considered as well. Data collection included parameters necessary for use of any of the standardized charts available (weight, height, frame, age).

Two other anthropometric measurements were used. Triceps skinfold (TSF) is a measurement of fat reserve.

Measurements are made using skin calipers on the upper arm and compared to a normal value table (Frisancho, 1974). Lange calipers were used to pick up a lengthwise skinfold in the upper middle area. Measurements were made at the beginning and end of therapy and at the follow up visit. Scoring was compared using the following:

>10th percentile	-	adequate
> 5th and ≤10th percentile	-	mild depletion
≤ 5th percentile	-	severe depletion

Midarm muscle circumference was used to estimate somatic protein stores. The mid upper arm circumference was measured at a point half way between the acromion process of the scapula and the olecranon process at the elbow. Measurements were obtained at the beginning and end of therapy and at the follow up visit. Mid arm muscle circumference was calculated as follows: MAMC = MAC (mm) - (.314 x TSF (mm)). Results obtained were compared to standardized charts. Scoring reflected the following scale:

>10th percentile	-	adequate
> 5th and ≤10th percentile	-	mild depletion
≤ 5th percentile	-	severe depletion

Reliability of these measurements has been improved by use of a standardized caliper for skin folds that produces equal pressure, by unstretchable tape measures, and by taking three measurements and using the mean of the three numbers obtained. Validity of the norms against which the obtained results are compared has been debated by many investigators. If the observer is not familiar with the patient's prediseased state, the distribution of fat and muscle compared to the normal for that individual is very difficult. Also, the patient's hydration status can interfere with obtaining accurate measurements (Murray, 1980). Since the triceps skinfold measurements change slowly, they are practical only for changes in nutritional status that occur over a period of time (Blackburn & Harvey, 1981). Mid arm muscle circumference changes slowly as well, and is only appropriate for long term changes. Whether or not the study period of 6 weeks plus one month post therapy was long enough to reflect changes in triceps skinfolds and mid arm muscle circumference is subject to debate.

Hard grip strength was used as another measure of muscle function. Hard grip has been proposed as a dynamic indicator of strength and was found useful in predicting surgical complications (Klidjian, Archer, Foster, and Karran, 1982). Measurements were taken at the beginning and end of therapy and at the follow up visit. Scoring reflected the following scale:

>95th percentile - adequate

86-95th percentile - mildly depleted

<86th percentile - severely depleted

Reliability of the hand grip measurements is improved by taking three measurements and using the mean of the three numbers obtained. Measurement was standardized by use of a Jamar adjustable dynamometer (ASIMOV Engineering Company, 1818 Franklin Street, Santa Monica, California, 90404). The patient's non dominant hand was used. The average of three observations was recorded for each data collection time. Validity of the norms has not yet been adequately established.

Treatment response was defined as the physician estimate of change in tumor at the completion of radiation therapy (Appendix N). These data were obtained from the patient's medical record. Responses were scored from no response to a complete response, partial or complete symptom relief, or no evidence of disease/microscopic disease only.

Quality of life was defined as the responses on the Quality of Life Index (Appendix O). The instrument measures patient perceptions of their psychological well-being, social well-being, physical well-being and symptom control. The general reliability and validity of this tool has been reported (Padilla et al., 1983). The reliability for cancer patients, including radiation therapy patients, is 0.88 indicating good internal consistency. The construct validity of the instrument was identified through factor analysis which yielded three well defined factors: psychological well-being, physical well-being, and symptom control. Discriminant validity was determined through comparisons of scores for normal subjects, radiation and chemotherapy outpatients, and chemotherapy inpatients. Analysis revealed that the tool discriminated between the quality of life for those expected to have higher and lower scores. The tool is composed of 14 linear analogue scales scored by the patient. It is easy to use and practical. The Quality of Life Index was administered at the onset of therapy and at the end of therapy.

Functional status was measured in two ways: the Katz (1963) Index of Activities of Daily Living (Appendix P) and two items on the quality of life index relating to the ability to carry out usual daily tasks, and the amount of strength present (Appendix O). The Katz index contains a diochotomous rating of six functions: bathing, dressing, going to the toilet, transfer, continence, and feeding. Analyses were conducted on the tool as a whole and then without the feeding aspect since feeding was manipulated in the independent variable. The Katz tool has been extensively studied and is reproducible at reliabilities of .94 and .97. Higher scores indicate increasing dependence. The Katz ADL was administered at the onset of therapy, weekly during therapy, and at the post therapy follow up appointment. The quality of life index was administered at the beginning and end of therapy.

Procedure

Five facilities were used for data collection. Clearance for human use studies was obtained at each institution prior to study implementation. Subjects were followed from the beginning of radiation therapy for head and neck cancer to the first follow up visit. Data were coded as they accumulated, and entered into the IBM-XT computer in the Department of Nursing Research, City of Hope National Medical Center. Analysis was done with BMDP software packages.

Subjects from a given facility who were elegible for the study and who consented, were randomized to either the experimental or the control group. For the experimental group, the audio-visual teaching program was shown the first week of radiation therapy. All baseline assessment data were collected as well. The knowledge test which checks on the manipulation of the independent variable was administered at the end of the first week of therapy and again at the end of therapy. Subjects were followed weekly during therapy and at the first post therapy follow up appointment, during which time the measures of the dependent variables and the mediating variables were collected (Table 3:4). The patients in the control group did not view the audio-visual teaching program, but were tested on the knowledge test at the same time periods as the experimental group and dependent and mediating variables were collected at the same time periods as the experimental group. Data on the dependent and mediating variables were collected as described above.

In order to minimize bias, staff in the facilities were not informed about whether the patient was assigned to the experimental group or the control group.

Table 3.4

Study Implementation Time Line

Variable	Instrument	Treatment Weeks 1	2	3	4	5	6	7	ET[a]	FU[b]
Independent										
Structured Teaching		X								
Age	Demographic Tool	X								
Weight Locus of Control	WLOC Tool	X								
Mediating & Dependent										
Knowledge of Nutrition	Knowledge Test	X							X	X
Self-Care Ratios	Self Care Tool	X	X	X	X	X	X	X	X	X
Anorexia	Anorexia Tool	X	X	X	X	X	X	X	X	X
3 Day Diet Intake	Dietary Intake	X	X	X	X	X	X	X	X	X
Nutritional Status	Nutrition Tool									
weight	" "	X	X	X	X	X	X		X	X
height	" "	X							X	X
wrist circumference	" "	X							X	X
MAMC	" "	X							X	X
triceps skinfold	" "	X							X	X
handgrip strength	" "	X							X	X
Treatment Response	Demographic Tool									X
Quality of Life	QLI	X							X	X
Functional Status	Katz ADL	X							X	X
Validating Factors										
POMS	POMS Tool	X							X	
Oral Assesment	Oral Assesment Tool	X	X	X	X	X	X		X	X
Social Factors	Semi Structured Interview	X							X	X

a = End of Therapy. b = Follow up appointment.

Data Management

Data collected the previous week were coded, verified, and entered into the computer. Data were coded to insure anonymity.

Sample and Site Limitations

The convenience sample resulted from participation by those who were willing and eligible. Thus, findings cannot be generalized to patients being treated in other types of settings or living in other parts of the country, or to patients unwilling to participate in a structured teaching program.

Because 5 different sites were involved, it was not always possible for the person collecting the data to be blind to the patient's group assignment. Thus, experimenter bias may be present in the data.

Data Analysis

Prior to data analysis, the accuracy of data coding was ascertained by using BMDP1D and P2D. Atypical scores were examined and rechecked with the original data to determine whether an error in coding or data entry occurred. Errors were corrected. Outliers remaining were examined closely.

Initial analysis was done using analysis of variance to determine whether any differences in age, location of tumor, and socio-demographics (e.g. income, education) occurred between the experimental and control groups.

Concurrent validity of the anorexia instrument was conducted in the following ways. Concurrent validity of the oral-gustatory subscale was conducted by comparing scores on the oral-gustatory subscale with scores obtained on the oral assessment tool. This comparison was done on a weekly basis throughout radiation therapy and at the post therapy follow up appointment. A correlation was used to evaluate this relationship.

Concurrent validity of the psychological subscale of the anorexia scale was conducted by comparing scores on the psychological subscale with scores on the depression-dejection and the tension-anxiety subscales of the Profile of Mood States. This comparison was done at the onset of therapy and at the end of therapy. A correlation was used to evaluate this relationship.

To extend data collected on the sociocultural subscale of the anorexia scale, scores were compared with content derived from the semi-structured interview on sociocultural factors affecting dietary intake. Non parametric statistics were used to evaluate this relationship.

Additional analyses were carried out in relation to the specific hypotheses posed as follows: Hypothesis 1a states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will have greater knowledge on how to maintain dietary intake than patients who receive the usual nursing care. Knowledge was determined by scores obtained on the paper and pencil knowledge test on maintaining dietary intake. This test was administered to all experimental and control subjects at the end of the first week of therapy and at the end of therapy. The mean score for the experimental group at the end of the first week was compared to the mean score for the control group using analysis of variance. The same procedure was used to compare scores at the end of the treatment period. In addition, the mean experimental group score for the first week was compared with the mean score for the experimetal group for the follow up time. This analysis for changes within a group across time was also done for the control group.

Hypothesis 1b states that the patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will demonstrate increased self care activity aimed at maintaining dietary intake than patients who receive the usual nursing care. Self care activity was defined as two ratio scores derived from the weekly self care activity logs; namely, the selected self care activity ratio and the total self care activity ratio. These two ratios were selected as they related to activities patients carried out specific to side effects reported. Scores for the experimental group were compared with the scores for the control group using analysis of variance.

Hypothesis 1c states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will demonstrate better overall management of side effects than patients who receive the usual nursing care. Management of side effects was defined as two ratio scores derived from the weekly self care activity logs; namely, the self care behavior efficacy ratio, and the overall management of side effects ratio. These two ratios were selected as they related most closely to how patients managed the reported side effects. Scores for the experimental group were compared with the scores for the control group using analysis of variance.

Hypothesis 1d states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will experience less anorexia than patients who receive the usual nursing care. Anorexia was defined in two ways. Subjective anorexia was defined as the score on the appetite scale and the score on the ability to eat scale and was scored weekly during therapy and at the post therapy follow up appointment. Subjective anorexia was to be tested using analysis of variance with subjects in the experimental group compared to those in the control group. Objective anorexia was defined as the percentage of recommended caloric intake ingested, and the percentage of recommended protein intake ingested. These percentages were calculated from a comparison of the weekly mean of the 3-day dietary intake sheets with the amount of individually recommended caloric and protein intake. Objective anorexia was tested using analysis of variance with subjects in the experimental group compared to those in the control group.

Hypothesis 2a states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will demonstrate less nutritional depletion than patients who receive the usual nursing care. Nutrition status was defined as weight loss during radiation therapy, mid arm muscle circumference changes during radiation therapy, and hand strength changes during radiation therapy. Weight loss during radiation therapy was evaluated in two ways. Present weight calculated as percentage of recommended body weight was done on a weekly basis during therapy and again at the post therapy follow up appointment. Analysis of variance was used to compare subjects in the experimental group with subjects in the control group. Weight loss was also calculated as the actual number of kilograms lost, and scored weekly during therapy and the post therapy follow up appointment. Analysis of variance was used to compare subjects in the experimental group with subjects in the control group.

Triceps skinfold was evaluated by classifying subjects into three groups: adequate, mild depletion, and severe depletion. Comparisons were made at the beginning of therapy, at the end of therapy and at the post therapy follow up appointment. Analysis of variance was used to compare subjects in the experimental group with subjects in the control group.

Mid-arm muscle circumference was evaluated by classifying subjects into three groups: adequate mild depletion, and severe depletion. Comparisons were made at the beginning of therapy, at the end of therapy, and at the post therapy follow up appointment. Analysis of variance was used to compare subjects in the experimental group with subjects in the control group.

Hand grip strength was evaluated by classifying subjects into three groups: adequate, mildly depleted, and severely depleted. Comparisons were made at the beginning of therapy, at the end of therapy and at the post therapy follow up visit. Analysis of variance was used to compare subjects in the experimental group with subjects in the control group.

Hypothesis 2b states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will demonstrate less decrease in functional status than patients who receive the usual nursing care. Functional status was defined in two ways: the five functions (omitting the sixth function of feeding) on the Katz Index of Activities of Daily Living and two items on the Quality of Life Index. The Katz index has a dichotomous rating of bathing, dressing, going to the toilet, transfer, and continence. Ratings for the Katz tool were obtained at the beginning of therapy, at the end of therapy, and at the post therapy follow up appointment. The Quality of Life Index was filled out at the beginning and end of therapy. Analysis of variance was used to compare ratings for subjects in the experimental group with subjects in the control group and to compare responses at the beginning versus the end of therapy.

<u>Hypothesis 2c</u> states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will demonstrate greater treatment response than patients who receive the usual nursing care. Treatment response was defined as the estimate of tumor change as identified by the physician at the end of radiation therapy or at the post therapy follow up appointment. Treatment response was tested by nonparametric statistics to compare scores of subjects in the experimental group with subjects in the control group at the end of therapy or at the post therapy follow up appointment.

<u>Hypothesis 2d</u> states that patients with head and neck cancer undergoing radiation therapy who participate in a structured teaching program will demonstrate less decrease in quality of life than patients who receive the usual nursing care. Quality of life was defined as the total score on the Quality of Life Index Quality of life was scored at the beginning and end of therapy. Analysis of variance was used to compare scores of subjects in the experimental group with subjects in the control group and to compare responses at the beginning versus the end of therapy.

<u>Hypothesis 3</u> states that older head and neck cancer patients undergoing radiation therapy will have a greater number of factors interfering with normal dietary intake than younger head and neck cancer patients undergoing radiation therapy. Number of factors interfering with normal dietary intake was defined as the number of factors reported on the

daily self care record by the patient and summarized weekly during therapy and the post therapy follow up appointment. A correlation was used to evaluate this relationship.

Hypothesis 4 states that older head and neck cancer patients undergoing radiation therapy will experience factors interfering with food intake and appetite to a greater extent than younger patients undergoing radiation therapy. Extent of factors interfering with normal dietary intake was defined as the score of the combined subscales on the anorexia tool (appetite-hunger + oral-gustatory + general symptoms + psychological + socio-cultural). A correlation was used to evaluate this relationship.

Hypothesis 5 states that younger head and neck cancer patients undergoing radiation therapy will report more self care activity aimed at alleviating side effects than older head and neck cancer patients undergoing radiation therapy. Self care activity was defined as two ratio scores derived from the weekly self care activity logs. The two ratios selected were the selected self care activity ratio and the total self care activity ratio since they referred to activities patients carried out specific to reported side effects. A correlation was used to evaluate this relationship.

Hypothesis 6 states that younger head and neck cancer patients undergoing radiation therapy will report better overall management of side effects than older head and neck cancer patients undergoing radiation therapy. Management of side effects was defined as two ratio scores derived from the weekly self care activity logs. The two ratios selected were the self care behavior efficacy ratio and the overall management of side effects ratio since they most closely related to how patients manage reported side effects. A correlation was used to evaluate this relationship.

Hypothesis 7 states that there is a relationship between the number of factors interfering with normal dietary intake and anorexia. Number of factors interfering with normal dietary was defined as the number of factors reported on the daily self care record by the patient and summarized weekly during therapy and at the post therapy follow up appointment. Anorexia was defined as the score on the appetite scale and the score on the ability to eat scale. A correlation was used to evaluate this relationship.

Hypothesis 8 states that there is a relationship between the extent of factors interfering with normal dietary intake and anorexia. Extent of factors interfering with normal dietary was defined as the total combined subscales score on the anorexia instrument. Anorexia was defined as the score on the appetite scale and ability to eat scale, as the percentage of recommended protein intake ingested. Correlations were used to evaluate this relationship.

Hypothesis 9 states that there is a relationship between the perception of control and knowledge on how to maintain dietary control in head and neck cancer patients undergoing radiation therapy. Perception of control was defined as the score on the weight locus of control scale (Saltzer, 1982) and knowledge was defined as a score on the knowledge test. A correlation was used to evaluate this relationship.

Hypothesis 10 states that there is a relationship between the perception of control and self care aimed at maintaining dietary intake in head and neck cancer patients undergoing radiation therapy. Perception control was defined as the score on the weight locus of control scale (Saltzer, 1982) and self care was defined as the four ratios derived from the weekly self care activity logs. A correlation was used to evaluate this relationship.

CHAPTER 4

RESULTS OF THE STUDY

Study Sample

The study sample consisted of 41 patients undergoing radiation therapy for head and neck cancer. They were accrued from five different facilities - one radiation oncology department located in a large medical-teaching center, and four private radiation clinics. After consenting to participate, twenty-one subjects were randomized to the experimental group, and twenty subjects were randomized to the control group. Age ranged from 24 to 84, with a mean of 56 (Table 4.1). Twenty-seven of the subjects were male and fourteen were female. The mean number of years of education was 14 with a range of 0 to 20. The vast majority of the subjects classified their cultural background as American. Twenty-six of the subjects were married, five were single, five were separated or divorced and three were widowed.

