IMPACT OF CHEMOTHERAPY ON THE QUALITY OF LIFE
AND FUNCTIONAL STATUS OF OLDER ADULTS
WITH NON-SMALL CELL LUNG CANCER

by

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To Evelyn and Salvatore
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Abstract

Lung cancer is the number one cause of cancer death in the United States and the incidence is increasing over 65 years of age. The lack of effective treatment for advanced non-small cell lung cancer makes factors other than long term survival important criteria when measuring treatment experiences. This longitudinal study described and compared the effects of an initial cycle of chemotherapy on quality of life (QOL) and functional status (FS) of adults (under and over 65 years of age) with non-small cell lung cancer. An untreated cohort was compared with the younger and older treated adults.

In this study, QOL was defined as the degree of disruption in multiple dimensions of everyday life due to illness and treatment as measured by the Cancer Inventory of Problem Situations (CIPS). FS was defined as both a subjective (Rand Physical Functioning Scale) and objective assessment (Karnofsky Performance Status) of independent physical activity.
Data were collected on 24 adults with non-small cell lung cancer at Time 1 (n=19 for Time 1 and Time 3). The mean age of all subjects was 60.3 years. Five subjects treated with chemotherapy were over 65 years. The subjects were tested pre, during and post chemotherapy. The patients receiving supportive care were tested within the same time frame.

Disruptions in global QOL over time were not significantly different for older as compared with younger adults, or as compared with the untreated cohort. Older adults were more severely limited in physical dimensions of QOL. Older adults had less psychosocial problems than younger adults except in the areas of cognition and worries about family coping. Older adults had significantly less disruptions in marital function as compared with younger adults. The measure of QOL was correlated with both measures of functional status (p<.005). Significant decline (p=.005) occurred in physical activities for untreated as compared with treated subjects. In a multiple regression, subjects with comorbid disease had a lower quality of life.
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CHAPTER 1

INTRODUCTION AND STATEMENT OF THE PROBLEM

The impact of an aging population is a world wide concern. The numbers of adults over sixty years of age increased by fifty percent throughout the world from 1960-1980 and there is continued expansion of this segment (Strumpf, 1985). Twelve percent of the population in the United States is currently over 65 years old. By the year 2050 this percentage is projected to increase to 21.1%. Such a shift in the elderly population, especially in that sector of people over 75 years old (an increase by 70% from 1980-2000), is posing new concerns for the country and for health care providers in particular (Yancik & Ries, 1989). Over 40% of acute hospital admissions are for individuals 65 years and older (US Senate Special Commission on Aging, 1985-86). Differential health care practices based on age alone are being challenged. Ethical issues of appropriate care for older adults include economic, as well as humane perspectives. Appropriate health care treatment for older adults is being reevaluated in light of knowledge from the growing science of Gerontology.

Historically, risks and benefits of cancer treatments have been assessed through scientific clinical trials in
patients with particular tumor types and characteristics. Until recently, much of cancer treatment toxicity data essential to clinical management were based upon studies derived from sample populations 65 years of age or younger, due to arbitrary age exclusion criteria used in many clinical trials (Begg & Carbone, 1983). This practice of eliminating elderly (over 65 years of age) cancer patients from participation in investigative studies based on chronologic age alone has been changed, but the presence of comorbid diseases in this population may independently exclude them from such studies (Begg, Cohen & Ellerton, 1980). This results in the absence of cancer treatment toxicity data on a critical population of cancer patients who may be at higher risk for difficulties with treatment. Mor, Masterson-Allen, and Goldberg (1985) note a continuing "ageism" in the selection of cancer treatment for the older adults regardless of premorbid or disease status.

The dimensions of response to cancer treatment in the elderly are largely uncharted, especially in terms of the impact on daily activity and quality of life. Current research in the physiologic tolerance of the aged to cancer treatment will provide some answers to the question of age-related concerns. However, research is needed which will describe the impact of cancer treatment on a more personal level. This knowledge would be of great
importance for strategic planning of clinical nursing interventions during cancer treatment.

Differences in the level and quality of function in day to day activities are relevant measures of responses to disease and treatment which may dictate the need for nursing care and support. Knowledge which can provide the foundation for nursing assessment and interventions to prevent, minimize, and effectively care for problems of older adults during cancer treatment is essential for quality health care. The maintenance of optimal levels of functioning in the aged is a primary concern of health care providers (Strumpf, 1987).

**Cancer in the Elderly**

Cancer, in fact, is largely a disease of the elderly. Over 50% of all cancers and 60% of all cancer deaths occur in those over 65 years of age. The biologic changes of aging may relate to mechanisms of carcinogenesis in the elderly (Lipshitz, Goldstein, Reis, Weksler, Bressler & Neilan, 1985). Whether or not aging promotes development of cancer on some physiologic or molecular level, mechanisms of such proposed relationships are not well understood (Butler & Gastel, 1979). It is clear, however that the incidence of cancer increases with age. The risk of getting cancer for those over 65 years old increases significantly with age. Doll and Peto (1981) and others (Peto, Roe, Lee, Levy, & Clack, 1975, Peto, Seidman &
Selikoff, 1982) have suggested that the increased incidence of cancer with age merely relates to the cumulative exposure to carcinogens over time.

Aging is associated with variable degrees of deterioration in organ status and function which can influence the incidence and manifestations of health related problems. Additionally, diminished cardiac, pulmonary, and renal function in particular, can limit therapeutic options. Toxic cancer chemotherapy can selectively affect these organs or depend upon their normal function for metabolism and excretion of the drugs. Age related physiologic changes may create differential responses and toxicities to cytotoxic drug therapies.

The limits of biologic life-span and characterization of morbidity in the elderly are important considerations when determining the goals and impact of cancer and cancer treatment. No human data provide a clear physiologic basis for a finite age limit (Schneider & Brody, 1983). Survival statistics suggest that the average life-span in the United States is increasing to 85 years of age (Fries, 1980). In fact, while physiologic decline has been well documented in the elderly, there has not been a direct correlation of mortality statistics with "old age" alone. Whether or not substantial increases in life span are possible is the focus of much current research (e.g. Fries, 1980, Schneider & Brody, 1983). Fries (1980) has
asserted that the elimination and prevention of many acute and chronic diseases will result in the compression of morbidity, with an increase in healthy elderly until the end of their predetermined life-span. Schneider and Brody (1983) however, present evidence that an increase in the dependent disabled sector of the elderly population is inevitable.

When therapies manifest substantial toxicity, which is the case with many recent intensive chemotherapy protocols, the ability of an elderly patient to withstand and benefit from the treatment is a serious question. But, because of the tremendous variability in age related physiologic changes, chronologic age alone is not a satisfactory criterion. The data in current studies examining the incidence of tolerance and toxicity to chemotherapy for the elderly are ambiguous and generally lacking in descriptions of disruptions of emotional, physical and social dimensions of day-to-day life.

**Age and Lung Cancer**

Lung cancer manifests with serious health care problems which become even more complex in the older adult. Lung cancer is the most common cause of death from cancer in all men over 35 (American Cancer Society, ACS, 1989). Lung cancer alone accounts for 20% of all cancers in men and 11% of all cancers in women. Figure 1.1 displays the dramatic increase in lung cancer in the past
Figure 1.1
Increase in Lung Cancer: 1955-1985

Figure 1.2
Deaths due to Lung Cancer by Age

*1985 ACS data
30 years. The average onset of lung cancer is 60 years of age. The incidence of lung cancer was estimated at 155,000 new cases in 1988 and an estimated 142,000 deaths (ACS, 1989). Over 50% of these deaths are in men over 55. For the past twenty years, it has been the second most common cause of cancer death for women and in 1989 was the number one cause of cancer induced death for women of all ages (20% of all cancer deaths) (ACS, 1989, Brown & Kessler, 1988). Comparison of deaths from lung cancer by age (Figure 1.2) demonstrates the increased mortality in older adults. There was a 345% increase in mortality from lung cancer from 1950-1985 in adults 65-74 years old, (a 35% increase from 1975-1980), and a 419% increase in elderly adults 75-84 years old (49% increase from 1975-1980) (National Cancer Institute, JNCI, 1989).

Cumulative exposure to cigarette smoking places the current cohort of male smokers in their seventies in the highest risk group (incidence of 487 per 100,000) (Harris, 1983). This has even more serious health care implications considering the proportional increase in this segment of the population. The current cohort of older men and women was not confronted with the dangers of smoking until the 1964 Surgeon General's report on smoking and cancer. These men were in their thirties and forties at the time of the release of the report. The lack of knowledge about the smoking-lung cancer link, the heavy promotion of smoking
by the tobacco industry, the subsequent increase in smoking behavior during World War I and II, the lag time in carcinogenesis, and the delayed manifestations of lung cancer (between 20 and 40 years), have contributed to the incidence of lung cancer in older adults (Brown & Kessler, 1988). The incidence of lung cancer has been reported as increasing progressively until age 70 and then declining (Newell, Spitz & Sider, 1989). Figure 1.3 displays the age-specific incidence of lung cancer for men and women over 65. While incidence and mortality due to lung cancer have dropped for men less than 55 years, the incidence in older men and in women is actually increasing (Brown & Kessler, 1988). Yet, Weinrich and Weinrich (1986) noted that only 21% of an elderly sample (n=198) recognized cough as a symptom of lung cancer as compared with 65% of a national sample of all ages.

Consumption of cigarettes peaked for the male population in 1965, but sales are still rising for women (Brown & Kessler, 1988). Doll & Peto (1981, pg 1292) noted that critical exposure to smoking in teenage years (which would have occurred in the current cohort of older adults in the 1930's and 1940's), along with overall smoking contribute significantly to recent lung cancer trends in older adults. Additionally, older adult smokers are more likely to continue the use of the more carcinogenic high-tar (unfiltered) cigarettes. Estimates from the 1978/80
Figure 1.3
Age-Specific Incidence of Lung Cancer in Adults over 65

NCI SEER Program 1981-85
(Yancik & Ries, 1989)
Health Insurance Survey (National Center for Health Statistics, 1984) document smoking prevalence at 40.6% for males and 32.3% for females.

Despite the recent decline in smoking behavior in the United States, and the decrease in tar content of cigarettes (from 37.5 mg in 1950's to 14 mg in 1980), Brown & Kessler (1988) predict little change in mortality in the immediate future for older adults. Mortality from lung cancer in fact, is not expected to peak for males, ages 65-79 until the year 2000, and for females, ages 65-79, until 2010 (because of the more recent increases in smoking prevalence).

The high mortality rate of lung cancer is due in part to delayed diagnosis, the aggressive biology of the tumor, with frequent metastasis to brain and other vital organs, and the ineffectiveness of conventional treatments. Approximately seventy to eighty percent of all lung cancers are labeled as "non-small cell" due to the similarity of important clinical features. This category includes the four histologic types of lung cancer: squamous cell carcinoma (30-35%), adenocarcinoma (25-30%), large cell carcinomas (15%), and a miscellaneous category (Matthews, Mackay & Lukeman, 1983). Histologic subtypes are now identified which may have future clinical implications (Gazdar, 1986). Seventy-one percent of elderly lung cancer patients were noted to have squamous
cell lung cancer (n=148) in a recent large retrospective study (DeMaria & Cohen, 1987). Often unresectable at the time of diagnosis, advanced non-small cell lung cancer is treated with palliative intent with either supportive therapy, radiation, or chemotherapy. Over 41% of all lung cancers diagnosed in 1979-1984 had distant metastasis at diagnosis and 30% had regional spread (ACS, 1989). Independent of stage, only 13% of all patients diagnosed with lung cancer survive longer than 5 years.

The treatment of non-small cell lung cancer is controversial. Survival statistics for adults with advanced non-small cell lung cancer are grim, usually measured in months. A 3% 5 year survival for white males over 75 years with all stages of lung cancer has been reported by the National Cancer Institute (Brown & Kessler, 1988). Critical prognostic variables, associated with improved survival and response rates for non-small cell lung cancers have been postulated. These include: high performance status, limited symptoms, limited extent of disease, short time since diagnosis and minimal weight loss.

The limited success of chemotherapy treatment in improving survival of non-small cell lung cancer has led to considerable debate about subjecting more vulnerable older patients to the toxic therapy. As a result, in non-small lung cancer, factors other than long term survival
are important criteria for measuring treatment outcomes. The question of benefit must be answered with data including dimensions of physical, emotional and social well-being along with data describing increase in survival. The effect of chronological age on the benefits and/or increased toxicity of various treatment regimens is not clear. Clinical trials of cisplatin based combination chemotherapy have exhibited the most encouraging results for longer survival in non-small cell lung cancer. This trial, however, excluded patients over 70 years (Rapp et al. 1988).

Quality of Life and Lung Cancer

A move to gather data describing the impact of treatment on disruptions and benefits in quality of life simultaneously with data on physiologic side effects and tumor specific response data, during clinical trials is gathering momentum (Aaronson, Bullinger, Ahmedzai, 1988, Bernheim, 1985, Freidman, Furberg, & De Mets, 1985, Schipper & Levitt, 1985, van Dam, Linssen & Couzijn, 1984). Quality of life in health related research generally refers to a multidimensional concept of emotional, social and physical aspects of everyday life which can be affected by illness and treatment. Emerging from a variety of theoretical and atheoretical constructs, quality of life has been a vague and elusive concept that has been variably defined and measured. A wide range of
instruments often lacking in reliability and validity for cancer patients has been used to measure the concept. The type of data emerging from quality of life studies varies substantially within the time frame in which the measurements are taken. Van Dam et al. (1984) suggested that behavioral indices may allow greater precision in differentiating patterns of response between different clinical interventions and different groups of patients than those indices focused on thoughts and feelings.

Data describing the disruptions in quality of life along with physiologic side effects of treatment will provide parameters for nursing assessment and interventions. These data will help focus nursing care to prevent or minimize the impact of emotional, social and physical sequelae of cancer treatment. This approach has been suggested in a pragmatic behavioral framework proposed by Shag, Heinrich and Ganz (1983) to identify disruptions in day-to-day life activities and important concerns associated with the diagnosis and treatment of cancer. Jones, Fayers and Simons (1987) have suggested that the ideal data collection schedule would be before, during, and after treatment.

The experiences of older adults during cancer chemotherapy treatment could be affected by an array of biological, physiological, psychological and sociocultural variables. The behavioral or quality of life sequelae of
chemotherapy are rarely included in reviews of nursing interventions for chemotherapy toxicity (for example, Mosely, 1987). There is a paucity of data which might clarify, or at the very least describe, patterns of age related behavioral similarities or differences to cancer and cancer treatment. Current studies depict a wide variation in the disruption of every day activities of adult cancer patients (for example, Cain & Henke 1978, Frank-Stromborg & Wright 1984, Ganz, Schag & Heinrich, 1985, Heinrich, Schag & Ganz 1984, Mages & Mendelsohn, 1979, Masiak, Gams, Lee & Jones, 1983, Mettlin, Cookfair, Lane & Pickern 1983, Meyerowitz, Heinrich & Schag 1983, Padilla & Grant, 1985, Schag et al. 1983). These data are rarely specific for the older cancer patient, or clearly address the effect of a cycle of chemotherapy on quality of life. The issue of importance and quality of independent functioning for the acutely ill older adult during treatment may be different than for younger adults.

The identification of circumstances or variables which might put the older adult with cancer at higher risk for difficulties in daily life during treatments can be derived from the extensive literature documenting alterations in activities of healthy and chronically ill elderly. Research evaluating independent functioning of healthy older adults in the community suggests that the majority do very well (Branch & Jette, 1981, Branch, Katz,

**Nursing Research and Lung Cancer**

Despite the significant morbidity and mortality associated with lung cancer, in the decade 1978-1988 two major cancer nursing research journals (*Cancer Nursing, Oncology Nursing Forum*), and the research journals *Nursing Research, and Research in Nursing and Health* contained only four research articles exclusively focused on the impact of lung cancer (Cooper, 1984, Brown, Carrieri, Janson-Bjerkle & Dodd, 1986, Driever & MCorkle, 1984, Germino & McCorkle, 1985). Two of these articles (Driever & MCorkle, 1984, Germino & McCorkle, 1985) were extensions of McCorkle and Quint-Benoliel's (1983) study comparing the psychosocial variables of lung cancer patients with cardiac patients. Published in a non-nursing journal, it remains the most comprehensive data based nursing research article on lung cancer patients. In cancer nursing studies with lung cancer patients as part of a larger sample (e.g. Frank-Stromborg & Wright, 1984, Gray, Adler, Fleming & Brescuam, 1988), the characteristics of the lung cancer
subset were not reported separately.

In nursing research articles, the type of lung cancer, and extent of disease often have been absent in descriptions of the lung cancer patients (e.g. Frank-Stromborg & Wright, 1984, Lewis, 1982). Other areas of nursing research which might contribute to a data base about the experiences and the nursing needs of lung cancer patients, for example, in the area of cancer related pain, often neglected to report medical diagnoses (e.g. Donovan & Dillon, 1987, Bressler, Hange & McGuire, 1986). This was also the case in research related to nausea and vomiting due to chemotherapy (e.g. Rhodes, Watson, Johnson, Madsen & Beck, 1987, Zook & Yasko, 1983). Even review and survey articles related to nursing care of lung cancer patients are rare. In a ten year review of the Cumulative Index for Nursing and Allied Sciences, only occasional case studies and articles focused on the dying lung cancer patient were found. Recently, the American Journal of Nursing (11:1987), published a section on the state of the art in lung cancer treatment. In 1987, Seminars in Oncology Nursing devoted an entire issue (Volume IV) to oncology nursing care and lung cancer.

The lack of research on the nursing problems of lung cancer is in sharp contrast to the hundreds of articles on investigations in lung cancer treatment in the medical literature. Several reasons for this inequity can be
postulated. First, adults with advanced lung cancer are often very ill and nurses may be reluctant to involve those who are weak and suffering from pain or dyspnea in research studies. Secondly, the majority of lung cancer patients may be cared for as outpatients, in clinics and private offices, where they are not as easily accessible for data collection. Even when in the hospital, such patients may be on general medical-surgical wards rather than on oncology units. Perhaps, a fatalistic attitude which evolves from the grim prognosis of lung cancer affects nurse researchers. Additionally, there is a poorly defined stigma associated with lung cancer, related to "blame because of past smoking behavior". Research into nursing care strategies, at this stage of limited medical treatment options, may make the most significant contributions to improving the quality of life of lung cancer patients.

A reevaluation of the toxicities and therapeutic outcomes of cancer treatment in the elderly, particularly those with lung cancer, brings to question the limits of a purely bio-physical model in delineating the impact of illness. On the other hand, purely psycho-social models fail to consider the inter-relationship of biological factors with psychosocial variables which influence illness behavior. Additionally, Riley (1983) and others have proposed that aging must be viewed from a
psychosocial as well as biologic framework. A multivariate perspective is essential for nursing investigations of the impact of cancer treatment in the older adult.

Nursing's focus on human responses in relation to actual or potential health care problems (American Nurse's Association, ANA, 1980) requires a scientific appraisal of the complex variables affecting the behavioral response of older adults to cancer treatment. The life span developmental model of aging (Ealtes, Reese and Lipsett, 1980, Reed, 1983, Riegel, 1976) supports a multivariate perspective integrating physiologic, psychological, sociocultural, and environmental variables to account for the tremendous variability in the behavior of older adults. In addition, the influence of chronologic age as well as birth cohort on responses to illness can be considered. Life span developmental models as proposed by Shaie (1986), consider developmental changes in response to illness experiences. Non-normative cohort events, such as the diagnosis of lung cancer and subsequent treatment, can be considered in the same way as a developmental influence in affecting behavior (Weekes & Rankin, 1988).

Purpose

The purpose of this study was to describe and compare the effects of an initial cycle of cancer chemotherapy for non-small cell cancer on the disruptions in quality of life and functional status in older adults (65 years and
older) with younger adults (less than 65 years) and with an untreated cohort. Comparisons were made at baseline by age and after a cycle of chemotherapy. Moderator variables which might influence the impact of chemotherapy on disruptions in quality of life and functional status in older adults were categorized according to the conceptual framework as person/environment variables (gender, socio-economic status, living situation, education), illness variables (extent of disease, type of symptoms, time since diagnosis, weight loss), and the biophysical variable of comorbid disease. These were examined for the modulation of age and treatment on disruptions in quality of life and functional status. Severity of side effects and disease progression were viewed as potentially confounding variables which could affect disruptions in quality of life and functional status in older adults post the chemotherapy cycle. This study is an initial step in building a necessary scientific clinical base for nursing care of older adults with non-small lung cancer receiving treatment with chemotherapy.
CHAPTER 2
REVIEW OF THE LITERATURE

Side Effects of Cancer Chemotherapy in the Elderly

Side effects of cancer chemotherapy usually are interpreted as adverse physiologic and/or organ specific toxicities. They may range from minor problems to life threatening events and may be expected or unexpected based on data from pharmacologic studies and clinical trials. Age related physiologic changes in the elderly may create differential response and toxicity to cytotoxic drug therapies, but these are not well documented (Walsh, Begg & Carbone, 1989). The time frame for the occurrence of chemotherapy related toxicity can be categorized as immediate, delayed, and long-term. Additional characteristics include the duration and the frequency of the effect. Recovery from drug related consequences also may vary. Side effects are moderated by an array of biological, and physiological variables. The documentation of untoward physiologic and organ specific side effects is an important part of standard chemotherapy treatment. Freidman, Furberg and DeMets (1985) noted however, that the documentation of adverse effects of chemotherapy was rarely done with the same scientific rigor as the evaluation of tumor response in clinical trials.
Evaluation of the interplay and relative weight of physiologic and psychosocial variables becomes particularly relevant when assessing the responses to treatment from a behavioral perspective. Recommendations of the Federal Drug Administration approval of antineoplastic agents included the statement that the drug protocol should have evidence of "beneficial effects on disease related symptoms and/or quality of life" (Cancer Letter, 1988). Schipper and Levitt (1985) suggested that the use of quality of life measures may significantly influence evaluation in clinical trials, particularly when cure is not possible.

The potential differential short and long-term impact of chemotherapy on quality of life and functional status on older cancer patients as compared with younger adults has important implications for nursing. Unfortunately, these sequelae, particularly for the older adult with lung cancer have not been described.

Effect of Age in Distribution and Absorption

Appropriate distribution of drugs within the body is essential for full therapeutic benefit in cancer treatment. The volume of drug distribution is determined by the ratio of the mass of drug in the body to the concentration in the blood (Gerber, 1982). The higher the affinity of the drug for tissue, the higher the volume of drug distribution. Changes associated with aging
theoretically make drug distribution less predictable. Significant physiological changes in older adults include the decreased relative as well as absolute total body water. Body composition changes result in a relative increase in adipose tissue and reduction of lean body mass.

Protein binding differences in the elderly due to the decreased plasma concentration of albumin may alter potential receptor sites for the chemotherapeutic drug (Gerber, 1982). This might result in enhanced systemic toxicity. For example, the chemotherapeutic agent cisplatin is protein bound, but data are not available to support differential distribution in the elderly (Kerr & Chabner, 1982). Comorbid cardiovascular disease, common in the elderly, may contribute to altered distribution of drugs due to changes in blood flow (Kerr & Chabner, 1983).

Changes of drug distribution in the elderly might suggest a need for changes in dosages of drugs as well as alteration of dose intervals, depending upon whether the volume of distribution has been increased or decreased by physiologic changes. There are little data to support pharmacological differences i.e. lower dosages of cancer chemotherapy in the elderly (Kerr & Chabner, 1983), though treatment alterations for the elderly have been predicated on this assumption.

Most chemotherapeutic agents are given intravenously,
but for those given orally, absorption of drugs via the gastrointestinal tract may be different in the elderly. Recognized changes in the aging gastrointestinal tract which might compromise absorption have not been well documented (Gerber, 1982). The most significant change which may potentiate toxicity is decreased gastrointestinal motility, resulting in increased absorption. Decreased blood flow to the aging small bowel could result in decreased concentrations of drug available for distribution.

**Drug Metabolism and Excretion**

Metabolism and excretion of chemotherapeutic drugs contribute to the creation of a therapeutic index (therapeutic dose/toxic dose). Two major organ systems, the kidney and the liver, are important factors in determining drug metabolism and excretion. Physiologic changes associated with aging have been noted in both of these systems.

Liver function is assessed carefully when chemotherapy treatment is planned. The biotransformation of certain chemotherapeutic agents (e.g. cyclophosphamide) to an active or inactive form generally occurs in the liver. The liver additionally metabolizes drugs to inactive compounds which are subsequently excreted in the bile. Hepatic dysfunction in excretion of certain drugs (e.g. doxorubicin, vincristine) can result in significant
toxicity (Haskell, 1985). The decrease in hepatic size and blood flow associated with aging may make the duration and potency of a particular drug difficult to predict, but hepatic metabolism does not appear to be altered dramatically by aging (Gerber, 1982). While physiologic differences in hepatic function of the elderly have been noted, they have not been correlated to meaningful clinical differences in toxicity of cancer chemotherapeutic agents. Dose alteration is considered in light of hepatic dysfunction particularly for drugs requiring high hepatic clearance (Haskell, 1985). In some studies, age alone has been used as a parameter for dose reduction even for those with normal indicators of hepatic function (Bonadonna & Valugussa, 1981).

The adequate excretion of chemotherapy drugs and their products by the kidney is essential to avoid untoward toxicity. Preexisting renal dysfunction may prevent the use of many drugs of therapeutic potential. The clearance of a drug by the kidney depends upon glomerular filtration. Decreased renal function (50% reduction for the 70 year old) is characteristic of the aging process (Gerber, 1982). Elevated creatinine clearance, reflecting decreased glomerular filtration rate, is associated with advanced age (Rowe, Andres, Tobin, Norris, Shock, 1976). Normal levels of serum creatinine clearance may be misleading due to change in
body mass of the elderly. If decreased renal function is so prevalent among the elderly, the representativeness of the elderly sample with normal renal function in clinical trials reviewed by Begg et al. (1980) and Begg & Carbone (1982) is questionable and limits generalizability of findings to the majority of older adults with cancer. Specific dose alterations for decreased renal function are suggested for many drugs, in addition to alterations for specific cancer chemotherapy agents (e.g. Bonadonna & Valagussa, 1981). Gerber (1982) suggests the assumption of renal dysfunction in the elderly with subsequent imposition of automatic dose reductions for all drugs. Drug alterations, leading to underdoses however, especially in cancer chemotherapy, may lead to treatment failures (Bonadonna & Valagussa, 1981).

**Drug Interactions**

Limitation of potential therapeutic responses in cancer treatment may occur with drug interactions. The elderly cancer patient may be more vulnerable to enhanced or decreased drug responses due to numerous prescriptions for comorbid conditions as well as frequent use of over the counter medications (Bressler, 1985).

Combination chemotherapy is generally employed to treat cancer to produce maximum benefit with minimal toxicity. The various actions of multiple drugs are used to maximize cytotoxicity. Agents with different types of
toxicity may be used in combination to augment therapeutic responses (Haskell, 1985). Use of different drugs may minimize drug resistance. Several undesirable drug interactions have been investigated in cancer chemotherapy. Methotrexate, for example, is bound and transported by the same mechanism (serum albumin) as aspirin, allowing competition and enhanced toxicity of the chemotherapy agent (Bressler, 1985, Haskell, 1985). The interaction of Allopurinol and 6-mercaptopurine (6-MP) results in untoward toxicity unless the 6-MP dose is reduced (Haskell, 1985).

Chemotherapy Side Effects and Toxicity

Hematologic Toxicity

Chemotherapy has its greatest impact on rapidly dividing cells. Leukopenia and thrombocytopenia are the result of suppression of precursor and stem cells in the bone marrow which are the cycling cells especially vulnerable to the effects of chemotherapy. Infection (secondary to leukopenia) and bleeding (secondary to thrombocytopenia) can cause life threatening situations for any cancer patient, but the elderly are thought to be particularly susceptible to the assault of vigorous myelosuppressive therapy. These life threatening toxicities are important considerations affecting treatment decisions. Physiologically, the bone marrow is less cellular in the elderly and thus, there are fewer
functional stem cells than in bone marrow of the younger adult (Hoagland, 1982). The results of studies investigating differential hematologic toxicity in the elderly have been unclear. Begg et al.'s (1980) retrospective analysis of data from six completed chemotherapy trials of the Eastern Cooperative Oncology Group (ECOG) for patients with primary lung, colorectal and breast cancer failed to demonstrate conclusive differences. All elderly patients included in the analysis had met the stringent criteria for entry onto the clinical trials (e.g., normal cardiovascular, renal, and hepatic function). Patients with serious comorbid disease also were excluded. The authors cite the similarities of the younger and older sample in terms of performance status prior to therapy, prior radiation therapy and presence/absence of liver metastasis.

Data from Begg et al. 1980, documenting how many elderly were excluded from the ECOG protocols or how many refused entry are not available for the lung and colorectal patients. Breast cancer patients were excluded from participation in the protocol if over 65 years old, therefore over 60 was accepted as "elderly" for this group. Of the 2,981 charts reviewed, the elderly comprised: 9.7% lung cancer, 14.4% colorectal and 22.2% breast cancer. Drugs used included: adriamycin, cyclophosphamide, CCNU (lung cancer); adriamycin,
vincristine, 5-FU, methotrexate, cyclophosphamide, fluoxymestosterone, prednisone, (breast cancer); 5-FU, cyclophosphamide, 6-TG, methyl CCNU, vincristine, DTIC, hydroxyurea (colon cancer). Patients are described as having advanced disease but data are not given to describe the specific type of malignancy, stage at start of treatment, and sites or degrees of metastases.

Chi-square analysis demonstrated no significant relationship between age and frequency of toxicity, or between age and relative frequency of more severe hematologic reactions. Only the most severe rating of hematologic toxicity (neutrophils less than 1000, platelets less than 50,000) noted during the trial was reported. The length of marrow suppression and time until recovery was not addressed. While the difference is not statistically significant, 10.9% of the elderly breast cancer patients experienced life-threatening hematologic reactions versus 8.5% of the younger breast cancer patients. Incomplete data were available regarding the potential issue of under-dosing of the elderly patients in the trials.

In a subsequent analysis of toxicity of the elderly in nineteen clinical trials (Begg & Carbone, 1983), life-threatening hematologic toxicity was noted in a few of the studies reviewed. Chemotherapy protocols in eight cancer sites were evaluated: lung, colorectal, gastric, sarcoma,
head and neck, melanoma, renal and ovarian. Of the 6,239 patients evaluated, 780 (13%) were over 70 years. Performance status, weight loss, and prior treatment were comparable for the younger and older patients. Severe hematologic reactions were more prevalent in protocols for head and neck cancer (methotrexate, C.Parvum, bleomycin, platinum; Dibromodulcital, maytansine, ICRF-159), and ovarian cancer (melphalan, 5-FU, methotrexate, Cytoxan; melphalan, thiotepa, methotrexate, Cytoxan, Adriamycin, 5-FU). Analysis of the protocols for the relative toxicity contribution of specific drugs indicates that methotrexate and methyl CCNU were responsible for significant hematologic toxicity in the elderly. Methotrexate was examined only as part of a combination chemotherapy regimen. Hansen (1971) also reported increased toxicity of methotrexate in the elderly when used as a single agent.