Smoking and alcohol history are risk factors for head and neck cancer. Information on alcohol intake was available from 39 of the subjects. Of these, 18 reported they drank alcohol, 8 reported they drank alcohol in the past but had quit, and 13 reported that they did not drink alcohol. Thirty-two of the subjects had a smoking history, with a reported mean of 40 pack years (calculated by multiplying the number of packs smoked per day by the number of years smoked) for those who smoked cigarettes. No significant differences (p>0.05) between the experimental and control groups were found in relation to these descriptive variables (Table 4.1).

Table 4.1

Description of the Sample

Selected Variables	Experimental Group	Control Group	Total
Subjects	21	20	41
Mean Age (Years)	55	58	56
Sex			
Males	14 (67%)	13 (65%)	27 (66%)
Females	7 (33%)	7 (35%)	14 (34%)
Mean Education (Years)	13	14	14
Cultural Background			
United States	18 (90%)	16 (80%)	34 (85%)
Mexico	1 (5%)	0 (0)	1 (3%)
Asia	1 (5%)	1 (5%)	2 (5%)
Europe	0	3 (15%)	3 (7%)
Marital Status			
Married	12 (63%)	14 (70%)	26 (66%)
Single	2 (11%)	3 (15%)	5 (13%)
Separated/divorced	4 (21%)	1 (5%)	5 (13%)
Widowed	1 (5%)	2 (10%)	3 (8%)

Table 4.1 (Continued)

Selected Variables	Experimental Group	Control Group	Total
Alcoholic Intake			
Yes	9 (48%)	9 (45%)	18 (46%)
Did, but quit	5 (26%)	3 (15%)	8 (21%)
No	5 (26%)	8 (40%)	13 (33%)
Smoking History			
Smokers	18 (86%)	14 (70%)	32 (78%)
Non-smokers	3 (14%)	6 (30%)	9 (22%)
Mean Packyears	37	44	40

All patients were receiving radiation therapy for head and neck cancer. Specific diagnoses indicated tumors of the oral cavity, tumors of the nasal cavity, tumors of the neck region including the salivary glands, tumors of the larynx, and some miscellaneous lesions (Table 4.2). No statistical difference ($p \geq 0.05$) was found in the distribution of these diagnoses between the experimental and control groups.

Table 4.2

Distribution of Diagnoses by Group

	Experimental		Control		Total	
	n	%	n	%	n	%
Oral Tumors	3	(14%)	2	(10%)	5	(12%)
Nasal Tumors	3	(14%)	0		3	(7%)
Neck, including Salivary Glands	9	(43%)	9	(45%)	18	(44%)
Larynx	5	(24%)	8	(40%)	13	(32%)
Other	1	(5%)	1	(5%)	2	(5%)
TOTAL	21	(100%)	20	(100%)	41	(100%)

Treatment Characteristics

When the sample was examined for differences in treatment characteristics, the average number of rads given to the patients in the experimental group was compared to the average number of rads given to the patients in the control group. Since patients with head and neck cancer receiving radiation therapy generally have radiation administered to more than one anatomical site in the head and neck region, rads for site 1 of radiation therapy and site 2 of radiation therapy were averaged for each group. When compared the average number of rads for site 1 was essentially equal for each group, but for site 2 was significantly higher for the experimental group as compared to the control group (Table 4.3). Likewise, the treatment length in days between groups was essentially equal for site 1 and significantly longer in the experimental group for site 2. Finally, the number of treatments was essentially the same for site 1, and more for the experimental group for site 2, but this difference was not statistically significant. The experimental group received significantly more radiation treatment than the control group.

Instrument Reliability and Validity

Several analyses were conducted to test the validity of the instrument used to measure anorexia. The concurrent validity of the oral-gustatory subscale was examined by correlating patients' scores on the oral gustatory subscale of the anorexia tool to scores obtained from nurses ratings of the oral condition on the oral assessment instrument. Comparisons were done weekly throughout therapy, at the end of treatment, and at the follow up appointment and ranged from $r=0.36$ to 0.62. All were statistically significant ($p\leq0.05$). The concurrent validity of the psychological subscale of the anorexia tool was examined by comparing the patient's beginning and end of treatment psychological scores with the depression-dejection and tension-anxiety subscales of the Profile of Mood States (POMS). Correlations ranged r=0.16 to 0.32 and none were statistically significant (p>0.05).

Table 4.3

Treatment Characteristics by Group

	Experimental		Control		f	df	p
	$\bar{X}$	n	$\bar{X}$	n			
Mean Total Rads							
Site 1	5206	21	5743	20	1.82	1	0.49
Site 2	5351	15	3362	10	5.28	1	0.03
Mean Treatment Length in Days							
Site 1	48.9	21	46.9	20	0.52	1	0.48
Site 2	52.3	15	36.9	10	7.54	1	0.01
Mean Number of Treatments							
Site 1	30.3	21	32.0	20	1.03	1	0.32
Site 2	31.9	15	25.8	10	3.15	1	0.09

These findings suggest that the oral-gustatory subscale of the anorexia scale and the oral assessment measured similar patient characteristics, whereas the psychological subscale of the anorexia scale measured something different from the POMS psychological subscales.

The rest of the results are reported in relation to the hypotheses posed. For statistical analysis, significance level of $p \leq 0.05$ was selected.

The first hypothesis relates to the major mediating variables and to anorexia. This hypothesis states that the patients participating in the structured teaching program (STP) would demonstrate increased knowledge of dietary intake, increased self care activity and self care management, and decreased anorexia as compared to the control group.

Nutritional Knowledge

Mean knowledge scores were calculated from the knowledge test administered at the beginning and end of therapy for each group. The knowledge test was completed by 15 out of 21 experimental subjects (71%) and 19 out of 20 control subjects (95%). This test was given to subjects during the first week, right after viewing the audio-visual program for the experimental subjects, and along with many other tools. Subjects who did not fill out or complete the knowledge test reported that they were too tired, did not know the answers, and/or did not understand how to fill out the test. Results indicate no significant difference between groups at the onset of therapy, although the mean score in the STP group was higher than that of the control group (Table 4.4). By the end of therapy, the mean score of the STP group increased slightly and was significantly higher than that of the control group. However, it should be noted that only 15 out of a possible 21 subjects in the experimental group completed the test at the beginning of therapy and this number increased by only one to 16 at the end of therapy. For the control group, the reverse occurred, with 19 out of a possible 20 subjects completing the test at the beginning of therapy, and only 13 subjects completing the test at the end of therapy. Since the actual mean scores for each group changed minimally, the statistical significance at the end of therapy may reflect artifact. For both groups, knowledge level appears stable over time.

Table 4.4

Knowledge Scores[a] by Groups

	Experimental		Control		f	df	p
Therapy Time	$\bar{X}$	n	$\bar{X}$	n			
Beginning	42.1	15	37.8	19	2.62	1	0.12
End	42.6	16	37.5	13	4.40	1	0.05

[a]Total possible score of 51

Self Care

Data on self care were obtained from Dodd's self-care logs filled out weekly by the subjects (Dodd, 1984). Some subjects filled out the log both consistently and extensively. Some filled it out incompletely and some did not fill it out at all - indicating that it took too much time, or that they were too tired. On the log, the subject identified and rated each side effect by defining the side effect, the date it occurred, rating how severe the side effect was, how much the side effect bothered the subject, what actions the subject took to alleviate the side effect, rating how effective the action taken was in alleviating the side effect, and finally identifying the source of the action taken.

Initial analysis of the self care logs revealed the distribution of subjects reporting occurrence or non occurrence of side effects specifically related to dietary intake, and the number of subjects who did not fill out the log (Table 4.5). Missing data ranged from 10 percent to 70 percent, with a trend towards increased missing data over the study period.

When the average number of side effects related to dietary intake was compared across the study period for the experimental and control groups, no differences between groups were revealed (Table 4.5) For the total sample reporting on side effects, the average number of side effects reported during week one of therapy was 0.9, by week four was 1.1, by end of therapy was 0.2, and by the follow up period was 0.2 (Table 4.6).

Table 4.5

Distribution of Subjects

Using Self-Care Logs by Groups

	Experimental						Control					
	Side Effects Reported				Missing Data		Side Effects Reported				Missing Data	
	Yes		No				Yes		No			
Time	n	%	n	%	n	%	n	%	n	%	n	%
Week 1	13	(62%)	4	(19%)	4	(19%)	9	(45%)	7	(35%)	4	(20%)
2	12	(57%)	6	(29%)	3	(14%)	15	(75%)	2	(10%)	3	(15%)
3	17	(81%)	2	(10%)	2	(10%)	14	(70%)	1	(5%)	5	(25%)
4	17	(81%)	1	(5%)	3	(14%)	16	(80%)	2	(10%)	2	(10%)
5	12	(57%)	2	(10%)	7	(33%)	12	(60%)	4	(20%)	4	(20%)
6	10	(48%)	2	(10%)	9	(43%)	10	(50%)	2	(10%)	8	(40%)
7	6	(29%)	2	(10%)	13	(62%)	5	(25%)	1	(5%)	14	(70%)
End of Therapy	11	(52%)	2	(10%)	8	(38%)	10	(50%)	2	(10%)	8	(4)%)
Follow-up	4	(19%)	4	(19%)	13	(62%)	4	(20%)	5	(25%)	11	(55%)

Table 4.6

Mean Number of Weekly Side Effects

by Groups

Time	Experimental		Control		Total		f	df	p
	$\bar{X}$	n	$\bar{X}$	n	$\bar{X}$	n			
Week 1	1.1	17	0.6	16	0.9	33	2.83	1	0.100
2	1.1	18	1.4	17	1.3	35	0.42	1	0.522
3	1.8	19	1.2	15	1.5	34	2.86	1	0.099
4	1.2	18	1.0	18	1.1	36	0.25	1	0.618
5	1.1	14	1.2	16	1.1	30	0.08	1	0.779
6	0.8	12	0.9	12	0.9	24	0.08	1	0.774
7	0.5	8	0.2	6	0.3	14	1.36	1	0.251
End of Therapy	0.3	13	0.1	12	0.2	25	1.14	1	0.292
Follow-up	0.1	8	0.3	9	0.2	17	0.77	1	0.385

Further analysis of the self-care logs was conducted using four ratios calculated on self care activity and self care management and using all side effects reported, some of which were not directly related to dietary intake (Dodd, 1984). The first ratio on selected self care activity included those behaviors for which effectiveness of the behavior was rated by subjects as 1, 2, or 3 on a 5 point scale, with 1 meaning not relieved at all and 5 meaning completely relieved. For this first ratio of selected self care activities, effectiveness ratings of 4 and 5 are not used. The second ratio was calculated using all (i.e. = 1, 2, 3, 4, or 5 behavior effectiveness ratings) self care activities reported divided by the total number of side effects reported. The third ratio evaluated the effectiveness of each behavior instituted by dividing the total effectiveness rating of each self care behavior by the total number of behaviors initiated. The fourth and final ratio was a rating of overall side effect management and was calculated by dividing the highest effectiveness rating for each self care behavior by the total number of reported side effects.

Results indicate that mean self care ratios compared across groups did not differ significantly in any of the time periods observed (Table 4.7). However, scores for selected activities, overall activities, and overall management of side effects were generally higher for the experimental group as compared to the control group scores, and this trend was evident over all data collection points.

Table 4.7

Self Care Ratios by Group

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
Selected Activity							
Week 1	1.0	13	0.6	9	1.6	1	0.22
2	1.0	13	0.8	15	0.7	1	0.41
3	0.7	17	0.6	12	0.10	1	0.76
4	0.8	17	0.7	13	0.32	1	0.58
5	0.7	12	0.5	12	0.30	1	0.59
6	0.7	12	1.1	7	1.13	1	0.30
7	1.2	6	0.4	5	1.54	1	0.25
End of Therapy	0.8	5	0.0	3	-	-	-
Follow-up	0.5	3	0.7	4	0.12	1	0.74
Total Activity							
Week 1	1.5	13	0.95	10	1.8	1	0.19
2	1.2	13	0.95	15	0.7	1	0.40
3	1.1	17	0.97	13	0.44	1	0.51
4	1.3	17	1.2	14	0.10	1	0.76
5	1.0	12	0.7	12	2.04	1	0.17
6	0.8	12	0.9	9	0.15	1	0.70
7	1.6	6	1.8	5	0.07	1	0.80
End of Therapy	1.3	5	1.3	3	0.02	1	0.90
Follow Up	0.8	3	0.8	4	0.00	1	0.99

Table 4.7 (continued)

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
Total Efficacy							
Week 1	2.8	13	1.7	8	3.47	1	0.08
2	2.3	13	2.7	15	0.40	1	0.53
3	2.9	16	3.1	13	0.05	1	0.82
4	2.4	17	2.6	13	0.18	1	0.67
5	2.8	11	2.6	12	0.18	1	0.68
6	2.3	12	2.1	7	0.06	1	0.81
7	2.4	6	3.0	5	0.44	1	0.52
End of Therapy	2.9	5	2.7	3	0.07	1	0.80
Follow Up	1.0	3	2.3	4	0.91	1	0.38
Overall Management							
Week 1	2.9	13	1.8	8	2.36	1	0.14
2	2.2	13	2.0	15	0.17	1	0.68
3	2.4	16	2.3	13	0.12	1	0.73
4	2.6	17	2.2	13	0.63	1	0.43
5	2.7	11	2.3	12	0.50	1	0.49
6	2.3	12	1.9	7	0.24	1	0.63
7	2.2	6	3.0	5	0.78	1	0.40
End of Therapy	3.1	5	2.7	3	0.18	1	0.68
Follow Up	1.0	3	2.2	4	0.84	1	0.40

Subjective Anorexia

Subjective anorexia scores were calculated from subject ratings of appetite and ability to eat (Table 4.8). These ratings, derived from 100 mm visual analogue scales show consistently lower mean scores (lower appetite and less ability to eat) for the experimental group as compared with ratings of the control group. Differences were not statistically significant. Trends show a general decline of both appetite and ability to eat for both groups as therapy progressed, with a beginning recovery starting by the post therapy follow up appointment.

Objective Anorexia

The objective rating of anorexia was defined as actual amounts of calories per day, grams of protein per day and a percentage of recommended calorie and protein intake ingested (Table 4.9). Results indicate consistently lower intake by the control group with statistical significance occurring on week 2 for percentage of recommended caloric intake. Trends indicate consistently better intake by the experimental group in both calories and protein.

In general, results for Hypothesis 1 indicate that the experimental group (STP) appeared to have greater knowledge and better caloric and protein intake than the control group. Surprisingly, the experimental group reported trends toward more difficulties with both appetite and the ability to eat. Self care appears to be fairly similar in both groups with

TABLE 4.8

Mean Appetite and Ability to Eat Scores by Group

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
Appetite							
Before Illness	55.8	21	67.7	18	2.42	1	0.13
Appetite							
Week 1	47.1	21	61.7	18	2.99	1	0.09
2	46.3	18	57.9	19	2.27	1	0.14
3	41.9	18	43.1	19	0.02	1	0.89
4	34.4	20	43.8	18	0.95	1	0.33
5	35.3	16	47.2	13	1.21	1	0.28
6	34.7	13	47.3	13	1.80	1	0.19
7	43.7	10	51.8	8	0.38	1	0.54
End of Therapy	38.7	20	42.8	19	0.23	1	0.64
Follow Up	48.0	14	49.5	10	0.01	1	0.91
Ability to Eat							
Week 1	53.7	21	68.1	18	2.81	1	0.10
2	48.1	17	64.5	19	3.89	1	0.06
3	43.6	18	46.4	19	0.10	1	0.75
4	42.1	20	45.6	18	0.15	1	0.69
5	35.7	16	48.8	13	1.89	1	0.18
6	45.9	13	49.4	13	0.10	1	0.75
7	40.9	10	52.8	8	1.12	1	0.30
End of Therapy	42.2	20	46.9	19	0.36	1	0.55
Follow Up	50.9	14	56.9	10	0.24	1	0.63

Table 4.9

Mean Dietary and Protein Intake Group

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
KCal/Day							
Week 1	2001	19	1769	18	1.06	1	0.31
2	2095	19	1653	17	4.24	1	0.05
3	1873	21	1609	20	1.20	1	0.28
4	1737	20	1633	20	0.23	1	0.63
5	1581	18	1633	17	0.05	1	0.83
6	1944	12	1687	14	0.79	1	0.38
7	1762	11	1499	8	1.58	1	0.22
End of Therapy	1608	21	1432	19	0.69	1	0.41
Follow Up	1856	13	1599	9	0.86	1	0.37
% of Recommended* Caloric Intake							
Week 1	79	19	59	18	3.59	1	0.07
2	84	19	56	17	6.73	1	0.01
3	75	21	56	20	3.70	1	0.06
4	70	20	54	20	2.66	1	0.11
5	61	18	53	17	0.71	1	0.40
6	73	12	57	14	1.58	1	0.22
7	69	11	51	8	3.83	1	0.07
End of Therapy	64	21	49	19	2.42	1	0.13
Follow Up	77	13	56	9	3.14	1	0.09

Table 4.9 (Continued)

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
Protein Intake in Grams							
Week 1	78.2	19	70.1	18	0.69	1	0.41
2	78.4	19	71.3	17	0.61	1	0.44
3	78	21	70	20	0.57	1	0.45
4	70	20	65	20	0.26	1	0.61
5	59	18	66	17	0.50	1	0.49
6	75	12	72	14	0.07	1	0.80
7	74	11	65	8	0.41	1	0.53
End of Therapy	63	21	61	19	0.02	1	0.89
Follow Up	74	13	65	9	0.56	1	0.46
% of Recommended** Protein Intake							
Week 1	120	19	92	18	3.26	1	0.08
2	128	19	94	17	3.38	1	0.07
3	127	21	93	20	3.26	1	0.08
4	111	20	85	20	2.55	1	0.12
5	91	18	85	17	0.15	1	0.70
6	114	12	96	14	0.67	1	0.42
7	113	11	88	8	1.57	1	0.23
End of Therapy	101	21	83	19	1.18	1	0.28
Follow Up	123	13	90	9	2.37	1	0.14

*40 KCal/day/kg body weight

**1 gram/day/kg body weight

trends toward more activity and more side effects management by the experimental group. Hypothesis 1 is partially supported.