The diminished renal clearance of the elderly may have contributed to the enhanced toxicity of this renally excreted drug. The risk of increased methotrexate toxicity for the elderly is estimated at between 19-29% (Begg & Carbone, 1983). The sample size of the elderly receiving methotrexate was only 66 with 27 (43%) experiencing severe toxicity. The reason for increased CCNU toxicity is not clear. Thirty-nine percent of the elderly (n=65) developed severe toxicity with this drug. Adriamycin does not appear to have age specific hematologic toxicity. Many of the
drugs were not included in the individual drug analysis because of insufficient data.

Hematologic toxicity was identified by Kahn et al. (1984) in a longitudinal investigation using full versus attenuated doses of chemotherapy (Daunorubicin, Cytosine Arabinoside, and 6-Thioguanine), TAD, in the treatment of elderly (70 years and older) patients with acute leukemia. The elderly patients who received full dose treatment (n=20) had an increased relative risk of dying within 60 days (n=12). The primary causes of death were hemorrhage and sepsis caused by bone marrow suppression (secondary to the disease as well as treatment). Only five patients in the attenuated dose arm of the protocol suffered an early death (within 60 days of treatment). The study was terminated after the significant differences in poor survival of elderly patients in the full dose treatment arm were noted.

Foon, Zighelboim, Yale and Gale (1981) in comparing older (60 years and older) with younger patients with acute leukemia using the same intensive induction TAD protocol found no significant difference in remission rate, remission duration, and or survival. Specific comparisons of toxicity were not described. Clamon, Auden and Pinnick (1982) reported that one of the over 70 year old patients (n=24) treated with a variety of chemotherapy protocols for small cell lung cancer died of treatment
induced granulocytopenia. Peterson et al. (1982) observed more frequent (33% as compared with 14% for young patients) hematologic toxicity in older patients (60 years and older) when treated with a variety of chemotherapy protocols for Hodgkin's disease. In multivariate analysis, age was the significant factor associated with leukopenia.

In a chemotherapy trial for small cell lung cancer Poplin, Thompson, Whitacre & Aisner (1987), reported increased toxicity and early death in patients over 65 years of age. Patients had received a protocol including doxorubicin, cyclophosphamide and etoposide. Ten out of 49 patients over 65 died primarily due to infection but this was not significantly different from other age groups. Survival was most clearly linked to performance status for all patients.

The fear of hematologic toxicity in the elderly is the rationale for differential treatment decisions in an unknown number of cases. The research support for these alterations is limited. Even less is known about the clinical manifestations of marrow suppression in the elderly. For instance, is the frequency of minor bleeding episodes higher in the elderly because of blood vessel fragility; or is the time period for infection longer in the aged. The supportive therapy received by many marrow suppressed cancer patients, such as: reverse isolation, platelet transfusions, and antibiotic therapy, may pose
unique concerns for the elderly. Additional research is needed to both describe and determine relative risk of hematologic toxicity for the elderly cancer patient and appropriate nursing care.

**Gastrointestinal Toxicity**

Gastrointestinal changes of aging include alteration in bowel patterns, though empirical data are equivocal (Vireling & Reichen, 1982). The resilience of the older gastrointestinal tract to toxic effects of chemotherapy is not well documented. Changes in eating behavior in the elderly have been related to changes in taste sensation, to gum and dental disease, and to oral pathology more commonly found in the elderly (e.g. leukoplakia). Social isolation and psychological disturbances which may be more prevalent in the elderly can contribute to problems of inadequate nutrition.

Nausea and vomiting are associated with many chemotherapy agents. Chemotherapy agents most frequently causing severe nausea and vomiting include cisplatin, nitrogen mustard, DTIC, nitrosoureas (e.g. CCNU), and adriamycin. Most chemotherapy induced nausea and vomiting is mediated by the vomiting center near the chemoreceptor trigger zone. This toxic effect of chemotherapy is the subject of many research investigations (Mitchell & Schein, 1982).

Begg et al.'s (1980) review of toxicity in the
elderly in the study previously discussed found no significant differences according to the ECOG classification of severe vomiting (intractable vomiting). Only the most severe episode of vomiting experienced during the trial was reported; not reported was the length of time during which the side effect was experienced.

Nausea as a symptom was not specifically measured. The validity and reliability of the ECOG toxicity criteria (Oken et al., 1982) for gastrointestinal side effects are not well supported. A subjective clinical judgment must be made as to the severity of the vomiting which may have been interpreted differently in the multiple ECOG sites. Nausea can be a very disabling symptom accompanied with significant side effects from medications for its treatment (e.g. drowsiness). However, the ECOG finding of no age related difference in vomiting is supported by other research findings (Begg & Carbone, 1983, Clamon et al. 1982, Foon et al. 1981, Kahn et al. 1984, Peterson et al. 1982). Anticipatory nausea and vomiting related to chemotherapy in the elderly has been investigated by Nerenz, Love, Leventhal & Easterling (1986) and Morrow (1982). Both studies report findings of less (conditioned) anticipatory nausea and vomiting in older adults (older than 55, in Morrow's study). The experience of the elderly with antiemetics (e.g. sedation and extrapyramidal effects) to control the side effects of
nausea and vomiting has not been reported. Measures other than the ECOG criteria are necessary to provide careful measurement of this side effect. Iatrogenic problems secondary to nausea, vomiting, and antiemetic therapy should be carefully assessed in the elderly patient who, because of physiologic differences, may be more vulnerable to problems e.g. electrolyte disturbances, dehydration, weakness, and weight loss (Mitchell & Schein, 1982).

Chemotherapy related nausea and vomiting have been a frequent subject for cancer nursing research (Table 2.1). Unfortunately, details of diagnoses and drug regimens often were not reported in these studies. Separate analysis for age was not reported. Lung cancer subjects have been identified in four of the studies but separate analyses have not been reported.

Higher risk of chemotherapy induced anorexia has not been reported in the elderly. The differential use of nutritional support (both enteral and parenteral) for the elderly cancer patient is not currently supported in the literature. Begg & Carbone (1983) compare weight loss of younger and older patients prior to the start of therapy, but it is not reported in terms of response to treatment. (ECOG toxicity parameters do not include weight loss during treatment.)

There has been little research about the differential nutritional requirements of the elderly (Chernoff & Ropka,
Table 2.1

NURSING RESEARCH (1978-89)
NAUSEA & VOMITING DUE TO CHEMOTHERAPY
FOCUS ON LUNG CANCER PATIENTS

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>SAMPLE</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gathercole, Connoly &amp; Birdsell (1982)</td>
<td>?/20</td>
<td>lung pts included # not reported</td>
</tr>
<tr>
<td>Daniels &amp; Belt (1982)</td>
<td>9/31</td>
<td>type &amp; extent of disease not reported</td>
</tr>
<tr>
<td>Lamb &amp; Cox (1982)</td>
<td>10/20</td>
<td>type &amp; extent of disease not reported</td>
</tr>
<tr>
<td>Zook &amp; Yasko (1983)</td>
<td>?/26</td>
<td>no specific dx reported</td>
</tr>
<tr>
<td>Berry-Opersteny &amp; Hesinkveld (1983)</td>
<td>2/15</td>
<td></td>
</tr>
<tr>
<td>Frank (1985)</td>
<td>?/15</td>
<td>lung pts included # not reported</td>
</tr>
<tr>
<td>Rhodes, Watson, &amp; Johnson (1986)</td>
<td>?</td>
<td>no specific dx reported</td>
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</tr>
<tr>
<td>Rhodes et al. (1987)</td>
<td>?/309</td>
<td>no specific dx reported</td>
</tr>
</tbody>
</table>

dx=diagnosis
pts=patients
ca=cancer
1988, Crapo, 1982). Several national surveys point to the problems of nutritional deficiencies, inadequate calorie intake, and obesity in those over 60 years old (Chernoff & Ropka, 1988). Impairment in glucose metabolism, often associated with aging, may be a cohort effect. Recent studies suggest that alteration in diet and exercise may reduce this health risk (Rowe & Kahn, 1987). Physiologic changes which occur in the elderly such as decreased calorie requirement (resulting in the need for nutrient dense foods), and preexisting chronic diseases (and accompanying physical disability), and social conditions (financial problems, social isolation) make the elderly more vulnerable to malnutrition. Cachexia which results from cancer and chemotherapy has not been reported as more of a problem for the elderly.

Stomatitis is another manifestation of the effect of chemotherapy on rapidly replicating cells (Peterson & Sonis, 1982). Drugs associated with a high incidence of stomatitis include: Methotrexate, 5-FU, adriamycin, Vinblastine, and Bleomycin. Studies investigating toxicity in the elderly patient receiving chemotherapy (Begg et al. 1980, Begg & Carbone 1983, Foon et al. 1981, Kahn et al. 1984, Peterson et al. 1982) have not identified stomatitis as a side effect with greater incidence or severity in the elderly. ECOG criteria for severe rating of stomatitis is "ulcers-cannot eat".
However, anorexia and subsequent poor intake may be due to many causes. A number of physiologic changes in the oral cavity would appear to make the elderly patient more vulnerable to severe toxicity: dental disease, periodontal disease, dentures or partials, decreased taste perception (Chernoff & Ropka, 1988, Crapo, 1982). Severe esophagitis secondary to chemotherapy and/or moniliasis may further complicate nutritional status (Mitchell & Schein, 1982). Diarrhea associated with chemotherapeutic agents is due to the impact of the drugs on the gastrointestinal crypt epithelium (Mitchell & Schein, 1982). Diarrhea evaluated by ECOG toxicity criteria as severe is grossly bloody. Frequency of stools is not reported, nor is responsiveness to antidiarrheal therapy.

Differential gastrointestinal toxicity in elderly cancer patients participating in clinical trials has not been reported as more severe. Age related changes in the normal aging bowel have received little study (Vierling & Reichen, 1982). The most noted change is the tendency to develop diverticula. Uncontrolled diarrhea can contribute to electrolyte disturbances, dehydration, and weight loss. Severe diarrhea can be dose limiting as well as very distressing to the patient (Mitchell & Schein, 1982). Constipation has been viewed as a common problem for the elderly, however research has been scant and does not support this common belief (Vierling & Reichen, 1982).
Paralytic ileus can be a life threatening side effect of Vincristine. The elderly have been suggested to be at greater risk for the development of bowel dysfunction due to the effect of the vinca alkaloids on the autonomic nervous system (Mitchell & Schein, 1982) but the research is unclear about this risk (Rosenthal & Kaufman, 1974).

**Renal Toxicity**

With aging there is an associated decrease in the glomerular filtration rate reflected in the elevation of urinary creatinine clearance (Rowe et al. 1976, Bichet & Schrier, 1982). This decline in organ efficiency has been described as a hallmark of "functional aging". Wide variation occurs in the rate of decline of renal function.

Elderly cancer patients are at increased risk for toxicity from chemotherapeutic drugs excreted or metabolized by the kidney. Alteration of doses of drugs may be required, and at the extreme, the potential omission of certain drugs that may decrease opportunities for effective treatment. Certain cytotoxic agents are nephrotoxic in their own right. Cisplatinum and methotrexate (in high doses) are examples of these agents.

Differential severe renal toxicity (creatinine over 4.0) in the elderly was not reported by Begg et al. (1980) or Begg and Carbone (1983). Methotrexate was associated with increased hematologic toxicity in the elderly, but not associated with increased renal toxicity in the ECOG
studies. However, adequate renal functioning was a pre-requisite for participation in the clinical trials examined. Clamon et al. (1982) as previously discussed, did not note renal toxicity in elderly patients treated for small cell lung cancer, nor did Kahn et al. (1984) report life-threatening renal toxicity. Hrushesky et al. (1984) also noted the lack of age-dependent nephrotoxicity in their study involving 24 hour creatinine clearances. Perhaps the lack of evidence of age related renal toxicity in current clinical trials is because of the stringent protocol admission requirements as well as rigorous guidelines for clinical care for known nephrotoxins.

**Pulmonary Toxicity**

The elderly as a group have an increased risk of significant respiratory problems, such as emphysema, due to decades of exposure to environmental hazards (e.g. smoking, pollution). Progressive weakening of respiratory muscles with age can result in decreased breathing capacity and respiratory reserve (King & Schwartz, 1982). Additional causes of pulmonary compromise are related to chest wall disorders including osteoporosis and kyphosis. Though a wide variability of pulmonary function is seen in older adults, in general, age is associated with increased pulmonary distress with drugs, procedures, and diseases which assault respiratory function.

Pulmonary toxicity is an infrequent but potentially
life-threatening side effect of some chemotherapeutic agents. Radiation to the chest may substantially compound this problem. Symptoms of chemotherapy induced toxicity commonly include progressive dyspnea, dry cough, and tachypnea (Ginsburg & Comis, 1982). Bleomycin has been documented to cause significant dose related toxicity in the elderly (Samuels et al. 1976). Other cytotoxic drugs e.g. BCNU, Busulfan, Mitomycin-C, which affect the respiratory system have not shown such age-specific differences (Ginsburg & Comis, 1982).

Preexisting pulmonary disease, and tobacco use have been associated as additional risk factors. These may be more prevalent in the elderly. But, perhaps due to the exclusion criteria in clinical trials, differential pulmonary toxicity was not reported by Begg et al. (1980) or Begg & Carbone (1983). However, Dixon et al. (1984) reported that older adults (n=23 over 59) with small cell lung cancer were significantly more likely to get pneumonia during intensive chemotherapy.

Cardiac Toxicity

Cardiac toxicity has been especially associated with the chemotherapeutic drug Adriamycin. Advanced age has been associated with an increased risk of Adriamycin induced congestive heart failure (Bristow et al. 1978). The elderly also may be at higher risk for Adriamycin induced cardiomyopathy (von Hoff, Rozensweig & Piccart,
1982). The reasons for age-related differences are not well documented. Functional changes in the aging cardiovascular system (e.g., decreased cardiac output, decreased heart size, increased systolic blood pressure) and pre-existing heart disease may be important factors in increased risk of cardiac morbidity in the elderly (Lindenfeld & Groves, 1982). Adequate cardiac function was necessary in order to have participated in the studies reviewed by Begg and his colleagues (1980, Begg & Carbone, 1983). Significant heart disease was an important exclusion criteria in this and many other clinical trials.

**Hepatic Dysfunction**

An increased risk of hepatic toxicity in the elderly patient receiving chemotherapy can be postulated because of age-related decrease in liver size and circulation (Vierling & Reichen, 1982). The chemotherapeutic drugs such as BCNU, Methotrexate, cytosine arabinoside, have been associated with liver damage (Perry, 1982). Decreased metabolism of certain chemotherapy drugs may lead to prolonged action or lack of biotransformation to an active drug. Dose alterations for Adriamycin (excreted in the bile) are required when there is evidence of hepatic dysfunction (Perry 1982). The research studies evaluating differential toxicity to chemotherapy in the elderly have not reported higher incidence of hepatic toxicity (Begg et al. 1980). However, normal liver
function tests are generally required before participation in clinical trials. Perry (1982) cautions the evaluation of etiology of toxicity when the patient is of advanced age. However, changes in drug metabolism associated with aging are not easily predicted (Lipshitz et al. 1985).

**Neurologic Side Effects**

Decremental changes in the central nervous system associated with aging include decreased coordination, short term memory loss, slowed reflexes, decreased concentration abilities and decreased mobility. The relationship between the impact of chemotherapy drugs on reflexes, balance, and coordination in the more vulnerable elderly population is an important area for future research. Substantial individual variability is present in aging adults. There is an increased sensitivity of the elderly to many medications, which affect the central nervous system, such as sleeping pills and sedatives (Bressler, 1985, Lipschitz et al. 1985). Biochemical abnormalities resulting from cancer and cancer treatment may indirectly lead to confusion and disorientation, for example, hypercalcemia.

Chemotherapy drugs associated with central nervous system toxicity (e.g. Procarbazine, L-Asparaginase) have not been routinely associated with more frequent or more severe side effects in the elderly (Kaplan & Weirnich, 1982, Rosenthal & Kaufman, 1974). Age-related
neurotoxicity was associated with advancing age in a study of high dose cytosine arabinoside (total dose 18g/m²) (Gottlieb et al. 1987). Four out of the five patients over 55 developed irreversible neurotoxicity. Ostchega, Donohue & Fox (1988) noted that age was significantly associated with severity of peripheral neuropathy resulting from high-dose cisplatin therapy (40mg/m² X 5 days) in a retrospective study of 30 patients previously treated for ovarian and testicular cancer. The age range of the subjects was 18 to 70 years, however, only 2 patients were over 60 years of age. The increase in symptoms of peripheral neuropathy was associated with an increased difficulty in performing activities of daily living. In this retrospective study, the majority of subjects (n=20) had been off chemotherapy treatment for a year or more (n=10 for three years or more).

Decreased hearing in the elderly has been projected at 25% (25 db) in those 65 years and older and is manifested by decreased auditory acuity (Jahnigen & LaForce, 1982). Cisplatin is a cytotoxic agent with known ototoxicity, especially with high single boluses of the drug (Haskell, 1985). Haskell (1985) recommends baseline audiograms prior to therapy with possible exclusion of those with preexisting hearing loss. Begg and colleagues (1980) and Begg and Carbone (1983) do not report differential central nervous system toxicity in their
analysis of elderly patients receiving known neurotoxins.

Dermatologic Side Effects

Alopecia is a side effect of numerous chemotherapy agents e.g. mecloretamine, methotrexate, 5-FU, Vincristine, Daunomycin (Dunagin, 1982). Hair loss may be a preexisting problem for elderly men and to some degree for elderly women (Tonnesen & Weston, 1982). Hair becomes thinner and has a shorter growth potential. Severity of alopecia and the nature of hair regrowth after chemotherapy has not been described as different for elderly men and women (Dungan, 1982). The emotional reaction to loss of hair due to treatment has not been specifically described for the elderly, though there is often an assumption that it is less traumatic for already balding older men.

Changes in aging skin, especially the decrease of subcutaneous tissue and elasticity, may make venous access for the delivery of intravenous chemotherapy agents more difficult. Age differential in the incidence of extravasation has not been reported (Dungan, 1982). The friability of aging skin may make risk of infection and bleeding due to injury (e.g. intravenous puncture), more important in the elderly. Severe skin reactions due to chemotherapy (ulceration, necrosis) were not more prevalent in the elderly in Begg & Carbone's (1983) retrospective analysis.
Sexual Side Effects

The changes in the sexual organs of the elderly may compound side effects on sexual functioning of some drugs. Ganz and colleagues (1985) observed in their investigation of 240 men with cancer (34% over 65 years) receiving a variety of treatments that sexual dysfunction was a significant problem for both younger and older patients. Seventy-three percent of those over 65 reported problems compared with 65% of the younger men.

Psychological Side Effects

Psychologically, older adults may have had more experiences dealing with illness and thus, may be better able to cope with the consequences. Cassileth et al. (1985) evaluated the psychological impact of chemotherapy on the elderly using the self-report tool, the Rand Mental Health Index. Comparing older age groups with younger age groups, they found that the elderly patients fared much better. The investigators suggest that the elderly may be more capable of tolerating at least the psychological assault of chemotherapy due to their life experiences with stress and their possibly limited expectations for cure.

A comparative study (Cassileth et al. 1984) of patients with chronic illness (n=758), including a subset of cancer patients (n=193), failed to demonstrate unique disease specific differences in psychological attributes (as characterized by the Mental Health Index), except for
those with clinical depression. Better mental health status was correlated with advancing age, whereas diagnosis of less than three months was associated with lower scores. Cancer patients (specific diagnosis or treatment characteristics not reported) receiving treatment had poorer psychological status than those who had completed treatment, but significantly better than those receiving palliative care alone. Those cancer patients with symptoms or seriously limited in activity, had significantly lower mental health scores than those with normal activity.

Nerenz et al. (1986) compared older with younger cancer patients receiving chemotherapy for breast cancer and lymphoma over 6 months for differences in emotional distress, difficulty with side effects and disruptions in activities. Subjects aged 19 to 83 years (n=238) who were about to receive an initial course of chemotherapy for varying stages of lymphoma or breast cancer were scheduled for five structured and taped interviews (one prior, and four after each cycle of therapy). The interviews focused on their concerns and side effects during treatment. One hundred and eighty completed all five interviews. The number of subjects in the older age groups are not reported. Interestingly, though there were no age differences in side effects experienced except that the older group (70-83 years) in both diagnostic categories
experienced fewer side effects. Older patients expressed less distress, disruption, difficulty and worry than young patients. In some cases, the older sample did receive fewer drugs and smaller doses of chemotherapy at the start of the treatment course but this is not clearly reported. Nerenz et al. (1986) suggests that the older subjects may cope with the side effects more easily because of past experience of similar symptoms in later life (for example, fatigue, hair loss).

In a continued analysis of this study (Love, Leventhal, Easterling & Nerenz, 1989) 90% of the sample reported some emotional distress from chemotherapy and 75% reported disruption in social life. Age breakdowns for these difficulties are not reported. Subjects with higher education (college) reported higher levels of distress.

Hughes (1985a) assessed depressive symptoms in newly diagnosed older adults with lung cancer (n=134, mean age 67 years, range 45-85). Using criteria for classification which were independent of symptoms associated with disease status, (for example, fatigue), sixteen percent were diagnosed with depression (n=22). Seventy percent of the patients had the diagnosis of non-small cell lung cancer and 46% had a previous history of depression. There were no significant statistical differences by age or sex differences. In a follow-up study (Hughes, 1985b) the lung cancer patients receiving chemotherapy and radiation
therapy treatment (n=50) were less depressed than the patients receiving supportive care only. Depression was associated with severe physical disability. Bleeker (1978) reported that only 1-2% of four hundred lung cancer patients required psychological intervention.

Psychological responses to different chemotherapy regimens may be linked to a neuro-biological mechanisms. Silberfarb et al. (1983) noted a significant difference in psychological responses as measured by the Profile of Mood States in small cell lung cancer patients receiving different protocols (n=77). Independent of tumor response, the regimen containing vincristine was associated with significantly increased depression and fatigue. Both groups are described as having comparable elderly subsets of those 65 years and older, however no sample size was given. Pharmacologically, the vinca alkaloids may decrease the availability of norepinipherine associated with positive mood.

Characteristics of Lung Cancer in Older Adults

Extent of Disease

The stage of disease at diagnosis is a major variable in the prognosis of non-small cell lung cancer. Various staging systems have been used in clinical studies to accurately describe the spread of this type of cancer. Previously, non-resectable disease had been differentiated into two major sub-groups: limited (limited to one
hemithorax and ipsilateral thoracic or supraclavicular nodes; disease encompassed within a single radiation port) and extensive (disease beyond these limits) (Zelen, 1973). Extensive disease at diagnosis as compared with limited disease was correlated significantly with decreased survival in the retrospective review of 7,500 patients with lung cancer (Hyde, 1973). This was confirmed by Lanzotti et al. (1977) (n=316) where distant metastasis was a major prognostic variable for poor survival. Additionally, tumor response to chemotherapy and radiation therapy has been negatively related to extent of disease (Byar et al. 1978).

Lack of bone, liver, and subcutaneous metastasis were linked with prolonged survival (over 1 year) in a retrospective analysis of 893 non-small-cell lung cancer patients entered in four comparative chemotherapy trials by the Eastern Cooperative Oncology Group (Finkelstein, Ettinger & Ruckdeschel, 1986). Most recently, this has been supported by the Southwest Oncology group's fourteen year review of clinical trials (Livingston, 1988) and the Williams, Woods, Levi and Page (1988) collaborative study in the United Kingdom and Australia.

An inverse relationship between advancing age (over 70 years) and extent of disease has been suggested by several studies (De Maria & Cohen, 1987, Holmes & Hearne 1981, Tetter, Holmes & McFarlane, 1987). In DeMaria and
Cohen's (1987) retrospective analysis of three age cohorts of lung cancer, 71% of patients seventy and over (n=209) presented with local disease as compared with 63% of the middle-aged cohort (n=822). Additionally, only 16% of the older cohort had distant metastases as compared with 25% of each of the younger cohorts. Despite the local extent of the disease, only 20% of the entire sample (n=1,545) received potentially curable surgical resections. Even for those treated surgically with curative intent, only 1 patient in the elderly group (n=10) survived beyond 2 years, as compared with 30 patients in the middle-age group (n=87). In a review of primary lung cancer, Ershler (1983) noted that over 70% of patients over 70 years (n=79) had localized not advanced disease. Tetter et al. (1987) suggest that the occurrence of local disease at diagnosis may be due to the higher incidence of squamous cell histology and a decline in adenocarcinoma and small cell lung cancer. Squamous cell lung cancer is more likely to be localized at diagnosis than other types of lung cancer. In their retrospective analysis of 9062 cases of lung cancer in Kansas and Missouri, approximately 40% of the lung cancer in adults over 70 years were diagnosed with squamous cell lung cancer as compared with 26% in the 40-49 year old group.

**Symptoms of Non-Small Cell Lung Cancer**

Symptoms of lung cancer have been recognized as an
indicator of stage and biologic behavior of a tumor. Feinstein (1966) first recognized the need for a formal structure and taxonomy for the identification and quantification of symptoms. Symptoms of lung cancer can be classified as primary (resulting from the direct effects of the tumor in an anatomic location, e.g. cough), systemic (symptoms remote from the tumor site but not anatomically related to the presence of the tumor e.g. anorexia), and metastatic (anatomically due to the spread of the tumor, e.g. bony pain due to metastasis). However, Pater and Loeb (1982) note that symptomatic history is not as important an indicator of prognosis if stage has been considered. Kukull, McCorkle and Dreiver (1986) reported that self-report of symptom distress (adjusted for age, functional status, and personality traits) at the time of diagnosis was the most important prognostic indicator for survival in a heterogeneous group of lung cancer patients receiving radiation therapy (n=54). Information about stage of disease was not reported. The Enforced Social Dependence scale (Benoliel et al. 1978) was used in that study as an unusual indicator of functional status. Finkelstein et al. (1986) reported that lack of symptoms, specifically shoulder or arm pain, was associated with longer survival.

Dyspnea was a more frequent presenting symptom in De Maria and Cohen's (1987) analysis of the elderly cohort
with lung cancer as compared with younger lung cancer patients from the Durham VA Medical Center. Whether this symptom was related to age related changes in pulmonary function and contributed to decreased functional abilities is not clear. Forty-four percent of the elderly sub-group had comorbid diseases in addition to the diagnosis of lung cancer, including, chronic obstructive pulmonary disease, congestive heart failure, and diabetes mellitus. This was compared with 40% intercurrent illness in the middle-aged group and 25% in the younger aged cohort. Separate prognostic analysis of this symptom was not reported.

Pain can be a significant symptom for adults with lung cancer. Nursing research studies (Table 2.2) have included lung cancer subjects in study samples, but usually the type and extent of the disease is not reported. Ferrel et al. (1988), for example, reported that lung cancer was the most common diagnosis in their study (n=37/206) but separate analysis for this subset were not reported. The nature and pattern of the pain experience for adults with lung cancer was not available in data based nursing research studies surveyed from 1978-88 (Cancer Nursing, Oncology Nursing Forum, Nursing Research, & Research in Nursing & Health).

Austin et al. (1986) reported, in a two year retrospective review of a hospice home care program, that men with lung cancer had serious pain control problems. Of
Table 2.2
NURSING RESEARCH (1978-88)
CANCER PAIN: FOCUS LUNG CANCER PATIENTS

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>SUBJECTS</th>
<th>COMMENTS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pierce &amp; Ya Deau (1980)</td>
<td>6/40</td>
<td></td>
</tr>
<tr>
<td>Degner, Fuiji, &amp; Levitt (1982)</td>
<td>1/1</td>
<td>case study</td>
</tr>
<tr>
<td>Bagley, Falinski, Garnigo (1982)</td>
<td>4/10</td>
<td>1 with oat cell 3 with non-small cell</td>
</tr>
<tr>
<td>Lindsey, Piper Stotts (1982)</td>
<td>1/1</td>
<td>case study of &amp; cachexia in small cell lung cancer</td>
</tr>
<tr>
<td>Rankin (1982)</td>
<td>6/40</td>
<td></td>
</tr>
<tr>
<td>Bressler, Hange &amp; McGuire (1986) and Barbour, McGuire, Kirchoff (1986)**</td>
<td>17/58</td>
<td>57% metastatic disease</td>
</tr>
<tr>
<td>Austin, Cody, Eyers, Hefferin, &amp; Krasnow (1986)</td>
<td>40/96</td>
<td>15 (severe pain) 14 (moderate pain) 11 (mild pain)</td>
</tr>
<tr>
<td>Donavan &amp; Dillon (1987)</td>
<td>?/96</td>
<td>no specific dx reported</td>
</tr>
<tr>
<td>Ferrel &amp; Schneider (1988)</td>
<td>14/75</td>
<td></td>
</tr>
<tr>
<td>Kane, Lehman, Dugger, Hansen &amp; Jackson (1988)</td>
<td>10/52</td>
<td></td>
</tr>
<tr>
<td>Ferrel, Wenzl &amp; Wisdom (1988)</td>
<td>37/206</td>
<td>Lung ca most common dx</td>
</tr>
</tbody>
</table>

*Type, extent of lung cancer not reported unless noted

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the forty subjects (total sample 96), 15 reported severe pain, 14 moderate pain, and 11 mild pain, on a modified McGill Melzack pain questionnaire. Two thirds of the lung cancer patients did not follow the prescribed analgesic regimen regardless of severity of pain. Older patients, in general, with a variety of diagnoses, however, reported less severe pain.

Symptoms of lung cancer can have a significant impact on the family. In an investigation of married home-bound cancer patients (n=447), lung cancer patients comprised 48% of the sample (n=215) (Wellish, Fawzy, Landsverk, Pasnaw & Wolcott, 1983). Families of male lung cancer patients had more significant mood disturbances (depression), and the spouses were more likely to be overwhelmed by home care. The authors explore the relationship of the patient's cognitive abnormalities due to central nervous system metastasis and respiratory impairment as the cause for family difficulty, but specific data are not presented.

Weight Loss

The extent of weight loss has been associated with the prognosis for lung cancer (Byar et al. 1978, Finkelstein et al. 1986, Zelen, 1973). But, the validity of the weight loss independent of changes in performance status as a prognostic factor is not clear. Loss of more than 6% of usual weight has been a negative prognostic
variable for patients with both limited and extensive disease (Lanzotti et al. 1977). Pater & Loeb (1982) note that substantial weight loss at diagnosis (over 20 pounds) was a serious negative prognosticator regardless of stage of disease. Approximately 50% of all patients in De Maria and Cohen's (1987) analysis exhibited weight loss. The older lung cancer patients were not at higher risk for weight loss in that study.