The second hypothesis relates to the major outcome variables of the study. It was predicted that the STP group would demonstrate less nutritional depletion, less decrease in functional status, greater treatment response, and less decrease in quality of life than the control group.

Nutritional Status

A number of parameters were used to evaluate nutritional status. History of weight loss was evaluated in relation to Blackburn's formula (1977), and, as displayed in Table 4.10, the STP group reported a greater historical weight loss than the control group during the six months prior to study onset. The difference was significant in relation to actual kilograms lost (p=0.05) and percentage of usual weight (p=0.03). It appears from these findings that the STP group were at greater nutritional risk at the onset of the study period than the control group.

Table 4.10
Mean Weight Loss History by Group

	Experimental		Control		f	df	p
	$\bar{X}$	n	$\bar{X}$	n			
Kilograms lost in last 6 months	5.7	21	2.5	20	4.13	1	0.05
Present weight as % of usual weight	91.5	21	96.6	20	5.19	1	0.03

Weight was evaluated in relation to the amount of weight loss in kilograms across the study period. The mean weight loss was calculated for each group and during each week of therapy throughout the study period (4.11). Mean weight loss was essentially the same in both groups. Analysis of variance for repeated measures was used to compare weight loss within each group from the beginning to the end of the study period. Results indicate statistically significant weight losses in both groups from beginning of therapy to follow up visit (p=0.00).

Table 4.11

Mean Weight Loss in Kilograms by Group

	Experimental		Control		f	df	p
Time	$\bar{X}$	n	$\bar{X}$	n			
Week 1	0	21	0	20			
2	0.4	18	0.5	19	0.07	1	0.79
3	0.76	20	1.2	20	0.61	1	0.44
4	1.31	21	1.52	19	0.13	1	0.72
5	1.8	18	1.98	18	0.05	1	0.82
6	2.1	15	2.2	15	0.01	1	0.93
7	2.9	14	2.5	11	0.12	1	0.73
End of Therapy	2.9	21	2.6	19	0.81	1	0.46
Follow Up	3.5*	18	3.9**	20	0.10	1	0.76

*p = 0.00 from first week to follow up for experimental group

**p = 0.00 from first week to follow up for control group

Weight was also evaluated by examining the percentage of usual weight at the beginning of treatment, the end of treatment and the follow up appointment. Data were collected by patient recall. Percentage of usual weight was significantly lower in the experimental group at the beginning and end of treatment, and lower, but not statistically significant, at the follow up visit (Table 4.12).

Table 4.12

Percentage of Usual Weight at Beginning, End of Therapy, and Follow-up by Group

	Experimental		Control		f	df	p
Therapy Time	$\bar{X}$	n	$\bar{X}$	n			
Beginning	92	21	97	20	5.19	1	0.03
End	89	21	95	20	6.90	1	0.01
Follow-up	89	19	93	17	3.21	1	0.08

Other parameters used in evaluation of nutritional status included evaluation of triceps skinfold, mid arm muscle circumference, and hand grip strength. Results of each of these scores were categorized into one of three groups adequate, mild depletion, and severe depletion. No statistically significant differences were found between groups at the beginning of therapy, end of therapy, or follow up appointment (Table 4.13).

Table 4.13

Nutritional Status Scores[a] at Beginning,
End of Treatment, and Follow-up by Group

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
TSF[b]							
Beginning	0.38	21	0.00	19	-	-	-
End of Therapy	0.45	20	0.06	17	3.54	1	0.07
Follow Up	0.44	16	0.15	13	1.14	1	0.29
MAMC[c]							
Beginning	0.09	21	0.00	20	0	0	0
End of Therapy	0.10	20	0.00	17	0	0	0
Follow Up	0.25	16	0.00	17	0	0	0
Handgrip Strength							
Beginning	0.40	20	0.60	18	0.30	1	0.59
End of Therapy	0.56	16	0.44	16	0.19	1	0.67
Follow Up	0.40	10	0.91	11	1.79	1	0.20

[a] 3-point scale of 1 = adequate, 2 = mild depletion, 3 = severe depletion

[b] Triceps Skin Folds. c = Mid Arm Muscle Circumference

Functional Status

In addition to nutritional status, three other outcome measures were used to evaluate the effectiveness of the independent variable, structured teaching program; namely, functional status, treatment response and quality of life. Functional status was evaluated in several ways; the Katz ADL instrument; two items on the quality of life scale, namely ability to work at usual daily tasks, and amount of strength; and the fatigue subscale from the POMS. The Katz ADL instrument was not sensitive to changes in the group, categorizing only 4 subjects as other than independent at the beginning of the study, and identifying no changes in subjects by the end of treatment or at the follow up visit. The two items on the quality of life scale were more sensitive to changes from the beginning of treatment to the end of treatment (Table 4.14). These two items were both rated by patients on 100 mm linear analogue scales. As scores decreased, ability to do work and strength decreased. Both STP and control groups decreased in ability to work at usual daily tasks, and strength from the beginning to the end of therapy. These differences were higher in the STP group than in the control group, but the groups were not statistically different. For the fatigue subscale from the POMS, the score was higher for the experiment group indicating more fatigue than for the control group but the difference was not statistically significant. The number of subjects completing the tools at the end of therapy decreased because subjects did not bring the tools back or did not return them in the stamped envelopes that were provided.

Table 4.14

Mean Functional Status Scores by Group

Time	Experimental $\bar{X}$	Experimental n	Control $\bar{X}$	Control n	f	df	p
Work Usual Tasks							
Week 1	51.5	19	55.7	20	0.22	1	0.64
End of Therapy	42.1	11	52.6	14	1.03	1	0.32
Strength							
Week 1	57.6	18	59.5	20	0.06	1	0.81
End of Therapy	46.8	11	54.1	14	0.60	1	0.45
Fatigue							
Week 1	7.8	16	5.1	16	2.24	1	0.15
End of Therapy	9.3	12	5.3	12	3.57	1	0.07

Treatment Response

Treatment response was evaluated by summarizing subjects' response to radiation therapy into one of three categories; namely, no tumor response or symptom relief, partial tumor response or partial symptom relief, and complete response or no evidence of disease. Results are summarized in Table 4.15. Information was derived from the physician and/or the patient's charts, and was available on only 20 subjects in the experimental group and 18 subjects in the control group. Chi square analysis indicated no statistical differences between groups.

Table 4.15
Treatment Response by Group

	Experimental		Control	
Response	n	%	n	%
No tumor response or symptom relief	2	(10)	2	(11)
Partial Tumor response or symptom relief	7	(35)	6	(33)
Complete response or no evidence of disease	11	(55)	10	(56)
TOTAL	20	(100)	18	(100)

$X^2 = 0.019$, $p=0.99$

Quality of Life

Quality of Life was scored at the beginning and end of therapy for each group. Possible scores ranged from 1 = lowest quality of life to 100 = highest quality of life. Summarized scores, indicate no significant differences between groups (Table 4.16). Mean quality of life score began at a lower level for the STP group as compared to the control group and ended at a lower level for the STP group as well. Both groups decreased in quality of life scores from beginning to the end of therapy, but this decrease was not significant. The number of subjects completing the tools at the end of therapy decreased because subjects did not bring the tools back, or did not return them in the stamped envelopes that were provided.

Table 4.16

Mean Quality of Life Scores for Beginning and End of Therapy by Group

	Experimental		Control		f	df	p
Time	$\bar{X}$	n	$\bar{X}$	n			
Week 1	55.1	19	60.7	20	0.86	1	0.36
End of Therapy	50.7	11	58.7	14	2.10	1	0.16

To summarize, analysis of variables for hypothesis 2 indicates that the experimental group (STP) had a medical history of significant weight loss, that both groups had continued and significant loss of weight during therapy, but this loss was not significantly different between groups. Other measures of nutritional status, namely triceps skinfold, midarm muscle circumference and hardgrip strength did not differ between groups. It appears that weight as compared to usual weight, and weight loss as it occurred during the study period were the most sensitive nutrition parameters measured. Functional status, treatment response, and quality of life did not differ significantly between the groups. Hypothesis 2 was only partially supported.

<u>Age</u>

The third through the sixth hypothesis relate to the impact of the independent variable age on patients' response to radiation therapy. It was anticipated that older patients would have greater interference than younger patients with factors which maintain dietary intake and that this interference would have an impact on nutrition status. The sample distribution for age revealed a mean age of 56, a median of 62 and a range of 26-84. Approximately half the population was 59 years of age and under and half was 60 years of age and older (Table 4.17). However, only 14% of the population was 70 years of age and older, and only 1 subject was 80 years or older. Age was treated as a continuous variable during analysis.

Table 4.17

Age Distribution

Range	n	%
≤39	8	19
40-49	6	15
50-59	6	15
60-69	15	37
70-79	5	12
≥80	1	2

The third hypothesis states that older patients have a greater number of factors interfering with normal dietary intake than younger patients. The number of factors was calculated from the side effects reported by subjects on their weekly self care diaries. The correlation between age and number of side effects revealed no significant relationship for any time during the study period.

The fourth hypothesis states that older patients have a greater extent of factors interfering with normal dietary intake than younger patients. The extent of factors was defined as the combined score of the anorexia tool, calculated as an average of scores from the appetite-hunger subscale, the oral-gustatory subscale, the general symptoms subscale, the psychological subscale, and the social subscale. Correlations between age and the combined anorexia scores are summarized in Table 4.18. A positive relationship was anticipated, but no significant relationship was revealed.

Table 4.18

Correlations Between Age and Anorexia

Time	r	*n*
Week 1	-.08	38
2	.07	37
3	-.09	37
4	-.21	38
5	-.29	29
6	-.28	26
7	.15	17
End of Therapy	-.00	38
Follow-up	.00	24

The fifth hypothesis states that younger patients report more self care activity related to side effects than older patients. Self care activity was defined as scores on the self care ratio of selected behaviors, and the self care ratio of total self care activity. Results are summarized in Table 4.19.

Table 4.19

Correlations Between Age and Self Care

Ratios Related to Activities

Time	r	n
Selected Activities		
Week 1	.15	22
2	.16	28
3	.06	29
4	-.18	30
5	.21	24
6	.28	19
7	-.12	11
End of Therapy	.06	19
Follow Up	.11	7
Total Activities		
Week 1	-.13	23
2	.05	28
3	.11	30
4	-.24	31
5	-.04	24
6	.34	21
7	-.21	11
End of Therapy	.03	21
Follow Up	.17	7

The number of subjects used in the calculations of ratio scores of self care was relatively small (Table 4.19). The reason for these low numbers is that data from only those subjects who reported side effects, and reported them completely in the self care logs, were used in the correlations with age. Excluded subjects included a group who did not report any side effects and a group who simply did not fill out the self care logs (Table 4.5). No significant relationships were evident between self care activity related to side effects and age.

The sixth hypothesis states that younger patients report better overall management of side effects as compared to older patients. Management was defined as scores on the self care ratio of effectiveness and of overall management. As with self care activity ratios, the number of subjects for which self care management ratios could be calculated was limited to those subjects who reported side effects in their self care logs (Table 4.5). Results are summarized in Table 4.20 and reveal no significant relationships. In summary, hypotheses three through six, relating age to factors interfering with dietary intake and to self care, were not supported by the findings.

Because self care ratios were calculated using side effects reported by subjects and some of these side effects were not directly related to dietary intake (e.g. eye irritation), further analysis for hypotheses five and six involved analyzing the number of side effects related to

Table 4.20

Correlations Between Age and Self Care Ratios Related to Management

Time	r	n
Effectiveness of Self Care Behavior		
Week 1	-.28	21
2	.01	28
3	.03	29
4	-.01	30
5	-.38	23
6	-.40	19
7	-.14	11
End of Therapy	-.08	19
Follow Up	.30	7
Final Effectiveness Score for Each Side Effect		
Week 1	-.30	21
2	-.09	28
3	-.02	29
4	-.01	30
5	-.24	23
6	.16	19
7	-.29	11
End of Therapy	.19	19
Follow Up	.29	7

dietary intake reported across age. Analysis revealed no significant differences in age for any number of side effects reported.

Factors Interfering with Diet Intake

The seventh and eighth hypotheses relate to the relationship between the mediating variable, factors which interfere with dietary intake, and the dependent variable, anorexia. Hypothesis seven states that there is a relationship between the number of side effects and anorexia. Results are summarized in Table 4.21. Correlations between the weekly number of reported side effects related to dietary intake and weekly appetite ratings are statistically inconsistent, but generally negative; i.e. as the number of side effects increases, appetite decreases, or vice versa. The relationship between the weekly number of side effects related to dietary intake and weekly ability to eat ratings follows a similar pattern. It appears that the relationship between the number of side effects related to dietary intake and both appetite and ability to eat was stronger at the beginning of the study period and decreased at the end of therapy and at the follow up appointment. In general, analysis reveals minimal support for hypothesis 7, that a relationship exists between the number of side effects and the occurrence of anorexia, as measured by appetite and the ability to eat. Trends indicate that the relationship, if present, is likely to be negative. Statistical significance is rare enough to be unmeaningful.

Table 4.21

Correlations Between Number of Side Effects and Anorexia

Time	r	n
Appetite		
Week 1	-.51*	32
2	-.17	34
3	-.33	31
4	-.28	34
5	-.16	24
6	-.20	21
7	.23	12
End of Therapy	-.18	25
Follow Up	-.36	17
Ability to Eat		
Week 1	-.55*	32
2	-.20	33
3	-.33	31
4	-.23	34
5	.07	24
6	-.38	21
7	.45	12
End of Therapy	-.19	25
Follow Up	-.31	17

*$p \leq 0.05$

The eighth hypothesis states that there is a relationship between factors interfering with normal dietary intake and anorexia. Results are summarized in Table 4.22. The extent of factors interfering with normal dietary intake is defined as the score on the anorexia tool formed by averaging the scores on all of the anorexia subscales. This weekly anorexia score was examined in relation to appetite, ability to eat, and percentages of recommended caloric and protein intake. Correlations of interfering factors with appetite were generally high and statistically significant during the first 6 weeks of therapy. Correlations between interfering factors and the ability to eat were statistically significant throughout the study period. In both cases, as interfering factor scores increased, appetite and the ability to eat decreased. The correlations between interfering factors and percentages of recommended caloric and protein intake were fairly low, and only statistically significant at the fourth week for both caloric and protein intake recommended percentages and at the end of treatment for percentage of recommended protein intake only. These relationships were generally negative, that is, as interfering factors increased, percentage of caloric and protein intake decreased. In summary, the eighth hypothesis was upheld in relation to subjective anorexia (patient rating of appetite and ability to eat) and not upheld in relation to objective anorexia (evaluation of dietary intake).

Table 4.22

Correlations Between Extent of Side Effects,[a] and Anorexia[b]

Time	r	n
Appetite		
Week 1	-.41*	37
2	-.52*	37
3	-.60*	37
4	-.49*	38
5	-.42*	29
6	-.39*	26
7	-.32	17
End of Therapy	-.29	38
Follow Up	-.27	24
Ability to Eat		
Week 1	-.52*	37
2	-.59*	36
3	-.63*	37
4	-.67*	38
5	-.54*	29
6	-.74*	26
7	-.56*	17
End of Therapy	-.63*	38
Follow Up	-.39*	24

Table 4.22 (Continued)

Time	r	n
% of Recommended Caloric Intake		
Week 1	.10	36
2	.29	35
3	-.15	37
4	-.36*	38
5	-.23	28
6	-.30	23
7	-.20	16
End of Therapy	-.25	37
Follow Up	.20	22
% of Recommended Protein Intake		
Week 1	.06	36
2	.08	35
3	-.16	37
4	-.37*	38
5	-.27	28
6	-.33	23
7	-.26	16
End of Therapy	-.32*	37
Follow Up	.00	22

* $p \leq 0.05$
[a]Combined Scores from Anorexia Subscales
[b]Appetite, Ability to Eat, % of Recommended Caloric Intake, % of Recommended Protein Intake

Weight Locus of Control

The ninth and tenth hypotheses relate to the independent variable weight locus of control and the ability of the patient to learn about supporting oral intake during radiation therapy, and to carry out self care behavior in relation to side effects experienced. The ninth hypothesis states that there is a relationship between the perception of control and knowledge on how to maintain dietary intake. Locus of control was measured on the Weight Locus of Control scale (Saltzer, 1982), which is a short scale composed of four items with two internally worded items and two externally worded items (Appendix Q). The tool was scored in the external direction with the scoring reversed for the internal items. Minimum score is 1 and, maximum score is 100. Thus, the higher the score, the more external the subject's perception of weight locus of control. The average score for the study population was 30.4 with a standard deviation of 21.5 and a range of 0 to 93.7. It appears that the majority of the population was internally oriented with respect to weight. The relationship of weight locus of control perception with knowledge scores at the beginning and end of therapy is summarized in Table 4.23. At the beginning of therapy, the correlation was high ($r = -0.40$) and statistically significant ($p. < .05$). The correlation was still fairly high at the end of therapy ($r = -0.33$) but no longer statistically significant. Weight locus of control ratings showed a population which was predominantly internally focused in relation to weight; that is, the population felt at the beginning of the study period that they were able to play a major part in their own weight control. This was reflected in the positive correlation between knowledge and weight locus of control scores.

The tenth hypothesis states that there is a relationship between the perception of control and self care. The number of subjects reported is low because the self care ratios were calculated only on those patients who reported side effects and omitted those who did not report side effects or simply did not fill out the self care log. In addition, only those subjects who completed the Weight Locus of Control instrument could be used and that included 36 of the 41 subjects. No consistent pattern of relationship between weight locus of control and self care during radiation therapy was evident (Table 4.23). Because self care ratios were calculated using side effects reported by subjects and some of these side effects were not directly related to dietary intake (e.g. eye irritation), further analysis for hypothesis ten involved analyzing the number of side effects related to dietary intake in relation to WLOC scores. Analysis revealed no significant differences in WLOC for any number of side effects reported.

Table 4.23

Correlations Between Weight Locus of Control and Knowledge About Maintaining Dietary Intake, and Self Care Ratios, Beginning of Therapy, End of Therapy and Follow Up

	r	n
Knowledge Scores		
Beginning of Therapy	-.40*	31
End of Therapy	-.33	26
Selected Self Care Activities		
Beginning of Therapy	-.23	20
End of Therapy	-.32	17
Follow Up	-.43	6
Total Self Care Activities		
Beginning of Therapy	.04	21
End of Therapy	.05	18
Follow Up	-.52	6
Effectiveness of Self Care		
Beginning of Therapy	.25	19
End of Therapy	-.22	17
Follow Up	-.18	6
Final Effectiveness of Self Care		
Beginning of Therapy	.12	19
End of Therapy	-.31	17
Follow Up	-.20	6

*$p \leq 0.05$

CHAPTER 5

DISCUSSION OF FINDINGS

Validity Issues

It is difficult to control the many patient characteristics and extraneous variables that may threaten the validity of a clinical study. The randomization process involved in implementing a quasi-experimental design is carried out in an attempt to equalize variables across the experimental and control groups. This is especially crucial for variables that may have major influence on the dependent variables of the study and variables whose influence is unknown. In this study two major and uncontrolled variables differed significantly between the experimental and the control groups: history of weight loss, and the amount of radiation administered. Analysis showed that the experimental group had lost a significantly greater amount of weight prior to the onset of the study as compared to the control group (5.4 kg versus 2.5 kg, $p=0.05$). In addition, the experimental group received a higher dosage of radiation treatment over more treatment days to site 2 of the radiation field as compared to the control group ($p=0.03$). Both of these factors have been linked in past studies to increased risk for nutritional depletion during radiation therapy (Donaldson, 1984). Thus it appears that the experimental and control groups were not equal, and furthermore it appears that the experimental group was more vulnerable to nutritional depletion during radiation treatment than was the control group. These differences were confirmed by the lower scores at the onset of the study by the experimental group in relation to appetite and the ability to eat (Table 4.8). Lower scores confirmed that the experimental group began the study in a more compromised condition in relation to nutritional status as compared to the control group.

Another factor to be considered in relation to the validity of the study has to do with the size of the sample completing the study. The planned sample size of a minimum of 54, was calculated in order to identify a difference of weight loss (the major dependent variable) with an alpha=0.05 and beta=0.08. Despite access to subjects in more sites than originally planned, and over a longer period of time than originally planned, only 41 subjects were accrued to the final sample. This sample size decreases the possibility of detecting differences between the two groups, and decreases the generalizability of study findings.

An additional characteristic of the study which threatens the validity of the data is the amount of missing data present. Missing data occurred because of fatigue and because of transportation problems which prohibited the patient from coming early or staying for a period of time after therapy to fill out data collection instruments. When possible, questionnaires were sent home with patients and included self-addressed, stamped envelopes for ease in return. Many patients completed questionnaires in this fashion. Some, however, lost questionnaires, forgot about them, or simply ignored them. It is with these validity issues in mind that the interpretation of the study results is made.

Limitations

The findings of this study are influenced by a number of limitations related to the design selected, the settings used, the population under study, and the instruments available.

Design

The characteristics of the quasi-experimental design selected include randomization, manipulation, and some control. A convenience sample of eligible subjects was randomized to the experimental or the control group. Because a convenience sample not a randomly selected sample was studied, generalization of the findings are limited to populations similar to those studied. While many of the demographic characteristics were typical of populations of patients with head and neck cancer, (Table 4.1) it is possible that characteristics typical of the larger population of head and neck cancer patients were not equally distributed between the experimental and the control groups.

A convenience sample also includes some degree of self selection by the subjects. Thus, those who participated in the study may be subjects who want to carry out self health measures, and who are more interested in learning to take care of themselves when compared to the population at large. This again limits generalization of the findings to the overall population of head and neck cancer patients.

The quasi-experimental design does provide control over some characteristics, such as the eligibility criteria; e.g. patients had to have a history of no previous radiation therapy, have the ability to speak and write English, not have any complicating metabolic diseases that could interfere with nutritional status, and had to have a functional gastrointestinal tract. Some characteristics were not controlled such as age and sex, and thus either of those variables has a potential interfering effect with the study findings.

Manipulation, the third characteristic of the quasi-experimental design refers to the manipulation of specific independent variables. In this study the independent variable, structured teaching program, was manipulated by assigning subjects to the structured teaching program or the "usual" care. Limitations to this manipulation arise from the variety inherent in "usual" care. Thus, some subjects may have experienced "usual" care that was very different from that of the structured teaching program, and some may have received "usual" care very similar to the structured teaching program. Feedback on caloric and protein intake, however, was not part of "usual" care for any subject assigned to the control group.

While random assignment of subjects to the experimental and control groups was not revealed to the usual hospital/clinic staff, and staff were not informed about subject assignment in order to prevent the staff from treating the two groups differently, some staff discovered subjects group assignments when treating patients. In fact, most staff wanted to have all patients be assigned to the experimental condition because they felt that patients should be exposed to the maximum amount of information. Differences in the way staff treated each group may have occurred as staff tried to insure that all patients had maximum amount of information on dietary intake and side effect management.

Setting

The setting used for the study included multiple locations; that is, one radiation oncology department located in a large medical-teaching center, and four private radiation clinics. The nature of this setting limits the ability to assure that the "usual" care across all settings was similar. In all settings, staff carried out reactive approaches to patient teaching - that is, when problems arose, staff taught patients what to do. In a broad sense, the control group can be considered as having reactive teaching as compared to the experimental group who received reactive plus proactive teaching.

Population

Characteristics of the population selected for study produced limitations as well. The study design required patients to participate heavily in data recording and reporting, especially in a written fashion. Thus the resulting participants may be more literate and verbal than the overall population.

The population selected, patients with head and neck cancer, have a high incidence of alcohol abuse. This was present in the medical history of the population participating (Table 4.1). Within this background there are many persons whose alcoholic intake produces behavior which would jeopardize the accuracy of the data collected. In addition, while the ability to read and to write English were prerequisites, some patients were not as capable as they indicated. These subjects were helped to fill out all possible data collection instruments, but priority was given to the anorexia tool, the nutrition tools, and the dietary intake tools, resulting in missing data for some of the subjects regarding other variables.

The study findings were also limited by the fact that data collection required a great deal of patient involvement and energy. The energy level was expected to drop for all participants by the time therapy ended, and this drop was expected to result in missing data as the study period progressed.

Instruments

Many of the instruments, by their very nature, produced limitations to the study findings. Nutrition has no direct measurement, thus several measures were selected and many of them were not very sensitive. The anorexia tool was a new tool and had only been used previously in one pilot study. Also, many of the instruments used were patient rated, and thus limited by the honesty and interest of the participants.

Knowledge of participants was rated on a knowledge test. Some participants did not like being 'tested' on their nutrition knowledge, and would not fill out the knowledge test. Other participants appeared to have some cognitive or language difficulties, and were unable to figure out how to answer the questions.

The functional status instruments selected were not very sensitive to changes seen by clinicians in patients undergoing radiation therapy. Measurement of functional status was thus limited.

Interpretation of Results

Hypothesis 1

Partial support for hypothesis 1 was obtained. The experimental group demonstrated greater knowledge of dietary intake by the end of the study than did the control group. Thus it appears that the experimental group gained information from the structured teaching program which increased their knowledge, and that this knowledge was retained over the study period. No differences in side effects reported or managed were revealed. The experimental group was able to ingest a consistently higher but not statistically greater mean percentage of recommended caloric and protein intake than the control group. This occurred despite the trend of greater interference with both appetite and the ability to eat in the experimental group. Differences between groups were not evident in the aspects of self care analyzed.

Previous studies involving nutritional counseling and education have not reported the impact of the program on patients' knowledge of nutrition (Chencharick & Mossman, 1983; Daly et al., 1984; Enig et al., 1986; Hamill, 1978). While some participants in this study had difficulty with the knowledge test, enough subjects completed the test to make analysis possible and even show some group differences. Results of this study confirm the clinical opinion that cancer patients can gain valuable knowledge when exposed to nutrition counseling and education programs (Dwyer, 1986).

Results of dietary intake were less than that reported by Daly and Associates (1984). In that study subjects were randomized to an oral intake group which averaged 75% of the recommended 40 KCal/kg of body weight and an enterally fed group which averaged 97.5% of the recommended 40 KCal/kg of body weight. The present study had no patients on enteral feeding. Weekly mean percentage of recommended intake ranged in the experimental group from 61% in week 5 to 84% in week

2, and in the control group from 49% at end of treatment to 59% at the start of treatment (Table 4.8). While the experimental group in the present study did significantly better than the control group, caloric intake did not begin to match that ingested by both groups in the Daly et al study (1984).

In summary, it appears that despite an anticipation that the experimental group would be more vulnerable to nutritional depletion during this treatment period, because of the history of weight loss and the more extensive radiation treatment, nutritional intake remained higher and more nutritious in the experimental group than in the control group. Important aspects of the structured teaching program as reported anecdotally by subjects included the nutrition knowledge, the list of side effects with related care, and the analysis of protein and caloric intake. Patients looked forward to the dietary intake evaluation, and examined it carefully to see how close they came to the calorie and protein recommendations.

<u>Hypothesis 2</u>

Hypothesis 2 was partially supported in relation to the impact of the structured teaching program on nutritional status, and not supported in relation to the impact of the structured teaching program on functional status, treatment response, or quality of life. Nutritional status is a difficult state to measure (Heber, et al, 1986). The results of this study however, confirm the clinical usefulness of weight and weight change as a clinical parameter useful in measuring nutritional status. History of weight change was information that all study participants were able to recall. Weight changes during a study period are fairly easy to obtain, and demonstrate gradual changes over time. Because radiation therapy is a treatment that extends a minimum of 6 weeks and as long as 8 or more weeks, weight is an appropriate monitor of nutritional status.

In this study, weight loss prior to the onset of the study was significantly more in the experimental group (8.5% of usual) as compared to the control group (3.4% of usual). These losses were less than that found by Bassett and Dobie (1983) wherein 32% of the sixty patients studied lost 15% of their body weight prior to the beginning of therapy. From this study and the present study it can be anticipated that patients admitted for radiation therapy for head and neck cancer may begin therapy with a history of considerable weight loss which can potentially threaten nutritional status.

One would expect the experimental group to perform poorly in respect to nutrition status during the study period considering their status at the onset of the study. On the contrary, weight loss during the study period proceeded at approximately the same rate for the experimental and the control groups. It appears that the structured teaching program led to the experimental group losing no more weight than the control group, despite a propensity for the experimental group to experience more nutritional depletion based on historical weight loss and receipt of a higher number of rads to the second radiation site.

These results are in agreement with findings by Hamill (1978), Chencharick and Mossman (1983) who found value in the nutritional counseling approach for patients undergoing radiation therapy for head and neck cancer. None of these groups however, have done as well as the enterally fed group in the Daly et al (1984) study.

It is noteworthy that weight loss continued for both groups through the follow up period. Apparently the study period was not sufficiently long enough to reveal the point of time when recovery of weight begins, if in fact it does.

In previous studies of patients undergoing radiation therapy for head and neck cancer, patterns of weight loss have varied from one study to another. In a study of 31 patients, Johnston et al, (1982) found that weight loss continued for the majority of patients until 6 months past therapy. In contrast, Chencharick and Mossman (1983) followed a group of 74 patients and reported that 90% of the subjects had a weight loss of 5 kg prior to therapy but weight stayed the same across the group during therapy.

Other measures of nutritional status, namely triceps skinfold, mid arm muscle circumference, and hand strength were not sensitive to changes in the two groups. The lack of sensitivity of anthropometrics as body fat measures and somatic protein stores paralleled findings of Enig et al, (1985). Changes in these parameters may be more evident over longer periods of nutritional depletion. Hand strength measurement had not been used in the reviewed studies.

Functional status did not differ between the experimental and the control groups even though several measures were used to measure it. The Katz activities of daily living tool was not sensitive to changes in either group, as evidenced by the fact that only 4 subjects showed any change at all during the study period. It was hoped that the items on the Quality of Life Index which referred to functional status would pick up group differences. Decreases in both ability to work at usual daily tasks, and strength occurred in both groups, but no significant differences occurred between the two groups. The fatigue scale from the Profile of Mood States was examined to see whether it was sensitive to any group differences. The increase in fatigue score for the experimental group was larger (from 7.8 to 9.3) than for the control group (5.1 to 5.3), but these differences only approached significance ($p=0.15$ at the beginning of therapy and $p=0.07$ at the end of therapy). Most staff involved in the clinical care of patients receiving radiation therapy report that patients begin therapy with an adequate functional status, but within the first few weeks for some and by the last week for almost all, patients become very fatigued and are barely able to do more than get themselves to and from therapy each day. The functional status tools selected for this study did not demonstrate the decrease in functional status expected. Instruments more sensitive to the changes observed anecdotally would make an important contribution to the tools used to assess patients' responses to radiation therapy.

Treatment response was measured at the end of the therapy period. No differences between patients' responses to treatment between groups occurred. Subjects, however, may not have been followed for a sufficiently long enough period of time following completion of treatment. Recurrence would not be apparent in the time period covered in this study. Treatment response at 6 month following therapy and 12 months following therapy may have revealed potential differences in the groups.

The lack of relationship between nutritional status and treatment response is not surprising. In general prospective randomized studies of various kinds of nutritional interventions for patients undergoing radiation therapy have failed to demonstrate any impact on treatment response or treatment tolerance (Donaldson, 1984).

The quality of life measurement did not reveal differences between the two groups. When the quality of life scores were compared with other previously studied populations of cancer patients, the means of both the experimental and the control group in the present study fell into a range similar to hospitalized cancer patients in other studies (Padilla et al. 1983). The hospitalized patients in the other studies constituted the most ill of the populations studied and reported the poorest quality of life. The means of quality life scores of both groups in the present study were lower than the means reported by previous populations of ambulatory cancer patients undergoing radiation therapy for pelvic cancer (Padilla et al. 1983). Thus, while quality of life scores did not demonstrate differences between groups in the present study, they did demonstrate the tremendous impact on quality of life for patients with cancer of the head and neck region.

To summarize the partial support for Hypothesis 2 came from the finding that the experimental group lost no more weight during the study period than did the control group. Differences between groups for other nutritional parameters were not shown. However, they did not appear as sensitive to changes throughout the study period as was weight. There was no support for differences between groups on functional status, treatment response, or quality of life.

Hypothesis 3

There was no support for Hypothesis 3, that older patients have a greater number of factors interfering with normal dietary intake as compared to younger patients. The factors were reported via patients' self care diaries. It appears that the method of evaluation does not detect age-associated differences if such exist. In addition, the sample studied may have been too small to detect differences based on age, and older patients may simply report a lower number of side effects than younger patients.

Hypothesis 4

There was no support for Hypothesis 4, that older patients have a greater extent of factors interfering with normal dietary intake than younger patients. The instrument used to measure extent of factors was the total score of the anorexia tool, and included subscales on appetite-hunger, oral-gustatory factors, general symptoms, psychological factors, and sociocultural factors. A lack of support for this hypothesis may have been related to the small sample size and the insensitivity of the instrument used to measure extent.

Hypothesis 5 and 6

Both Hypothesis 5 and Hypothesis 6 refer to differences in self care activities and management in relation to age. There was no support for these two hypotheses. The instrument used to measure self care did not pick up any differences related to age. In addition, when side effects related to dietary intake were examined in relation to age, no statistical relationship was revealed. In summary, study findings did not suggest age differences for factors interfering with normal dietary intake or various aspects of self care.

Findings of Hypotheses 3 through 6 are in accordance with those of other studies of head and neck cancer patients. Johnston et al. (1982) did not demonstrate an age difference in the 31 patients followed, nor did Daly et al. (1984) and Enig et al. (1985). Nevertheless, studies on aging indicate that increased factors potentially interfering with oral intake are present in the older patient (Baum, 1981; Grzegorczyk et al, 1979; Siurala, 1968). Upon closer examination, it is noted that some of these changes are evident above the age of 60, (e.g. decreased stomach secretions) whereas others are apparent above the age of 70 (decreased intestinal enzymes, esophageal motility). It is possible that the study population did not include a sufficient number of patients over 70 years of age. It is also possible that older patients simply do not report and record information as much as younger patients despite the occurrence of more problesms.