Lindsey, Piper and Stotts (1982) have reported that the progressive physical deterioration results from the phenomenon of cachexia. Weakness, fatigue, and decreased tolerance of physical activity were behavioral dimensions of the paraneoplastic phenomenon. Depression and accompanying decline in functional status are correlates of progressive cachexia. Clinical implications for nursing practice are suggested in a case study of a man with small cell lung cancer. Decreased food intake accompanied a mean 13% weight loss in 10 men with small cell lung cancer receiving chemotherapy followed over a 5 month period (Lindsey & Piper, 1985). Subjects over 67 were excluded and the mean age was 55 years. A minimal drop was seen in functional status of the patients during the five months.

Alterations in Functional Status

Historically, prognosis for patients with inoperable lung cancer has been correlated to level of "performance status" (also termed functional status) more clearly than
any other variable (Byar et al. 1973, Klastersky & Sculier, 1985, Sarna, Holmes, Petrovich & Figlin, 1985, Stanely, 1980). It is not clear whether this is a proxy measure of the biologic aggressiveness of the tumor alone, or has wider psycho-physical implications. O'Connell et al. (1986) among other investigators, have concluded that chemotherapy should only be given to patients with good performance status.

The Karnofsky Performance Status is the best known tool to measure performances status. Possible scores range from 100% (normal, no complaints) to 0 (dead) at 10% intervals. Hyde's (1973) classic study observed the natural course of lung cancer (untreated). Adults with extensive disease (all types of lung cancer) and with a Karnofsky Performance Status (KPS) of 40% had a median survival of 4 1/2 weeks, those with 60% KPS had a median survival of 9 1/2 weeks, and those with 90% KPS had a median survival of 22 weeks. Zelen (1973) supported the value of a measure of functional status (Karnofsky Performance Status) when evaluating lung cancer patients with extensive disease. A linear relationship between median survival and initial Karnofsky Performance Status was revealed in the investigation of placebo treatment for lung cancer patients with extensive disease (n=776). This factor was more important than histologic type as a predictor of survival. Lanzotti et al. (1977) discovered
that "symptom status" (modeled after the Zubrod scale of functional status) was a major variable in predicting survival for lung cancer patients with extensive disease. A critical determinant was whether the patients were bedridden more than 50% of the time. Pater and Loeb (1982) found that the gross dichotomy of performance status as ambulatory or bedridden was significant for prognosis. Ability to ambulate was an important predictor of long term survivors (over 1 year) treated with chemotherapy (Finkelstein et al. 1986). Thirty-two out of the 893 non-small cell lung cancer patients survived longer than 2 years. These patients presented with improved or maintained functional status as early as three months after initiation of treatment. The Southwest Oncology group (Livingston, 1988) reported that higher performance status (not in bed longer than 2 hours) was related to increased chance of initial response as well as increased survival at one year. Folman & Rosman (1988) also cite good performance status (80-100) as the most important predictive variable for survival (12 months) in a community trial of mitomycin C., vinblastine, and cisplatin (n=52). The study included patients aged 34-81 years. Symptomatic responses were seen within 3 weeks.

Unfortunately, descriptions of performance status were not reported in the age specific analysis of older adults with lung cancer by DeMaria and Cohen (1987). The
15% severity in pulmonary function abnormalities in the elderly as compared with approximately 10% of the younger groups may give some indication of age related difference in functional status. Simes (1985) supports the importance of performance status as an indicator of benefit as well as prognosis in a retrospective analysis of data from ECOG lung cancer clinical trials (n=2,714). Twenty-six percent of the sample was 65 years or older.

Treatment in Advanced Lung Cancer

The use of chemotherapy in the treatment of non-small cell lung cancer is controversial because of the equivocal data supporting palliation of symptoms and prolonging survival at the risk of potentially diminishing existing quality of life (Hansen, 1987). This is quite different from the routine chemotherapy treatment for adults with small cell lung cancer which is very responsive, for the short-term, to chemotherapy. Most patients with non-small cell lung cancer have metastatic disease or are inoperable at diagnosis and require systemic treatment.

Various experimental protocols have been used to control symptoms and prolong survival in non-small cell lung cancer (Sarna et al. 1985, Gralla & Kris, 1988). In fact, Mackillop, O'Sullivan, and Ward (1987) found that the majority of oncologists surveyed about the treatment of non-small cell lung cancer would not wish to be treated in a clinical trial with chemotherapy due to its toxicity.
and lack of efficacy. Interestingly, the example situation
given to the oncologists was the situation confronting a
sixty-four year old with metastatic non-small cell lung
cancer.

Exploration of many regimens of chemotherapy which
could offer increase in survival with limited toxicity
have resulted in ambiguous results. Only 10-20% of
previously untreated non-small cell lung cancer patients
may respond to single agent chemotherapy treatment (Sarna
et al. 1985). Patients who have tumors which initially
respond to chemotherapy have a definite survival advantage
when compared to those who do not. Combination drug
therapies have been linked to variable response rates of
25-40% in some studies with a median survival of 8-12
months for those who do respond to treatment (Aisner &
(1983) reported a 5% response to chemotherapy in adults
with lung cancer who were 70 years and older (n=104) which
lasted 27 weeks, as compared to the 4% response and 22
week survival of younger adults (n=966). In Simes's (1986)
retrospective analysis of risk/benefit in chemotherapy
trials (single and combination therapy) conducted by the
Eastern Cooperative Oncology Group, only 15% of patients
achieved a tumor response. Median survival of the patients
was 4.2 months with the median duration of the treatment
1.4 months. Toxicity has been substantial in many of these
trials with minimal changes in prognosis.

Cisplatin based regimens appear superior in terms of response over other regimens (Sarna et al. 1986). Recently, the National Cancer Institute of Canada conducted a prospective randomized clinical trial for advanced non-small cell lung cancer which compared best supportive care with two previously studied chemotherapy regimens: VP (vindesine and cisplatin), and CAP (cyclophosphomide, doxorubicin, and cisplatin) (Rapp et al. 1988). Two hundred and fifty one patients entered on the trial had histologically confirmed unresectable limited or extensive disease. The median age of the subjects was 56.6-58.7 years with over 40% of the subjects in each treatment group equal to or over 60 years of age. Patients over 70 years were not included in the trial. Functional status of the subjects as measured by the ECOG Performance Status revealed equal distributions of 0,1 and 2 in each group. Patients with significant cardiac disease were excluded from the trial.

Each subject group was stratified according to histology, performance status, and weight loss in the previous 3 months. Supportive care included palliative radiation for problems such as superior vena cava obstruction, brain metastasis. Antibiotics and corticosteriods were used to control symptoms. Some investigators in the multi-site study refused to enter
patients in the no-chemotherapy arm of the protocol because of ethical considerations.

A partial response was seen in 25.3% of the patients evaluable for response (n=87) on the VP protocol (vindesine 3 mg/m² IV weekly X 4, then every 2 weeks, cisplatin 120 mg/m² IV day 1, day 29, then every 6 weeks). Approximately fifteen percent of the patients (n=85) treated with CAP (cyclophosphamide 400 mg/m² IV, doxorubicin 40 mg/m² IV, cisplatin 40 mg/m² IV every 4 weeks) experienced a partial response. Age was not a significant predictor of response. Only weight loss of over 10 KG in the previous 3 months was a significant predictor of partial response in a logistic regression of multiple potential prognostic factors.

The VP protocol resulted in longer progression-free survival (17.7 weeks) than the CAP therapy (12 weeks). Better performance status, and longer delay of onset of symptoms until treatment, were the only factors linked with prolonged progression free survival. Overall median survival in the chemotherapy groups was significantly better for the chemotherapy groups (32.6 weeks for VP, 24.7 weeks for CAP) as compared with the supportive care only group (17 weeks) but the differences were not large. Patients treated with VP had a significant survival advantage when compared with best supportive care; 22% on VP and 21% on CAP were alive one year after the start of
the trial as compared with 10% of the untreated group. Poorer survival was associated with squamous cell histology. For the chemotherapy patients better performance status (ECOG 0 or 1), limited disease, and duration of symptoms, were associated with improved survival. Only 8 of the chemotherapy patients (total n=87) and 2 of the supportive treatment only group (n=50) experienced improved performance status. Few patients demonstrated improved weight gain in each of the three groups. Moderate dose reduction of cisplatin occurred in each protocol over the period of the study. Serious leukopenia was observed in approximately 40% of the patients receiving chemotherapy. 21% receiving VP, as compared with 11% on CAP, experienced severe vomiting. Serious neurologic symptoms were experienced in 14% of the patients on VP. Four patients died due to the toxicity associated with the chemotherapy treatment. Toxicity was not related to initial performance status.

Despite attempts to gather concurrent quality of life information during the trial, data were not available due to poor patient compliance. Prospective quality of life measures were recommended by Rapp et al. (1988) to accompany future clinical trials of chemotherapy to evaluate more completely the modest improvement in survival for patients treated with aggressive chemotherapy.
In a recent review of fourteen years of follow-up on 2,500 patients from the Southwest Oncology Group (Livingston, 1988), it was concluded that chemotherapy treatment for non-small cell lung cancer was most effective in patients with limited disease and higher performance status. Benefit was seen however, even for those with extensive disease, if they were ambulatory. Patients who were bed-ridden were excluded from these clinical trials since 1980. Cisplatin based regimens offered response rates ranging from 11%-33%, but the overall survival of 15% at one year remained, regardless of the regimen used.

Both dose and treatment regimen have been associated with differences in survival (Gralla & Kris, 1988). Higher doses of cisplatin (100 mg/M²) also have been linked with higher response rate and better survival at one year in some studies and further investigations are underway (Gralla & Kris, 1988). Nursing care has been cited as a critical variable in the safe delivery of the more toxic treatment (Grall & Kris 1988, Folman & Rosman, 1988). Blumenreich et al. (1987) have reported significant toxicity and lack of survival benefit of high dose cisplatin chemotherapy trials.

Dose intensity (dose over time) has been suggested as an important consideration in lung cancer trials. Combinations of cisplatin and etoposide (VP-16) have been
linked with greater response rates (51% in limited disease, 22% for advanced disease) and better survival rates (43% for limited disease, 25% for advanced disease) (Murray, 1988). Significant differences by age were not reported for these trials, nor were changes in performance status and quality of life. Chemotherapy trials in combination with radiation therapy, and as preoperative treatment, are underway for patients with limited disease (Gralla & Kris, 1988). The data are not conclusive.

Impact of Chemotherapy on Disruptions in Quality of Life

Rarely are the risks/benefits of chemotherapy treatment for non-small cell lung cancer patients reported from a quality of life perspective (Harwood, 1987). The difficulties of defining and measuring the subjective and objective dimensions of this vague but inherently meaningful concept are well known (de Haes & van Knippenberg 1987, Jones et al. 1987, van Dam et al. 1986). Aaronson et al. (1987) noted the glaring lack of psychosocial data in the literature focused on adults with lung cancer. This is a critical area of concern because of the ambiguities surrounding the benefits of treatment for patients with advanced disease. The act of undergoing treatment may be an important coping strategy for patients, independent of the therapeutic outcome (Saunders & McCorkle, 1987).

In a similar clinical situation, Coates et al. (1987)
report that quality of life assessments revealed new information, independent of the usual prognostic factors, in a clinical trial of continuous vs intermittent treatment for advanced breast cancer (n=133). To the surprise of the investigators, continuous chemotherapy treatment was associated with the patient's perceptions of higher quality of life though there were no significant survival differences. However, a significant flaw in this study was the lack of data collected during the off treatment periods for the intermittent group. Specific age-related data were not reported.

Traditionally, the only indicators of quality of life used in chemotherapy clinical trials have been the objective ratings of functional status or physical functioning (Karnofsky Performance Status and the ECOG scale). However, this is usually not evaluated by the patient, but by the physician or nurse in terms of their assessment of the patient's ability to participate in a variety of day-to-day activities. Ability to participate in physical activity is an important dimension of quality of life, but the emotional and social impact of treatment also are important aspects for assessment. Chemotherapy toxicity data may not be directly related to the impact of treatment on the patient's physical activity, and psychosocial well-being.

The amount of time spent on treatment is another
indication of disruptions in quality of life due to treatment. For instance, Sime's (1986) reports that the average patient participating in the ECOG non-small cell lung cancer trials spent 50% of their remaining life receiving chemotherapy treatment, with 20% never getting off treatment. Measures of time without symptoms and toxicity (TWiST) and the development of quality-adjusted survival analysis (Q-TWiST) are examples of clinical application of the concept of quality of life (Goldhirsch, Gelber, Simes, Gasziou & Coates, 1989). Lynn (1986) admonishes clinicians who bar certain options of treatment due to prejudicial assessments of the negative impact on the patient's quality of life. Presented with a scenario of an acutely ill elderly man, physicians (n=205) were more likely to use quality of life considerations as an argument to withhold treatment than to support decisions for active treatment (Pearlman & Jonsen 1985).

Few empiric studies exist which document the impact of cancer on life activities (Friedenbergs et al. 1981-2, Mages & Mendelsohn, 1979). Schag noted in an appraisal of results using the instrument "Cancer Inventory of Problem Situations" that in over 500 cancer patients 72% had difficulty walking after cancer treatment, and 44% had disruption in recreational activities (Parachini, Los Angeles Times, 1987). Gordon et al. (1980) reported that disruption in activities of daily living was a frequent
complaint of cancer patients with a variety of diagnoses in their experimental study of psychosocial interventions (n=136). Cain & Henke (1978) noted that 36% of ambulatory cancer patients (n=50) with various cancer diagnoses and undergoing a variety of treatments described disruption in function in daily work since their illness. Thirty-eight percent indicated they could not engage in their former leisure activities. Age was not reported as a significant factor in diminishing activities.

Age emerged an important variable when related to concrete physical (including ambulation, self care), and instrumental (for example, meal preparation, transportation) needs of adults with advanced cancer (Mor, Guadagnoli & Wood, 1987). A random sample of 217 cancer patients (mean age 63, 25% with lung cancer, 78% women) who were interviewed, described significant needs in physical functioning (especially the need for assistance with walking) and day-to-day activities.

Mettlin et al. (1983) described the impact of cancer on ability to carry out usual activities in a survey of 1,902 patients treated over a decade at Roswell Park Memorial Hospital. Advancing age was significantly related to decreased capacity for independent functioning across disease sites. Older patients (over 59 Years) with lung cancer reported the most impairment in functioning (70%). Stage of disease was not directly related to impairment.
Over 60% of older patients on chemotherapy were not fully capable in their everyday activities, as compared with about 40% of patients 30-59 years old.

Ochs et al. (1988) and others have rejected the single index measures of quality of life as meaningless for clinical application. The majority of studies which have attempted to describe the impact of cancer and cancer treatment on day-to-day activities and quality of life have been done on heterogeneous samples. Adults with different sites of cancers, at varying stages, undergoing different types of cancer treatments, and different symptomatology may have markedly different experiences in living with their illness. Generalizability of findings to those experienced during particular illnesses and treatments are difficult. In many studies time since diagnosis may vary widely. More or less permanent changes in patterns of daily living may occur over time. Most of the existing studies have been done on small samples. The lack of standardized instruments, and the use of measures of global concepts rather than specific behavioral indicators make measurement of daily activities of cancer patients difficult (Bloom & Ross, 1982).

Padilla and Grant (1985) have proposed the use of quality of life as an outcome variable for interventions in cancer nursing. Physical functioning is a component of their quality of life tool (Quality of Life Index) along
with aspects of eating, working, strength, appetite, and sex. No significant correlation was reported between degree of physical well-being, as conceptualized in this tool, and advanced age.

Masiak et al. (1983) attempted to identify psychosocial concerns of a heterogeneous group of elderly cancer out-patients. Overall, the elderly cancer patients (defined as 60 years and older) were less depressed and had less distress than the younger patients during a one time assessment. Immobility was a frequent complaint by older patients.

In an initial survey, using a problem focused instrument, the Cancer Inventory of Problem Situations, 60% of a heterogeneous group of cancer outpatients (n=84), demonstrated severe disruptions in physical activity (Heinrich et al. 1984). A subsequent study (Ganz et al. 1985) specifically evaluated the impact of cancer on life activities of elderly men with cancer (multiple sites and treatments) with the same instrument. Older men (over 65) were found to have less difficulty than younger men in chemotherapy related problems and discomforts during treatment. Both groups noted significant disruptions in problems of daily living and sexual functioning. Despite significant comorbid disease among the elderly (for example, cardiovascular) their illness experiences were not more severe. This study was based upon data collection
at one point in time.

Frank-Stromborg and Wright's (1984) assessment of a heterogeneous group of ambulatory cancer patients (n=323) uncovered that 65% of the adults with cancer experienced a decrease in physical activity as a primary concern. Seventy-six of those reporting a change in physical activity noted that daily activities were curtailed. Twenty-five were 66-88 years of age, but correlations of concerns with age were not reported.

The lack of longitudinal studies describing changes in quality of life due to cancer and cancer treatment over time is evident. Recently, attempts have been made to assess the impact of cancer treatment on lung cancer patients by conducting longitudinal investigations on quality of life indicators during clinical trials. In a clinical trial comparing chemotherapy treatments for patients with small cell lung conducted by the European Lung Cancer Cooperative Group and the Study Group on Quality of Life, measures of quality of life were taken frequently during the multi-cycle year course of therapy (Aaronson et al. 1988). Tools to measure the multidimensional dimensions of quality of life of cancer patients were developed and included items to tap changes in functional status (personal and role functioning), symptoms of lung cancer, side effects of treatment, fatigue and malaise, psychosocial distress, sense of well
being, and social interaction. The conceptual and theoretical design of the instrument was based in part on the work done by the Rand Corporation (Stewart, Ware, Brooks & Davis-Avery, 1978). The mean age of the patients was 60 years. Preliminary analysis of the data reveals that less than 5% of those patients were unable to participate in self-care activities. One third of the patients had no limitations in their everyday role activities, but 1/5 had extensive limitations. Twenty-eight percent of the patients were not satisfied with their quality of life.

Ganz, Haskell, Figlin, La Soto, and Siau (1988) described their frustration with attempts to measure quality of life monthly during a randomized trial of combination chemotherapy versus supportive care for patients with advanced non-small cell lung cancer. The Functional Living Index-Cancer (FLIC) was used in this study (Schipper, Clinch, McMurray & Levitt, 1984). Missing data, variable sites of administration, and patient difficulties in filling out the self-report analogue scale, confounded their ability to analyze meaningful responses. A Karnofsky Performances Status (KPS) rating of the patients was significantly correlated with the physical activity component of the initial baseline measure of the FLIC. Ganz et al. (1988) note that the compromised functional status of their patients, with a
decline from 81.5% KPS at the beginning of the study to a drop of 65.5% KPS six months into the study, may have contributed to the patient difficulties with participation in the data collection. Finkelstein et al. (1988) report similar problems with compliance and use of the FLIC. Over a 6 month period of time, only 33% (7/21) completed the questionnaire every month in a randomized clinical trial with lung cancer patients.

Nursing Research and Needs of Lung Cancer Patients

As previously discussed, there is a paucity of nursing research on the needs of adults with lung cancer (Table 2.3). Four studies focused on adults with lung cancer were found in a decade review of Cancer Nursing, Oncology Nursing Forum, Nursing Research, and Research in Nursing and Health.

Not included in this review was the classic study by McCorkle & Benoliel (1983) which was published in a non-nursing journal. Using a modified Symptom Distress Scale (McCorkle & Young, 1978) they compared symptom distress of 56 lung cancer patients with 65 patients who had suffered a recent heart attack one and two months post diagnosis. Specific data about diagnosis were not reported. Subjects were recruited from radiation therapy, but treatment status was not reported. The mean age of the cancer patients was 62 years, almost 25% of the sample was seventy years and older, and approximately 62% were male.
Table 2.3
CANCER NURSING RESEARCH FOCUSED ON LUNG CANCER PATIENTS (1978-1988)

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>SAMPLE SIZE*</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooper (1984)</td>
<td>15</td>
<td>focus: family relationships type, extent of lung ca not reported all dx within 2-9 months*</td>
</tr>
<tr>
<td>Driever &amp; McCorkle (1984)</td>
<td>15</td>
<td>focus: pt concerns type, extent of ca not reported 3 &amp; 6 months post dx*</td>
</tr>
<tr>
<td>Germino &amp; McCorkle (1985)</td>
<td>56</td>
<td>focus: awareness of life threatening disease type, extent of lung ca not reported symptom distress reported</td>
</tr>
<tr>
<td>Brown, Carrieri, Janson-Bjerkle &amp; Dodd (1986)</td>
<td>30</td>
<td>focus: dyspnea 28 on chemo 20 with oat cell, extent of disease not not reported</td>
</tr>
</tbody>
</table>

* Treatment status not reported
** Only subjects with lung cancer listed
Lung cancer patients noted significantly more symptom distress than cardiac patients, especially fatigue, pain, cough, lack of appetite and insomnia. The potential for the significant influence of the extent of disease, and radiation therapy on the critical differences of vigor and fatigue in the cancer patients is noted but not accounted for statistically. According to assessments with the Profile of Mood States, mood disturbances were significantly higher for the cancer patients. The lung cancer patients noted less concerns and better mood one month after the initial assessment even though symptom distress was unchanged.

Cooper's (1984) pilot study of fifteen lung cancer patients and their spouses documented the profound impact of lung cancer on family relationships. The type of lung cancer of the subjects was not revealed, and no patients were over 65 years. Medical treatment characteristics were not presented.

Driever and McCorkle (1984) and Germino and McCorkle (1985) have published data derived from the McCorkle and Benoliel (1983) study. Thirty one of the patients were over 60 years of age and all were receiving radiation therapy. Qualitative analysis in Driever and McCorkle's (1984) study of concerns 3 and 6 months post diagnosis reflect a wide disruption in usual activities for all age groups (range 30-89, 18 over 70 years).
Dyspnea in lung cancer was described by Brown, Carrieri, Janson-Bjerkle & Dodd (1986). This was one of the largest nursing research studies with adults with lung cancer (n=30). Twenty of the subjects had small cell lung cancer), 28% were receiving chemotherapy, but the extent of disease was not specifically reported.

Another nursing research study not directly related to the impact of the diagnosis and treatment, but with a non-small cell lung cancer population was conducted by Knudsen, Schulman, van den Hoek & Fowler (1985). Nurse members of the lung cancer study group revealed that adults diagnosed with non-small cell lung cancer continued to smoke even after curative treatment. Ages of the study population were not reported.

Other nursing research studies published in 1978-1988 (Tables 2.4) have included samples of 20 or more adults with lung cancer within their larger samples. However, even with large sample subsets separate statistical analyses by diagnoses were not reported. Type of lung cancer, extent of disease and treatment status were missing from sample descriptions. Lung cancer subjects have been included in smaller numbers in many other nursing research studies (Table 2.5, 2.6). Again subject characteristics of type of lung cancer, extent of disease and treatment were missing. Clearly, the pattern of responses in lung cancer, have received minimal attention.
<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>SAMPLE</th>
<th>COMMENTS**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frank-Stromborg &amp; Wright (1984)</td>
<td>58/323 (18%)</td>
<td>focus: physical &amp; psychosocial concerns***</td>
</tr>
<tr>
<td>Arenth (1985)</td>
<td>25/168 (14.8%)</td>
<td>focus: pt classification system***</td>
</tr>
<tr>
<td>Hiratzka (1985)</td>
<td>21/125 (16.8%)</td>
<td>focus: unproven treatments***</td>
</tr>
<tr>
<td>Kesselring, Dodd &amp; Strauss (1986)</td>
<td>20/45 (44%)</td>
<td>focus: attitudes of Swiss ca pts 24 subjects on chemo</td>
</tr>
<tr>
<td>Gray, Adler, Brescaum (1988)</td>
<td>210/1103 (19%)</td>
<td>focus: Fleming &amp; hospitalized ca pts with advanced disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>39% lung ca pts dx less than 6 mo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>39% of lung ca pts: brain metastasis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>most common dx for men over 65 yrs</td>
</tr>
<tr>
<td>Herth (1989)</td>
<td>23/120 (19%)</td>
<td>focus: hope &amp; coping undergoing chemo</td>
</tr>
</tbody>
</table>

* Separate statistical analysis not reported for lung cancer group

** type, extent of disease not reported

*** treatment status not reported
Table 2.5
CANCER NURSING RESEARCH STUDIES (1978-89)
WITH LUNG CANCER PATIENTS AS PART OF A LARGER STUDY
(SAMPLE SIZE 5-19)

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>SAMPLE</th>
<th>FOCUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Lung ca/other ca dx)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RELATED TO CHEMOTHERAPY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wagner &amp; Bye (1979)</td>
<td>10/77</td>
<td>alopecia &amp; body image</td>
</tr>
<tr>
<td>Valentine (1979)</td>
<td>6/27</td>
<td>chemotherapy</td>
</tr>
<tr>
<td>Baxley, Erdman, Henry &amp; Roof (1984)</td>
<td>10/40</td>
<td>alopecia &amp; body image</td>
</tr>
<tr>
<td><strong>RELATED TO RADIATION THERAPY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kubricht (1984)</td>
<td>12/30</td>
<td>self care needs &amp; radiation rx</td>
</tr>
<tr>
<td>King, Nail, Kramer, Srohl &amp; Johnson (1985)</td>
<td>15/96</td>
<td>perceptions of radiation rx</td>
</tr>
<tr>
<td>Fernsler (1986)</td>
<td>5/30</td>
<td>self care needs &amp; radiation rx</td>
</tr>
<tr>
<td>Dodd &amp; Ahmed (1987)</td>
<td>7/60</td>
<td>info needs &amp; radiation rx</td>
</tr>
<tr>
<td><strong>RELATED TO TERMINAL CARE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legge &amp; Reilly (1980)</td>
<td>5/36</td>
<td>home care</td>
</tr>
<tr>
<td>Lewis (1982)</td>
<td>13/57</td>
<td>quality of life &amp; control in late stages hospice use</td>
</tr>
<tr>
<td>Hays (1986)</td>
<td>16/50</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14/50</td>
<td></td>
</tr>
</tbody>
</table>
Table 2.6

MISCELLANEOUS CANCER NURSING RESEARCH STUDIES (1978-89)
WITH LUNG CANCER PATIENTS AS PART OF A LARGER STUDY
(SAMPLE SIZE 5-19)

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>SAMPLE (# Lung ca pts/ # ca pts)</th>
<th>FOCUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coward (1988)</td>
<td>5/40</td>
<td>hypercalcemia knowledge</td>
</tr>
<tr>
<td>Frank-Stromborg (1986)</td>
<td>10/122</td>
<td>health promotion</td>
</tr>
<tr>
<td>Kesselring, Lindsey, Dodd &amp; Lovejoy (1986)</td>
<td>18/42</td>
<td>social support (Swiss pts)</td>
</tr>
<tr>
<td>Garrison, Abner, Oakley &amp; Hogan (1983)</td>
<td>18/78</td>
<td>use of pt ed materials</td>
</tr>
<tr>
<td>Dardiarian &amp; Forsythe (1983)</td>
<td>11/163</td>
<td>assmt based on a model</td>
</tr>
</tbody>
</table>

ed=education
assmt=assessment

*Type of lung cancer, extent of disease not reported for any of these studies
Conceptual Framework

Functional Status and Quality of Life as Concepts for Nursing

The core concepts of functional status and quality of life as responses to chemotherapy were integrated into the conceptual framework for this study. A life span developmental model was used to study how age modulated the impact of chemotherapy on quality of life and functional status (Figure 2.1). The experience of chemotherapy treatment was considered as a non-normative event which could evoke differential developmental changes in older adults (Shaie, 1986). A multivariate perspective of biological, environmental, and illness factors was considered as influencing age-related responses in functional status and quality of life. Disruptions in physical and psychosocial aspects of day-to-day activities were monitored as behavioral responses to illness and treatment.

Analysis of such patterns of change during the course of illness and treatment can add to nursing science and lead to focused nursing interventions. Along with other categories of responses to medical and nursing interventions, levels of functional status and quality of life can serve as indicators of toxicity as well as benefit of treatment (Arcand, 1985). These behavioral
Figure 2.1
Conceptual Model of Impact of Age and Treatment
On Quality of Life and Functional Status

Moderators
Illness
Biophysical
Person/Environment

Age

Quality of Life

Chemotherapy

Functional Status
indicators can provide a holistic dimension of response to illness and treatment, in addition to the usual measurement of organ specific responses and separate assessments of emotional health. In this study age was conceptualized as the major independent variable moderating the impact of chemotherapy behavioral responses manifested as disruptions in functional status and quality of life. There are competing findings as to whether the effect of aging increases or decreases quality of life. Additionally, while some decline in functional status due to physical deterioration associated with aging may be inevitable, the quality and timing of this decline is not universal. It is even less clear how physical deterioration in function is accelerated in older people who are ill and whether this deterioration can be reversed.

Optimum functioning, interaction with the environment and positive changes in health status are three recurring themes identified by Donaldson and Crowley (1978) as central to nursing research. The concepts of functional status and quality of life integrate all three themes (function, environment, and health) in depicting a behavioral response to illness and treatment. Levels of functioning in relation to health and illness have been viewed as major thrusts of current conceptualizations in nursing, but these concepts have variable definitions in
the nursing literature (Donaldson & Crowley 1978, Gortner, 1983). Research on aspects of functional status and quality of life can contribute to basic scientific nursing knowledge by leading to generation of descriptive as well as prescriptive theories for clinical practice (Dickoff & James, 1968).

**Evolution of the Concept of Functional Status**

Conceptually, functional status portrays a level of physical performance and participation in the usual activities of everyday life. The concept has been viewed from different perspectives, i.e. limitations vs. abilities, and as encompassing a variety of behavioral domains (Feinstein, Josephy & Wells, 1986). Influencing the development of the concept have been varying health-illness paradigms. The recognition of problems of chronic illness in the 1950's produced the emergence of classification systems to assess disability beyond the disease characteristics alone (e.g. Commission on Chronic Illness) (Katz et al. 1983). The performance of comprehensive functional status assessment by health care workers has been mandated by the Health and Public Policy Committee of the American College of Physicians (1988).

Katz, Ford, Moskowitz, Jackson and Jaffe (1963) brought the concept of functional status as a dimension of health status to the fore in the acute care setting. Within Katz's framework, functional status was defined by
the performance of "activities of daily living" (ADL). The phenomenon of functional status comprised levels of independent performance in ADL: dressing, bathing, transfer, toileting, feeding and continence. Reflecting a social and biological context, it was used to monitor response to illness and medical treatment. As a measure of the impact of chronic illness, the concept was useful in allowing prediction of loss and recovery of independent function in a hierarchial manner of increasing complexity, e.g. first lost, last to return (Katz & Akomp, 1976). Thus, dressing and bathing as more complex behaviors would be recovered after independence in simpler activities such as eating. Katz & Akpm (1976) postulated that this pattern of loss and return of behavior was related to patterns of child development and behavioral evolution of primitive societies. Katz and colleagues (1983) have continued to use this concept to predict probability of maintenance of independent functioning among the aged (termed "active life expectancy").

Activities of daily living is a familiar concept to nursing. Even rudimentary care in acute and chronic facilities involves attempts to assess individual capacity for independence in eating, bathing and toileting. At the least, this information is used to delegate nursing assistance and monitor the amount of health care required. Assessment of functional capacity also can be considered
in focusing rehabilitation efforts, and degrees of functional impairments can serve as important predictors of recovery.

Departures from normal role functioning are critical components of sociologic views of health-illness behaviors and relate to the concept of functional status. Role dysfunction, in itself, is not a distinguishing characteristic of illness behavior since there are many non-medical or physical factors contributing to role impairment, e.g. retirement. Reynolds, Rushing & Miles (1974) have considered the quality of role performance as an indicator of health or functional status. Change in role performance may be a better representation of the impact of illness upon the individual than is suggested by a medical diagnosis alone. Twaddle (1974) equated health with functional effectiveness: the ability to conform to socially acceptable norms of activity. These norms become less well defined for older adults. Most parameters used in health care to measure morbidity do not give a clear indication of the personal impact of illness on an individual's day-to-day existence. Currently, previous role related aspects of functional status are being seen in measures of quality of life. Functional status continues to be grounded in descriptions of physical activity.

Various models have utilized the broad concept of
function as it relates to the impact and recovery from illness. Kaplan et al. (1976) combined level of well-being with the stability of that state, in a conception of health. In that model, alteration in role performance due to illness resulted in changes in well-being. Included in the dimensions of well-being were levels of mobility, physical activity, and social activity, which were constructed after a survey of medical literature. Symptom/problem complexes were included in this evaluation.

Functional level emerged as a critical dimension in Patrick, Bush and Chen's (1973) social construct of health. Here, the concept was consistent with a Parsonian view of sick role behavior with disturbances in biological, personal and social function. The potential for expected transitions or behavioral changes from one level of health to another, plus the status of the current functional level, produced an indication of overall health status. Consideration of individual perception of functional disturbances was an important addition to the more objective evaluation of functional ability.

The relationship of aging and functional status within these various models was not well defined. Rowe and Kahn (1987) noted the effect that diet, exercise, personal habits and psychosocial factors have on the heterogeneity of functional abilities in older adults. In specific
cohort groups, the potential for successful aging (less morbidity and functional impairment) due to healthy habits must be considered in age-related cohort comparisons.

Levels of functional status in older adults, as reflected by participation and disruptions in daily activities, have been evaluated recently in several longitudinal studies (Branch & Jette, 1981, Branch et al. 1984, Chirikos & Nestel, 1985, Palmore et al. 1985). The consensus of these studies was that decrease in independent functioning in the elderly was substantially less dramatic than earlier projections. Branch and Jette (1981) revealed high levels of functioning in their analysis of elderly cohorts in the Framingham Disability study. Over fifty percent of the 1,625 non-institutionalized elderly surveyed in this study were independent in activities of daily living. Assessments of mobility were the most sensitive in differentiating decreasing capability with age.

Difficulty in performing strenuous physical activities, according to the Framingham data, significantly increased with age (Jette & Branch, 1981). Women had more functional difficulties in all areas assessed. Correlations of chronic illness with degree and nature of functional disability were not reported.

Considerable variations among individuals assessed over time were noted in a longitudinal study by Palmore et
al. (1985). Advancing age was most closely linked to decreased functional abilities, with increasing acceleration of loss of function over time. Palmore et al. (1985) note that cross-sectional studies may have inflated decremental functional changes over time. Decreases in mental function were associated with decreases in social interaction. Functional dependence generally increased over time, though there was evidence that it was not necessarily irreversible, even in the older age groups. In a survey of 4,938 men, functional disability was a significant predictor of mortality in the elderly (Chirikos & Nestel, 1985).

German (1981) asserted that assessing functional status for the elderly is the most crucial component of any conceptualization of health status for that age group. Yet, it is an over-simplification to view the elderly as having declining functional capacities due to increasing physical disability. The aging process and vulnerability to particular diseases which affect physical function is extremely individualistic (Baltes & Willis, 1977).

The concept of functional status converges with the construct of quality of life as a clinical outcome measure because it is less abstract and potentially more directly related to health/illness factors (Fayers & Jones, 1983, Feinstein et al. 1986, Deyo, 1984). Maintenance of optimal function has been interpreted as the goal of quality
health care (Cluff, 1981). However, if this is to be achieved, evaluation of health care must include parameters which evaluate the impact of the illness and treatment within behavioral dimensions. Chronic illness clearly affects all major life activities in varying degrees, for example, ability to work, to manage a household and to attend school. Yet, assessment of functional capabilities are not routinely and rigorously evaluated.

Ware (1984) proposed a model for measurement of health outcomes that would include disease, personal functioning, psychological distress, general health perceptions, and social role functioning. As a model of health status, physical functioning is one component in a multivariate perspective of the impact of disease. Personal functioning was defined as the performance of everyday activities: self care, mobility, and physical activities.

To have relevance in clinical practice, functional status goals must be evaluated from the individual's current activity level and potential rather than from preset levels. Changes in functional status may be due to emotional or social responses to illness rather than just the physical consequences of disease and medical treatment alone. Supportive care by nurses can be directed to the impact of functional changes rather than specific
diagnostic characteristics of the illness.

The relationship of age and "usual activities" must be considered in conceptualizations of functional status (Berdit & Williamson 1973). Level of participation and satisfaction with quality of that participation in daily life activities, are two important considerations of "usual activities" for the elderly. In addition to being an important outcome measure for health care, conceptually, physical well-being is the foundation for a construct of quality of life for the elderly (George & Bearon, 1980). However, if measures of functional status and quality of life are normed on roles and activities of younger adults such instruments may be inappropriate for the elderly.

Components of Functional Status

The concept of functional status as it relates to physical health has included various components. There has been a lack of consensus over which categories of behavior should be aggregated in a measure of functional ability. In the literature review and conceptualization for Rand's Health Insurance Experiment (HIE), six behavioral constellations emerged in varying combinations and degrees of importance as indicators of personal functional status (Stewart et al. 1978, Stewart, Ware, Brook, 1982). Four of these included physical activities, mobility, and self-care activities. Two domains included
role activities, including household activities, and leisure activities were aspects of personal functioning in an earlier version of functional status. Fourteen percent of the 4,603 subjects (aged 14-61 five different cities in three states) involved in the HIE were limited in vigorous activities and less than 1% were limited in self-care activities.

Stewart and Ware (1989) have narrowed the critical components of functional status be considered in assessments of physical functioning. This latest conceptualization focuses on the physical dimensions of function and include vigorous activities, moderate activities, walking distances, stair climbing, bending, lifting, dressing and bathing. Functional status measures which were developed for the HIE studies evolved from a conceptualization of functional status which would have meaning in an otherwise "healthy" population. Changes in function over time were then related to need for health care services.

Usually, these functional status levels have been conceived as ordinal measures, that is, on a continuum from better to worse. Levels of behavioral function implied specific measurable performances. However, functional ability is a relative concept and age-specific criteria may be essential for valid comparisons. (von Glaserfeld & Kelly, 1982). Assessments of increases or
decreases in functional ability may depend upon the conceptual and at times arbitrary agreement of what a fixed level of function is, and how well the specific behavior matches it.

**Physical Activities.** Capacities to perform physical activities such as running, walking, stair climbing and lifting have been used as indicators of physical health in measures of functional status. In the HIE study assessing of the degree of physical activity limitation, only the most severely limited had associated changes in role activity.

Changes in physical capacity among the elderly is almost considered a hallmark of aging (Kenney, 1982). There are suggestions that limitation in activities sharply rises after the age of 65 (Lowenstein & Schrier, 1983). Kane & Kane (1981) have noted that the elements of physical activities: frequency, speed, accuracy, complexity, initiation, and completion, must be explicit if actual performance of the behavior rather than the potential capacity is to be evaluated. These assessments are difficult in the hospital environment. The perceived value or importance of a physical activity by the individual has relevance for nursing. Yet, this personal evaluation is rarely considered by the health care team. Both inability to initiate or inability to complete an activity are examples which indicate dysfunction. Changes
in frequency or duration of the activity and decreased desire or opportunity to participate must be considered in assessments of behavioral change. Assessments of function thus contains dimensions of quantity and quality along with a temporal aspect. Whether or not an activity of daily living is performed is only one aspect of a gross assessment. Specific disease and treatment factors may influence physical performance. But, other than the broad diagnostic category, these variables and related symptoms, i.e. pain, are rarely considered in studies evaluating functional status. This may be due to the evolution of the concept from a sociologic paradigm of health rather than the medical model.

Disruptions in activities often included in functional status measures have been considered as part of nursing assessments for a variety of studies. Activity was identified as a phenomenon in Lindsey's (1982) review of physiologic variables related to nursing, but research focused on the impact of activity in terms of physiologic cost rather than as a behavioral measure of performance. Competence in everyday activities was evaluated as part of a social dependency scale to assess the requirements for assistance in role activities and document the impact of living with cancer (Benoliel, McCorkle & Young, 1980).

Alteration in activity has been considered part of symptom distress in assessment of the impact of cancer.
(McCorkle & Young 1978). Lewis, Firish and Parsell (1979) utilized the Roy Adaptation Model to guide cancer nursing assessment. Activity level (mobility, hygiene, feeding), as well as attitudes toward the patient's level of function, were evaluated. In a survey of life style changes for ambulatory cancer patients, change in level of activity was the most troublesome for the majority of patients (Frank-Stromborg & Wright 1984). Based on the Johnson Behavioral System Model, assessments of changes in physical dependency were considered by Derdiarian (1983) in an analysis of behavioral changes due to cancer as part of an assessment.

**Mobility.** Mobility is the capacity to get around both in and out-of-doors. Viewed in this manner, it is more than mere ambulation. Social and psychologic factors may influence the options for mobility. Kane & Kane (1981) point out the frequent lack of consideration of these variables when evaluating mobility in the elderly. Age related changes and comorbid diseases may explain changes in mobility more than the onset of a particular disease. Mobility is usually considered along a continuum from independent to fully dependent.

**Self Care Activities.** Self care activities such as feeding, bathing, dressing and going to the bathroom often are evaluated in terms of independent functioning. Significant limitation in self care activities will affect
other aspects of function as well. Inability or unwillingness to participate in self care is not well differentiated in many self care measures. The support available in the environment may be a pivotal factor for the elderly in maintenance of independence. Decremental changes (e.g. failing eyesight) associated more frequently with the older adult may affect self care more than a particular illness. Certain treatments depend upon patient participation in order to avoid undue side effects and toxicities. Interestingly, in Dodd's (1982) study of self care for side effects of chemotherapy, the perceived functional status (Karnofsky Performance Scale) did not alter significantly during chemotherapy despite the occurrence of troublesome side effects. However, diminished functional status could have a significant impact on the ability to carry out self care.

Disruptions in functional status in this study included the subjective assessment of ability to engage in day-to-day activities as assessed through the latest evolution of Physical Functioning scale developed by Stewart and Ware (1989) and a traditional objective measure of functional status used in cancer clinical trials, the Karnofsky Performance Status. Both measures considered behavioral manifestations of illness and treatment. Neither measure was obviously biased in assessments of older adults (i.e. scores were lowered if
the subject was not working).

Quality of Life

Multiple conceptions of health address the concept of quality of life. In a sense, functional status is a narrow view of quality of life which relies on elements of physical well-being as a proxy variable for the whole. Schipper & Levitt (1985) describe current research attempts to measure quality of life constructs as predominately function oriented, with conceptual domains of physical/occupational function, psychological state, sociability, and somatic discomfort.

An evaluation of functional response to illness which reflects quality of life can be used as an adjunct to evaluations of patient responses in cancer clinical trials (Schipper et al. 1984). Historically, the Karnofsky and Zubrod performance status scales have been used in clinical trials as oblique measures of quality of life, focusing on mobility and independence in ADL. Recently, several researchers have explored the utility of quality of life as a viable concept as a measure of toxicity/benefit in cancer treatment (Priestman & Baum, 1976, Spitzer et al. 1981, Schipper et al. 1984). Padilla & Grant (1985) included physical function in normal activities as one dimension of a visual analogue scale to evaluate quality of life for cancer patients undergoing treatment. Van Dam et al (1987) noted in their review of
the literature on quality of life, that significant methodological and research issues cloud the applicability of findings from many current studies. Primarily, these are due to the problems of small sample size, and the lack of conceptual and theoretical congruence.

The concepts of quality of life and functional status are intimately related. Both are related to the fluctuations of quality and quantity of participation in life activities as they relate to levels of health and illness. Functional status is a more concrete concept with specific empirical referents and an inherent hierarchical structure of increasing levels of independent and more demanding physical activity. A theoretical assumption in concepts of functional status is that independence and performance of increasingly complex behaviors are related to levels of wellness. The behaviors usually included in measurement attempts of functional status are: physical activity, mobility, self-care, and role activity. These behaviors can be objectively evaluated.

The concept of quality of life has been described as a multidimensional concept including, emotional, physical, and social aspects. For clinical validity, evaluations of quality of life are thought to be best if self determined (Schipper & Levitt, 1985). Evaluations of quality of life by cancer patients should relate to their experiences with the diagnosis and treatment. Changes in life activities
during illness and treatment may be quite individual and varied. An example of an age bias in quality of life assessments is the study of Pearlman & Uhlman (1988) where physicians significantly underrated the quality of life of elderly patients with chronic illness (n=126) when compared with the patient's self assessment. The potential nonlinear fluctuations in measurement of quality of life during the cancer trajectory must be considered.

**Quality of Life and Day-to-Day Activities**

Alterations in activities of daily living were cited as an area of concern for many cancer patients but have received little empirical study (Flanagan, 1982, Freidenbergs et al. 1981-1982). Problems in day-to-day living have often been overshadowed by studies focused on the emotional distress of the cancer patient. Meyerowitz et al. (1983) have proposed a model for coping with cancer which focuses on specific behavioral disruptions associated with the diagnosis and treatment. This was modified (Ganz et al. 1985, Schag & Heinrich, 1988) and included specific categories of problems encountered in day-to-day living with cancer: interactions with the health care team, chemotherapy-related problems, discomfort during medical procedures, anxiety in medical situations, physical functional status, communication at work, job-related difficulties, weight maintenance, body image, clothing, difficulty communicating with others,
interacting with families and friends, worry, cognitive problems, communication with partner, affection, sexual dysfunction, interaction, sexual interest, care.

In this research study, disruptions in quality of life were defined as negative changes in multidimensional aspects of day-to-day life. It was measured by the Cancer Inventory of Problem Situations, a problem specific questionnaire developed specifically to tap the difficulties faced in living with cancer. This quality of life measure includes physical, psychosocial, sexual, and marital dimensions affected by illness and treatment as well as problems faced in interacting with the health care team. Only problems which pertain to the individual are considered in scoring, thus eliminating potential biases which could result from assessing older patients who were not working.

**Variables Affecting Disruptions in Quality of Life and Functional Status**

Functional status and quality of life were conceptualized as manifestations of the impact of chemotherapy as modulated by advancing age. Three categories of moderator variables emerged within a life span developmental framework which might affect functional status and quality of life: illness, person/environment, and biophysical (Figure 2.2). These elements fit well within the metaparadigm described by Fawcett: person,
Figure 2.2
Quality of Life and Functional Status
Conceptual model of Moderator Variables

AGE

Illness

Biophysical

Person/

Environment
environment, health and nursing (Fawcett, 1984).

For this study, illness variables encompassed disease and treatment parameters often considered separately in medical models of care or not at all in quality of life studies. Person/environment variables included aspects of individuals in relation to their environment which might contribute to alterations in independent functioning and disruptions of day-to-day activities. The biophysical variable included an indicator of the premorbid health status of the individual prior to the diagnosis of cancer which might have significantly altered the course of treatment as well as the behavioral disruptions in life activities.

The behavioral responses of older adults during cancer treatment, specifically disruptions in quality of life and functional status, were the primary interest of this investigation. Changes in functional status and quality of life were conceptualized as resulting from the interaction of the biological, psychological and social sequelae of illness. These interactions have been the focus of previous research in cancer nursing (Benoliel, 1978, McCorkle & Lewis, 1980).

Illness Variables. Disease variables were considered as critical factors in determining impact of cancer treatment on the quality of life and functional status of older adults. However, in the sociological conceptions of
health/illness, disease characteristics often are not considered except in a global way when related to health status e.g. diagnosis. Specific dimensions of the disease were included in efforts to determine characteristics associated with certain levels of functional status and quality of life in older adults.

The specific illness variables which were of interest in this research were extent of disease, type of symptoms, and weight loss prior to treatment and length of time since diagnosis. The relationship of these moderators to the impact of age and chemotherapy on quality of life and functional status is displayed in Figure 2.3.

Biophysical Variable. The behavioral responses evoked by illness must be considered in light of the individual's physical status prior to the diagnosis to cancer. Additive and interactive effects of some diseases (i.e. lung cancer and emphysema), may further compromise functional status. The experience of physical illness can produce varying degrees of assault on physiologic integrity which in turn can impact on functional status, especially in older adults. These changes may be ambiguous in their affect on day-to-day activity (Twaddle, 1974). Comorbid disease was the one major biophysical variable considered in this study. The theoretical relationship of this variable and the impact of age and treatment on quality of life is shown in Figure 2.4.
Figure 2.3
Illness variables as Moderators

Symptoms
Weight Loss
Extent of Disease
Time since Diagnosis

AGE

QUALITY OF LIFE

FUNCTIONAL STATUS

CHEMOTHERAPY

Figure 2.4
Biophysical Variable as a Moderator

Comorbid disease

AGE

QUALITY OF LIFE

FUNCTIONAL STATUS

CHEMOTHERAPY

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**Person/Environment Variables.** The experience of illness can be altered by variables affecting the person and the environment. Emphasis on person-environment interaction provides consideration of behavior within a contextual setting. The patient's perception of illness has been described as construction of reality which shapes how illness is viewed and drives the subsequent behavioral responses (Kleinman, Eisenberg & Good 1978). Gender may be a critical factor influencing responses to illness.

The environmental milieu encompasses socio-economic variables as well as the physical realities of the day-to-day living situation. Living alone may be a critical factor in the alteration of day-to-day activities for the cancer patients if support of others is not available. Socioeconomic factors may be pivotal influences in determining the availability of supportive services. The contextual characteristics of the experience of illness must be considered with change over time, particularly for the elderly (Hultsch & Hickey 1978).

Consideration of alterations of functional status and quality of life in the older adult as the result of person-environment interaction is in keeping with a dialectical view of development (Riegel 1976). Through this multi-dimensional perspective, qualitative and quantitative changes can be considered. External validity of inferences from research data applied to the elderly
Figure 2.5
Person/Environment Variables as Moderators

Figure 2.6
Side Effects and Treatment Response
As Confounding Variables
must be questioned if the environmental context are not evaluated (Hultsch & Hickey 1978).

Person/Environment Variables of interest for this study were: gender, living alone and income (as it reflects socioeconomic status). The relationship of these variables to the impact of age and chemotherapy on quality of life and functional status is depicted in Figure 2.5.

Confounding Variables. The therapeutic responses of cancer chemotherapy (tumor response) to cancer treatment may improve quality of life and functional status even if temporary disruptions in day-to-day activities occur due to the side effects of chemotherapy. Even though the relationship between functional status and prognosis in the non-small cell lung cancer patient has been well demonstrated, but the relationship of therapeutic outcomes to quality of life and functional status is not clear. Detailed characteristics of the tumor responses (disease progression) and the toxicity of the treatment were essential when considering evaluations of quality of life and functional status for the older adult undergoing chemotherapy. The variables of severity of chemotherapy side effects and tumor response were considered as confounding variables in this study.
Research Questions

Several research questions addressed the nature of disruptions in quality of life of adults with non-small cell lung cancer and the changes that occur after a cycle of chemotherapy. Differences in changes in quality of life by age and treatment subgroup are considered as well.

Question #1

Are there increased disruptions at Time 1 in quality of life in older adults with non-small cell lung cancer as compared to younger adults?

Question #2

Are there increased disruptions at Time 1 in quality of life in adults with non-small cell lung cancer as compared to other cancer patients (normative data)?

Question #3

What are the major disruptions in quality of life in adults with non-small cell lung cancer at Time 1?

Question #4

Are there increased disruptions in quality of life after a cycle of chemotherapy (Time 1 to Time 3) for non-small cell lung cancer in treated older adults as compared to treated younger adults and, as compared to an untreated cohort?
Question #5
Are there increased disruptions in quality of life over time (Time 1 to Time 3), independent of treatment status, in older adults with non-small cell lung cancer adults as compared to younger adults?

Question #6
Are there increased disruptions in quality of life after one cycle of chemotherapy (Time 1 to Time 3) in treated as opposed to untreated adults with non-small cell lung cancer?

Question #7
What are the major disruptions in quality of life after a cycle of chemotherapy (Time 1 to Time 3) in adults with non-small cell lung cancer?

Additional research questions addressed the level of functional status of adults with non-small cell lung cancer and the changes that occur after chemotherapy. Differences in changes in functional status by age and treatment subgroup were examined.

Question #8
Are there increased disruptions in functional status in older adults with non-small cell lung cancer as compared to younger adults at Time 1?
Question #9
What are the major disruptions in functional status over time (Time 1, Time 2, Time 3), independent of treatment status in adults with non-small cell lung cancer?

Question #10
Are there increased disruptions in functional status during and after a cycle of chemotherapy (Time 1 to Time 2, to Time 3) for non-small cell lung cancer in older as compared to younger treated adults, and as compared to an untreated cohort?

Question #11
Are there increased disruptions in functional status after one cycle of chemotherapy (Time 1 to Time 2, to Time 3) in younger as compared with older adults?

Question #12
Are there increased disruptions in functional status after one cycle of chemotherapy in treated as opposed to untreated adults with non-small cell lung cancer?

Question #13
What are the major subjective disruptions in functional status pre and post a cycle of chemotherapy (Time 1, Time 2, Time 3) in adults with non-small cell lung cancer?
The proposed theoretical relationship of quality of life, functional status and moderator variables were explored.

Question #14
What is the relationship between disruptions in quality of life and levels of functional status, independent of treatment, over time (Time 1 and Time 3)?

Question #15
What is the relationship between disruptions in quality of life and levels of functional status over time (Time 1 and Time 3) after a cycle of chemotherapy?

Question #16
What are the relationships between age, weight loss, time since diagnosis and disruptions in quality of life and functional status in adults with non-small cell lung cancer (Time 1)?

Question #17
In addition to age and treatment status, which combination of moderator variables (gender, weight loss, income, time since diagnosis, education, symptoms, comorbidity) best predict disruptions in quality of life and functional status in adults with non-small cell lung cancer over time (Time 1 and Time 3)?
CHAPTER 3

METHODS

Purpose

The purpose of this study was to describe and compare the effects of an initial cycle of chemotherapy for non-small cell lung cancer on the disruptions in quality of life and functional status of older adults as compared with younger adults, and with an untreated cohort. Moderator variables which might influence the impact of chemotherapy on disruptions in quality of life and functional status were categorized according to the conceptual framework as person/environment variables (gender, income, living situation, education), illness variables (extent of disease, type of symptoms, time since diagnosis, weight loss), and the biophysical variable of comorbid disease. Severity of side effects and tumor response (disease progression) are viewed as confounding variables.

Definitions

1. Age was the chronological age in years for the patients in the study. Younger adult was defined as less than 65 years of age. Older adult was defined as 65 years of age or older.

2. Treatment included either a therapeutic chemotherapy
cycle: type of drugs, dose, sequence, and route of administration; untreated referred to a plan for supportive care to ameliorate symptoms excluding chemotherapy or radiation therapy.

3. **Quality of life** was a multidimensional assessment of aspects of everyday life which could be affected by cancer and cancer treatment. This personal assessment included physical dimensions (including aspects of self care, mobility), psychosocial dimensions (including interpersonal relations, fears and concerns), marital relationships, sexual functioning and quality of interaction with the health care team.

4. **Functional Status** was defined as the assessment of the physical ability to engage independently in a variety of daily physical activities normally associated with good health. Both a personal and objective appraisal of physical function was obtained.

5. Illness variables

   a. **Extent of Disease** of advanced lung cancer was dichotomized as limited (limited to one hemithorax and supraclavicular nodes; disease encompassed within a single radiation port), or extensive (advanced disease beyond "limited" parameters) (Zelen, 1973).

   b. **Symptoms** of lung cancer were categorized similar to the taxonomy developed by Feinstein (1966).
Local symptoms were those attributed to the local
effects of the lung cancer, e.g. cough. Systemic
symptoms were those remote from the primary lung
cancer site, but not anatomically related to tumor
spread, e.g. anorexia. Metastatic symptoms were
those related to distant spread of the lung
cancer, e.g., bone pain. Varying combinations of
symptomatology could be present.

c. Weight loss was defined as the number of pounds lost
from normal weight of the individual in the 6 months
prior to start of the study.

d. Time since diagnosis was defined as the number of
months since the medical diagnosis of lung cancer.

6. Biophysical Variable

a. Comorbid disease referred to the presence and
severity of concurrent diseases independent of the
diagnosis of cancer.

7. Person/Environment Variables

a. Living Arrangement determined whether or not the
patient lived alone.

b. Income was average annual income as reflection of
socioeconomic status.

c. Education was determined by the number of years and
level of schooling completed.

d. Gender was either male or female.
8. Confounding Variables

a. Side effects to chemotherapy were described as both organ specific and systemic toxicities attributed to the cycle of chemotherapy treatment.

b. Tumor response was a clinical judgment by the oncologist of evidence of clinical response, disease progression, or no change due to the chemotherapy cycle; for the untreated cohort, changes in disease status over the previous month.

Design

In order to detect if there was a differential impact in disruptions in quality of life and functional status between older and younger adults with non-small cell lung cancer experiencing an initial cycle of cancer chemotherapy and a cohort receiving supportive care, a short term longitudinal design was indicated. The comparison of a treated with untreated cohort helped to distinguish disease related from treatment related disruptions in functional status and quality of life.

Responses of the older adults (65 and older) receiving chemotherapy were compared with younger adults (less than 65 years) to clarify disruptions to chemotherapy which might covary with age. Adults with non-small cell lung cancer who received supportive care (either because they were not eligible or who declined to
receive chemotherapy treatment) were followed over a comparable period of time.

A longitudinal design was essential to establish a baseline of disruptions in quality of life and functional status prior to treatment in order to compare with the disruptions noted after the impact of the chemotherapy treatment. Functional status was measured at the beginning (baseline) of an initial chemotherapy treatment cycle, in the middle of the treatment cycle (approximately 2 weeks later), and at the end of a single cycle of chemotherapy (approximately 4 weeks after the first data collection). Disruptions in quality of life were measured before (baseline) and after (4 weeks) the cycle of chemotherapy. The same 4 week time frame was used for the supportive care only group.

Unlike the treatment of small cell lung cancer, where multiple cycles of chemotherapy may be used for treatment, chemotherapy treatment for non-small cell lung cancer may last only one or two cycles due to poorer clinical responses. The short time period of one cycle of chemotherapy (3-4 weeks) was selected for this initial exploration because changes in quality of life and functional status were more likely to be due to side effects of the treatment as opposed to indicators of disease progression. The potential cumulative nature of such side effects need to be investigated in future
studies which would follow patients during an entire course of chemotherapy treatment and supportive care (several months).

**Sample**

Subjects with non-small cell lung cancer were selected as the population of interest because of several intriguing issues. First, the goal of therapy for advanced lung cancer is strictly palliation and improvement in quality of life. Second, evaluation of the outcome of such therapy in terms of benefits may be less clear if decline in functional status and major disruptions in quality of life occur during the course of treatment, especially for older adults. And lastly, data regarding disruptions in quality of life and functional status assessments can contribute to formulations of a data base to describe the nursing care needs and issues of the understudied population of older adults with non-small cell lung cancer.

Criteria for subject eligibility included:
1. histologically confirmed advanced non-small cell lung cancer which was either metastatic, or inoperable; 2. ages 40-64 years (younger adults); ages 65 and older (older adults); 3. Karnofsky performance status of 60% (requires occasional assistance, but is able to care for most personal needs) or better; 4. capable of understanding and providing informed consent for the study; 5. willing to
be contacted by phone; 6. for the treated groups: at the beginning of a first cycle of chemotherapy; 7. for the older untreated group: subjects met requirements 1-5 but were either not offered or refused cancer chemotherapy. Patients were excluded from participating in the study if they had been previously treated with chemotherapy for their cancer or had radiation therapy within the last month.

In order to detect a clinically meaningful difference in quality of life and functional status between older adults treated with chemotherapy and an untreated cohort a power analysis was performed with the alpha level set at .05, the power (1-B) set at .80. The proportion of older adults with non-small cell lung cancer receiving chemotherapy who experience changes in quality of life and functional status is not known. A clinically meaningful difference would support differential nursing care needs and indicate therapeutic benefits. Hypothesized by the investigator, at least ninety percent of the older adults receiving treatment as compared with fifty percent of older adults on supportive care only are projected to experience major quality of life and functional status changes from baseline. A sample size of 24 treated older patients, 24 treated younger adults, and 24 untreated adult patients was necessary to insure adequate statistical power for a two-tailed test on proportions
(Fleiss, 1981). Detecting a difference of this magnitude would have serious implications for the modifications of nursing care based on age.

**Data Collection Instruments**

Four instruments were utilized to assess the impact of a cycle of chemotherapy on the disruptions in functional status and quality of life (dependent variables) in adults with non-small cell lung cancer patients. Disruptions in functional status were measured objectively with the Karnofsky Performance Status scale, and subjectively, with the Physical Functioning scale. Disruptions in quality of life were subjectively measured by the Cancer Inventory of Problem Situations (CIPS). The independent variables of age and treatment were measured as part of the background patient and physician data sheet accompanying the Cancer Inventory of Problem Situations. Moderator variables (person/environment, illness, biophysical) were included as part of this data sheet. The confounding variables of severity of side effects and tumor response (including disease progression) were evaluated by the Eastern Cooperative Oncology Group (ECOG) Toxicity Criteria and tumor response sheet.
Independent Variables

Age. Age was the primary independent variable of interest in this study. The age of the subjects was ascertained from the CIPS Background Information sheet (filled out by patient). Subjects were considered older adults if they were 65 years or older, and younger if they were less than 65 years of age at the time of the study. This information was taken at baseline (pretreatment).

Treatment. Treatment was the secondary independent variable of interest. Details of the chemotherapy treatment regimen (dose, drugs, schedule) were filled out from the physician's record and were included in the Medical Summary sheet. The untreated cohort was subjects who were on supportive care only and did not receive chemotherapy or radiation therapy during the study.

Dependent Variables

Functional status was measured from a subjective and objective perspective. The subjective (patient's) view of his capacity to engage in physical activities was measured by The Physical Functioning Scale (Stewart & Ware, 1989). The objective assessment of functional status was performed by the physician or researcher using the Karnofsky Performance Status Scale (Karnofsky & Burchenal, 1949). This measurement was taken at baseline and at 4 weeks.
Physical Functioning Scale

The Physical Functioning Scale is a ten item scale which includes the concepts of self care, mobility, and physical activity. Each item has a Likert type response ranging from 1 (limited a lot) to 3 (not limited at all). An additional item assesses subjective satisfaction with the level of physical functioning on a six point Likert response ranging from 6 (completely dissatisfied) to 1 (completely satisfied).