Hypothesis 7

There was some evidence to support hypothesis 7, that there is a relationship between the number of side effects and anorexia. These data were patient reported from two different tools - the anorexia tool and the patient self care diary. A trend towards a negative relationship was evident, as side effects increased, anorexia decreased. This is an expected outcome as indicated by similar findings by Chencharick and Mossman (1983) and Johnston et al. (1982).

These results indicate that the anorexia instrument shows beginning promise as a valuable measure of anorexia in head and neck cancer patients undergoing radiation therapy.

Hypothesis 8

Hypothesis 8, that there was a relationship between the extent of side effects and anorexia, was supported. Support was consistent throughout the study period for the relationship of the ability to eat to the extent of side effects, and consistent for the first 6 weeks of the study period for appetite. Findings appear to indicate that side effects experienced during radiation therapy, do, indeed, have an impact on anorexia, with a strong impact on the patient's physical ability to eat, and a moderately strong impact on the patient's perception of appetite.

When the results of Hypothesis 7 and 8 testing are considered with the results of the validity of the anorexia subscale on oral-gustatory factors, the value of the anorexia instrument in head and neck cancer patients undergoing radiation therapy is confirmed. Results of this study add further validity to the development of the anorexia tool. (Grant, 1985). This subjective tool rated by the patient provides information on appetite and ability to eat as well as other problems that could interfere with dietary intake. These aspects reveal topics for future studies.

Hypothesis 9

Hypothesis 9 was partially supported by the data. The relationship between the nature of control in the study population, which was one of predominantly internally oriented control and the scores on the knowledge test given at the onset of therapy were significantly negative. This relationship diminished by the end of therapy but this may have occurred because of less subjects completing the knowledge test at the end of the treatment period. One has to wonder whether a tendency toward internally oriented control would change when patients are confronted with the large external force of radiation therapy.

Hypothesis 10

Hypothesis 10 was not supported by the data. No evidence was found for a relationship between WLOC and self care activities or management. Future studies would be needed to reveal whether this relationship does not occur, or was not measured by sensitive enough instruments. The weight locus of control instrument appears to be sensitive to changes in the state of control experienced by the subject as is evident in Saltzer's previous work (1982) wherein weight locus of control is viewed as a changing predisposition rather than a static characteristic. Multiple measurements with WLOC across the radiation treatment and follow up period would be needed to demonstrate such a dynamic characteristic.

In summary, results of this study show moderately strong support for the use of the major independent variable, structured teaching program and support for the continued development and use of the anorexia scale. Age, as an independent variable influencing nutritional reactions of patients undergoing radiation therapy was not supported, and needs further development of more sensitive measurements and with more vulnerable populations such as those above the age of 75. Locus of control, as an independent variable, shows initial trends in relation to nutrition knowledge, pointing to the need for more extensive measurement to tease out the significant aspects of this concept in the management of patients with head and neck cancer undergoing radiation therapy.

Theoretical Considerations

The theoretical relationships that provided direction for the design and conduction of this study can be evaluated in relation to the study findings. These findings are relevant to the redundant food intake model, the impact of cancer and cancer treatment on food intake, the concept of anorexia, the impact of nutritional status on specific study outcomes, and the relationship of age and locus of control to the concept of anorexia and the impact of cancer treatment on nutritional status.

The redundant food intake model describes the biopsychosocial factors that appear to be influencial in maintaining dietary intake (Figure 2.1). The teaching program developed and tested in the present study included biological or physical recommendations such as oral care, psychological recommendations such as ways to reduce tension, and recommendation for sociocultural foods and familiar eating settings (Figure 2.6). While the content of this teaching program was only one aspect of the structured teaching approach, the success of the program on maintaining a more nutritious intake in the experimental group gives support to this biopsychosocial approach.

The sensitivity of the anorexia tool used in the study gives further support for the usefulness of the redundant food intake model. The anorexia tool was comprised of linear scales on appetite and ability to eat, followed by linear scales which provided the subject with an opportunity to relate various biopsychosocial factors to appetite problems (Appendix H). Analysis of Hypothesis 8 revealed significant correlations between the measurement of appetite and ability to eat to these various factors. Further analyses and testing to identify the influence of the physical versus the psychological versus the sociocultural aspects would be an appropriate next step in future testing of the redundant food intake model.

Study findings give support to the impact of cancer and cancer treatment on nutritional status. While this relationship has been described in a number of previous studies (Donaldson, 1984; Heber et al; 1986; Kaminski et al;

1982), the present study findings provide further information on the nature of the weight loss reported by others. The history of weight loss present at the onset of therapy confirms the impact of cancer on body weight and leads to the conclusion that changes have occurred in dietary intake, digestion and assimilation, and/or metabolic needs prior to diagnosis. Subjects' evaluation of their present appetite and ability to eat at the start of therapy as compared to their usual perceptions of these sensations revealed a lowered score at study onset (Table 4.8). In other words, the population studied demonstrated the influence of cancer of the head and neck area on nutrition status prior to the onset of treatment. The impact of cancer treatment in the population studied was revealed by the steady weight loss that occurred during treatment for both the experimental and the control group (Table 4.11).

Study findings also provide a valuable contribution to the definition of anorexia as a concept related to nutrition status changes in head and neck cancer patients. Various definitions of anorexia have been developed (Costa, 1977; De Wys, 1977; Morrison, 1980). Included in the definitions have been the subjective aspects of appetite as perceived by the individual and the objective aspects of decreases in dietary intake. For this study anorexia was defined as a decrease in appetite associated with a decrease in food intake (Figure 2.5). The measurement of anorexia included both of these aspects. Measurement of appetite was separated into appetite and ability to eat. Subjects rated these two aspects separately and differently, although both decreased during radiation therapy (Table 4.8). It appears that both perceptions are important in the occurrence of anorexia in cancer patients. Objective aspects of anorexia measured were defined as actual calorie and protein intake and the percentages of each in relation to recommended standards. Neither the experimental or the control group were able to maintain dietary intake at recommended standards during the treatment period (Table 4.9), thus confirming the occurrence of decreased dietary intake as an important aspect of anorexia. Further support for the need to include dietary intake evaluation in testing interventions for anorexia is evident from the consistently better caloric and protein intake seen in the experimental group (Table (4.9). It appears possible from the results of the study to maintain dietary intake or decrease the expected diminishment of dietary intake during radiation therapy in spite of the occurrence of decreased perceptions of appetite and the ability to eat. In other words the experimental group maintained dietary intake at a level higher than the control group despite losses of appetite and the ability to eat. These changes are reflected in the resulting adaptation of Figure 2.6 found in Figure 5.1. In this new figure, cancer and cancer treatment impact on the redundant food intake model leading a decrease in the ability to eat and a decrease in appetite, while the teaching program stimulates increased

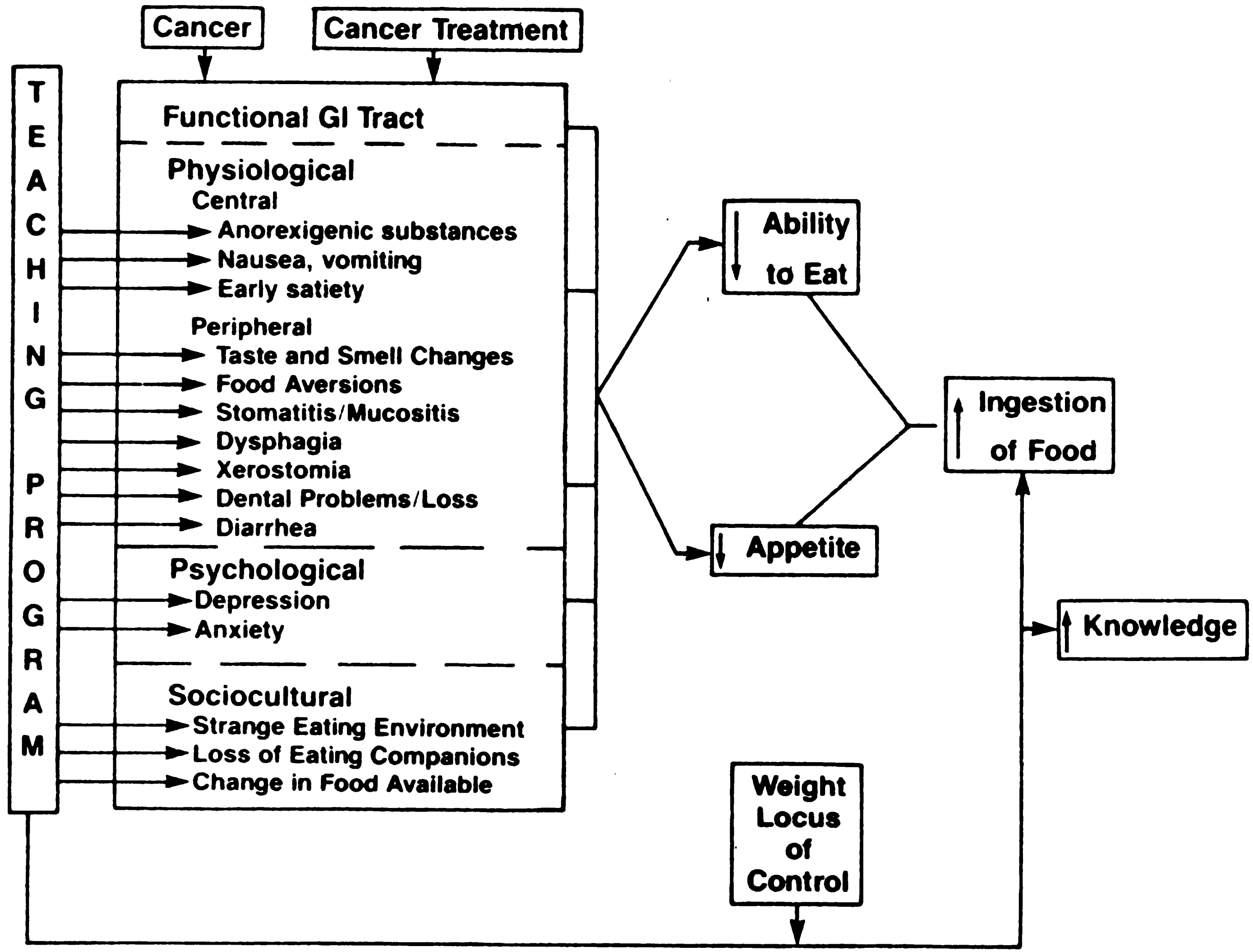


Figure 5:1. Impact of Teaching Program for Patients with Head and Neck Cancer Undergoing Radiation Therapy

nutrition knowledge and increased food ingestion. Age and self care are removed from the diagram. These results point out the need to separate the subjective and objective aspects of anorexia. Separate measurement of each of these aspects is needed in future studies in order to have the results of one study build on other studies.

The findings of the present study were also examined in relation to the impact of changes in nutritional status on functional status, treatment response and quality of life (Figure 2.4). Measurements of functional status proved to be difficult. The Katz activities of daily living tool was not sensitive to the changes anticipated. Examination of two factors on the quality of life instrument related to function - namely the ability to perform usual daily tasks and strength - did not show differences between groups, but did show decreases over the radiation treatment period (Table 4.12). The fatigue scale from the Profile of Moods State showed a trend toward functional status decrease for the experimental group. It appears that functional status does decrease during radiation therapy, along with nutritional status, but instruments to measure this decrease need further development in order to be more sensitive.

Findings on the impact of nutritional depletion on treatment response were not significant. The experimental and control subjects responded similarly. It is likely that no subject experienced sufficient nutritional depletion during the study period to impact on the treatment response, as patients' average percentage or recommended caloric intake ranged from a low of 49 percent to a high of 84 percent (Table 4.9), and percentage or recommended protein intake ranged from a low of 83 percent to a high of 128 percent (Table 4.9). It is also likely that subjects were not followed for a period of time sufficiently long enough to reveal this relationship. Future studies should follow patients at 6 month and 12 month periods following completion of radiation therapy in order to test this relationship more thoroughly.

Findings related to the relationship of radiation treatment and quality of life show a decrease in quality of life scores. No differences in quality of life scores occurred between the experimental group which received the structured teaching program and the control group (Table 4.16). The lack of difference may be again related to low quality of life scores at study onset and to the mild occurrence of nutrition depletion that occurred in both groups. If patients were followed during major disease progression, the relationship between nutritional depletion and decreased quality of life may become stronger. Future studies should follow patients for longer periods of time and during periods of rapid disease progression in order to further examine this proposed relationship.

Theoretical consideration in relation to aging and its impact on nutritional depletion in patients undergoing cancer and cancer treatment are identified in Figure 2.3. Results of this study do not provide any insight on the accuracy of the theoretical consideration in relation to aging. Confirmation or refutation of the aging perspective awaits future studies. The theoretical considerations of weight locus of control and the relationship to the present study relate to the ability of the subject to learn about supporting oral intake during radiation therapy and the carrying out of self care behaviors related to experienced side effects. Study findings revealed an internally oriented population sensitive to the weight locus of control scale. Further examination of this concept in other populations of patients undergoing cancer treatment may reveal characteristics helpful in planning nutrition interactions.

In summary, findings of the present study have provided some evidence for the further study of the theoretical relationship proposed. Of particular importance is the confirmation of both objective and subjective aspects of anorexia, and the need to include both aspects in future studies.

Implications for Nursing

Results of this study have implications for nursing practice and nursing research. The results support the use of a structured teaching program for maintaining nutritional intake during radiation therapy for head and neck cancer. This structured teaching approach should include an audio visual program on common problems and their treatment recommendations, written guidelines for self care of nutrition problems, specific recommendations for protein and caloric intake, and feedback on dietary intake analysis regarding the calories and protein being ingested.

Patients participating in this study who were in the experimental group repeatedly told the investigator and the other data collectors that they appreciated the information on caloric and protein intake from analysis of dietary intake. When confronted with a factual approach which revealed exactly what they had eaten and the exact amount of calories and protein ingested, patients were able to continue ingestion of nutritious foods, and add others that were nutritious in order to meet the recommended intake standards. Patients could clearly see the impact of adding, for example, one egg to their daily intake. Such feedback for other patients vulnerable to nutritional depletion may be valuable intervention for nurses to implement. Coordination with the dietitian would provide a potentially more cost effective approach to the implementation of this intervention.

Results have implications for nursing research as well. The theoretical basis for this study included a redundant model for dietary intake. The study capitalized on this theoretical approach by creating an audiovisual program which included physical, psychological, and sociocultural problems and approaches reflecting the redundant model. Within this theoretical perspective, the structured teaching program showed its effectiveness. This approach could be used for additional patient populations experiencing oral intake problems, as well as for other problems for which a redundant explanatory model is evident.

Recommendations for Future Research

Both replication and follow up studies are needed. Replication should include another group of head and neck cancer patients, examined for a longer a period of time. Extensions of the study should include following subjects for at least a year post therapy in order to identify when weight loss stops, and how long nutritional repletion takes. Future studies should continue to explore other parameters for evaluating nutrition status, but include accurate measurement of weight prior to, at the onset and throughout therapy and at follow up.

Future studies should stratify for history of weight loss, in order to avoid the differences in experimental and control groups that occurred in this study. Stratification should also include radiation therapy projections regarding rads and treatment days. Use of WLOC as a repeated measures test throughout radiation therapy is needed to demonstrate whether changes within patients occur. Additional recommendation for future research have been identified above under theoretical considerations.

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APPENDICES

APPENDIX A

MEASUREMENT OF ENERGY EXPENDITURE IN HOSPITALIZED PATIENTS

Energy required daily for metabolic processes, homeostasis, repair of tissues, maintenance of body temperature, and usual physical activity is obtained through ingestion or infusion of sufficient kilocalories (Silberman and Eisenberg, 1982). The amount of kilocalories and of protein needed is determined by the amount of energy expended in the body. Several methods are available to calculate calories needed daily. The most direct method for calculating the amount of energy expended daily is through direct chamber calorimetry. This method is based on the law of conservation of matter and energy wherein matter can be transformed from one form to another, but is not lost or gained. In direct calorimetry the assumption is made that the amount of heat produced should be equivalent to the amount of energy required for equilibrium (Silberman and Eisenberg, 1982). Thus, the patient is placed in an insulated chamber and heat loss is computed by using data from changes in the temperature of water and air which circulate through the chamber, and by the analysis of the water vapor (Wilmore, 1977). This method involves elaborate equipment and facilities as well as subjects able to endure the discomforts associated with confinement. Direct calorimetry is not a method of practical value in the clinical situation or for estimating energy expenditure in ill patients.

Indirect calorimetry is another method, and involves determination of energy expenditure from data on gas exchange. When the body is in a steady state, the amount of oxygen consumed and the amount of carbon dioxide produced are related quantitatively to the release of energy from the body. In direct calorimetry, the measurement of inspired oxygen (VO2), expired carbon dioxide (VCO2), and excreted nitrogen are needed. The nitrogen is obtained via urinary nitrogen and is required because protein is not completely oxidized at the cellular level, but urea produced is a metabolic end product. The three measurements obtained, oxygen consumption, carbon dioxide production, and urea production are then analyzed using Weir's formula for calculation of metabolic free energy conversion (Weir, 1949).