Empirical background. The measurement of functional status has undergone extensive study and testing as part of the Health Insurance Experiment (HIE) conducted by the Rand Corporation (Stewart, Ware & Brook, 1981, Stewart et al 1982). Three basic components of physical functioning are tapped in this measure of functional status. They include: physical activity (vigorou activities, moderate activities), mobility (walking various distances, bending, lifting or climbing stairs), and self care (dressing, bathing).

The most recent evaluation of the measurements of physical function have resulted in a "short form" of physical functioning status. Aggregation of items from previous tools items resulted in two physical Functional Status scales (Functional Limitations Battery, Physical Capacities Battery) (Ware, Sherbourne, Davis, & Stewart, 1986). The physical function scale has been used as
components of a "General Health Survey" but it can be used independently (Stewart & Ware, 1989). Response time for filling out the scale was estimated as less than 3 minutes.

In addition to fielding forms of the physical function instruments in over 10,000 people in the general population as part of the HIE, recent investigations have supported its validity in a patient population of over 6,000 (Stewart & Ware, 1989). Forty percent of the patient sample has exhibited disruptions in physical/role functioning. The 3 item response set ("1" limited alot) in this tool was similar to that used in the Physical Capacity Battery (Stewart et al. 1982).

**Scoring.** Cumulative scores can range from 10-30 if all items are answered. Lower scores are associated with greater functional limitation. The poorest responses ("1" limited a lot) to individual items were rank ordered according to the percent of the subjects affected. This was calculated at baseline for all subjects and after a cycle of chemotherapy treatment. Various levels of satisfaction with physical activity were reported for all subjects at baseline and over time.

**Reliability and Validity.** Detailed reliability and validity investigations have been performed with healthy and ill samples (Stewart et al. 1978, Stewart et al. 1982). Scalogram analysis (CR = .89, CS = .57) of the
physical functioning items supported a hierarchical Guttman pattern (less strenuous to more strenuous activities). Internal consistency was demonstrated by the range of inter-item correlations of the scale (between 0.41 and 0.74). Reliability of the Physical Functioning Scale was determined by the use of Cronbach's Alpha coefficient (.88).

**Karnofsky Performance Status Scale**

The Karnofsky Performance Status scale is an observer rated tool developed to describe the functional status of cancer patients in response to the impact of disease and treatment (Karnofsky & Burchenal, 1949). The Guttman character of the scale assumed that each succeeding score indicated more independent function. A variety of behaviors are included in the assessment for independent function (normal activity, self care, need for assistance, need for special care). Descriptors of severity of illness (e.g. moribund) are included along with the behavioral assessment.

**Empirical background.** The Karnofsky Performance Status (KPS) is the earliest and most well-known tool used in cancer treatment to assess levels of behavioral function in response to disease or treatment. It has been used as a prognostic indicator as well as a criterion measure of comparability between subgroups of patients undergoing treatment in clinical trials. Some have suggested its

Multiple concepts are contained within each functional level e.g. ability to work and carry on self-care activities. However, since it is an observational tool it can be used when cognitive, language, and visual difficulties make the use of self-administered forms impractical. The Karnofsky Performance Status scale has been useful as a predictor of response to treatment and mortality from lung cancer (Livingston, 1988).

**Scoring.** Possible scores range from 100 percent (Normal, no complaints, no evidence of disease) to 0 (dead) at 10% intervals. In this study 60% (requires occasional assistance but is able to care for most personal needs) was the minimum rating for entry into the study.

**Reliability and Validity.** While this tool has been widely used in cancer clinical trials, reliability and validity have been assumed. Recently several examinations of this classic tool's reliability and validity have been published. The observer rated tool was not based upon standardized methods of observation. However, Mor, Laliberte, Morris, & Weimann (1984) found that when observations were standardized, as in the intensive training program of interviewers in the National Hospice Study (n=500), the inter-rater reliability was 0.97. Hutchinson et al. (1979) questioned reliability when there
was a lack of operational criteria of each level of function. Yates, Chalmer & McKeogne (1980) reported that investigations of validity of KPS ratings of patients with advanced cancer \( n=52 \) supported the tool as an indicator of overall functional status related to other indicators sensitive to problems of physical function (e.g. difficulty with balance, difficulty on stairs). KPS demonstrated convergence with measures of positive affect but not negative affect. Level of pain was not related to KPS. In assessments of inter-rater reliability, the researchers noted the difference in at-home versus in-clinic appraisals (lower rating inside the home).

One criticism of this global functional status measure is its lack of ability to pinpoint specific areas of disruption. Grieco and Long (1984) evaluated the reliability of KPS in a variety of patients with different diseases (e.g. psychiatric outpatients, terminally ill patients, general medical patients). Inter-rater reliability was high (Spearman rank correlation .86) using a standardized procedure. However, reliability of this procedure was not compared with the traditional method of evaluation.

Concurrent validity of the KPS was explored by Greico and Long (1984) with three measures: a revised KPS which attempted to clarify behaviors (e.g. "may work part-time but does not work 40 hours per week" rather than "unable
to carry out normal work"), the Quality of Well-Being measure (Kaplan & Bush, 1982) and the Health Perceptions Questionnaire (Ware, Davies-Avery & Donald, 1978). Inter-rater reliability was improved with the revised KPS which also correlated well with the original KPS format. The scores on the KPS correlated significantly with the Quality of Well-being Questionnaire but was not associated with the Health Perceptions Questionnaire.

Validity of the KPS was examined further by correlation of 18 variables selected from the Cancer Inventory of Patient Situations (CIPS) (Schag, Heinrich, & Ganz, 1984). Significant correlations of the KPS scores were reported with items describing difficulty working full time, difficulty driving, difficulty with ambulation, difficulty grooming, fatigue, and weight change.

Mor et al. (1984) supported the validity of the KPS as a measure of independent function in a terminally ill population. Performance of activities, as assessed by a primary care provider using a modified Katz ADL Index and physical quality of life assessment, were used to construct a severity index of physical dysfunction. A chi-square test demonstrated statistically significant differences for each category of the functional level. In this population, no significant correlations were found between functional status, physical symptoms, and pain. However, the authors questioned the impact of these
variables in patients with already seriously compromised functional status. Correlations of the KPS score (researcher rated) with two quality of life measures (Functional Living Index-Cancer and Quality of Life Index), in forty adults with a variety of cancer diagnoses undergoing initial chemotherapy, were statistically significant (Monahan, 1988).

For this study, the data from this instrument were used as objective indicators of functional status before and after a cycle of chemotherapy treatment for the treated group and over a month of supportive care only (week 1 and week 4) for the untreated cohort. The KPS rating was performed by the researcher or physician.

**Cancer Inventory of Problem Situations**

Disruptions in quality of life in adults with non-small cell lung cancer and after treatment with chemotherapy were measured by a self-administered questionnaire, the Cancer Inventory of Problem Situations (Schag et al. 1983). The Cancer Inventory of Problem Situations (CIPS) was developed to aid in the documentation of day-to-day quality of life issues of cancer patients and to facilitate interventive strategies (Heinrich et al. 1984). Schag and Heinrich (1988) have suggested its use as an outcome measure for clinical studies where positive and negative aspects of the impact of treatment can be measured in behavioral terms.
Additionally, the originators of the tool envisioned the data as describing specific characteristics of disease and treatment experiences for cancer patients.

The CIPS continues to undergo refinement and revision. In its most recent form it has been retitled as the CARES (Cancer Rehabilitation Evaluation System, CARES). In the CARES, two items have been deleted from the version used in this study (#83, 28), and the sequence of the items has been altered. The version of the CIPS used in this study had 144 items. Two items were funnel questions (#96, #121), and two items were gender specific (#99, #100). This resulted in 141 actual problem statements.

Empirical background. A behavioral approach was selected in the development of the CIPS in order to assess the multidimensional psychosocial and physical disruptions in living with cancer. A competency-based model of coping with chronic illness was suggested by Meyerowitz et al. (1983) to focus on information about pragmatic everyday behavioral responses to actual problems experienced by patients with different types of cancer and experiencing a variety of treatments. Problem specification in the CIPS was the critical first phase in this problem-focused model. The subsequent aspects of the theoretical model which will require future investigation and testing are response enumeration and response evaluation. This will
depend upon the validity of the instrument in accurate problem identification. Rather than an enumeration of intrapsychic mechanisms used in more abstract research on quality of life, this tool has direct implications for problem specific health care interventions (Meyerowitz et al. 1983). The CIPS has now been used in over 1100 cancer patients as a self report to describe disruptions in quality of life manifested in day-to-day life activities associated with cancer and cancer treatment (Schag & Heinrich, 1988). The CIPS provides a systematic method for data collection of a domain of problems encountered by adults experiencing cancer and cancer treatment. Of particular interest for this study, the CIPS has been used successfully to describe the experiences of a heterogeneous group of elderly cancer patients at various stages of therapy (Ganz et al. 1985).

**Scoring.** A variety of scores can be produced by the CIPS data to provide detailed clinical information. These include four different levels of scoring patterns. A Likert type 5 point response, ranging from "0" not at all to "4" very much, is attached to each of the problem statements. An additional component of the tool (but not used in this research study) is the option to request help for each problem cited. Schag & Heinrich (1988) consider the overall CIPS score and the higher-order factors as the most basic scoring dimensions.
1. The most detailed score is the individual endorsement of 141 problem statements. (For this study the maximum possible problem statements which could apply to adults on chemotherapy is 136; for adults receiving supportive care alone, 128 items. Additional subgroupings based on sex, marital status, employment status, and existence of children limit the number of applicable problem statements. The sum of all items endorsed is used in calculation of the global scores.

2. Five superscales scores, or higher-order factors, which describe physical, psychosocial, medical interaction, marital, and sexual domains can be constructed for each subject.

3. Description of more specific problems within each superscale can be grouped within 31 subscales (plus 7 miscellaneous items).

4. A global score for the CIPS is calculated from the total severity rating (summation of the severity rating of each applicable problem endorsed); and the summation of total number of items of applicable potential problems; summation of total applicable problem statements that are endorsed (rated 1-4) (endorsed problems). The global score is calculated by dividing the total severity rating by the number of potential problems. An average severity
rating has been reported in other studies: total severity rating divided by the total number of endorsed problems. A global score can be calculated for each of the five superscales as well.

Data describing the global quality of life and the superscale dimensions and the 31 subscales, and data ranking individual problem items were reported in this study. A standardized norm for cancer patient populations was used for comparison with all subjects and with scores of younger and older subjects, and treated and untreated subjects at Time 1 and Time 3. This required conversion of the raw CIPS scores to T scores (normalized standard Z scores based on frequency distributions plus or minus 50). Score conversions were computed for the global CIPS score and each of the five superscale scores (physical, psychosocial, medical interaction, marital, sexual). The T scores were graphically charted and compared to the selected normative sample. The normative sample used for comparisons in this study was the all male cancer patients (n=701). In the normative comparison group, 65% were 50–69 years old, 21% were over 70 years, 38% were on chemotherapy; 36% had metastatic disease; 73% were married; 79% had a high school education or higher, and 99% had a KPS of 60% or above. The normative scores for all female cancer patients group were similar, and thus,
the all male sample was used for pragmatic reasons.

**Validity.** Unlike many instruments used to evaluate quality of life changes due to cancer and cancer treatment, the CIPS was developed exclusively for cancer patients. The goal of the behaviorally based assessment was the creation of a data base for better problem identification and intervention (Schag & Heinrich, 1988). To ensure the validity of an inventory of problem situations faced by cancer patients with multiple diagnoses, undergoing various treatments, and at different points in the health-illness trajectory, several strategies were pursued. Initially, a comprehensive survey of the pertinent literature resulted in a list of problems which a patient might experience (Meyerowitz et al. 1983). Interviews with 100 cancer patients and their spouses resulted in further refinement of potential problem identification. (Schag et al. 1983). This list of problems encountered in living with cancer was reviewed by medical oncologists, oncology nurses, mental health professionals, and a chaplain. A final listing of problem situations comprised the initial 131 statements in the CIPS questionnaire.

The psychometric properties of the CIPS have been examined and have resulted in refinement of the tool (Schag & Heinrich, 1988). After factor analysis, the preliminary tool was revised (104 from original tool and
creation of 38 new items) which resulted in the 141 problem specific statements used in this study (including the two funnel and one gender specific item). Thirty subgroupings of the items (with 9 miscellaneous items) into various problem domains were established a priori. Factor analysis (orthogonal varimax rotation) resulted in 26 factors (items with eigen values greater than 1). Inter-item alpha coefficients for the individual factors averaged \( r = .84 \).

Further factor analytic techniques including Maximum Likelihood extraction and Unweighted Least Squares extraction with varimax and oblique rotations were performed on data from 479 cancer patients. Thirty-five factors with eigen values greater than 1 were produced. Thirty-one of these were consistent and clinically relevant (excluding 7 miscellaneous factors). Twenty six of these were the same as the a priori assumptions. Mean alpha coefficients of .81 in the 31 subscales indicated good internal consistency.

Factor analysis of the 31 subscales resulted in seven higher order factors. Five of these groupings (physical, psychosocial, marital, sex, medical interaction) were clinically relevant for the majority of subjects. The two additional subscales included chemotherapy and dating concerns. The five higher order factors form the superscales of the CIPS.
Concurrent validity of the CIPS was established with the positive correlation with the SCL-90-R (r=.69) an index of psychological distress (Schag, Heinrich & Ganz, 1983). The latter study demonstrated a strong correlation with the KPS, the Dyadic Adjustment Scale, and an overall quality of life score (Schag & Heinrich, 1988).

Reliability. Test-retest reliability (r=.89) was obtained with a random sample of cancer patients (n=71) with heterogeneous tumor types and treatment experiences at one week intervals (Schag et al. 1983). The frequency of agreement for consistent rating of presence or absence of the problems was high (87%). Further investigations of reliability (Schag & Heinrich, 1988) resulted in between 84-88% percent agreement of the existence of the problem after a ten day test-retest (n=120). (Seventy-seven percent of the time the endorsement of the severity of the problem was the same; in 93% of the time the scores only differed by a rating of one.)

The CIPS has been compared with a standard method of assessing psychosocial problems of cancer patients, the interview. The CIPS was more sensitive in detecting problem areas than an interview (Schag et al. 1983). A second study (Ganz, Rofessart, Schag & Heinrich, 1986) confirmed this. The authors have suggested that patients may be more willing to acknowledge problems in pen and paper self-assessments than face to face.
Moderator Variables

Several potentially influential and confounding variables were measured in order to assess their influence on the impact of chemotherapy and age on disruptions in quality of life and functional status.

Person/environment variables related to disruptions in quality of life and functional status were evaluated by data in the Background Information sheet included with the CIPS. These items included: gender, living alone, annual income, and education.

Illness variables which have been related to disruptions in quality of life and functional status were obtained by data in the Medical Summary accompanying the CIPS. These included: extent of disease at diagnosis, symptoms, time since diagnosis and weight loss.

Comorbid disease included history of other illnesses prior to the diagnosis of cancer and was evaluated objectively as part of the CIPS Medical Summary.

These data were collected at time one only (pre-treatment). The chemotherapy protocol (drugs, dose, schedule and route) were recorded on the Medical Summary.

Eastern Cooperative Oncology Group (ECOG) Toxicity Criteria.

Two confounding variables associated with response to chemotherapy treatment: severity of side effects, and tumor response were measured by the Eastern Cooperative
Oncology Group Toxicity Criteria and an accompanying tumor response (disease progression) form.

**Empirical background.**

The Eastern Cooperative Oncology Group (ECOG) Toxicity Criteria were developed to facilitate standardized data collection of toxicity and response in chemotherapy clinical trials (Oken et al. 1982). These criteria have been used extensively in clinical trials for patients with solid tumors. The chemotherapy toxicity criteria include assessment of leukopenia, thrombocytopenia, anemia, hemorrhage, infection, genitourinary dysfunction, hepatic dysfunction, nausea and vomiting, diarrhea, pulmonary dysfunction, cardiac dysfunction, neurological dysfunction, skin and mucosal alterations, alopecia, allergic responses, fever, and local toxicity at the site of administration. Each side effect or toxicity is graded from 0 (no toxicity) to 5 (lethal). The physician or research nurse was asked to describe the most severe reaction in each criterion category which occurred during the cycle of chemotherapy.

**Scoring.** The ECOG Severity Index was filled out at the Time 3 data collection period (end of chemotherapy cycle) to determine the severity of side effects of chemotherapy experienced by the younger and older adults with non-small cell lung cancer. Each individual side effect as listed in the criteria was scored from 0-5 to indicate level of
toxicity. Side effects were rank ordered by prevalence and identified according to age subgroup. Toxicities of grade 3 or more were specifically identified.

The tumor response to chemotherapy was rated by the physician as no response, partial response, and complete response at the end of the cycle of chemotherapy based on clinical judgment. For the untreated cohort, disease progression (no change, deterioration, improvement) was rated by the physician at the end of the 4 weeks.

Reliability and Validity. The reliability of the ECOG Toxicity Scale is not routinely reported though it is a part of many stringent clinical trials in cancer research. Reports of validity of the tool are not available. The clinical content was developed through the collaboration of scientists working in the Eastern Cooperative Oncology Group (Oken et al. 1982).
Procedure

Data were collected over an 18 month period (September 1987-April 1989) in five facilities (two private offices, one health maintenance organization, one university medical center, and one Veteran's hospital) in the greater Los Angeles area and central valley. Clearance for human use studies was obtained at the University of California, San Francisco and at each of the participating institutions prior to implementation of the study. The patients were contacted primarily in outpatient clinical settings. Multiple facilities were used because of variability in treatment patterns and because of the difficulty in obtaining an adequate sample size of adults with non-small cell lung cancer treated with chemotherapy. Many physicians approached did not think that chemotherapy was a viable treatment option for advanced non-small cell lung cancer, regardless of age, due to the poor response rate and significant toxicity.

A letter was sent to selected Oncologists in private practice in the greater Los Angeles area to approve participation of their patients in the study. (Twelve sites agreed to participate in the study, however due to a variety of logistic problems only five sites actually contributed subjects to the study.) A follow-up phone call was made to answer questions and confirm participation. If agreed, the researcher or assistant contacted the nurse or
physician in the private office to arrange for participation in the study. The researcher or assistant made follow-up phone calls every week to discuss sample accrual.

Preparation and training of research assistants

Research assistants were used in the study to help gather data at the multiple sites. Graduate nursing students, office nurses in private practice and clinic nurses in medical centers served as research assistants. The preparation and training of research assistants was coordinated by the investigator. The investigator informed the assistants of the details and rationale for the data collection procedure. The assistants were asked to demonstrate their performance in the data collection procedure including: how to gain informed consent from the subjects, obtaining data from the physician or nurse for the Medical Summary (CIPS), obtaining data from the subject from the Background Information sheet (CIPS), obtaining data from the subject from the CIPS, and the Physical Functioning Scale. Interpersonal skills in dealing with the lung cancer patients, physicians and nurses were considered in the hiring and preparation of the assistants. The investigator was available via telephone to the research assistants in case of questions.
Data Collection Sequence

**Time 1.** The data collection sequence and use of instruments are displayed in Table 3.1 and Table 3.2. After institutional approval and approval from the individual physician at the data collection site, the investigator or research assistant approached the potential subject (prior to the beginning of a cycle of chemotherapy administration for the treated groups). The study was explained, and if the subject was willing an informed consent was obtained prior to administration of the data collection instruments. The patients who did not receive treatment were identified and approached for participation in the study in the same manner as the treated subjects.

The subject filled out the data collection instruments (Cancer Inventory of Problem Situations including the background information, and Physical Functioning Scale) at the clinic, hospital or office environment and returned the instruments to the investigator or research assistant. The instruments were placed in a separate envelope. At that time, the subject was given the Physical Functioning instrument to be filled out at the end of week 2. An addressed, stamped envelope was provided for the subject to use to mail back the questionnaire to the investigator. The date for return was noted on the front of the instrument. The investigator or research assistant filled
Table 3.1

**Time Frame for Data Collection**

**Independent and Dependent Variables**

<table>
<thead>
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<th>Variable</th>
<th>Instrument</th>
<th>Weeks</th>
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</thead>
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<td>Treatment</td>
<td>Medical Summary</td>
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<td>X</td>
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<tr>
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<tr>
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<tr>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Subjective</td>
<td>PFS</td>
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<tr>
<td></td>
<td></td>
<td>X</td>
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<td></td>
<td></td>
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</tbody>
</table>

KPS=Karnofsky Performance Status

CIPS=Cancer Inventory of Problem Situations

PFS=Physical Functional Status
Table 3.2

**Time Frame for Data Collection**

**Moderator Variables**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Instrument</th>
<th>Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 2 3 4</td>
</tr>
</tbody>
</table>

**Person/Environment**

<table>
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<th>Background Info</th>
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<tbody>
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<td>X</td>
</tr>
<tr>
<td>Education</td>
<td>Background Info</td>
<td>X</td>
</tr>
</tbody>
</table>

**Illness**

| Extent of disease | Medical Summary | X |
| Symptons          | Medical Summary | X |
| Time since Dx     | Medical Summary | X |
| Weight Loss       | Medical Summary | X |

**Biophysical**

| Comorbid disease | Medical Summary | X |

**Confounders**

| Side Effects      | ECOG | X |
| Tumor Response    | Response Form | X |

Info= information  
Dx= diagnosis  
Econ=economic  
ECOG=Eastern Cooperative Oncology Group
out the Medical Summary from information supplied by the
physician or from the medical record and noted the
subject's Karnofsky Performance Status. The type of
chemotherapy, including dose, route, and schedule, were
noted on the medical summary.

Time 2. The patient mailed back the Physical Functioning
Scale in the stamped return envelope. A phone call was
used to encourage patient participation in the second data
collection point. A phone call was placed to the patient
prior to the scheduled physician visit to remind them of
the impending data collection.

Time 3. The investigator or the research assistant
administered the data collection instruments (CIPS,
Physical Function Scale) for both treated and untreated
subjects at the time of the follow-up clinic visit, or
prior to any additional treatment (4 weeks). The
researcher or assistant visited the home of the subjects
if the follow-up data collection could not occur in the
medical treatment facility.

For the treated subjects, the ECOG Severity of Side
Effects and Tumor Response form which described the side
effects and therapeutic response that resulted from the
cycle of chemotherapy, was filled out by the researcher or
assistant from chart and physician information. The
Karnofsky Performance Status for the patient at that time
was recorded. For the supportive care only group, the
disease progression sheet was filled out from physician
information and the KPS was recorded.

Sample and Site Limitations

The subjects consisted of a convenience sample of
those meeting the entry criteria and willing to
participate for the one month data collection. Findings
cannot be generalized to adults with non-small cell lung
cancer who are below a 60% Karnofsky Performance Status
(requires considerable assistance and medical care).

Data Management

Data were checked for missing data, inconsistencies
and potential inaccuracies, and coded periodically for
statistical analysis via K-Edit on a personal computer.
All data were processed by number code to assure
anonymity. The data file was evaluated for missing data
and inaccurate coding by a SAS personal computer screening
program (clean3 SAS). Corrections were made prior to
analysis when possible.

Data Analysis

All data analysis was performed using the SAS
personal computer statistical software. Descriptive
statistics were used to describe the sample factors at
baseline. Subjects were divided into three major
subgroupings (older and younger treated adults and
untreated adults) for further analysis. Because of the
sample size the age demarcation was set at older and
younger than 65 years of age for subgroup comparisons. Where possible the findings of older and younger untreated subjects were described. Statistical analysis resulting in significance levels of $p \leq 0.05$ was reported.

Descriptive statistics were used to assess the potential moderator and demographic variables. Since these factors could influence the direction and magnitude of potential disruptions in quality of life and functional status, preliminary comparisons were made by age (younger and older than 65 years) in the treated subjects, and by treatment status (supportive status or chemotherapy). Comparability of categorical factors (income, education, gender, comorbid illnesses, type of cancer, extent of disease, site of metastasis, type of symptom, type of chemotherapy regimen, site of data collection, marital status, living alone, ethnicity, work status, religion) for inherent differences, grouping by age and treatment, was investigated by contingency tables organized by age and treatment. Frequency data and percents for each subgroup cell (treated, untreated, older, younger) were available for description. Tests for significant differences between the groups for age and treatment status, income, education, type of non-small cell lung cancer, extent of disease were performed using a form of chi-square for multi-dimensional contingency tables, the generalized Fisher's Exact Test (2-tailed).
After preliminary investigation for normal distribution of the continuous variables (age, weight loss, time since diagnosis), the non-parametric Wilcoxon's Rank Sum test was selected for comparison of significant differences of these variables between the age and treatment groups. Mean, standard deviation, median, maximum and minimum scores were reported, grouping by age and treatment. Time since diagnosis also was grouped (less than 3 months, 3-6 months, 7-1 year, and over 1 year) and reanalyzed for significant differences in a contingency table with a Fisher's Exact Test (two-tailed).

The confounding categorical variables of treatment response (due to chemotherapy) and treatment side effects were examined with summary descriptive statistics. Rank order of frequency of major chemotherapy side effects was presented by age group. Grade III serious side effects were identified.

Research question #1 considered whether there was a differential impact of non-small lung cancer on disruptions of quality of life in younger as compared with older adults. This was achieved by using the Cancer Inventory of Problem Situations (CIPS) as a multidimensional measure of quality of life. In this paper and pen tool, higher scores indicated more problems or disruptions in quality of life. The mean global score of quality of life, the mean scores of the six superscales
(physical, psychosocial, marital relations, sexual function, medical interaction, miscellaneous); and the mean scores of the 31 subscale scores were compared for each age group. Examination of the baseline scores (Time 1) of the CIPS (global and superscales) for all younger and older adults subjects at Time 1 are reported. The mean, standard deviation, and median are reported for the CIPS (global score, Superscale scores, and subscale scores) for all subjects, and by age (younger and older than 65 years). Differences in average baseline scores for subjects in the two age groups were found to be similar regardless of treatment (by interaction in analyses of variance). Mean baseline CIPS scores are thus formally compared between age groups with t-tests. The baseline CIPS scores for the three subjects who died during the study, and the one subject who was too depressed to continue, were examined individually, and as a subgroup (mean, standard deviation, median) and informally compared with the other subgroups.

Research Question #2 asked whether there were more disruptions in quality of life in adults with non-small cell lung cancer than adults with other cancer diagnoses. The mean global score of the CIPS and the mean scores for each of the superscales for all subjects at Time 1 were compared with the normative standard for adult male cancer patients (n=701) developed by the authors of the CIPS.
Conversion of the mean scores to T-scores and to percentile ranks were performed with the standard score charts in the CARES Manual (Schag & Heinrich, 1988). The resulting percentile scores for the global score and five of the superscales (physical, psychosocial, sexual function, marital relations, medical interaction) were compared with the normative data base.

Research Question #3 asked for a depiction of the major disruptions in quality of life experienced by adults with non-small cell lung cancer. Contingency tables of the individual responses, categorized by age and future treatment status, were developed for each of the 141 problem statements of the CIPS. These data were examined for the entire sample (n=24) at Time 1 for the frequency of items depicting serious disruptions. All problems rated 2 (a fair amount) or more (3-4) were defined as serious disruptions. This allowed for rank ordering of common problems (affecting the majority of the entire sample) within each superscale.

Research Question #4 asked whether there were increased disruptions in quality of life after a cycle of chemotherapy in treated older adults as compared to younger adults and, as compared to an untreated cohort. This necessitated comparisons of the mean CIPS (global and superscale) baseline scores (Time 1) with the mean scores after chemotherapy (Time 3) or 4 weeks later for the group
on supportive care only. The range of the mean scores of disruptions in quality of life were presented. Only subjects who completed Time 1 and Time 3 questionnaires were available for comparison. Changes over time were analyzed for 19 subjects (79.2% of the original sample). This included 14 treated subjects (10 younger and 4 older adults) and 5 untreated subjects (2 younger and 3 older adults). A repeated measures analysis of variance, grouping by age and treatment, was performed to consider significant changes in disruptions of quality of life over time (Time 1 to Time 3) in the CIPS global score, and each Superscale, and to determine if there were any interactions of age and treatment. Subsequently, since there were no such interactions, paired t-tests were performed to compare changes in the global, superscale and subscale dimensions of the CIPS. Differences between groups at Time 1 and Time 3 were determined by t-tests. The results of the t-tests are reported. The changes over time in the multiple dimensions of quality of life were graphically depicted for the three groups. Changes in CIPS scores by age in the untreated subgrouping were examined (mean, standard deviation, median, range), but due to the small sample size, formal statistical tests were not performed.

Research question #5 asked if there were increased disruptions in quality of life over time, independent of
treatment status, in older adults as compared to younger adults. Comparisons of increased disruptions in quality of life changes over time were made with the mean CIPS scores of the younger and older adults from Time 1 to Time 3. These comparisons between the older and younger adults also were graphically represented. Statistical comparisons were made with t-tests between age groups on Time 1 to Time 3 differences (which was equivalent to a repeated measures analysis of variance).

Research Question #6 inquired whether there were increased disruptions in quality of life after one cycle of chemotherapy in treated as opposed to untreated adults. Statistically significant changes from Time 1 to Time 3 of the mean CIPS scores of the treated and untreated subjects were determined by Paired t-tests. Comparison between treatment groups of Time 1 to Time 3 changes was done using analysis of variance.

Research Question #7 asked for identification of the major disruptions in quality of life experienced by the subjects after a cycle of chemotherapy. Contingency tables of the individual responses (n=14) at Time 3, categorized by age and treatment status, were developed for each of the 141 problem items of the CIPS. These data were examined for the subjects who received chemotherapy. The frequency (percent) of items depicting serious disruptions, rated 2 (a fair amount) or more (3-4), were
presented. This allowed for rank ordering of common problems (affecting the majority of the sample) within each superscale.

Research Question #8 asked whether older adults had increased disruptions in functional status as compared with younger adults. This analysis used the mean baseline scores of both an objective (Karnofsky Performance Status) and subjective (Physical Functioning Scale) assessment of functional status. Younger adults were compared with older adults by the paper and pencil Physical Functioning Scale (PFS) and the observer rated Karnofsky Performance Status (KPS) scale. Descriptive data for baseline scores for all patients at Time 1 (mean, standard deviation, median, range) according to age and treatment subgroup were presented.

Research Question #9 asked for a depiction of the major subjective disruptions in functional status over time, independent of treatment status, for all subjects. The frequency (percent) of each item on the PFS rated as severe "1" (limited a lot) were reported for all subjects at Time 1 to describe the prevalence of perceived functional limitation. The PFS was the only scale which had data at three points in time. Additionally, data on "satisfaction with activity", a self-rated component of the PFS were analyzed for frequency (percents) at each data point.
Research Questions #10 asked if there were increased disruptions in functional status during and after chemotherapy in older adults as compared to younger adults, and as compared to an untreated cohort. A repeated measures 2-way ANOVA (grouping by age and treatment) was performed over the 3 time periods. The mean scores of the subjective assessment of functional status, PFS, were compared for the three subgroups at each of the three data points. Only subjects who had complete data for all three time periods were included in the analysis. When the ANOVA detected significant differences, paired t-tests were performed among subgroups and over time. The changes over time for three subgroups were graphically displayed.