A recent approach to the bedside measurement of indirect calorimetry involves use of a portable cart called the Metabolic Measurement Cart (Beckman Instruments, Anaheim, California). This instrument measures the partial pressure of oxygen and carbon dioxide in mixed expired air, volume temperature, time and barometric pressure (Feurer, 1983). These data are fed directly into a programmable calculator which determines and prints out at one minute intervals oxygen consumption, carbon dioxide production, minute ventilation, and respiratory quotient. The calculator signals when the steady state has been reached and then calculates the metabolic rate.

When indirect calorimetry is determined under "basal" conditions, the basal metabolic rate (BMR) is obtained. Basal is defined as obtained when a recumbent subject who has been an overnight fast is measured in a darkened room (Kirkpatrick, 1983). If measurements are made on persons in a normal life situation while at rest and under conditions of thermal neutrality, the resting metabolic expenditure (RME) is obtained (Silberman & Eisenberg, 1982). BMR and RME are frequently but inaccurately used interchangeable in the clinical situation.

One of the oldest and still clinically useful methods of estimating daily caloric need is the Harris-Benedict formula, which is an age and sex specific formula that includes measurements of height, weight, and age as follows:

Men: RME (kcal/day) = 66.4730 + 13.7516 (W) + 5.0033 (H) - 6.7550 (A)

Women: RME (kcal/day = 655.095 + 9.563 (W) + 1.8496 (H) - 4.6756 (A)

Additional calories are added to the Harris-Benedict calculations to provide for whatever level of physical activity is present. In the formula, (W) stands for actual body weight in kilograms, (H) stands for actual body height in centimeters, and (A) stands for age in years (Harris & Benedict, 1919). Determination of energy requirements as predicted from the Harris-Benedict formula closely approximate the RME of healthy persons using indirect calorimetry (Long, Schaffel, Geiger, Schiller, & Blakemore, 1979). Additional work by Long has resulted in a number of correction factors to account for additional energy demands during specific disease conditions (Long et al, 1979). Patient groups tested have included burn patients, sepsis-peritonitis patients, trauma patients, and elective surgery patients. Information on cancer patients is not yet available.

APPENDIX B

FUEL SOURCE CHANGES DURING STARVATION

The absorptive phase of metabolism refers to that time during which food is present in the gastrointestinal tract and is being absorbed for normal daily metabolic need (Meguid, Collier, & Howard, 1981). The basic fuel source during this time period is blood glucose; glucose is absorbed from the gastrointestinal tract and used directly by cells for oxidation. Excess glucose not used for cellular oxidation is 1) stored as glycogen in the liver, muscle tissue, bone marrow, renal medulla, and other glycogen storing organs, and 2) converted into fats and stored as adipose tissue. Fatty acids that are absorbed from the digestive tract are stored in adipose tissue as well. The amino acids that are absorbed are used directly by the cells in the synthesis of proteins, and also are converted to keto acids by the liver, which are then either used by the liver for energy or converted to fats (Stein & Buzby, 1981).

During the postabsorptive or fasting state, absorption of glucose, amino acids and fatty acids from the gastrointestinal tract no longer occur. Instead, glycogen stores in the muscles, liver, and from other glycogen stores in the muscles, liver, and from other glycogenic tissues are used to provide glucose for cellular oxidation. This state occurs during an overnight fast in normal individuals. If the fast persists for 2-3 days, the glycogen stores are depleted and the acute starvation phase begins. Amino acids begin to be used to provide glucose for cellular oxidation. These amino acids are released from peripheral tissues, taken up by the liver and converted to glucose, with accompanying production of urea as a waste product. Alanine and glutamine comprise the majority of amino acids used in this fashion (Meguid, Collier, & Howard, 1981). The increased amount of urea found in the urine is illustrative of the negative nitrogen balance present. Rapid proteolysis occurs and glucose is still the major fuel source for tissues. However, it is derived from amino acids via the process of gluconeogenesis. If this stage were to continue, 15% of the total muscle mass would be lost in 10 days and 30% would be lost in 20 days (Brennan, 1977).

Acute starvation is replaced by a starvation adaptation in which metabolism of fats provides the fuel source for cellular oxidation. An important change occurring in this phase is the ability of the brain to switch from glucose to ketones as the major source of fuel (Young, 1977). During this stage the patient lives off stored energy or fatty tissue and gluconeogenesis is decreased. In the chronically starving man, only 2% of the total body muscle mass will be lost in a 20 day period of starvation adaptation (Brennan, 1977). The net result of this adaptation is a sparing of protein. If the individual has large stores of fatty tissue, and adequate water is provided, starvation can continue for a long period of time without disastrous results.

The pattern of starvation is quite different in patients undergoing major stress, such as multiple trauma or an extensive burn injury. Such stresses produce a hypermetabolic state and weight loss is profound (Meguid, Collier & Howard, 1981). For example an uncomplicated long bone fracture can increase the resting metabolic expenditure by 15 to 30%, multiple injuries can increase it by 50 to 100% (Kinney, 1972). The switch from glucose to ketone as the primary fuel source does not occur, and glucose continues to be provided through gluconeogenesis. Starvation in the stressed individual obviously follows a different pattern from that seen in starvation adaptation. For these patients a 23% loss of total lean tissue mass will occur if the situation continues for a 10 day period (Brennan, 1977). This is a most drastic loss as compared to the phases of acute starvation and starvation adaptation.

The outcome of starvation and loss of lean tissue mass is seen clinically as a loss of weight. It has been predicted that death for the patient occurs when the weight loss reaches 30 to 50% (Figure A-1); however, the rapidity and severity of the weight loss is more predictive than the actual amount of weight lost (Brennan, 1977).

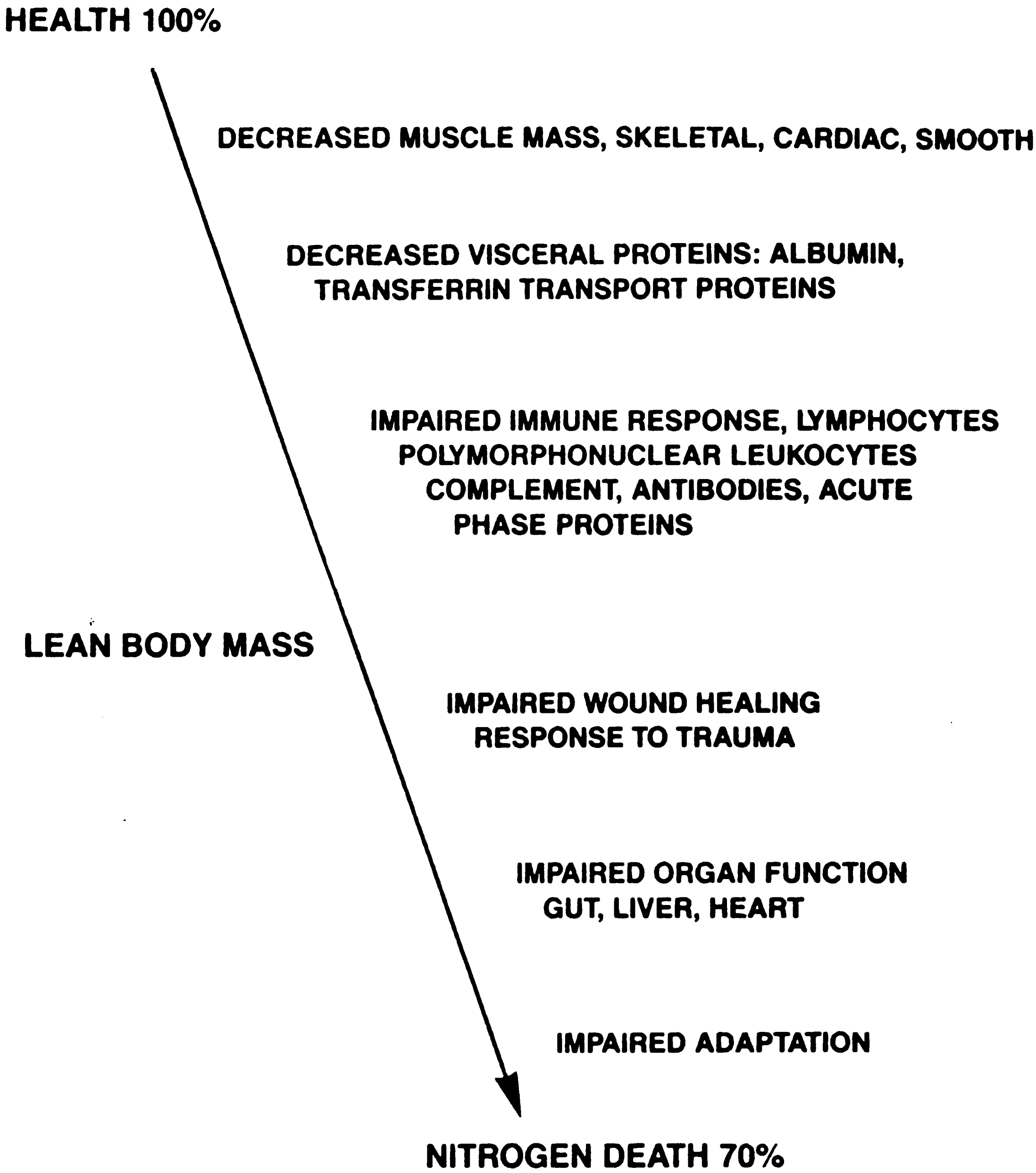

Figure A:1. Clinical Effects of Loss of Lean Body Mass*

*Adapted from Steffee, W.P. (1980). Malnutrition in hospitalized patients. *Journal of the American Medical Association*. *244*, 2630-2635.

APPENDIX C

MEASURING PROTEIN METABOLISM

The oldest method used to measure protein metabolism is nitrogen balance wherein the amount of nitrogen ingested and/or infused is measured and compared to the amount of nitrogen that is excreted via urine, feces, drainages, and other secretions. A correction factor for the nitrogen lost through the skin is usually included. This method was used by Brennan and Burt in studies of the reestablishment of nitrogen balance in malnourished patients repleted via total parenteral nutrition (1981). The major disadvantages of this method are the difficulty of obtaining complete samples of nitrogen output when subjects are located in routine clinical settings, and the difficulty of finding a "steady state" of 2-3 days in each of the subjects (Brennan & Burt, 1981).

An alternative to the classic nitrogen balance studies is the use of urinary urea nitrogen levels to estimate nitrogen output. This calculation includes estimated factors for nitrogen lost through stool and skin. This methodology is accepted only for patients whose losses of nitrogen in stool and fistula, and skin are negligible. A third method involves various radioactive substances for estimation of different body compartments. One of these methods estimates protein metabolism by using radioactive amino acids to determine total protein flux. Assumptions of this method include the need for a steady state of nitrogen in the subjects, and the flux of the amino acid in and out of the body protein pool (Brennan & Burt, 1981).

Still another method used in studies of body protein metabolism is to measure body composition via a potassium isotope. Since most potassium is intracellular, the amount present in the body gives an indication of cellular mass. Total body potassium determinations using radioactive potassium scans have revealed changes in body cell mass before and after nutritional repletion in malnourished cancer patients (Warnold, Lundholm, and Schersten, 1978).

If protein sources (i.e. amino acids) are being metabolised to maintain blood glucose levels, gluconeogenesis is occurring and the body is in a state of potentially rapid weight loss (Kurzer & Meguid, 1986). This is the state seen in acute starvation, before starvation adaptation has begun. Based on this theory, measurements of radioactive amino acids have been used to demonstrate the extent of gluconeogenesis. By comparing levels of these radioactive amino acids before and after a nutritional repletion intervention, the changes in gluconeogenesis that occurs can be estimated. This method is one of the more recent approaches to protein metabolism measurement.

APPENDIX D

RADIATION THERAPY: AN IMPORTANT TREATMENT FOR THE ELDERLY CANCER PATIENT

Radiation therapy is an important treatment modality for cancer patients. Approximately 48-60% of all cancer patients require therapeutic radiation at some time during the course of their disease (Kramer, S. Hanks, G.E., Herring, D.F., & Davis, L.W., 1982). Radiation therapy is a locally effective treatment, with doses dependent on the size and extent of tumor present. The advantages of radiation therapy include the ability to treat a larger volume of tissue than may be possible to remove surgically. The disadvantages include the prolonged, usually daily, treatment which spans from 4-6 weeks, and the radiation injury to normal tissue (American Cancer Society, 1983).

Therapeutic radiation destroys cells by ionization - i.e. it ejects electrons from atoms or molecules with which it interacts (Prosnitz, Kapp, & Weissberg, 1983). While the biological manifestations of this ionization are very complex, it is thought that DNA is the primary biologic target, thus eliminating the cell's ability to reproduce. Time for destruction is variable depending on the normal tissue present, and the tumor-cell kinetics. The rate of tumor regression is not necessarily related to the potential for cure (Prosnitz, Kapp, & Weissberg, 1983). Tumors of up to 3 cm in size are generally cured with radiation does of from 6000 to 7000 rads over a six to seven week period (Prosnitz, Kapp, & Weissberg, 1983). Daily radiation, or 5 day per week radiation is usual. The intent of radiation therapy for head and neck cancer may be curative, palliative, or adjunctive to surgery (Wang, 1981).

Radiation therapy is an important treatment for elderly patients, especially for those unable to tolerate surgery. In addition the elderly cancer patient may be more likely to present with advanced cancer due to factors which delay seeking care (Kessler & Seton, 1978). Thus, radiation therapy may be the only treatment of choice for these patients.

Elderly patients receiving radiation therapy may be more prone to the side effects of therapy because of physiological changes associated with the aging process. Aging may produce hydroxyl radicals (Sinex, 1977). Aging may also be accompanied by a decrease in free radical scavengers, e.g. antioxidants (Sanadi, 1977), resulting in increased concentrations of circulating free radicals (Groer et al, 1979). These free radicals combined with those produced by radiation increase the potential for cellular damage (Sinex, 1977). Aging also results in a decrease in the ability of the cells to repair themselves (Sinex, 1977). Thus, when radiation is combined with aging changes, patients are at higher risk for developing more pronounced negative sequelae.

In summary, radiation therapy is an important treatment modality for elderly cancer patients. However, it may be accompanied by more severe side effects than those seen in the non elderly population. Little is known, however, about the specific relationships among radiation therapy, aging, anorexia, and treatment outcomes.

APPENDIX E
STRUCTURED TEACHING PROGRAM TEXT

*BETTER NUTRITION DURING RADIATION THERAPY
OR
*WHEN EATING RIGHT IS A REAL JUNGLE

This program contains information about the nutritional aspects of your care during radiation therapy.

Overview of Content

* There are several problems that frequently occur. This program presents several of these problems with things to do to care for them.

Introduction

* During radiation therapy maintaining weight is an important task. You will be given a specific number of calories and a specific amount of protein to eat each day in order to maintain your weight.

* Even if you are overweight, do not try to lose weight while you are receiving radiation therapy. After you finish your treatments, talk with your doctor about losing weight.

Loss of Appetite

* You may find that you will lose your appetite and may lose weight during radiation therapy.

In order to maintain daily calories and protein you can change the way you eat in several ways.

* Eat when you are hungry, even if it is not your usual mealtime.

Eat 6 small meals a day, 3 at the regular mealtime, and 3 between meals.

* Eat concentrated foods, such as Carnation Instant Breakfast, and supplements such as Ensure. Milk shakes, custards, eggnog, or puddings also provide high calories and protein.

* Eat your meals in an attractive setting with good company. Soft music may help make the setting more pleasant.

* Keep snacks that you like on hand. You will be more likely to eat if the food is readily available.

* You may need to take a new approach to eating, and make it a needed part of your treatment.

Nausea, Vomiting	* Some patients experience nausea and vomiting when they get radiation therapy. There are a number of things you can do to eat enough calories and protein even when you have nausea and vomiting.
	* Some patients prefer boiled or baked meats, fish or poultry rather then fried foods. Bland foods generally cause less nausea. Crackers and soda pop are often used when patients are nauseated.
	* Decrease the amount of food you eat just before therapy. Eat small, frequent meals and eat slowly. Note the times of the day when you are least nauseated, and have that be the time when you eat foods that are high calorie and high in protein.
	* Try relaxing 30 minutes before you eat. Concentrate on various muscles - toes, ankles, legs, back, chest, arms, neck - and breath slowly and regularly to relax.
	* Eat in a pleasant room with a nice view and good company. If the smell of food is nauseating, stay out of the kitchen.
	* Report your nausea and vomiting to the nurse or physician and ask for anti nausea medication. Take the medication at least 30 minutes before you eat or as ordered.
Early Satiety	* One of the changes that may occur in your ability to eat during radiation therapy is that you feel full more quickly. It is important to eat enough protein and calories despite this full feeling.
	* Try making breakfast the best meal of the day, since the feeling of fullness often increases throughout the day.
	* Make every swallow count. Use concentrated high protein foods such as milk shakes, eggnogs, or dietary supplements.
	* Reduce the amount of liquid you drink with your meal. Drink fluids 1 hour before or after meals instead.
	* Avoid greasy foods, butter, and rich sauces. These foods make you feel full very quickly.
Taste and Smell Changes	* Changes in taste are experienced by some patients receiving radiation therapy.

Food Aversions	If your taste sensation changes, substitute foods that will provide the same nutritional value.