The mean KPS scores, the objective measures of functional status, of the younger and older adults who received chemotherapy were compared at Time 1 and Time 3 along with the mean score of the untreated cohort. A KPS of 60% was required for entry into the study which resulted in skewness of scores. Thus, non-parametric analyses were appropriate. The Wilcoxon's rank sum test was used for comparisons between groups. The Wilcoxon's signed rank test was used to test for significant differences over time. These data were displayed in a graphic format.

Research Question #11 asked whether older adults experienced greater disruptions in functional status after
chemotherapy than did younger adults. The mean scores of the PFS of the chemotherapy subjects, grouped by age, were compared for all three time periods (Time 1 vs Time 2, Time 1 vs Time 3, and Time 2 vs Time 3) by ANOVA. When the ANOVA detected significant differences, paired t-tests were performed among subgroups and over time. The mean scores of the KPS of the chemotherapy subjects also were grouped by age and compared at the two data points, before and after treatment (4 weeks). The non-parametric Wilcoxon tests were used to test for significant differences over time. Graphic comparisons for the two age groups are presented.

**Research Question #12** asked if there were increased disruptions in functional status in subjects who underwent chemotherapy as compared to those who remained on supportive care only. The mean scores of the PFS were compared for the treated and untreated subjects at each time period (Time 1 vs Time 2, Time 1 vs Time 3, and Time 1 vs Time 3) by ANOVA. The mean scores of the KPS for the treated and untreated subjects were compared by treatment status at Time 1 and Time 3. Tests for significant differences were performed using the Wilcoxon's rank sum and signed rank test. The data are graphically presented.

**Research Question #13** sought to identify the major subjective disruptions in functional status after a cycle of chemotherapy. The frequency (percent) of each item on
the PFS rated as severe "1" (limited a lot) were reported for the subjects who received chemotherapy (N=17) at Time 1, Time 2 and Time 3, to describe the prevalence of perceived functional limitation.

Research Question #14 explored the theoretical relationship between disruptions in quality of life and levels of functional status, independent of treatment, over time, for adults with non-small cell lung cancer. The mean global score of the Cancer Inventory of Problem Situations and the mean scores of each of the five Superscales for all subjects at Time 1 were correlated (Pearson Product Moment) with the objective (Karnofsky Performance Status) and subjective (Physical Functioning Scale) assessments of functional status. The relationship of the two measures of functional status also was evaluated through Pearson correlations. The magnitude and direction of the correlations were evaluated and tested for statistical significance.

Research Question #15 explored the relationship between disruptions in quality of life and levels of functional status after a cycle of chemotherapy. The mean global score of the Cancer Inventory of Problem Situations and the mean scores of each of the five Superscales at Time 1 and Time 3 were correlated (Pearson Product Moment) with the objective (Karnofsky Performance Status) and subjective (Physical Functioning Scale) assessments of
functional status at Time 1 and Time 3. The relationship of the two measures of functional status at Time 1 and Time 3 also was evaluated through correlations. Only the scores for subjects who received chemotherapy (n=15) and completed both Time 1 and Time 3 data collection were included in the analysis. The magnitude and direction of the correlations were evaluated and tested for statistical significance.

Research Question #16 asked about the relationship between age, weight loss, time since diagnosis, and disruptions in quality of life and levels of functional status. A correlation analysis of these theoretically important variables was performed with the mean CIPS, PFS and KPS scores at Time 1 and Time 3. Statistically significant relationships p≤ .05 are reported.

Research Question #17 asked which combination of moderator variables (gender, weight loss, income, time since diagnosis, education, symptoms, and comorbidity), along with age and treatment best predicted disruptions in quality of life and functional status in adults with lung cancer over time. Multiple regression (Stepwise) was performed with data from the entire sample at Time 1 and Time 3. The mean CIPS, PFS, KPS scores were as used as outcomes in separate analyses. Comorbidity was entered as a dichotomous dummy variable (present or absent). The multiple R² and tests for statistical significance
(p ≤ .10) reported in this exploratory analysis. The
direction of the relationship (positive or negative) was
reported for all significant variables.
CHAPTER 4
RESULTS OF THE STUDY
Study Sample

Subject Accrual

Twenty-four patients with non-small cell lung cancer consented to participate in the study. Data were collected on 7 subjects receiving supportive care and 17 patients receiving an initial one month cycle of chemotherapy. Subjects were entered onto the study from September, 1987 until April, 1989. They were accrued from five different facilities in the greater Los Angeles area and central valley: a large university medical center, the out-patient clinic of a veteran's hospital, an out-patient clinic of a health maintenance organization, and two private medical offices. These settings provided access to urban, suburban, and rural populations. A difference in treatment pattern was noted during data collection. The majority of subjects receiving chemotherapy were from the university teaching hospital (9 of 17; 52.9%), while the majority of the total sample of untreated patients were from the veteran's hospital, (4 of 7; 57.1%). Analyzed differently, 9 of the 10 patients followed at the university were treated with chemotherapy; 4 out of 6 at the health maintenance organization; all 4 at the private offices; and none at the veteran's hospital.
Subject accrual was difficult for several reasons. Thirty-one patients were approached to participate in the study but 5 were eventually excluded from data collection. Subjects excluded included 2 chemotherapy patients who met initial screening criteria, were willing to participate, but became too ill just prior to initiation of the study. Two patients who were willing to participate were excluded after it was learned that they had brain metastases (including one who was to receive chemotherapy). Three potential subjects refused to participate in the study. Two, on supportive care only, stated they were too depressed to participate, and one (about to receive treatment) was too nervous to participate.

The initiation of a combination chemotherapy, radiation protocol for non-small lung cancer patients with limited but unresectable disease at the major university medical center limited the number of potential subjects treated with chemotherapy alone. The necessity of enrolling patients prior to the start of the initial chemotherapy treatment required timeliness of potential subject identification, initiation of consent procedures, and processing of questionnaires at a potentially stressful and busy time for the subjects and their families.

Three subjects died during the study, after the completion of the Time 1 instruments. Two of these were in
the treated group (ages 74 and 51 years) and one was on supportive care only (age 67). Additionally, two subjects only completed the Time 1 series of questions because of other reasons. This included one untreated subject who refused to continue in the study because he was "too depressed", and one treated subject who was lost to follow-up when he left the state. This resulted in 19 subjects with data at Time 1 and Time 3 (14 treated and 5 untreated). Fifteen of the 19 subjects mailed back the physical function questionnaire at Time 2 (11 treated and 4 untreated). The treatment group with data for Time 1 and Time 3 consisted of two age subgroups: 10 younger adults and 4 older adults. For Time 2, complete data were available on 10 younger (8 treated, 2 untreated) and 5 older subjects (3 treated, 2 untreated). Additional missing data occur, primarily in the CIPS, due to unanswered questions by subject choice, or by subject error.

Age and Treatment Status

To investigate the age related disruptions of chemotherapy on quality of life and functional status, subjects were divided into three subgroupings for statistical analysis. These consisted of two chemotherapy treatment subgroups dichotomized by age as younger than 65 years, and 65 years and older; and a small cohort of untreated non-small cell lung cancer patients. Data on
untreated subjects are presented by age (younger and older) as well, but the small number of subjects prevent further statistical comparisons. Age and treatment were the primary independent variables of interest in this study. Data describing age by treatment status at baseline are displayed in Table 4.1.

Table 4.1

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</tbody>
</table>

Ages ranged from 42 to 76 years for all subjects, with an average age of 60.3 years, similar to the mean age for patients with lung cancer (Brown & Kessler 1988). The average age of those subjects who received treatment was 59.06 years. The average age for the younger treatment subgroup was 54 years, and 71.2 years for the older treated subgroup.

Subjects described at baseline and subjects with data
for Time 1 and Time 3 are described by age and treatment status in Table 4.2. At baseline, ten (41.6%) subjects in the study were 65 years or older, as displayed in Table 4.2. Seven (36.8%) older subjects had data over time. Only 5 of these elderly subjects were treated with chemotherapy (29.4% of the treated group). Data over time were available for 4 (28.5%) of the older treated subjects. Ages ranged from 52 to 70 years for those subjects who

Table 4.2

Comparison of Subjects by Treatment and Age Subgroup Over time

<table>
<thead>
<tr>
<th>Age</th>
<th>No Chemotherapy</th>
<th>Chemotherapy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (Percent)</td>
<td>N (Percent)</td>
<td></td>
</tr>
<tr>
<td>&lt;65 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>2 (14.3)</td>
<td>12 (85.7)</td>
<td>14</td>
</tr>
<tr>
<td>Time 1 &amp; 3</td>
<td>2 (16.6)</td>
<td>10 (83.3)</td>
<td>12</td>
</tr>
<tr>
<td>≥65 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>5 (50)</td>
<td>5 (50)</td>
<td>10</td>
</tr>
<tr>
<td>Time 1 &amp; 3</td>
<td>3 (42.8)</td>
<td>4 (57.1)</td>
<td>7</td>
</tr>
</tbody>
</table>
received supportive care only. The mean age of the untreated group was 63.4 years, with 5 subjects over 65 years of age. Sixty percent (n=3) of the untreated subgroup with data over time were over 65 years of age. No significant difference were detected between the ages of the treated and the non-treated groups (P=.32).

**Person/environment**

Treatment status by age was analyzed according to the primary demographic variables of gender, living situation, and income. These are displayed in Table 4.3. The representative subject in this study was a well educated, white, married, protestant male who was not currently working, and who had a middle income. The sample was skewed to a higher level of education and economic status than the population at large. (Note that only 23 subjects completed items for marital status and income).

**Gender.** Men (n=14) composed 58.3% of the sample. The 41.6% fraction of women subjects in the study perhaps reflects the increase in lung cancer in women. In the older treated group, there were 3 men and 2 women. Seventy percent of the women subjects were treated as compared with 52.9% of the men subjects. There were no statistically significant differences in distribution of men and women in the treated and untreated groups, or when dichotomized by age (younger or older than 65 years) in
Table 4.3

Selected Person/Environment Variables

<table>
<thead>
<tr>
<th>Var</th>
<th>No Treatment</th>
<th>Chemotherapy</th>
<th>Total</th>
<th>&lt;65</th>
<th>&gt;65</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>6</td>
<td>2</td>
<td>10</td>
<td></td>
<td>(41.6)</td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>14</td>
<td></td>
<td>(58.3)</td>
</tr>
<tr>
<td>Marital Status*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>3</td>
<td>7</td>
<td>2</td>
<td>12</td>
<td></td>
<td>(52.1)</td>
</tr>
<tr>
<td>Divorced</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td></td>
<td>(21.7)</td>
</tr>
<tr>
<td>Separated</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td></td>
<td>(4.3 )</td>
</tr>
<tr>
<td>Widowed</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td></td>
<td>(8.6 )</td>
</tr>
<tr>
<td>Living Together</td>
<td></td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>(13.0)</td>
</tr>
<tr>
<td>Living Alone</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td></td>
<td>(4.3 )</td>
</tr>
<tr>
<td>Income*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;$10K</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td></td>
<td>(17.4)</td>
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<tr>
<td>$10-25K</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>11</td>
<td></td>
<td>(47.8)</td>
</tr>
<tr>
<td>$35-40</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td></td>
<td>(4.1 )</td>
</tr>
<tr>
<td>&gt;$40</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>7</td>
<td></td>
<td>(30.4)</td>
</tr>
</tbody>
</table>

*percentages based on N=23 responses
the treated group.

Marital status. Only one chemotherapy subject (under 65) in the study lived alone at the time of data collection, even though 8 (34.7%) classified themselves as divorced, separated, or widowed. Fifty percent the total sample (12 of 24) were married and 13% (3) of the subjects described their situation as "living together". Fifty-nine percent of the chemotherapy subjects were married. Two of the older subjects who were treated with chemotherapy were married as were seven of the younger subjects. Forty-two percent of the untreated cohort were married. There were no statistically significant differences in marital status according to age or treatment status.

Income. The subject's income (percentages calculated on n=23 responses) ranged from less than $10,000 a year (17.4%, n=4) to over $40,000 (30.4%, n=7); 47.8% (n=11) were in the $10-25,000 category. There were no significant differences in range of income between the treated and untreated groups, or when dichotomized by age (younger or older than 65 years).

Education. The sample was well educated; 73.9% (n=17 of 23 responses) had education beyond high school. Approximately 43% (n=10) of the subjects had completed some college, with 21.7% (n=5) with a college degree. Only 3 (13%) subjects did not complete high school. There were no statistically significant differences in educational
level between the treated and untreated groups, or when
dichotomized by age (younger or older than 65 years).

**Ethnicity/religion.** The sample was predominately
caucasian (83.3%, n=20). Four subjects were from minority
groups: 12.5% (n=3) were Black, and 4.2% (n=1) were Asian.
The treated group was 88.2% Caucasian. The majority of the
sample (70.8%) was Protestant, (n=17) and 12.5% were
Jewish (n=3).

**Work status.** At Time 1, 39% (n=9 out of 23 responses)
described themselves as currently working. (One subject
did not complete this item.) All of these subjects were
less than 65 years old, and 8 of the 9 working patients
received treatment. The younger subjects undergoing
treatment were more likely to describe themselves as
currently working than older subjects(p=.03).

**Illness Variables**

Major illness variables of interest included extent
of disease, type of symptoms, time since diagnosis, and
weight loss. The representative subject had
adenocarcinoma, with lymph node metastases, with symptoms,
with a diagnosis of 3 months or less prior to study entry,
and with a 12.3 pound weight loss in the previous 6
months.

The two major types of non-small cell lung cancer
were well represented in the sample: 37.5% (n=9) squamous
cell lung cancer; 45.8% (n=11) adenocarcinoma.
Additionally, 16% (n=4) had other histologies. Seven (29.1%) with squamous cell were treated, and 8 (47%) with adenocarcinoma received chemotherapy. There were no statistically significant differences in type of non-small cell lung cancer in the treated (dichotomized by age) and untreated groups.

**Extent of disease.** Sites of metastasis were categorized for each group at the beginning of the study. No subjects had documented brain metastases. By entry criterion of advanced or unresectable disease, subjects with lymph node metastases were common in both the treated and untreated groups (n=15, 62.5% overall). Approximately seventy-six percent of subjects who received chemotherapy had lymph node metastases (13 of 17). Nine subjects (37.5%) had bony metastases. This included 5 of the subjects (29.4%) in the chemotherapy group (1 over 65 years). Four of the subjects (57.1%) in the supportive care group had bony metastases. All of the older patients treated with chemotherapy had lymph node metastases, including one with bone involvement and one with involvement of the contralateral lung. There were no statistically significant differences in the extent of disease between the treated (dichotomized by age) and untreated group. Two patients (8.3%) in the treated group had disease involving the contralateral lung. Only 1 subject in the treated group (less than 65 years) had
documented liver metastases. Other sites of metastasis were noted in 37.5% (n=9) of the subjects.

**Type of symptoms.** Local, metastatic, and systemic symptoms of advanced lung cancer were apparent in both the treated and untreated groups. Metastatic symptoms were noted in 37.5% (n=9) of the sample; 6 of these subjects were in the treated group. Systemic symptoms were described in 16.6% (n=4) of the subjects (only 1 in the treated group). Symptoms due to the local effects of lung cancer were described in 37.5% (n=9) of the subjects: 8 of these subjects were in the treated group. Two subjects (8.3%) in the treated group were described as having no apparent symptoms (1 in the older group). There were no statistically significant differences in the frequency of observed symptoms between the treated and the untreated groups. Forty percent of the older treated patients (n=2) had systemic or metastatic disease similar to the 41.6% frequency in the younger treated patients.

**Time since diagnosis.** In this study, the time from diagnosis to study entry ranged over a wide distribution, as some patients previously treated with curative intent for lung cancer had relapsed with unresectable disease a substantial time after diagnosis. This is displayed in Table 4.4. In the supportive care only group, the time since diagnosis ranged from almost 2 months to 1 year, with a mean of 6 months. The range for subjects receiving
Table 4.4

Time since Diagnosis

<table>
<thead>
<tr>
<th>Time since Dx</th>
<th>NO</th>
<th>%</th>
<th>YES</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>less 3 months</td>
<td>1</td>
<td>14.3</td>
<td>9</td>
<td>52.9</td>
</tr>
<tr>
<td>3-6 months</td>
<td>2</td>
<td>28.6</td>
<td>1</td>
<td>5.8</td>
</tr>
<tr>
<td>7 months-1 yr</td>
<td>3</td>
<td>42.9</td>
<td>3</td>
<td>17.6</td>
</tr>
<tr>
<td>over 1 year</td>
<td>1</td>
<td>14.3</td>
<td>4</td>
<td>23.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>7</td>
<td>17</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

treatment was from 6 months to almost 3 years. Considering age alone (Table 4.5), the average time since diagnosis for subjects less than 65 years was approximately 8 1/2 months; for those 65 years and older, 6 1/2 months. There were no statistically significant differences in time since diagnosis between the younger and older (65 years and older) subjects. When considering treated patients regardless of age, 52.9% (n=9) had been diagnosed within the previous three months. There were no statistically significant differences in length of time since diagnosis between those who received treatment and those who received supportive care only.
Table 4.5

Months Since Diagnosis by Age

<table>
<thead>
<tr>
<th>Var</th>
<th>&lt;65 years</th>
<th>&gt;65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Mean</td>
<td>8.4</td>
<td>6.5</td>
</tr>
<tr>
<td>STD</td>
<td>9.2</td>
<td>7.7</td>
</tr>
<tr>
<td>Maximum</td>
<td>34</td>
<td>26</td>
</tr>
<tr>
<td>Minimum</td>
<td>.5</td>
<td>.7</td>
</tr>
<tr>
<td>Median</td>
<td>5.6</td>
<td>3</td>
</tr>
</tbody>
</table>

**Weight loss.** The average weight loss for all subjects over the six months prior to study entry was 11.8 pounds (SD 12.4). In the untreated group, the average loss was 18.29 pounds (SD 14.03) with a range of 3 to 40 pound weight loss. The treated group appeared to have experienced less weight loss prior to treatment, with an average of 8.94 pounds (SD 10.95) and range of 0 to 30 pounds. This difference between the groups showed a trend toward statistical significance (p=.07).

When weight loss was dichotomized by age alone prior to treatment, the younger patients (less than 65 years) had a mean weight loss of only 7 pounds (range 0 to 30 pounds, SD 8.7) while the older patients had a mean loss of 18 pounds (range 0 to 40 pounds, SD 14.13). This
difference in weight loss for the older patients also showed a trend toward statistical significance (p=.06).

**Biophysical Variable**

**Comorbid diseases.** Presence of comorbid disease was considered as a biophysical variable influencing subject responses. The typical subject in this study did not have comorbid diseases in addition to lung cancer. Forty-one percent (n=10) of the subjects acknowledged illnesses other than lung cancer. Heart disease was noted by 16.6% (n=4) of the subjects; 3 of these subjects received chemotherapy. Two of those with heart disease were 65 years or older. One older subject (untreated) identified high blood pressure as a health problem. Twenty percent (n=5) of the subjects stated that they had difficulty hearing (2 older untreated subjects and 3 younger treated subjects). One younger subject (treated) described shortness of breath as a health problem, independent of lung cancer. Two untreated subjects (younger and older) reported problems with arthritis or joint problems.

**Treatment Characteristics**

The subjects receiving chemotherapy were treated with a variety of drugs (Table 4.6). All of the treated subjects (n=17) received cisplatin containing regimens. Additionally, Velban was administered to 52.9% (n=9) of the chemotherapy patients and VP-16 (etoposide) to 29.4% (n=5) of those treated. Other subjects received
Table 4.6

Chemotherapy Drug Combinations

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Number of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisplatin/ Velban</td>
<td>8</td>
</tr>
<tr>
<td>Cisplatin/ VP 16</td>
<td>6</td>
</tr>
<tr>
<td>Cisplatin/ other</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17</strong></td>
</tr>
</tbody>
</table>

cyclophosphamide, doxorubicin, or 5-Fluorouracil along with the cisplatin. Choice of chemotherapy drug regimen did not vary significantly with age.

Dose reduction was not a major confounder in this study. Fifteen out of the 17 patients (88%) received the usual dose of cisplatin, 100 mg per M², and 2 out of 17 (12%) received 50mg per M².

Chemotherapy Side effects. Severity of side effects of the first cycle of chemotherapy was evaluated according to the ECOG toxicity index. All side effects rated 1 or more were identified and findings were dichotomized by age (Table 4.7). One of the most common side effects for both age groups was central nervous system toxicity as characterized by aspects of depression, anxiety, headache, and lethargy. Nausea and vomiting also were common side effects, affecting 58.3% of the younger treated subjects. Fifty percent of the younger subjects experienced
Table 4.7

Rank Order of Chemotherapy Side Effects

<table>
<thead>
<tr>
<th>Type of Side Effect</th>
<th>Age</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;65</td>
<td>&gt;65</td>
<td>% Affected</td>
<td></td>
</tr>
<tr>
<td>N=12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuro-Toxicity</td>
<td>4</td>
<td>4</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Nausea &amp; Vomiting</td>
<td>7</td>
<td>1</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Alopecia</td>
<td>6</td>
<td>1</td>
<td>41.1</td>
<td></td>
</tr>
<tr>
<td>Leukopenia</td>
<td>4*</td>
<td>1</td>
<td>29.4</td>
<td></td>
</tr>
<tr>
<td>Fever/Infection</td>
<td>5*</td>
<td></td>
<td>29.4</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3</td>
<td></td>
<td>17.6</td>
<td></td>
</tr>
<tr>
<td>Genitourinary</td>
<td>2</td>
<td>1</td>
<td>17.6</td>
<td></td>
</tr>
<tr>
<td>Stomatitis</td>
<td>3</td>
<td></td>
<td>17.6</td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>3</td>
<td></td>
<td>17.6</td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>2*</td>
<td></td>
<td>11.8</td>
<td></td>
</tr>
<tr>
<td>Hepatic</td>
<td>2</td>
<td></td>
<td>11.8</td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>1</td>
<td></td>
<td>5.8</td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>1</td>
<td></td>
<td>5.8</td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>1</td>
<td></td>
<td>5.8</td>
<td></td>
</tr>
</tbody>
</table>

* one each with Grade 3 Severity (ECOG)
alopecia. One of the younger patients experienced grade III leukopenia (1.3 WBC), and one had grade III fever. None of the older subjects experienced fever or infection during this initial phase of treatment. However, two patients died after initiation of treatment (one in the older age subgroup and one in the younger subgroup); the immediate cause of death was unclear. One of the younger patients also experienced grade III pulmonary symptoms requiring intermittent O₂.

Treatment response and disease progression.
Responses to the single cycle of chemotherapy were evaluated subjectively by the physician and were not based on the careful measurement of tumor response which are required in clinical trials. The subjective evaluations ranged from evidence of clinical improvement to death during treatment. Fifty percent of those treated with chemotherapy (n=8) were thought to have demonstrated clinical improvement, 37.5% (n=6) did not show any evidence of change in condition, and 12.5% (n=2) died during treatment. In the untreated cohort, none were noted to have improved, 3 patients were stable and 3 were thought to have deteriorated during the previous month.

Disruptions in Quality of Life
Analysis of CIPS Scores

Because of the complexities of the data describing the disruptions in quality of life, the overall global
score and scores for each of the six Superscales (including subscales and individual items) were presented separately to address the research questions. Thus, the research questions were repeated in each dimension of the CIPS. Each section included baseline data followed by presentation of data describing disruptions in quality of life after one cycle of treatment. In the CIPS each item had a potential score of 0 (no problem) to 4 (very much). Higher mean scores indicated greater problems.

Changes over time were analyzed for the 19 subjects (79.2% of original sample) who completed both pre (Time 1) and post (Time 3) questionnaires. This included 14 treated (10 younger and 4 older adults) and 5 untreated (2 younger, and 3 older adults). It is important to note that the small sample sizes of the treated and untreated subgroups make a Type II error (failure to find significant difference when there is one) more likely.

Global Scores of Quality of Life

Baseline. In response to research question #1 (which asked if older adults with lung cancer had more disruptions than younger patients), disruptions in quality of life, as represented by the CIPS Global score, of older adults with non-small cell lung cancer were not statistically different than those of younger patients. The disruptions in overall quality of life in younger (n=14) and older (n=10) adults with non-small cell lung
cancer at Time 1, independent of future treatment status, are revealed by the Global score of the CIPS for all subjects (Table 4.8). Separation by age subgroups (< 65 and ≥ 65 years) demonstrates the similarities and differences, prior to future treatment decisions, for the total sample.

Table 4.8
Age and Impact of Lung Cancer on Disruptions of Quality of Life
CIPS Global Scores*

<table>
<thead>
<tr>
<th>Scale</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;65 Years</td>
<td>14</td>
<td>.92</td>
<td>.68</td>
</tr>
<tr>
<td>≥ 65 year</td>
<td>10</td>
<td>.93</td>
<td>.47</td>
</tr>
</tbody>
</table>

*CIPS= Cancer Inventory of Problem Situations

Differences in mean global CIPS score were analyzed as a function of demographic variables. Subjects with other illnesses had a higher mean score (1.09), indicating more disruptions in quality of life, than those without comorbid disease (.65). When evaluated by income alone, subjects at the highest income level had the lowest score (mean.6), indicating the highest quality of life. Males
(.85) and females (.87) had similar global mean scores, but women had a wider range of scores (.3 to 2.4) than men (.07 to 1.4). Considering education alone, subjects with the least education (junior high school or less), had the lowest mean scores (.62) or highest quality of life. Scrutiny of the baseline global scores for the three subjects who died after entry onto the study and the one subject who was too depressed to complete Time 3 data, showed higher CIPS scores (mean score of 1.29).

Research question #2 asked if adults with non-small cell lung cancer had more disruptions in quality of life than adults with other cancer diagnoses. The CIPS scores for both the younger and older adults with non-small cell lung cancer indicated disruptions in quality of life higher than the 80\textsuperscript{th} percentile of the cancer patient norm.

After Chemotherapy. Research question #4 asked if older adults had more disruptions in quality of life than younger adults treated for non-small cell lung cancer, and more than an untreated cohort. Comparison of the mean global CIPS scores pre and post chemotherapy did not demonstrate statistically significant differences in disruptions in quality of life in older treated patients as compared to younger treated patients or to an untreated cohort (Table 4.9). The minimal difference between the subgroups is displayed in Figure 4.1. Table 4.10 displays
Table 4.9
Disruptions in Quality of Life During Chemotherapy
By Age and Treatment Status
CIPS Global Scores*

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td><strong>Treated</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>10</td>
<td>.78</td>
</tr>
<tr>
<td>≥65</td>
<td>4</td>
<td>.78</td>
</tr>
<tr>
<td><strong>Untreated</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>2</td>
<td>.70</td>
</tr>
<tr>
<td>≥65</td>
<td>3</td>
<td>.83</td>
</tr>
</tbody>
</table>

*CIPS= Cancer Inventory of Problem Situations

a small increase in disruptions in global quality of life for the treated subjects.

Research question #5 asked if there were differences in quality of life between younger and older adults with non-small cell lung cancer, independent of treatment. There were no statistically significant differences when the older adults were compared with the younger adults.
Figure 4.1
Disruptions in Quality of Life by Age and Treatment*

Note-higher scores mean more problems
*No significant differences
Table 4.10

Quality of Life* Before and After a Cycle of Chemotherapy

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>0.78</td>
<td>0.85</td>
</tr>
<tr>
<td>SD</td>
<td>0.59</td>
<td>0.58</td>
</tr>
<tr>
<td>Median</td>
<td>0.70</td>
<td>0.85</td>
</tr>
</tbody>
</table>

*CIPS Global score

N=14 treated subjects

over time, independent of treatment status, as displayed in Figure 4.2.

Research question #6 asked if there were differences over time in disruptions in quality of life in treated as compared to untreated adults with non-small cell lung cancer. The Global scores at Time 3 showed a small average decrease in quality of life (increased problems) for all subjects, but differences between treated and untreated groups were not statistically significant (Figure 4.3). However, there was a wide range in scores of treated subjects at Time 3 (.07 to 2.4). The mean baseline (Time 1) score (.78) for the untreated group was comparable to the treated group, but the untreated subjects had a higher score (.88) at Time 3.
Figure 4.2
Disruptions in Quality of Life by Age*

CIPS Global Score

0 0.2 0.4 0.6 0.8 1

0 1 2 3 4 5

Weeks

Younger

Older

N=12  N=7

Note: higher scores mean more problems
*No significant differences
Figure 4.3
Disruptions in Quality of Life by Treatment Status*

CIPS Global Score

0.8 -

0.6 -

0.4 -

0.2 -

0 1 2 3 4 5

Weeks

Treated

Untreated

N=14

N=5

Note: Higher scores mean more problems
*No significant differences
One possible indication of benefit from treatment is seen in the subjects (n=8) who were felt by physicians to have demonstrated clinical improvement after treatment. They had a very low mean CIPS score (better quality of life), .70, (SD .44) at Time 3. However, this was still an increase from their low baseline score, .64, (SD .43).

**Summary.** The findings of this study indicate that adults with non-small cell lung cancer have profound disruptions in quality of life when compared with a normative cancer sample. There were not significant differences in disruptions in quality of life in older as compared with younger lung cancer patients. There were increased disruption in quality of life for both the younger and older treated adults after a cycle of chemotherapy, and for the untreated cohort, but these differences were not statistically significant. Subjects with the highest scores (most disruptions) in quality of life were those who had died or were too depressed to complete the study, and had no treatment benefit.

**Physical Activity Superscale**

**Baseline.** The Physical Superscale detected specific disruptions in quality of life related to physical changes and problems in daily activity. These included the subscales of ambulation, recreational difficulties, activities of daily living, difficulty working, pain, weight loss, and the fit of clothing.
In answer to research question #1, older adults did not have statistically significant differences in physical activity than younger adults (Table 4.11). However, the older adults with non-small cell lung cancer had greater problems in specific areas (ambulation, daily activities, recreation, and working) than younger adults. Older adults identified minimal problems with weight loss, even though objective assessment in the medical record had revealed a trend toward increased weight loss in the older adults when compared with younger adults. The older adults also had less pain, and problems in fit of clothing than their younger cohorts. The average Physical Superscale baseline score for all subjects was 1.29 (SD .82) with a median of 1.12. There was a trend toward significant difference at baseline (p=.08) between those who remained untreated (1.26) and those who eventually received chemotherapy (.90), suggesting that those who received treatment had had less prior disruptions in physical activity.

Standardized comparisons of the CIPS scores place both age groups in the 80th percentile of disruptions in physical activity (research question #2). The disruptions place the older subgroup in the 85th percentile ranking of physical disruptions.

In response to research question #3, which asked for identification of serious physical disruptions. CIPS items rated 2 "a fair amount" or more in adults with non-small
Table 4.11

Age and Impact of Lung Cancer on Physical Activity

Baseline CIPS: Physical Superscale*

<table>
<thead>
<tr>
<th>Scale</th>
<th>Under 65 years</th>
<th>At least 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Physical*</td>
<td>14</td>
<td>1.21</td>
</tr>
<tr>
<td>Ambulation</td>
<td>14</td>
<td>1.90</td>
</tr>
<tr>
<td>Daily Act</td>
<td>14</td>
<td>.90</td>
</tr>
<tr>
<td>Recreation</td>
<td>14</td>
<td>1.40</td>
</tr>
<tr>
<td>Weight loss</td>
<td>14</td>
<td>.66</td>
</tr>
<tr>
<td>Working</td>
<td>11</td>
<td>1.91</td>
</tr>
<tr>
<td>Pain</td>
<td>14</td>
<td>1.20</td>
</tr>
<tr>
<td>Clothing</td>
<td>13</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Global Score

cell lung cancer were rank ordered at baseline independent of age or future treatment status. Problems with strenuous activities and lack of energy were the most common physical disruptions, as noted in Table 4.12. While the strenuous activities and change in recreation might be expected, 43.5% of the subjects claimed difficulty with
Table 4.12

**R**ank **O**rder of Major* Physical **D**isruptions in

**A**dults with Lung **C**ancer

<table>
<thead>
<tr>
<th>Rank Order</th>
<th>Items</th>
<th>N**</th>
<th>% Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1</td>
<td>Difficulty with Strenuous Activities</td>
<td>22</td>
<td>95.5</td>
</tr>
<tr>
<td># 2</td>
<td>Lack of Energy</td>
<td>24</td>
<td>79.2</td>
</tr>
<tr>
<td># 3</td>
<td>Change in Recreational Activities</td>
<td>23</td>
<td>60.9</td>
</tr>
<tr>
<td># 4</td>
<td>Loss of Interest in Recreational Activities</td>
<td>23</td>
<td>52.2</td>
</tr>
<tr>
<td># 5</td>
<td>Difficulty with Household Chores</td>
<td>23</td>
<td>43.5</td>
</tr>
<tr>
<td># 6</td>
<td>Frequent Pain</td>
<td>23</td>
<td>43.5</td>
</tr>
</tbody>
</table>

*Rated 2 or more on CIPS

**N**=number responding to question

household chores. Frequent pain was a problem for 43.5% of the total sample.

**A**fter **C**hemotherapy. Disruptions in the physical activity dimension of quality of life after chemotherapy was examined by comparing the mean scores of the Physical Superscale for Time 1 and Time 3. In answer to research question #4, there were statistically significant
differences in physical activities for older treated as compared with the untreated cohort at Time 3 (p< .005), but there were no significant differences when compared with younger treated subjects after a cycle of chemotherapy (Table 4.13). The untreated group had significantly more disruptions when compared with the younger treated group at Time 1 (p<.0025) and Time 3 (p<.005). These differences are graphically displayed in Figure 4.4.

Table 4.13

<table>
<thead>
<tr>
<th>Age</th>
<th>Time 1</th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Treated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>10</td>
<td>.82</td>
<td>.54</td>
<td>.94</td>
</tr>
<tr>
<td>≥65</td>
<td>4</td>
<td>1.11</td>
<td>.54</td>
<td>1.0</td>
</tr>
<tr>
<td>Untreated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>2</td>
<td>1.27</td>
<td>.17</td>
<td>1.81</td>
</tr>
<tr>
<td>≥65</td>
<td>3</td>
<td>1.25</td>
<td>.36</td>
<td>1.61</td>
</tr>
</tbody>
</table>

*Global Superscale score

Overall, the average problems in the physical subscales were not severe. A mean rating of 1 denotes a
Figure 4.4
Disruption in Physical Function by Age and Treatment*

CIPS Physical Global Score

2

1.5

1

0.5

0

0 1 2 3 4 5

Weeks

Younger Treated

Older Treated

Untreated

N=10

N=4

N=5

Note: higher scores mean more problems
*Significant differences at Time 3 between treated and untreated groups
problem which bothers the subject "a little". No mean
global score in the Physical subscales is above a 2 ("a
fair amount"). The mean overall score for the untreated
cohort was 1.26 (SD .27) at Time 1 and 1.69 (SD .52) at
Time 3. This indicated an increase in problems, with a
trend toward significant differences in physical
deterioration over time (p=.08).

When dichotomized by age alone, (independent of
treatment status), to address research question #5,
different trends appear to occur in disruptions of
physical activity over time for the older and younger
patients. The mean baseline score of the overall physical
activity dimension indicated more severe problems in the
older subjects (1.17 as compared with .90), but this small
difference, as displayed in Figure 4.5, was not
statistically significant. For the patients under 65
years of age, all problem areas demonstrated increases in
the mean scores over time. None was statistically
significant. However in the older age group, the mean
scores of the subscales of ambulation, pain, and
difficulties working indicated less problems over time
than for the younger adults.

In response to research question #6, differences over
time in physical activity by treatment status approached
statistical significance (p=.08) (Figure 4.6). The
untreated subjects started with more disruptions and
Figure 4.5
Disruptions in Physical Function by Age*

Note-higher scores mean more problems
*N: No significant differences

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Figure 4.6
Disruptions in Physical Function by Treatment*

CPS Physical Global Score

0 0.5 1 1.5 2

0 1 2 3 4 5

Weeks

Treated Untreated

N=14 N=5

Note: higher scores mean more problems
*No significant differences

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showed a greater increase in physical disruptions over time (1.26 to 1.69) (p=.08). When subscales were analyzed, the wide standard deviations in some items (notably, ambulation, and working) over time indicate a greater range of difficulties (Table 4.14). Problems in ambulation were serious concerns in the physical activity category,

Table 4.14
Disruptions in CIPS Physical Subscales after Chemotherapy

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th></th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scale</td>
<td>N</td>
<td>Mean*</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Physical*</td>
<td>14</td>
<td>.90</td>
<td>.53</td>
<td>.96</td>
<td>.65</td>
</tr>
<tr>
<td>Ambulation</td>
<td>14</td>
<td>1.7</td>
<td>.98</td>
<td>1.68</td>
<td>1.06</td>
</tr>
<tr>
<td>Daily Activities</td>
<td>14</td>
<td>.61</td>
<td>.76</td>
<td>.68</td>
<td>.73</td>
</tr>
<tr>
<td>Recreation</td>
<td>14</td>
<td>1.14</td>
<td>.79</td>
<td>1.13</td>
<td>.84</td>
</tr>
<tr>
<td>Weight Loss</td>
<td>14</td>
<td>.38</td>
<td>.55</td>
<td>.49</td>
<td>.60</td>
</tr>
<tr>
<td>Working</td>
<td>9</td>
<td>1.56</td>
<td>1.53</td>
<td>2.17</td>
<td>1.84</td>
</tr>
<tr>
<td>Pain</td>
<td>14</td>
<td>.86</td>
<td>.71</td>
<td>.68</td>
<td>.68</td>
</tr>
<tr>
<td>Clothing</td>
<td>13</td>
<td>.49</td>
<td>.69</td>
<td>.85</td>
<td>1.18</td>
</tr>
</tbody>
</table>

*Global Superscale score

but did not appear to worsen over time. Pain was the only
problem area which showed a significant trend towards improvement over time (.86 to .68) in the treated group, as compared with the untreated group (1.0 to 1.69) (p=.02). While difficulties in ambulation slightly improved for the untreated subjects (from 2.30 to 2.13), these scores were considerably higher (worse) at both Time 1 and Time 3 than those of the treated patients. Work-related problems and clothing showed the largest increase in problems for the untreated group over time.

The subjects who appeared to have clinical improvement after treatment demonstrated a small decrease in physical problems after treatment (from .90, SD .58 to .84, SD .55). In comparison, the baseline mean score for physical activity for the subjects who died and the subject who became too depressed to continue participation in the study indicated substantially higher disruptions (2.42). After treatment, the standardized comparison of the physical Activity dimension of quality of life indicate a T score for the chemotherapy patients of physical disruptions in the 70th percentile.

Research question #7 required a repeated ranking of serious disruptions in physical activity of treated patients. There was little difference from the pre-treatment ranking (Table 4.15). Pain frequency decreased in those treated, but was relatively unchanged in those receiving supportive care only, (3/5 complained of pain).
Table 4.15

Rank Order of Major* Physical Disruptions
After Treatment with Chemotherapy for Lung Cancer

<table>
<thead>
<tr>
<th>Rank Order</th>
<th>Items</th>
<th>N**</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1</td>
<td>Difficulty with Strenuous Activities</td>
<td>14</td>
<td>83.3</td>
</tr>
<tr>
<td># 2</td>
<td>Lack of Energy</td>
<td>14</td>
<td>71.4</td>
</tr>
<tr>
<td># 3</td>
<td>Loss of Interest in Recreation</td>
<td>12</td>
<td>46.1</td>
</tr>
<tr>
<td># 4</td>
<td>Change in Recreation</td>
<td>12</td>
<td>41.7</td>
</tr>
<tr>
<td># 5</td>
<td>Clothes don't Fit</td>
<td>14</td>
<td>35.7</td>
</tr>
<tr>
<td># 6</td>
<td>Difficulty with Household Chores</td>
<td>14</td>
<td>35.7</td>
</tr>
</tbody>
</table>

*Rated 2 or more on the CIPS
**N=respondents to question

Only 23.1% of those on chemotherapy complained of frequent pain.

Summary. The findings suggest that adults with non-small cell lung cancer, especially older subjects, are more severely limited in physical activities than other cancer patients. Older subjects appeared more limited in a variety of physical activities than younger subjects, but there were no statistically significant differences in disruption of physical activities after a cycle of chemotherapy. The major disruptions in physical activity affecting more than 50% of the sample included: difficulty
with strenuous activities, lack of energy, and changes in and loss of interest in recreational activities. After a cycle of chemotherapy, the scores of the treated group indicated less pain when compared with the untreated group. The untreated subjects indicated significantly more disruptions in physical activities over time when compared to the younger and older treated subjects. When analyzed by age alone, independent of treatment status, younger subjects demonstrated increasing disruptions in physical activity in all problems areas over time, but these were still less than the physical disruptions experienced by older subjects. Major disruptions in physical activities after chemotherapy were similar to those before treatment.

**Psychosocial Superscale**

**Baseline.** The Psychosocial Superscale is concerned with the emotional responses to disease and treatment. It encompasses the subscales of psychological distress, cognitive problems, body image problems, anxiety in medical situations, work related concerns, difficulties interacting with children, difficulty communicating with family and friends, and the perceived difficulty of friends and family communicating with the patient. There were no statistically significant differences in the Psychosocial Superscale score between the older and younger adults with non-small cell lung cancer at baseline as displayed in Table 4.16 (research question #1). When
Table 4.16

Age and Impact of Lung Cancer on Psychosocial Function

<table>
<thead>
<tr>
<th>Var</th>
<th>Under 65 years</th>
<th></th>
<th></th>
<th>At least 65 years</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----</td>
<td>-------</td>
<td>---------</td>
<td>-----</td>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td>Psychosocial*</td>
<td>14</td>
<td>.93</td>
<td>.85</td>
<td>10</td>
<td>.86</td>
<td>.60</td>
</tr>
<tr>
<td>Body Image</td>
<td>13</td>
<td>.94</td>
<td>1.21</td>
<td>10</td>
<td>.83</td>
<td>1.11</td>
</tr>
<tr>
<td>Psychological Distress</td>
<td>14</td>
<td>1.36</td>
<td>1.13</td>
<td>10</td>
<td>1.25</td>
<td>.82</td>
</tr>
<tr>
<td>Cognition</td>
<td>14</td>
<td>.74</td>
<td>.99</td>
<td>10</td>
<td>.77</td>
<td>1.14</td>
</tr>
<tr>
<td>Communication with Friends</td>
<td>14</td>
<td>.64</td>
<td>1.18</td>
<td>10</td>
<td>.49</td>
<td>.49</td>
</tr>
<tr>
<td>Communication with Patient</td>
<td>14</td>
<td>.51</td>
<td>.65</td>
<td>10</td>
<td>.29</td>
<td>.36</td>
</tr>
<tr>
<td>Anxiety Medical Situations</td>
<td>14</td>
<td>1.01</td>
<td>.83</td>
<td>10</td>
<td>.93</td>
<td>.78</td>
</tr>
<tr>
<td>Worry</td>
<td>13</td>
<td>2.00</td>
<td>1.21</td>
<td>8</td>
<td>2.14</td>
<td>1.37</td>
</tr>
<tr>
<td>Relate with Children</td>
<td>6</td>
<td>1.28</td>
<td>1.44</td>
<td>1</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Work Concerns</td>
<td>8</td>
<td>.38</td>
<td>.58</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*CIPS Global Superscale score

the psychosocial data were analyzed by subscale scores, the older adults with non-small cell lung cancer had lower scores (less problems) than the younger subgroup in the
majority of psychosocial subscales: body image, psychological distress, communication, interaction, medical anxiety, work, concerns about children, work-related concerns. The older adults demonstrated slightly more difficulty in the areas of cognition and worry than younger adults.

There was a significant difference (p=.03) between the global psychosocial baseline scores of those who eventually were treated (2.21) and those of the untreated subjects (.47). The subjects who went on to treatment expressed significantly more concern about disease progression. The mean psychosocial functioning baseline score for all subjects was .90. The mean baseline score for the subjects who died and the patient who was too depressed to continue was 1.14. The mean worry subscale score for the three subjects was 2.62, the highest of any of the subgroups.

The adults with non-small cell lung cancer appear to have increased disruptions in psychosocial aspects of quality of life when compared with other cancer patients (research question #2). Standardized comparisons of the CIPS scores for both age groups place these subjects in the 80th percentile ranking of emotional distress when compared with other cancer patients.

A rank order of psychosocial disruptions is displayed in Table 4.17, to address research question #3.
Table 4.17

Rank Order of Major* Psychosocial Disruptions in Adults with Lung Cancer

<table>
<thead>
<tr>
<th>Rank Order</th>
<th>Items</th>
<th>N**</th>
<th>% Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1</td>
<td>Worry about Cancer Progression</td>
<td>21</td>
<td>76.2</td>
</tr>
<tr>
<td># 2</td>
<td>Worry about Family Coping</td>
<td>20</td>
<td>60.0</td>
</tr>
<tr>
<td># 3</td>
<td>Frequent Anxiety</td>
<td>24</td>
<td>50.0</td>
</tr>
<tr>
<td># 4</td>
<td>Worry about Self-care Activities</td>
<td>21</td>
<td>42.9</td>
</tr>
<tr>
<td># 5</td>
<td>Overwhelmed</td>
<td>24</td>
<td>41.7</td>
</tr>
<tr>
<td># 6</td>
<td>Discomfort with Body Changes</td>
<td>22</td>
<td>40.9</td>
</tr>
</tbody>
</table>

*Rated 2 or more on the CIPS
**N=number responding to question

Worries about cancer progression and family coping were the most frequent concerns for all of the subjects. Half of the subjects experienced frequent anxiety.

After Chemotherapy. The disruptions in the Psychosocial Superscale were examined at Time 1 and Time 3 for those subjects (n=14) who had received chemotherapy. In response to research question #4, there were no
statistically significant differences between the older treated adult subgroup (n=4) when compared with the younger treated group, but the untreated cohort had significantly less at Time 3 (p< .025) (Table 4.18). This is graphically displayed in Figure 4.7. Older adults had the most disruptions in psychosocial function over time. The untreated subjects noted substantially less problems.

Table 4.18

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td><strong>Treated</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>10</td>
<td>.93</td>
<td>.92</td>
<td>.89</td>
</tr>
<tr>
<td>≥65</td>
<td>4</td>
<td>.82</td>
<td>.55</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Untreated</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>2</td>
<td>.29</td>
<td>.02</td>
<td>.51</td>
</tr>
<tr>
<td>≥65</td>
<td>3</td>
<td>.75</td>
<td>.97</td>
<td>.71</td>
</tr>
</tbody>
</table>

*CIPS= Cancer Inventory of Problem Situations
Figure 4.7
Disruptions in Psychosocial Function by Age and Treatment*

GIPS Psychosocial Global score

Younger Treated N=10  Older Treated N=4
Untreated Cohort N=5

Note: Higher scores mean more problems
*Significant differences between older and untreated groups at Time 3

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When older and younger subjects were compared over time, independent of treatment status, (research question #5), there were no statistically significant differences in the mean global scores of psychosocial function. This similarity is displayed in Figure 4.8.

There were no statistically significant differences between the mean score of the Psychosocial Superscale when the treated adults were compared with the untreated adults (research question #6), as displayed in Figure 4.9. Even though there appear to be substantial differences between the untreated and treated subjects at baseline, these differences did not reach statistical significance (p=.43) perhaps, because of the small sample size.

Worry about cancer progression in the treated subjects decreased from a mean of 2.21 (median 2.50) at Time 1 to a mean of 2.06 (median 1.75) at Time 3, but this difference was not statistically significant. Both younger and older treated groups continued at Time 3 to be in the 80th percentile ranking of disruptions in psychosocial function when compared with the CIPS normative standard for male cancer patients. The subjects who received chemotherapy reported increased difficulty with cognition: Time 1 (.6) as compared with Time 3 (.88), however this was not statistically significant. The untreated subjects showed a decrease in cognition as well as increased disruptions with communications with friends. Difficulties
Figure 4.8
Disruptions in Psychosocial Function by Age*

Note: higher scores mean more problems
*N: No significant differences
Figure 4.9
Disruptions in Psychosocial Function by Treatment Status*

Note: Higher scores mean more problems
*N: No significant differences
in cognition between treated subjects as compared with untreated patients were not statistically significant over time (p=.16).

When changes in the subscale scores are considered by age independent of treatment status, worry was the problem area with the highest average rating for younger and older subjects. The oldest treated subjects rated worry with the highest mean global score of 2.15 (median 3.0) at Time 3. Psychological distress appeared to decrease for the older treated subjects (Time 1 mean, 1.24; median 1.17 as compared with Time 3 mean, 1.10; median .92). Fifty percent (of n=16) of adults with lung cancer reported that the disease and treatment kept them from working. During treatment, 55% (of n=9) reported that they were not able to work.

To address the major disruptions in the psychosocial dimension of quality of life after chemotherapy, (research question #7), problems were rank ordered for the treated subjects (Table 4.19). Worry and psychological distress subscales were noted as the most serious problems over time. For those treated with chemotherapy, worries about family coping, cancer progression, and effectiveness of treatment were common concerns. None of the subjects over 65 years of age were nervous about diagnostic tests. Six subjects (54.5%) found that treatment interfered with their work. Thirty percent of the older subjects felt
Table 4.19

Rank Order of Major* Psychosocial Disruptions in Adults Treated with Chemotherapy for Lung Cancer

<table>
<thead>
<tr>
<th>Rank Order</th>
<th>Items</th>
<th>N**</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected</td>
<td>Worry about Family Coping with Death</td>
<td>12</td>
<td>64.3</td>
</tr>
<tr>
<td></td>
<td>Worry about Cancer Progression</td>
<td>14</td>
<td>57.1</td>
</tr>
<tr>
<td></td>
<td>Worry if Treatments Working</td>
<td>14</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>Uncomfortable Seeing Others Treated</td>
<td>11</td>
<td>36.4</td>
</tr>
<tr>
<td></td>
<td>Frequent Anxiety</td>
<td>14</td>
<td>35.7</td>
</tr>
<tr>
<td></td>
<td>Worry about Caring for Self</td>
<td>14</td>
<td>35.7</td>
</tr>
</tbody>
</table>

*Rated 2 or more on the CIPS
**N=respondents to question

overwhelmed by their situation. Even those subjects who responded to chemotherapy had an increase in psychosocial problems as reflected in mean superscale scores: .66 (SD .47) to .74 (SD .47) (not statistically significant).

Summary. The findings of disruptions in the
psychosocial aspects of quality of life indicated that adults with non-small cell lung cancer have higher emotional distress than most other adults with cancer. Older adults perceived more disruptions in overall psychosocial function. They experienced greater problems in cognition and worry. The major psychological disruptions for 50% or more of all subjects included: worry about cancer progression, worry about family coping and frequent anxiety. Those younger subjects who went on to receive chemotherapy appeared to have significantly more psychosocial disruptions than untreated adults at Time 1. There were no statistically significant differences in psychosocial disruptions between older and younger adults after a cycle of chemotherapy, but disruptions appeared to increase for the older subjects. Subjects who received chemotherapy had difficulties over time in cognition. Worry about family coping with death, progression of disease, and effectiveness of treatment were major concerns of subjects after treatment with chemotherapy.

Sexual Superscale

Baseline. The disruptions in the Sexual Superscale of the CIPS were examined for all subjects (n=24) at Time 1 (Table 4.20). Sexual disruptions in older adults with non-small cell lung cancer were not statistically different than those of younger adults (research question #1). The
### Table 4.20

**Age and Impact of Lung Cancer on Sexual Function**

<table>
<thead>
<tr>
<th>Var</th>
<th>Under 65 years</th>
<th>At least 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Sexual*</td>
<td>11</td>
<td>1.05</td>
</tr>
<tr>
<td>Interest</td>
<td>11</td>
<td>.95</td>
</tr>
<tr>
<td>Dysfunction</td>
<td>4</td>
<td>.25</td>
</tr>
</tbody>
</table>

*CIPS Global Superscale Score

Mean score on the Sexuality superscale for all subjects was 1.5 (SD 1.37) with a range of 0-4. Older adults had more difficulty in sexual functioning in general (1.89) as compared with a mean superscale score of 1.3 in younger adults. In subscale analysis, this difficulty occurred specifically in areas of sexual interest (1.26 for older adults as compared with .95 for younger adults) and dysfunction (1.17 for older adults as compared with .25 for younger adults).

For descriptive analysis, the global Sexual Superscale was compared with the standardized norm of the CIPS, *(research question #2)*. The older adults placed in the 80th percentile ranking of sexual disruptions when compared with other cancer patients.
The assessments of major disruptions in the sexual dimension of quality of life, (research question #3), were rank ordered. Half of the subjects diagnosed with lung cancer were not interested in or had difficulty with sexual arousal (Table 4.21).

Table 4.21

Rank Order of Major* Sexual Disruptions in Adults with Lung Cancer

<table>
<thead>
<tr>
<th>Rank Order</th>
<th>Items</th>
<th>N**</th>
<th>% Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1</td>
<td>Difficulty with Sexual Arousal</td>
<td>16</td>
<td>50</td>
</tr>
<tr>
<td># 2</td>
<td>Not Interested in Sex</td>
<td>22</td>
<td>50</td>
</tr>
<tr>
<td># 3</td>
<td>Erectile Difficulty#</td>
<td>7</td>
<td>42.8</td>
</tr>
<tr>
<td># 4</td>
<td>No Sexual Desire</td>
<td>22</td>
<td>40.9</td>
</tr>
<tr>
<td># 5</td>
<td>Decreased Frequency</td>
<td>11</td>
<td>36.4</td>
</tr>
</tbody>
</table>

*Rated 2 or more by CIPS   #Male only
**N=number responding to question

After Chemotherapy. There were no significant disruptions as shown by responses for the Sexual Superscale of the CIPS over time for older treated adults
as compared with younger treated adults and with an untreated cohort (research question #4) as presented in Table 4.22. This is displayed in Figure 4.10. Older treated subjects and the untreated cohort demonstrated decreased problems over time (less problems with sexual desire, interest in sex, and arousal) but younger subjects showed little change.

Table 4.22
Age and Sexual Function Superscale of CIPS*

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th></th>
<th></th>
<th>Time 3</th>
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<td>SD</td>
<td>Mean</td>
<td>SD</td>
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<tr>
<td>Treated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
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<td>.84</td>
<td>1.06</td>
<td>1.06</td>
<td>.88</td>
</tr>
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<td>&gt;65</td>
<td>4</td>
<td>1.88</td>
<td>1.37</td>
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<td>.82</td>
</tr>
<tr>
<td>Untreated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>&lt;65</td>
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<td>2.00</td>
<td>.71</td>
<td>1.19</td>
<td>1.50</td>
</tr>
<tr>
<td>&gt;65</td>
<td>2</td>
<td>1.05</td>
<td>1.14</td>
<td>1.56</td>
<td>.62</td>
</tr>
</tbody>
</table>

*CIPS= Cancer Inventory of Problem Situations

The specific changes of lack of interest in sex, and the decreased frequency continued after chemotherapy treatment
Figure 4.10
Disruptions in Sexual Function by Age and Treatment*

Note: Higher scores mean more problems
*No significant differences

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(no statistically significant differences over time). As displayed in Table 4.23, sexual dysfunction increased over time with minimal changes noted in sexual interest while the global score remained unchanged. The younger subjects had a slight increase in sexual problems, however this increase was still less than the level of problems in the older subgroup.

Table 4.23

<table>
<thead>
<tr>
<th>Var</th>
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<th>Time 2</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Sexual*</td>
<td>13</td>
<td>1.16</td>
</tr>
<tr>
<td>Interest</td>
<td>13</td>
<td>1.03</td>
</tr>
<tr>
<td>Dysfunction</td>
<td>6</td>
<td>.67</td>
</tr>
</tbody>
</table>

*CIPS Global superscale score

In response to research question #5, older subjects appeared to have less sexual problems over time when compared to younger subjects, but this was not statistically significant (Figure 4.11). The two younger untreated subjects had a decrease in problems over time,
Figure 4.11
Disruptions in Sexual Function by Age*

Note: higher scores mean more problems
*No significant differences
but the two older subjects indicated increased problems.

When treatment versus no treatment subgroupings were compared, (research question #6), there were no statistically significant differences over time. The untreated subgroup appeared to have more problems than the treated group in sexual function at Time 1 but this difference was not statistically significant (Figure 4.12).

Rank ordering of specific disruptions in sexuality (research question #7) showed little difference from pretreatment problems (Table 4.24). The mean score of sexual disruption in those adults who appeared to responded to treatment remained unchanged (1.1) over time.

Table 4.24

<table>
<thead>
<tr>
<th>Rank Order</th>
<th>Items</th>
<th>N**</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1</td>
<td>Decrease in Frequency</td>
<td>7</td>
<td>57.1</td>
</tr>
<tr>
<td># 2</td>
<td>Not interested in Sex</td>
<td>12</td>
<td>50</td>
</tr>
<tr>
<td># 3</td>
<td>No Sexual Desire</td>
<td>12</td>
<td>41.6</td>
</tr>
<tr>
<td># 4</td>
<td>Erectile Difficulty#</td>
<td>5</td>
<td>40</td>
</tr>
</tbody>
</table>

*Rated 2 or more on CIPS  **N=respondents to question
#Male
Figure 4.12
Disruptions in Sexual Function by Treatment*

CIPS Sexual Global Score

Weeks

Treated    Untreated

N=13  N=4

Note—higher scores mean more problems
*No significant differences
Summary. Older adults with lung cancer had substantially more disruptions in sexual function than younger adults, but these were not statistically significant. Major disruptions for 50% of the subjects included: difficulty with sexual arousal and lack of interest in sex. The findings of disruptions in sexual function of adults with non-small cell lung indicated that they have more disruptions than most cancer patients. There were no statistically significant differences in disruptions in the sexual superscale score in subjects after chemotherapy, but there was a substantial increase noted in the dysfunction subscale. The older treated subjects had some improvement over time but still evidenced more sexual dysfunction than the younger treated group. Prevalence of major disruptions in sexual function did not appear to change after treatment.

Marital Superscale

Baseline. The Marital Superscale contained subscales associated with problems with a spouse and thus were only relevant for married subjects. These related to interaction, affection, communication, neglect of care, and overprotection by the partner. The disruptions in the marital function in adults with non-small cell lung cancer were determined by examining the baseline score of the Marital Function Superscale for all married subjects (N=16, 7 younger and 5 older adults) older at Time 1.
Overall, in response to research question #1, the older adults appeared to have less marital problems (.21) when compared with younger adults with lung cancer (.41), but this difference did not reach statistical significance (Table 4.25). The baseline mean score for all subjects on the Marital superscale was .33 (SD .2). The older adults with lung cancer had fewer disruptions in the areas of communication, expression of affection, problems in

Table 4.25

Age and Impact of Lung Cancer on Marital Function

<table>
<thead>
<tr>
<th>Scale</th>
<th>Under 65 years</th>
<th>At least 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Marital*</td>
<td>10</td>
<td>.41</td>
</tr>
<tr>
<td>Communicate</td>
<td>10</td>
<td>.89</td>
</tr>
<tr>
<td>Affection</td>
<td>10</td>
<td>.03</td>
</tr>
<tr>
<td>Interaction</td>
<td>10</td>
<td>.10</td>
</tr>
<tr>
<td>Overprotect</td>
<td>10</td>
<td>.55</td>
</tr>
<tr>
<td>Neglect</td>
<td>9</td>
<td>.22</td>
</tr>
</tbody>
</table>

*CIPS Global Superscale score

interaction with spouses, and feelings of neglect than the
younger subjects. The only area in which the older subjects had more problems than the younger subjects was in feelings of overprotectiveness by their spouses.

In response to research question #2, standardized comparisons with other cancer patients placed younger adults in 70th percentile of patients with marital disruptions, and older adults within the 50th percentile of marital disruptions.

In answer to research question #3, frequency of serious marital problems were evaluated. However, in this subscale there were no major disruptions affecting 40% or more of the subjects.

After Chemotherapy. Disruptions in marital function after treatment were determined by comparing the Time 1 Marital Superscale mean score with the Time 3 score (Table 4.26). The results of research question #4 determined that there were no significant differences in marital disruption in older as compared with younger treated subjects. Younger treated subjects had significantly more disruptions when compared with the untreated group at Time 1 (p< .0025) and Time 3 (p< .0025). There was no significant difference between the older and untreated groups. This is displayed in Figure 4.13.

When disruptions by age alone over time were considered, as depicted in Figure 4.14, the younger subjects had significantly more disruptions in marital
Figure 4.13
Disruptions in Marital Status by Age and Treatment*

CIPS Marital Global Score

Weeks

- Younger Treated N=7
- Older Treated N=3
- Untreated Cohort N=2

Note: higher scores mean more problems
*Significant differences between groups
Figure 4.14
Disruptions in Marital Function by Age*

CIPS Marital Global Score

Weeks

--- Younger

--- Older

N=7  N=5

Note: higher scores mean higher problems
*Significant differences over time

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Table 4.26
Impact of Age and Treatment on Marital Function

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th></th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Treated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>7</td>
<td>.45</td>
<td>.23</td>
<td>.58</td>
<td>.35</td>
</tr>
<tr>
<td>&gt;65</td>
<td>3</td>
<td>.17</td>
<td>.15</td>
<td>.37</td>
<td>.33</td>
</tr>
<tr>
<td>Untreated</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;65</td>
<td>3</td>
<td>.14</td>
<td>.12</td>
<td>.22</td>
<td>.16</td>
</tr>
</tbody>
</table>

function when compared with the older subjects (p=.008). The younger treated subjects appeared to have substantially more disruptions in marital function than the older treated subjects at baseline (Table 4.27). This difference approached statistical significance at p=.09.