* If meat doesn't taste right, substitute milk, bland cheese, chicken, fish or eggs. Ask your doctor, nurse, or dietitian to help you make these food exchanges.

* You may want to try eating small, frequent meals. Prepare foods that appear and smell pleasing. A liquid, high protein diet supplement, such as Ensure, may also be used.

* Foods may taste better if cold or at room temperature.

* Changing the seasonings you use on your food may make them taste better. Try basil, rosemary, and other mild herbs.

* The smell of foods cooking may aid in producing a sense of taste. Foods that look appealing may be more appetizing.

Remember to continue to eat even though taste changes may be present.

Stomatitis, Mucositis	* There are several things you can do to make eating easier if your mouth and tongue become sore during radiation therapy.

* If you can, continue to brush your teeth daily but use a soft toothbrush. If brushing is too irritating, rinse your mouth thoroughly before and after meals and more frequently as needed for comfort.

* Use a mouth wash of 1 teaspoon to 1 tablespoon baking soda with or without 1 teaspoon of salt in a quart of warm water.

* If your mouth is sore, avoid hot, spicy, or abrasive foods, such as citrus juices, nuts, crisp vegetables, raw fruits, spaghetti and pizza.

Soft foods and liquids are recommended. Puddings, applesauce, *ice cream, strained cream soups, and custards will be soothing to your mouth. Blended foods, and nutrition supplements such as Sustacal and Ensure can be used to get the calories and protein you need.

* Ask your nurse or doctor for a prescription for medication to swish in your mouth to decrease the

discomfort. Dyclone or xylocaine are used by many patients ten to thirty minutes before eating. They are sprayed, gargled, or swished and bring temporary local relief of pain. Some patients find cool yogurt is soothing.

* If mouth discomfort prevents you from eating enough, be sure to report this to your physician and/or nurse.

Dysphagia

* Some patients find that swallowing problems occur during radiation therapy. If you experience difficulty in swallowing, try eating soft cooked foods cut into small pieces and moistened with gravy, sauce, mayonnaise, or other liquids.

* Because it is difficult to swallow, you may find that you cannot eat much at one time. To maintain your caloric and protein foods, you need to eat smaller amounts of high calorie, high protein foods as frequently as possible - at least six meals a day.

* If you find you can swallow only very small amounts or nothing at all, be sure to report this to the nurse, doctor or dietitian.

Xerostomia

* Another side effect that some patients experience while having radiation therapy is a dry mouth and thick saliva. You can do several things.

* Try soft, bland foods with a high liquid content such as ice cream and puddings. Moisten solid foods with gravy and/or sauces. Dunk bread and baked goods in tea or another favorite beverage.

* Rinse your mouth frequently. Carry a water bottle with a pump spray to keep your mouth moist.

* Increase the amount of fluid you drink. Thin liquids are best. Avoid milk.

* Keep lips moist with lanolin or lip balm.

* Ask your doctor for a prescription for artificial saliva.

* Make sure you brush your teeth and rinse your mouth thoroughly each day. Mouth wash of 1 teaspoon to 1 tablespoon of soda in a quart of water with or without a teaspoon of salt may be used. * Avoid commercial mouthwash. They tend to be very drying to your mouth.

Dental Problems

* Prior to therapy, the dentist may have filled or removed some teeth. This may make it difficult for you to eat.

* If chewing is a problem, change your diet to soft foods and liquids.

Make sure they are high in calories and protein so that you keep your weight from dropping.

Diarrhea

* You may experience diarrhea during radiation therapy. The foods you eat can help to decrease your diarrhea.

* Avoid lactose or milk sugar, or use milk products with "lactaid", or soybean milk. Avoid fatty foods, such as rich sauces, and gassy foods, such as cabbage and beans.

* Use cooked fruits and vegetables, and bland foods such as mashed potatoes, and rice.

* Report cramping and diarrhea to your doctor or nurse. They may order a medication to decrease your diarrhea.

Depression and Anxiety

Your emotions and moods can also interfere with eating the proper amount of calories and protein.

During therapy, you may feel sad, depressed, or just too tired to eat. You can do several things to improve the way you feel.

* Reduce any nervousness by using those methods that have worked for you in the past.

* Talk with your family and friends. Their support may help you during the treatments.

This is a time to pamper yourself. Do special things for yourself that you otherwise put off for lack of time.

* You may want to schedule more rest periods if you feel tired, but try to continue some regular activities, and some leisure time activities.

* If you would like to help in finding other ways to reduce nervousness or stress, ask your doctor or nurse. They will be able to make some suggestions to you or will refer you to another person.

Sociocultural

* Becuase your eating schedule is different, your food is different, or you may not be living at home during radiation therapy, it may be more difficult for you to eat. There are some things you can do.

* Bring something special with you that is from your kitchen or dining room at home, and keep it in the area in which you are eating. This may be a favorite placemat, a picture, or a favorite dish.

* Eat with your usual eating companions as much as possible. Have a family member or friend be your eating companion or helper throughout therapy. This person can encourage you to eat adequate calories and protein.

* Try to continue to eat those foods that you usually eat, as long as they are high in calories and protein. While you may not be able to eat all your favorite foods during therapy, you can look forward to eating them again when therapy is completed.

Conclusion

* In summary, maintaining your weight during radiation therapy is very important. * There are many things you can do to help yourself and avoid getting all tied up in knots. * You can eat high calorie, high protein foods.

Protein rich foods, include meat, fish, poultry, eggs, milk products, cheese, beans and peas.

Foods that add calories to your meals include mayonnaise, butter, peanut butter, hwipping cream, and ice cream.

* You can eat smaller, more frequent meals, and snack when you feel hungry.

You can relax before and after meals.

You can eat appetizing foods in pleasant surroundings.

* And you can remind yourself that eating is an important part of your treatment.

* If you have any questions, do not hesitate to talk with the nurse, doctor, or dietitian.

* This concludes the teaching program on nutrition during radiation therapy.

Content Validity - Teaching Program

The content of the structured teaching program was derived from references that generally reflect the experienced opinion of those who work on a day by day basis with cancer patients undergoing treatment. Few of the following references reflect organized research or clinical trials. Rather they are written by clinicians and present approaches that appear to work in the clinical care of these patients. Content from these references was used in the development of the content for the independent variable manipulation, structured teaching program on maintaining dietary intake during radiation therapy for head and neck cancer.

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APPENDIX F

Name ____________

Pt. No. ____________

Date ____________
Time ____________

Nutritional Information

1. How many calories should you eat each day?

2. How many grams of protein should you eat every day?

3. Name three foods that provide you with protein?

   a.
   b.
   c.

4. During radiation therapy, a common change when you eat is that you fill up quickly. Which one of the following will help you to still eat enough calories and protein?

   a. Make breakfast the best meal of the day.
   b. Drink plenty of fluids with meals.
   c. Increase fatty foods.

Please check whether these are true or false.

	True	False	
5.	____	____	If you have a dry mouth, avoid drinking large amounts of liquid.
6.	____	____	Eat at least 6 small meals a day.
7.	____	____	Eat with your usual eating companions.
8.	____	____	Try to take low calorie, high protein foods.
9.	____	____	Fruits and vegetables are examples of high protein foods.
10.	____	____	Eat the foods you usually eat if they are high in calories and taste all right.
11.	____	____	If meats taste different, you may substitute poultry, fish, eggs or milk products.

12. Circle the foods that add calories to your diet.

   a. Mayonnaise
   b. Milk
   c. Butter
   d. Tea and coffee

13. Circle the things you can do to make eating easier when your mouth is sore.

    a. Use a soft toothbrush to brush teeth daily.
    b. Avoid coarse foods such as crisp toast and popcorn.
    c. Use blended foods, puddings and nutrition supplements to keep calories and protein high.
    d. If you use medications for mouth pain, use them 10-30 minutes before mealtime.

14. Circle which of the following are high in calories and protein.

    a. Carnation Instant Breakfast
    b. Coffee
    c. Eggnog
    d. Milkshakes
    e. Soda pop

15. Identify two ways you plan to use to decrease nervousness during therapy.

    a.
    b.

16. Name three things you can do to increase your appetite.

    a.
    b.
    c.

17. Name two foods to avoid if you get diarrhea.

    a.
    b.

18. If you have nausea and vomiting, one of the things you can do is:

    a. Decrease the amount of food you eat just before therapy.
    b. Increase the amount of food you eat just before therapy.
    c. Eat a meal right after therapy.

19. Circle those things that may help if you have taste changes.

    a. Substitute mild protein such as bland cheese and chicken.
    b. Change the seasonings you use on foods.
    c. Prepare and select foods that look appetizing, such as fresh fruit.

20. If you begin to experience difficulty in swallowing, name two foods you could use to make sure you eat enough calories.

    a.
    b.

21. Circle the things you can do if you have a dry mouth and thick saliva.

    a. Use commercial mouthwash.
    b. Carry a thermos or spray water bottle and use often.
    c. Try soft bland foods.
    d. Dunk breads and other dry foods in milk, tea, or some other liquid.

22. Name 2 ways you plan to use to make mealtimes pleasant.

    a.
    b.

23. Name 2 ways to maintain your weight that have worked for you in the past.

    a.
    b.

APPENDIX G

SELF-CARE

PT. NO. _ _ _
Time _ _
Agency _
Date _ _/_ _/_ _

SIDE EFFECTS/ PROBLEMS	ACTIONS TAKEN	RESULT	SOURCES OF ACTIONS
______ a) How severe? 1 2 3 4 5 (barely noticeable … most severe) Date of onset	a.______ date:____	1 2 3 4 5 (NOT RELIEVED AT ALL … COMPLETELY RELIEVED)	a.______
	b.______ date:____	1 2 3 4 5	b.______
b) Does it bother you? 1 2 3 4 5 (a little … extremely)	c.______ date:____	1 2 3 4 5	c.______
	d.______ date:____	1 2 3 4 5	d.______
______ a) How severe? 1 2 3 4 5 (barely noticeable … most severe) Date of onset	a.______ date:____	1 2 3 4 5	a.______
	b.______ date:____	1 2 3 4 5	b.______
b) Does it bother you? 1 2 3 4 5 (a little … extremely)	c.______ date:____	1 2 3 4 5	c.______
	d.______ date:____	1 2 3 4 5	d.______

APPENDIX H

Anorexia Tool

Pt. No. _ _ _
Time _ _
Agency _
Date _ _/_ _/_ _

1. Please place an "X" on the line at the spot to indicate what your appetite was like before you first became ill. _ _ _

No appetite |————————————————| Large appetite

Place an "X" on the line that corresponds to the way you have felt <u>during the last week.</u>

2. How has your appetite been during the last week? _ _ _

No appetite |————————————————| Large appetite

3. How has your ability to eat been during the last week? _ _ _

Unable to eat |————————————————| Very easy to eat

4. Have you had any <u>taste changes</u>? No ___ Yes ___
   If yes, have they affected your appetite? _ _ _

Not at all |————————————————| A great deal

5. Have you had any nausea? No ___ Yes ___
   If yes, has this affected your appetite? _ _ _

Not at all |————————————————| A great deal

6. Have you had any vomiting during the last week?
No ___ Yes ___
If yes, has this affected your appetite?

Not at all ⊢——————————————⊣ A great deal ___

7. Has it been difficult to swallow solid food? No ___ Yes ___
If yes, has this affected your appetite?

Not at all ⊢——————————————⊣ A great deal ___

8. Have you felt sad? No ___ Yes ___

If yes, has this affected your appetite?

Not at all ⊢——————————————⊣ A great deal ___

9. Have you been eating alone? No ___ Yes ___
If yes, has this affected your appetite?

Not at all ⊢——————————————⊣ A great deal ___

10. Have you had hunger pains? No ___ Yes ___
If yes, has this affected your appetite?

Not at all ⊢——————————————⊣ A great deal ___

11. Have you had any difficulty preparing your meals?
No ___ Yes ___
If yes, has this affected your appetite?

Not at all ⊢——————————————⊣ A great deal ___

12. Have you had a dry mouth during the last week?
No ___ Yes ___
If yes, has this affected your appetite? ___

Not at all ⊢——————————————⊣ A great deal

13. Have you felt a desire to eat? No ___ Yes ___
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

14. Have you felt embarrassed eating with others?
No ___ Yes ___
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

15. Have you had any pain in your mouth? No __ Yes __
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

16. Have you felt tired? No__ Yes__
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

17. Have you felt depressed? No__ Yes__
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

18. Have you had a sore tongue? No __ Yes __
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

19. Have you felt tense or anxious? No __ Yes __
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

20. Have you felt hungry? No __ Yes __
If yes, has this affected your appetite?

Not at all ____________________ A great deal ---

21. **Have your lips been <u>dry and cracked</u>? No __ Yes __**
If yes, has this affected your appetite? ___

Not at all |________________________________| **A great deal**

22. **Have you gotten <u>nauseated</u> after you eat? No __ Yes __**
If yes, has this affected your appetite? ___

Not at all |________________________________| **A great deal**

23. **Have you had any <u>interest in eating</u> during the last week? No __ Yes __**
If yes, has this affected your appetite? ___

Not at all |________________________________| **A great deal**

24. **Have you changed the <u>times when you usually eat</u>?**
No __ Yes __
If yes, has this affected your appetite? ___

Not at all |________________________________| **A great deal**

25. Have you had a <u>feeling of fullness</u> shortly after beginning to eat? No __ Yes __ ___
If yes, has this affected your appetite?

Not at all |________________________________| A great deal

26. Are you having any problems with foods that are hot in temperature? __yes __ no _

27. Are you having any problem with foods that are cold? _
__yes __ no

28. Describe the types of foods you have been able to eat in the last week. __

____

____

____

5/85

APPENDIX I

ORAL ASSESSMENT TOOL

Agency
Date _ _/_ _/_ _

Pt. No. _ _ _
Time _ _

		0	1	2	3	4	5	
1.	Infection	None	Requires Rx					_
2.	Pain	None	Requires no Rx	Requires non-narcotic analgesics	Requires narcotics	Uncontrolled		_
3.	Erythema	None	Pinkish	Mild borders of field seen	Moderate	Severe "sun-burn" quality		_
4.	Pigmentation	None	Light	Mild distinct field borders seen	Moderate	Severe		_
5.	Dry desquamation	None	Fine scale	Thick scale				_
6.	Moist reaction	None	Small area appears raw. Loss of upper layers, red base	Clear cut with crust ~ 10%	Moderate < 50% field	> 50%		_
7.	Epilation	None	Occurs	< 50%	> 50%			_
8.	Lips	Normal	Swollen	Lesion or fissure	Lesion bleeding			_
9.	Cheeks	Normal	Film and/or swollen	Film or ridges bite line	Film patches ridges	Film patches ridges lesions	Film patches ridges lesions bleeding	_
10.	Hard Palate	Normal	Film	Patches	Lesion	Patches lesion	Patches lesion bleeding	_
11.	Soft Palate	Normal	Film	Patches and/ or inflamed red	Inflamed red lesions	Inflamed red lesions bleeding		_
12.	Tongue	Normal	Film ridges	Film or cracked or edema	Discolored	Cracked bleeding	Lesion bleeding	_
13.	Sublingual	Normal	Patches	Lesion	Patches lesion	Patches lesion bleeding		_
14	Secretion	Normal	Increase	Clear thick	White thick	Stringy		_
15	Labial mucosa	Light pink normal	Inflam. or film	Inflam. and film	Inflam & film with oozing or bleeding or lesion	Inflam. and film with oozing, or bleeding and lesion		_
16.	Gingiva	Normal light pink	Inflamm. or edema	Inflamm. and edema	Inflamm. and edema with bleeding or lesion	Inflam. and edema with bleeding and lesion or exudate	Inflam and edema with bleeding and lesio and exudate	_

Week 1 weight Kg ______

Present weight Kg ______

Weight loss Kg ______
since treatment

APPENDIX J

POMS

Pt. No. ___
Time __
Agency _
Date _ _/_ _/_ _

Please circle the answer that describes how you feel at this moment. Please answer every question.

	Not at all	A little	Moderately	Quite a bit	Extremely	Office Use
1. Friendly	0	1	2	3	4	_
2. Tense	0	1	2	3	4	_
3. Angry	0	1	2	3	4	_
4. Worn Out	0	1	2	3	4	_
5. Unhappy	0	1	2	3	4	_
6. Clear-headed	0	1	2	3	4	_
7. Lively	0	1	2	3	4	_
8. Confused	0	1	2	3	4	_
9. Sorry for things done	0	1	2	3	4	_
10. Shakey	0	1	2	3	4	_
11. Listless	0	1	2	3	4	_
12. Peeved	0	1	2	3	4	_
13. Considerate	0	1	2	3	4	_
14. Sad	0	1	2	3	4	_
15. Active	0	1	2	3	4	_
16. On edge	0	1	2	3	4	_
17. Grouchy	0	1	2	3	4	_
18. Blue	0	1	2	3	4	_
19. Energetic	0	1	2	3	4	_
20. Panicky	0	1	2	3	4	_
21. Hopeless	0	1	2	3	4	_
22. Relaxed	0	1	2	3	4	_
23. Unworthy	0	1	2	3	4	_
24. Spiteful	0	1	2	3	4	_
25. Sympathetic	0	1	2	3	4	_
26. Uneasy	0	1	2	3	4	_
27. Restless	0	1	2	3	4	_
28. Unable to concentrate	0	1	2	3	4	_
29. Fatigued	0	1	2	3	4	_
30. Helpful	0	1	2	3	4	_
31. Annoyed	0	1	2	3	4	_
32. Discouraged	0	1	2	3	4	_

	Not at all	A little	Moderately	Quite a bit	Extremely	Office Use
33. Resentful	0	1	2	3	4	_
34. Nervous	0	1	2	3	4	_
35. Lonely	0	1	2	3	4	_
36. Miserable	0	1	2	3	4	_
37. Muddled	0	1	2	3	4	_
38. Cheerful	0	1	2	3	4	_
39. Bitter	0	1	2	3	4	_
40. Exhausted	0	1	2	3	4	_
41. Anxious	0	1	2	3	4	_
42. Ready to fight	0	1	2	3	4	_
43. Good-natured	0	1	2	3	4	_
44. Gloomy	0	1	2	3	4	_
45. Desperate	0	1	2	3	4	_
46. Sluggish	0	1	2	3	4	_
47. Rebellious	0	1	2	3	4	_
48. Helpless	0	1	2	3	4	_
49. Weary	0	1	2	3	4	_
50. Bewildered	0	1	2	3	4	_
51. Alert	0	1	2	3	4	_
52. Deceived	0	1	2	3	4	_
53. Furious	0	1	2	3	4	_
54. Efficient	0	1	2	3	4	_
55. Trusting	0	1	2	3	4	_
56. Full of Pep	0	1	2	3	4	_
57. Bad-tempered	0	1	2	3	4	_
58. Worthless	0	1	2	3	4	_
59. Forgetful	0	1	2	3	4	_
60. Carefree	0	1	2	3	4	_
61. Terrified	0	1	2	3	4	_
62. Guilty	0	1	2	3	4	_
63. Vigorous	0	1	2	3	4	_
64. Uncertain about things	0	1	2	3	4	_
65. Bushed	0	1	2	3	4	_

APPENDIX K

H&NII

Semi Structured Interview

Pt.No. _ _ _
Time _ _
Agency _
Date _ _/_ _/_ _

1. **With whom do you live?**

   a. Alone _
   b. With spouse, children, or other family members
   c. With a friend
   d. Other, specify

2. **Has who you are living with changed since you started radiation therapy?** _

   a. No
   b. Yes, I live with some now, specify
   c. Yes, I live alone now

3. Who usually shops for food in your household?

   a. I do
   b. My spouse/significant other does _
   c. We do it together
   d. Other, specify

4. Has there been a change in the pattern of shopping?

   a. No
   b. Yes, I do it now and I didn't before
   c. Yes, I can no longer do it _

5. Who usually prepares meals at your house?

   a. I do
   b. My spouse/significant other does _
   c. We do it together
   d. Other, specify

6. Has there been a change in the pattern of who cooks? _

   a. No
   b. Yes, I do it now and I didn't before
   c. Yes, I can no longer do it
   d. Other, specify

7. Has there been a change in the environment in which you eat? _

   a. No
   b. Yes, I eat at more places than I use to
   c. Yes, I eat at less places than I use to
   d. Yes, I eat in an entirely different environment than I use to eat it

8. **How many meals per day, at what time, and with whom did you eat before you became ill?** _

Time of day **With whom** _

9. How many meals per day, at what time, and with whom were you eating just before you started therapy? _

Time of day With whom _

10. How many meals per day, at what time, and with whom do you eat now? _

Time of day With whom _

11. What foods have you given up during therapy that are foods you have eaten all your life? _ _

12. What foods are you eating now that you haven't eaten before? _ _

13. How do you like them? _ _

14. If you received the following, how helpful were they?

a. Book
not at all ——— a great deal _ _ _

b. Film
not at all ——— a great deal _ _ _

c. Self-care list
not at all ——— a great deal _ _ _

d. Review of diet intake
not at all ——— a great deal _ _ _

15. If you received the following, how helpful were they? indicate who s/o ______________________________

Book ⌊____⌋ - - -
not at all a great deal

Film ⌊____⌋ - - -
not at all a great deal

Self-care list

⌊____⌋ - - -
not at all a great deal

Review of diet intake

⌊____⌋ - - -
not at all a great deal

16. Are there any other changes that have happened that have changed what you are eating?

APPENDIX L

Dietary Intake Form
(one per day)

PT. No. _ _ _

Date _ _/_ _/_ _

Time _ _

Record all food eaten.

Agency _

Breakfast

Amount Food

Morning Snack

Amount Food

Lunch

Amount Food

Afternoon Snack

Amount Food

Dinner

Amount Food

Evening Snack

Amount Food

APPENDIX M

NUTRITIONAL ASSESSMENT

Patient No. _ _ _

Time _ _

Agency _

Date _ _/_ _/_ _

Part 1

Age _ _

Usual Height (cm) _ _ _
Present Height (cm) _ _ _
Usual Weight (kg) during the 6 months prior to illness _ _ _ .

Weight loss (within last 6 months, kg) _ _._
% of usual weight _ _

Wrist Circumference (cm) ___ (right, left) _ _._

BEE

Men

66.47 + (13.75 x wt in kg) + (5 x ht in cm)-(6.75x age)

Women

655.9+(9.56x wt in kg)+(1.85 x ht in cm)-(4.67x age) _ _ _ _ _

* Handgrip Dynamometer Observation in pounds _ _ _

1 ____
2 ____
3 ____
Total ____
Mean ____

* = beginning and end of therapy only

*Mid arm circumference (MAC) mm ____ (right, left) ___

*Triceps Skin Fold (TSF) mm (right, left)

observation 1 ______

observation 2 ______

observation 3 ______

Total ______

Mean ______ ___

Derived Scores

Body Build

Height/wrist circumference

r= _____/_____

Frame ________
sm,med,lg

Actual wt/ideal weight

_____/_____=_____% ___

Height/Weight/Frame

Score
1= severe <95% of lowest figure
2= mild, 95-99% of lowest figure within normal range
3= within normal range
4= 100-119% of high figure of normal range
5= > 120% of high figure of normal range

*Mid arm muscle circumference (MAMC):

MAC_{mm}-(0.314 x TSF) = $MAMC_{mm}$

____- (0.314 x ____) = _____ ___

*Skeletal Score - (S_1)

Mid Arm Muscle Circumference (MAMC)

0= adequate > 10th percentile
1= mildly depleted 5th-10th percentile
2= severely depleted<5th percentile

*Skeletal Score - (S_2)
Handgrip Ratio
Actual/10% tile

_____/_____ = _____

0= >95 - adequate
1= 86-95 mildly depleted
2= <86 severely depleted

*Fat Score (F) Triceps Skin Fold

0=adequate ≥10th percentile
1=mildly depleted 5th-10th percentile
2=severely depleted <5th percentile

*Visceral Protein Score (V)

Albumin gm% _____

0= adequate > 3.5
1= mildly depleted - 2.8 - 3.4
2= severely depleted - < 2.8

*$F+S_1+S_2$ = Marasmus Score (M)

__ + __ + __ = _______

*Combination Score

1= MARASMUS-KWASHIORKOR, MILD
(M=1-3 and V=1 or M=1-3 and V=2 or M=4-6 and V=1)

2= MARASMUS-KWASHIORKOR, SEVERE
(M=4-6 and V=2)

*Albumin

*Total Lymphocyte Count $\frac{\text{\% lymphocytes x WBC}}{100}$

APPENDIX N

THERAPY VARIABLES & TREATMENT RESPONSE

Pt. No.
Time given: _ _ _
Agency: _ _
Date: _ _/_ _/_ _

Diagnosis:
1. oral cavity
2. oropharynx
3. nasal cavity & paranasal sinus
4. nasopharynx
5. salivary glands
6. larynx & hypopharynx _ _
7. other, specify ______________________

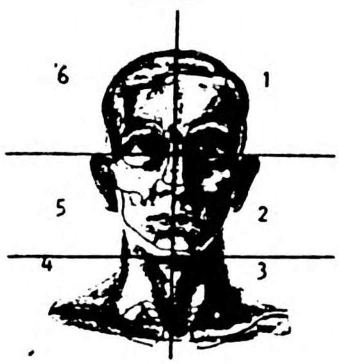
1. Staging: Stage I = 1 _
   Stage II = 2
   Stage III = 3
   Stage IV = 4

2. Purpose of radiation:
   1. local control
   2. symptom relief
   3. pre-op planned
   4. post-op planned
   5. post-op salvage
   6. with chemotherapy
   7. pre-chemo
   8. post-chemo
   9. chemo resistant
   10. recurrent symptom relief
   11. sandwich
   12. other ________________ _ _

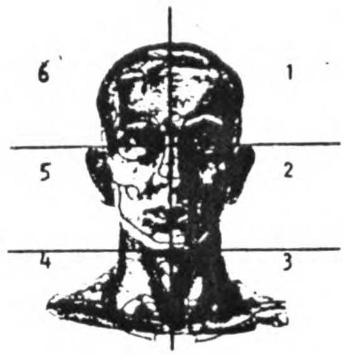
3. Type of treatment:
   1. Primary (≥6000 rads)
   2. Adjuvant or recurrent (4500-5999 rads) _

4. Site of therapy: site 1 _ _ _ _ site 2 _ _ _ _

Site 1



Site 2



5. Size of field (cm):

	(AP) W	(CC) L
site 1	_ _	x_ _
site 2	_ _	x_ _

Site 1

____W x ____ L
(AP) (CC)

Site 2

____W x ____ L
(AP))CC)

6. Total rads ordered: Site 1 _________ _ _ _ _
Site 2 _________ _ _ _ _

7. Total daily rads ordered: Site 1 ___________ _ _ _ _
Site 2 ___________ _ _ _ _

8. Change in therapy dose during treatment course:
Site 1: 1. no 2. yes _
Site 2: 1. no 2. yes _

9. If question 8 is yes, <u>total</u> rads received prior to change in dose: Site 1 _________ _ _ _ _
Site 2 _________ _ _ _ _

10. First change, number of treatment days after start date: Site 1 ________ _ _
Site 2 ________ _ _

11. Daily rads ordered as a result of first change:
Site 1 _______ _ _ _ _
Site 2 _______ _ _ _ _

12. Total rads first change: Site 1 _____ _ _ _ _
Site 2 _____ _ _ _ _

13. Second change, number of treatment days since first change: Site 1 ______ _ _
Site 2 ______ _ _

14. Daily rads ordered as a result of second change:
Site 1 _____ _ _ _ _
Site 2 _____ _ _ _ _

15. Total rads second change: Site 1 _____ _ _ _ _
Site 2 _____ _ _ _ _

16. Total rads received over complete course of therapy: Site 1 ______ _ _ _ _
Site 2 ______ _ _ _ _

17. Total length of therapy in days: Site 1 _____ _ _
Site 2 _____ _ _

18. Total number of treatments received: Site 1 ______ _ _
Site 2 ______ _ _

Subject # _ _ _

19. Number of changes in dose from original prescription:
    Site 1 _____ __
    Site 2 _____ __

Change in treatment site:

20. Change in site: Site 1: 1. no 2. yes _
    Site 2: 1. no 2. yes _

21. Change 1 - cone down: Site 1: 1. no 2. yes _
    Site 2: 1. no 2. yes _

22. Change 1 - addition: Site 1: 1. no 2. yes _
    Site 2: 1. no 2. yes _

23. Change 2 - cone down: Site 1: 1. no 2. yes _
    Site 2: 1. no 2. yes _

24. Change 2 - addition: Site 1: 1. no 2. yes _
    Site 2: 1. no 2. yes _

25. Tumor response:

    1. increase in size
    2. no response
    3. partial response ≤ 50%
    4. partial response > 50%
    5. complete response
    6. complete symptom relief
    7. partial symptom relief _
    8. no symptom response

26. Were rest periods planned at start of therapy.
    1. no 2. yes _

27. Were rest periods ordered in therapy course due to patients' condition? 1. no 2. yes _

28. Time from initial diagnosis to start of radiation:

    1. less than 3 months
    2. 3-5 months
    3. 6-11 months
    4. 12-23 months
    5. 24-35 months
    6. over 3 years _

29. Has previous treatment included:

    Surgery 1. no 2. yes _

    date:
    1. concurrent
    2. less than 3 months
    3. 3-5 months
    4. 6-11 months
    5. 12-23 months
    6. 24-35 months
    7. over 3 years _

    specify ____ __

Subject # _ _ _

Has previous treatment included:

Radiation Therapy   1. no   2. yes

Date:
1. concurrent
2. less than 3 months
3. 3-5 months
4. 6-11 months
5. 12-23 months
6. 24-35 months
7. over 3 years

Specify ____________________

Chemotherapy   1. no   2. yes

Date:
1. concurrent
2. less than 3 months
3. 3-5 months
4. 6-11 months
5. 12-23 months
6. 24-35 months
7. over 3 years

Specify ____________________

Immunotherapy   1. no   2. yes

Date:
1. concurrent
2. less than 3 months
3. 3-5 months
4. 6-11 months
5. 12-23 months
6. 24-35 months
7. over 3 years

Specify ____________________

ADL status pre

end

1st FU

30. Number of rest days each calendar consecutive week during therapy.

DATE	WEEK	# of Rest Days*
____	1	____
____	2	____
____	3	____
____	4	____
____	5	____
____	6	____
____	7	____
____	8	____
____	9	____
____	10	____
____	11	____
____	12	____
____	13	____

* See data dictionary

APPENDIX O

Quality of Life Tool

Pt. No. ___

Time given: __

Agency: _

Date: __/__/__

Week _

1. **How much fun do you have (hobbies, recreations, social activity)?** ___

   none |————————————————| **a great deat**

2. **Do you worry about the cost of your medical care?** ___

   not at all |————————————————| **a great deal**

3. How much pain do you have? ___

   none at all |————————————————| excruciating

4. **How useful do you feel?** ___

   not at all |————————————————| **extremely useful**

5. **How much happiness do you feel?** ___

   not at all |————————————————| **a great deal**

6. **How satisfying is your life?** ___

   not at all |————————————————| **extremely**

7. **Is your sexual activity sufficient to meet your needs?** ___

not at all |————————————————| extremely

8. **How much can you work at your usual tasks (heusework, garden, job)?** ___

not at all |————————————————| a great deal

9. **How is your present ability to concentrate?** ___

extremely poor |————————————————| excellent

10. **How much strength do you have?** ___

none at all |————————————————| a great deal

11. **Do you tire easily?** ___

not at all |————————————————| a great deal

12. Is the amount of time you sleep sufficient to meet your needs? ___

not at all |————————————————| completely

13. How good is your quality of life? ___

extremely poor |————————————————| excellent

14. Is the amount you eat sufficient to meet your needs? ___

not at all |________________| **completely**

15. Are you worried about your weight? ___

not at all |________________| **a great deal**

16. How much nausea do you have? ___

none |________________| a great deal

17. How much vomiting do you have? ___

none |________________| a great deal

APPENDIX P

ACTIVITIES OF DAILY LIVING

Pt. No. _ _ _

Time given _ _

Agency _

Date _ _/_ _/_ _

(The word "assistance" means supervision, direction of personal assistance)

BATHING - either sponge bath, tub bath, or shower

__ Receive no assistance (gets in and out of tub by self, tub is usual means of bathing)
__ Receive assistance in bathing only one part of body (such as back or a leg)
__ Receive assistance in bathing more than one part of body (or not bathed)

DRESSING - get clothes from closets and drawers - including underclothes, outer garments and using fasteners (including braces, if worn)

__ Gets clothes and gets completely dressed without assistance
__ Gets clothes and gets dressed without assistance except for assistance in tying shoes
__ Receives assistance in getting clothes or in getting dressed, or stays partly or completely undressed.

TOILETING - going to the "toilet room" for bowel and urine elimination; cleaning self after elimination and arranging clothes

__ Goes to "toilet room," cleans self, and arranges clothes without assistance (may use object for support such as cane, walker, or wheelchair and may manage night bedpan or commode, emptying same in morning)
__ Receives assistance in going to "toilet room" or in cleansing self or in arranging clothes after elimination or in use of night bedpan or commode
__ Doesn't go to room termed "toilet" for the elimination process

TRANSFER -

__ Moves in and out of bed as well as in and out of chair without assistance (may be using object for support such as cane or walker)
__ Moves in or out of bed or chair with assistance
__ Doesn't get out of bed

CONTINENCE -

__ Controls urination and bowel movement completely by self
__ Has occasional "accidents"
__ Supervision helps keep urine or bowel control; catheter is used or is incontinent

FEEDING -

__ Feeds self without assistance
__ Feeds self except for getting assistance in cutting meat or buttering bread
__ Receives assistance in feeding or is fed partly or completely by using tubes or intravenous fluids

APPENDIX Q

LOCUS OF CONTROL

Pt. No. _ _ _
Time _ _
Agency _
Date _ _/_ _/_ _

1. Whether I gain, lose, or maintain my weight is entirely up to me. _ _ _

   Strongly Disagree ———————————— Strongly Agree

2. Being the right weight is largely a matter of good fortune. _ _ _

   Strongly Disagree ———————————— Strongly Agree

3. No matter what I intend to do, if I gain or lose weight or stay the same in the future, it is just going to happen. _ _ _

   Strongly Disagree ———————————— Strongly Agree

4. If I eat properly, and get enough exercise and rest, I can control my weight in the way I desire. _ _ _

   Strongly Disagree ———————————— Strongly Agree