In response to research question #6, neither the treated or untreated groups had statistically significant differences in marital function over time (Figure 4.15). As seen in Table 4.28, marital disruptions increased over the treatment course but these changes were not
Figure 4.15
Disruptions in Marital Function by Treatment*

Note-higher scores mean more problems
*No significant differences

N=10  N=2
Table 4.27

**Age Differences in Marital Function Superscale over Time* After Chemotherapy**

<table>
<thead>
<tr>
<th>Age</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;65</td>
<td>7</td>
<td>.45</td>
<td>.23</td>
<td>.58</td>
<td>.35</td>
</tr>
<tr>
<td>&gt;65</td>
<td>5</td>
<td>.16</td>
<td>.12</td>
<td>.31</td>
<td>.26</td>
</tr>
</tbody>
</table>

*p=.008

Table 4.28

**Changes in Marital Disruptions After Chemotherapy***

<table>
<thead>
<tr>
<th>Var</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
<th>P**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital</td>
<td>10</td>
<td>.37</td>
<td>.24</td>
<td>.52</td>
<td>.34</td>
<td>.12</td>
</tr>
<tr>
<td>Communicate</td>
<td>9</td>
<td>.90</td>
<td>.72</td>
<td>1.04</td>
<td>.69</td>
<td>NS</td>
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<td>Affection</td>
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<td>0</td>
<td>0</td>
<td>.19</td>
<td>.35</td>
<td>NS</td>
</tr>
<tr>
<td>Interaction</td>
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<td>.18</td>
<td>.17</td>
<td>.38</td>
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<td>.05</td>
</tr>
<tr>
<td>Overprotect</td>
<td>10</td>
<td>.60</td>
<td>1.35</td>
<td>.60</td>
<td>.94</td>
<td>NS</td>
</tr>
<tr>
<td>Neglect</td>
<td>9</td>
<td>.11</td>
<td>.22</td>
<td>.11</td>
<td>.22</td>
<td>NS</td>
</tr>
</tbody>
</table>

* Global Superscale score
**Significance of changes over time (Paired t-test)
statistically significant. Because of the small sample size of the untreated group (n=2), statistical comparisons between the groups over time were not possible. There appeared to be differences in problems in the interaction subscale between spouses in the treated group, independent of age (.18 to .38) (p<.05).

There were minimal marital concerns expressed by the majority of the subjects. The results for research question #7 showed that the most frequent concern of the married subjects was difficulty in talking about death with their spouse. After treatment, 45.5% of the treated subjects had these concerns.

Summary. Older adults with lung cancer had less disruptions in marital function than younger adults. The findings of the disruptions in the Marital Superscale reveal that adults with non-small cell lung cancer have similar disruptions to the majority of other adults with cancer. There were no significant differences in marital function in treated as compared with the untreated subjects, except in the area of spousal interactions, (treated subjects had more problems). Younger treated subjects did have significantly more disruptions than the untreated subgroup. Older adults did not have significantly more disruptions in marital function when compared with younger adults after a cycle of chemotherapy. The major marital concern of adults with
non-small cell lung cancer was difficulty in talking about death with their spouse. This remained the major marital concern post chemotherapy.

**Medical Interaction Superscale**

**Baseline scores.** Disruptions in communication with the health team in adults with lung cancer were examined by the baseline score of the Medical Communication Superscale for all subjects \((n=24)\). Problems experienced with the health care team were minimal as displayed in Table 4.29. The baseline scores for difficulty with medical communication for all of the adult lung cancer patients was \(.36 (SD .46)\) with a small range of 0 to 1.4.

**Table 4.29**

*Age and Impact of Lung Cancer on Interaction with Health Team*

<table>
<thead>
<tr>
<th>Scale</th>
<th>Under 65 years</th>
<th></th>
<th>At least 65 years</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
</tr>
<tr>
<td><strong>Meu.Interact</strong></td>
<td>14</td>
<td>.36</td>
<td>.47</td>
<td>10</td>
</tr>
<tr>
<td>Obtain info</td>
<td>14</td>
<td>.30</td>
<td>.57</td>
<td>10</td>
</tr>
<tr>
<td>Communicate</td>
<td>14</td>
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<td>.53</td>
<td>10</td>
</tr>
<tr>
<td>Control</td>
<td>14</td>
<td>.73</td>
<td>.83</td>
<td>10</td>
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</tbody>
</table>

*Global Superscale score*
In response to research question #1, the older adults appeared to have less problems (.26) in communication than the younger adults (.43), specifically in the areas of communication with the health team and areas of control, but this was not statistically significant. In response to research question #2, the Medical Interaction Global score placed the adults with lung cancer in the 70th percentile when compared with difficulties with medical communication experienced by other cancer patients.

Research question #3 addressed the most frequent serious disruptions in interaction with the health team. The most frequent concern (16%) regarded difficulty understanding treatment. Only 12.5% of the patients had difficulty expressing their feelings to their physicians.

After treatment. Differences in problems in communication with doctors and nurses were examined in those subjects who received chemotherapy (n=14). There were no significant changes over time between the younger and older treated subgroups and the untreated cohort in communication with the health team (Table 4.30). However, the baseline scores of the younger treated subjects were significantly higher than the older treated subjects at Time 1 (p=.05). The untreated subjects had significantly less disruptions than the older treated subjects at Time 1 (p<. 005) and Time 3 (p<. 025) These data, in response to
Table 4.30  
*Changes in Medical Interaction Superscale*

<table>
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<tr>
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<th></th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
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<td></td>
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<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
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<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>10</td>
<td>.41</td>
<td>.50</td>
<td>.36</td>
<td>.55</td>
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<td></td>
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<tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
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<td>.19</td>
<td>.15</td>
<td>.21</td>
</tr>
<tr>
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<td>.41</td>
<td>.53</td>
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<td>.64</td>
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</tbody>
</table>

*CIPS Global superscale score

research question #4, are graphically displayed in Figure 4.16. In subscale analysis, subjects who received chemotherapy had more problems in the area of control (.55) at Time 1 than those who did not receive treatment (.25), but this was not significantly different.

There were no statistically significant differences when changes over time in medical interaction were considered by age (research question #5). The younger subjects appear to have substantially more difficulties in interaction with the health team prior to treatment, as
Figure 4.16
Disruptions in Interaction with Health Team by Age and Treatment*

Note: higher scores mean more problems
*Significant differences between groups at Time 1
displayed in Figure 4.17, but this is not statistically significant. When dichotomized by treatment status, the treated subjects appear to have more difficulty with communication with the health team over time, as depicted in Figure 4.18, but this was not statistically significant (research question #6). The findings indicated that subjects who received chemotherapy had more initial problems in the area of control than those who were not treated. There were no major problems in medical communication affecting more than 40% of the subjects (research question #7).

Summary. There were no significant differences in disruptions in medical interaction in older as compared with younger adults, but older adults appeared to have less problems than younger adults. Younger treated subjects had significantly more disruptions at baseline than older treated subjects. The findings of disruptions in communication with the health team indicated that adults with non-small cell lung cancer had more problems than most other cancer patients. The major concern in disruptions in medical communication involved difficulty understanding treatment, but this affected only 16% of the subjects. There were no significant differences between the older and younger treated subjects over time or as compared with an untreated cohort. Older subjects, regardless of treatment status had less difficulty in this
Figure 4.17
Disruptions in Medical Interaction by Age*

Note - higher scores mean more problems
*N = 12
*No significant differences

N = 7
Figure 4.18
Disruptions in Interactions with Health Team by Treatment*

Note-higher scores mean more problems
*N: No significant differences
area than younger subjects. The treated subjects experienced more problems in communication with the health team over time than the untreated cohort.

**Miscellaneous Disruptions with Lung Cancer**

**Baseline.** The miscellaneous scales of the CIPS cover a variety of disparate concerns which could be experienced by cancer patients. When the total sample was compared by age subgroups at Time 1, to answer research question #1, the older patients did not have significantly different disruptions than the younger subjects. The older subjects experienced less economic problems (.44) when compared with younger adults (1.15). They also experienced less pain with medical tests than younger adults (1.10 as compared with 1.92). Normative data comparisons are not available for the miscellaneous subscales thus this component of research question #2 was not addressed. There were not severe disruptions which affected the majority of subjects (research question #3). Painful tests received the highest rating of the miscellaneous items of 1.80.

**After treatment.** Disruptions in the miscellaneous Superscale were examined at Time 1 and Time 3 for those subjects who were treated (n=14) (Table 4.31). Since there was not a global score in the Miscellaneous Superscale, (research question #4), differences over time by age and treatment were not statistically analyzed. Subscale analysis of changes over time did not reveal any
statistically significant differences. After treatment, complaints of painful tests had the highest mean score at Table 4.31

Disruptions after Chemotherapy in Miscellaneous Subscales

<table>
<thead>
<tr>
<th>Var</th>
<th>Time 1</th>
<th></th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Compliance</td>
<td>14</td>
<td>.05</td>
<td>.20</td>
<td>.02</td>
<td>.07</td>
</tr>
<tr>
<td>Economic</td>
<td>12</td>
<td>.58</td>
<td>1.18</td>
<td>.44</td>
<td>.93</td>
</tr>
<tr>
<td>Weight Gain</td>
<td>8</td>
<td>.75</td>
<td>1.16</td>
<td>.38</td>
<td>1.06</td>
</tr>
<tr>
<td>Painful Tests</td>
<td>12</td>
<td>1.42</td>
<td>1.38</td>
<td>1.58</td>
<td>1.44</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>14</td>
<td>.36</td>
<td>.63</td>
<td>.36</td>
<td>.50</td>
</tr>
<tr>
<td>Bladder Control</td>
<td>13</td>
<td>.38</td>
<td>.38</td>
<td>.15</td>
<td>.38</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>5</td>
<td>.51</td>
<td>.73</td>
<td>1.22</td>
<td>.93</td>
</tr>
</tbody>
</table>

both data periods. Chemotherapy concerns increased from pre-treatment evaluations. When disruptions over time were analyzed by age alone, independent of treatment status (research question #5) there were no significant differences. Statistical analysis comparing changes over time in the treated and untreated groups was not possible in most instances because problems were not identified in
many subscales in the small untreated cohort *(research question #6)*. Approximately 35% (n=5) of the subjects said they were nervous when receiving chemotherapy *(research question #7)*. Twenty-eight and one-half percent complained of nausea; 2 out of 4 of these subjects were in the older age group, but only 1 older patient complained of problems with vomiting.

**Summary.** The findings indicated that older adults had less economic problems, and less pain than younger adults, but these differences between age groups were not statistically significant. There were no differences by age or treatment in disruptions in the variety of miscellaneous subscales. Items reflecting disruptions due to chemotherapy increased over time for both age groups.

**Disruptions in Functional Status**

Disruptions in functional status in adults with non-small cell lung cancer were described by the Physical Functioning Scale (PFS), *(subjective assessment)*, and the Karnofsky Performance Status (KPS), *(objective assessment)* for all subjects at Time 1.

**Subjective Evaluations**

**Baseline.** The Physical Functioning Scale (PFS) allowed ratings of various physical activities from 1 to 3 with a summated total possible scores of 10-30. A lower number indicated worse function. When compared by age at Time 1, the physical function scores of the older subjects
(20.4) were not significantly different than the younger adults (20.3) (research question #8).

As displayed in Table 4.32 the rank ordering of serious physical disruptions ("limited a lot") experienced by all subjects over time, independent of treatment status, almost fits a hierarchical structure. Difficulties with increasingly demanding physical tasks were more prevalent than difficulties with less strenuous tasks. In response to research question #9, most adults with lung cancer experienced serious difficulties in strenuous and moderate physical activities. The pattern of types of disruptions in physical function was similar over time, however a decrease in the prevalence of the severity of the disruptions appeared to occur at Time 2 and Time 3. This may have been a statistical artifact due to the loss of less functional subjects due to death (n=3) or depression (n=1), resulting in higher evaluations of physical function over time by subjects who were more physically fit.

After Chemotherapy. Disruptions in functional status over time were evaluated by the patient's assessment of their physical functioning (Table 4.33). Research question #10 asked if there were increased disruptions in functional status during and after a cycle of chemotherapy in older as compared with younger treated adults and as compared to an untreated cohort. Changes in physical
<table>
<thead>
<tr>
<th>Activity</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigorous Activities</td>
<td>95.8%</td>
<td>63%</td>
<td>64.7%</td>
</tr>
<tr>
<td>Walking Several Blocks</td>
<td>79.1%</td>
<td>57.8%</td>
<td>35.2%</td>
</tr>
<tr>
<td>Stair Climbing Several Flights</td>
<td>70.8%</td>
<td>52.6%</td>
<td>52.9%</td>
</tr>
<tr>
<td>Walking More Than a Mile</td>
<td>62.5%</td>
<td>63.1%</td>
<td>47%</td>
</tr>
<tr>
<td>Moderate Activities</td>
<td>54.1%</td>
<td>36.8%</td>
<td>35%</td>
</tr>
<tr>
<td>Walking One Block</td>
<td>37.5%</td>
<td>21%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Stair Climbing One flight</td>
<td>33.3%</td>
<td>21%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Lifting</td>
<td>33.3%</td>
<td>17.6%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Bending, Kneeling, or Stooping</td>
<td>29.1%</td>
<td>16.6%</td>
<td></td>
</tr>
<tr>
<td>Bathing or Dressing</td>
<td>16.6%</td>
<td>10.5%</td>
<td></td>
</tr>
</tbody>
</table>

*Rated 1 "limited alot"
functioning over time can be observed in these subgroups as displayed in Figure 4.19. There were no significant

Table 4.33

Subjective Assessment of Disruptions in Functional Status In Treated and Untreated Subjects

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th></th>
<th></th>
<th>Time 2</th>
<th></th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Treated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>8</td>
<td>19.2</td>
<td>5.3</td>
<td>18.2</td>
<td>4.8</td>
<td>20.5</td>
<td>4.8</td>
<td></td>
</tr>
<tr>
<td>&gt;65</td>
<td>3</td>
<td>23.3</td>
<td>.6</td>
<td>22.3</td>
<td>4.7</td>
<td>23.0</td>
<td>4.4</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>11</td>
<td>20.4</td>
<td>.48</td>
<td>19.3</td>
<td>4.9</td>
<td>21.2</td>
<td>.46</td>
<td></td>
</tr>
<tr>
<td>Untreated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>2</td>
<td>24.5</td>
<td>.21</td>
<td>16.0</td>
<td>1.4</td>
<td>16.0</td>
<td>4.2</td>
<td></td>
</tr>
<tr>
<td>&gt;65</td>
<td>2</td>
<td>16.0</td>
<td>1.4</td>
<td>15.5</td>
<td>.7</td>
<td>14.5</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>4</td>
<td>20.2</td>
<td>5.1</td>
<td>15.8</td>
<td>1.0</td>
<td>15.3</td>
<td>2.9</td>
<td></td>
</tr>
</tbody>
</table>

differences in physical functioning between the older and younger treated or untreated subjects at Time 1. Older treated subjects had the highest mean (best functional status) at each data collection point.

There were no significant differences in functional
Figure 4.19
Disruptions in PFS by Age and Treatment*

Note: Higher scores mean better function.
*Significant differences time 1-2, 2-3
status changes over time between younger and older subjects who were treated (research question #11). These changes are displayed in Figure 4.20. The older subjects appeared to have less difficulty than the younger subjects at Time 2 (2 weeks), but this difference was minimal.

When treatment status alone was considered, to answer research question #12, decreases in physical functioning became significantly different (p=.04) at Time 2, and at Time 3 (p=.04). This difference is displayed in Figure 4.21. This demonstrated a decline in physical functioning in untreated subjects. There was not a statistically significant difference in physical functioning from Time 1 to Time 3. However, there was a subtle but statistically significant difference (p=.02) in physical activity after treatment, from Time 2 to Time 3, perhaps reflecting problems with chemotherapy side effects. The older untreated subjects had the poorest (lowest) mean physical activity score. The highest ratings were for older patients prior to treatment, At Time 2 (2 weeks later), the older patients who received chemotherapy had a slight decrease in mean physical functioning, but some recovery was noted at Time 3. In comparison, the older untreated subjects demonstrated a decrease in mean physical activity over time.

Adults who appeared to respond to chemotherapy showed improvement in physical functioning at Time 1 (22.6), to
Figure 4.20
Disruptions in PFS by Age*

Rand Physical Function Scale

Weeks

- Younger

- Older

N=10
N=5

Note: Higher score means better function
*No significant differences.
Figure 4.21
Disruptions in PFS by Treatment*

Note: higher scores mean better function
*N=10
*Significant differences at time 2 & 3
Time 3 (23.5). When the ratings of subjects who died were examined, all three rated serious limitations in all physical activities, even though objectively they had been rated at least 60% on the Karnofsky Performance Status scale. They were the only subjects who claimed to be severely limited in all physical activities.

To address research question #13, the prevalence of types of severe physical dysfunctions of subjects treated with chemotherapy over time were rank ordered (Table 4.34). This showed a hierarchical pattern of increasing disruptions in strenuous activities. Due to the deaths of two subjects during treatment, and the loss of one subject to follow-up, only 14 treated subjects completed the Time 2 data collection. An additional 3 subjects did not complete the Time 3 questionnaire (2 due to attrition and 1 due to error).

Satisfaction with activity. Personal satisfaction with physical activity level was assessed at each data collection point. Fifty-eight percent of all \( n=24 \) subjects were very or completely dissatisfied (ratings 5 or 6) with their activity status. Despite a diagnosis of advanced lung cancer, 20.8% were completely or very satisfied (ratings 1 or 2). A higher percent of the treatment subgroup (29.4%) were satisfied with their activity at Time 1 than the untreated group, though 47% the treatment group experienced severe dissatisfaction
Table 4.34

Rank Order of Serious Disruptions in Functional Status

Over Time

<table>
<thead>
<tr>
<th>Activity</th>
<th>Pre-Chem</th>
<th>4 weeks</th>
<th>4 weeks</th>
<th>4 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1</td>
<td></td>
<td>Time 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=17</td>
<td>N=14</td>
<td>N=11</td>
<td></td>
</tr>
<tr>
<td>Vigorous Activities</td>
<td>76.4%</td>
<td>78.5%</td>
<td>54.5%</td>
<td></td>
</tr>
<tr>
<td>Walking More than a Mile</td>
<td>58.8%</td>
<td>57.1%</td>
<td>27.2%</td>
<td></td>
</tr>
<tr>
<td>Stair Climbing Several flights</td>
<td>52.9%</td>
<td>64.2%</td>
<td>54.5%</td>
<td></td>
</tr>
<tr>
<td>Walking Several Blocks</td>
<td>47.0%</td>
<td>57.1%</td>
<td>27.2%</td>
<td></td>
</tr>
<tr>
<td>Stair Climbing One flight</td>
<td>42.8%</td>
<td>36.3%</td>
<td>.1%</td>
<td></td>
</tr>
<tr>
<td>Moderate Activities</td>
<td>41.1%</td>
<td>35.7%</td>
<td>36.3%</td>
<td></td>
</tr>
<tr>
<td>Walking One block</td>
<td>35.7%</td>
<td>14.2%</td>
<td>.1%</td>
<td></td>
</tr>
<tr>
<td>Bending, Kneeling, or Stooping</td>
<td>23.5%</td>
<td>21.4%</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Lifting</td>
<td>17.6%</td>
<td>21.4%</td>
<td>27.2%</td>
<td></td>
</tr>
<tr>
<td>Bathing or Dressing</td>
<td>17.6%</td>
<td>.1%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
with their activity level.

There was relatively little change in the prevalence of dissatisfaction (52.9%) with activity status in all subjects (n=17) at Time 2. Only 11.7% were satisfied with their activity level at Time 2. In the treatment group (n=13), 15.3% claimed they were satisfied with their activity, as compared with (38.46%) of those who complained of serious disruption.

At Time 3, only 25% of all (n=16) subjects who completed the question rated their dissatisfaction this severe, and 25% stated they had no disruption. After the cycle of chemotherapy, approximately 18% of the chemotherapy group were dissatisfied with their activity level, but 36.6% claimed no dissatisfaction with their activity level.

Summary. Older adults with non-small cell lung cancer had more disruptions in functional status than younger adults. Major disruptions in functional status experienced by more than 50% of the subjects included: vigorous activities, walking several blocks, climbing several flights of stairs, walking more than a mile, and moderate activities. The untreated subjects had statistically significant decreases in physical functioning over time when compared with treated subjects. Subjects who received chemotherapy showed a statistically significant decrease in function in the 2 weeks after
treatment, but then demonstrated some recovery at Time 3 (4 weeks after treatment). Older untreated subjects showed the greatest disruptions in subjective assessments of functional status.

**Objective Disruptions in Functional Status**

**Disruptions in KPS**

**Baseline.** Objective assessment of physical capacity was examined with the physician rated Karnofsky Performance Status (KPS). Rated from 0-100%, in decade demarcations, higher scores indicate better function. Subjects were excluded from the study if they had less than a 60% KPS rating. In answer to research question #8, there were no significant differences in the KPS baseline scores by age (Table 4.35). The mean for all subjects was 79.17% (SD .13) with a median of 80%. When symptoms alone were considered, the subjects without symptoms had the highest mean KPS rating (90%).

**Table 4.35**

**Age and Impact of Lung Cancer on Karnofsky Performance Status**

<table>
<thead>
<tr>
<th>Age</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 65 years</td>
<td>80%</td>
<td>12.4</td>
<td>85%</td>
</tr>
<tr>
<td>&gt; 65 years</td>
<td>78%</td>
<td>12.3</td>
<td>80%</td>
</tr>
</tbody>
</table>

N=24
After Chemotherapy. In response to research question #10, there were no significant differences between the younger and older treated subgroups and the untreated cohort over time (Table 4.36). This is displayed in Figure 4.22. Little difference in KPS was seen over time when older subjects were compared with younger subjects, independent of treatment status (research question #11). This is displayed in Figure 4.23.

Table 4.36

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th></th>
<th></th>
<th>Time 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Treated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>10</td>
<td>83.00</td>
<td>10.59</td>
<td>81.0</td>
<td>9.94</td>
</tr>
<tr>
<td>&gt;65</td>
<td>4</td>
<td>82.50</td>
<td>9.57</td>
<td>85.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Untreated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>2</td>
<td>85.00</td>
<td>7.07</td>
<td>85.00</td>
<td>7.07</td>
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<td>3</td>
<td>76.67</td>
<td>15.28</td>
<td>70.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*Karnofsky Performance Status
Figure 4.22
Disruptions in KPS by Age and Treatment*

Karnofsky Performance Status

00 -

80 -

60 -

40 -

20 -

0 1 2 3 4 5

Weeks

--- Untreated cohort N=7  --- Younger-Treated N=9
--- Older-Treated N=3

Note—higher scores mean better function
*No significant differences
Figure 4.23
Disruptions in KPS by Age*

Karnofsky Performance Status

Weeks

Younger

Older

N=12

N=7

Note: higher scores mean better function
*No significant differences

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When changes over time in the KPS rating are compared by treatment status alone, (research question #12) there are no significant differences (Figure 4.24). In the treatment group, the older subjects indicated an increase in function over the month, but the younger subjects who received chemotherapy exhibited a slight but not statistically significant decrease in function. The older untreated patients demonstrated the greatest deterioration in KPS over time.

Summary. The findings indicated that older adults with non-small cell lung cancer did not have more disruptions in functional status than younger adults. Objective assessments of functional status did not differ over time for the treated or untreated subjects. The older untreated subjects appeared to have the greatest change and the lowest level of functional status over time.

Relationship of Quality of Life and Functional Status

Baseline. In answer to research question #14, the relationship of quality of life and functional status over time, independent of treatment status, was investigated by Pearson correlations of the mean scores of the CIPS (Global score, and Superscales) with the mean KPS and PFS scores over time (Table 4.37). Additionally, the relationship of the subjective (PFS) and objective (KPS) evaluations of functional status was evaluated at Time 1
Figure 4.24
Disruptions in KPS by Treatment*

Karnofsky Performance Status

100 -

80 -

60 -

40 -

20 -

0 1 2 3 4 5

Weeks

Treated

Untreated

N=12

N=7

Note—higher scores mean better function
*No significant differences
Table 4.37
Correlation of Quality of Life and Functional Status Scores

<table>
<thead>
<tr>
<th></th>
<th>KPS</th>
<th>PFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIPS</td>
<td>24</td>
<td>-.61**</td>
</tr>
<tr>
<td>PHYS</td>
<td>24</td>
<td>-.69**</td>
</tr>
<tr>
<td>PSY</td>
<td>24</td>
<td>-.45*</td>
</tr>
<tr>
<td>MED</td>
<td>24</td>
<td>-.49*</td>
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<tr>
<td>MAR</td>
<td>16</td>
<td>-.09</td>
</tr>
<tr>
<td>SEX</td>
<td>24</td>
<td>-.20</td>
</tr>
<tr>
<td>KPS</td>
<td></td>
<td>.63***</td>
</tr>
</tbody>
</table>

*p ≤ .05, **p ≤ .005, ***p ≤ .0005

CIPS: global score
PHYS: physical functioning superscale
PSY: psychosocial superscale
MED: medical interaction superscale
MAR: marital superscale
SEX: sexual superscale

and Time 3 data collection points. Note that negative correlations relate to the opposite directions of measurement of the functional status scales (higher number means better function) and the CIPS scale (lower number means less disruptions). Caution must be used in
interpreting the results because of the small sample size. Additionally, there were missing values in the Time 3 calculations. (7 missing observations in the correlations at Time 3 for the global CIPS score and the PFS score.)

Quality of life (global score) was significantly correlated with objective and subjective measures of functional status. As expected, there was convergence of the physical superscale of the CIPS and the two dimensions of functional status. There was a significant relationship between the psychosocial functioning and the functional status scores. Increased problems in communication with the health care team occurred in subjects with poorer functional status. Neither marital interaction or sexual function were significantly related to functional status. Both subjective and objective measures of functional status were correlated.

After Chemotherapy. In answer to research question #15, relatively few changes in the relationship of quality of life and functional status were seen when only scores of the treated subgroups were examined (Table 4.38). Psychosocial function had a weaker relationship with functional status at Time 3. Sexual function appeared to be more strongly related in this subgroup to initial subjective assessment of functional status.
Table 4.38

Impact of Chemotherapy on Correlation of CIPS, KPS, and PFS

<table>
<thead>
<tr>
<th>TIME 1 SCORES</th>
<th>TIME 3 SCORES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>KPS</td>
</tr>
<tr>
<td>N=17</td>
<td></td>
</tr>
<tr>
<td>CIPS</td>
<td>-.84***</td>
</tr>
<tr>
<td>PHYS</td>
<td>-.88***</td>
</tr>
<tr>
<td>PSY</td>
<td>-.70**</td>
</tr>
<tr>
<td>MED</td>
<td>-.58*</td>
</tr>
<tr>
<td>MAR</td>
<td>-.17</td>
</tr>
<tr>
<td>SEX</td>
<td>-.47</td>
</tr>
</tbody>
</table>

*p≤ .05, **p≤ .005, ***p≤ .0005

CIPS: global score
PHYS: physical functioning superscale
PSY: psychosocial superscale
MED: medical interaction superscale
MAR: marital interaction superscale
SEX: sexual superscale

Impact of Age, Weight Loss, and Time Since Diagnosis.
The relationship of age, and the two moderator variables: weight loss and time since diagnosis, were further examined in a correlation analysis (Table 4.39) in order
Table 4.39

Correlation Analysis of Moderator Variables and Quality of life and Functional Status for Adults with Lung Cancer

<table>
<thead>
<tr>
<th>Time 1 Scores</th>
<th>N=24</th>
<th>Age</th>
<th>Weight Loss</th>
<th>Time since Dx</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIPS</td>
<td>.14</td>
<td>.22</td>
<td>.1</td>
<td></td>
</tr>
<tr>
<td>PHYS</td>
<td>.09</td>
<td>.49*</td>
<td>.22</td>
<td></td>
</tr>
<tr>
<td>PSY</td>
<td>.15</td>
<td>-.03</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>MAR</td>
<td>-.18</td>
<td>-.23</td>
<td>-.25</td>
<td></td>
</tr>
<tr>
<td>MED</td>
<td>-.09</td>
<td>-.03</td>
<td>.14</td>
<td></td>
</tr>
<tr>
<td>SEX</td>
<td>.34</td>
<td>.39</td>
<td>-.25</td>
<td></td>
</tr>
<tr>
<td>PFS</td>
<td>-.24</td>
<td>-.43*</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>KPS</td>
<td>-.09</td>
<td>-.47*</td>
<td>-.13</td>
<td></td>
</tr>
</tbody>
</table>

* p ≤ .05

CIPS: global score
PHYS: physical functioning superscale
PSY: psychosocial superscale
MED: medical interaction superscale
MAR: marital interaction superscale
SEX: sexual superscale
to answer research question #16. Weight loss was negatively correlated with levels of functional status and had a direct significant relationship to the CIPS Physical Superscale. Length of time since diagnosis did not demonstrate a strong relationship to overall quality of life or psychosocial function.

**Predictive factors and Quality of Life.** Research question #17 asked which moderator variables, (gender, weight loss, income, time since diagnosis, education, symptoms, comorbidity), along with age and treatment, best predicted disruptions in quality of life and functional status. For exploratory analysis, these variables were included in a multivariate stepwise regression with the measure of quality of life (CIPS global score and subscale scores) and with subjective (PFS) and objective (KPS) measures of functional status (Table 4.40). Potential predictive factors of $p \leq 0.10$ are reported. Because of the small sample size, results must be interpreted with caution. Additionally, when factors are highly correlated with each other, for example age and comorbidity, one may serve as a proxy for another. Thus, this preliminary investigation has more explanatory power in interpreting factors which were included, than in invalidating factors which were irrelevant (not statistically significantly) to the regression model.
Table 4.40

Predictors of Decrease in Quality of Life and Functional Status in Adults with Lung Cancer

<table>
<thead>
<tr>
<th>Scale</th>
<th>Variable</th>
<th>Dr</th>
<th>Time 1 N=21</th>
<th>Time 3 N=16</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIPS</td>
<td>Comorbidity*</td>
<td>+</td>
<td>Comorbidity*</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Income**</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>Income***</td>
<td>-</td>
<td>Comorbidity*</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Weight loss***</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial</td>
<td>Income**</td>
<td>-</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>Education**</td>
<td>-</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Sexual</td>
<td>None</td>
<td></td>
<td>Gender (male)**</td>
<td></td>
</tr>
<tr>
<td>PFS</td>
<td>Weight loss**</td>
<td>-</td>
<td>Treatment**</td>
<td>+</td>
</tr>
<tr>
<td>KPS</td>
<td>Weight loss**</td>
<td>-</td>
<td>Weight loss***</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Education**</td>
<td></td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

***p<.005  CIPS=Cancer Inventory or Problem Situations
**p<.05   PFS= Physical Functioning Scale
*p<.10    KPS= Karnofsky Performance Status

DR=direction
Low income and comorbidity accounted for much of the disruptions in quality of life (CIPS Global Score) (Multiple $R^2$ .43) for all subjects at Time 1. The presence of comorbid disease emerged as the only significant variable in explaining quality of life at Time 3 with a Multiple $R^2$ (.20).

Level of disruptions in physical functioning, as reflected in the Physical superscale of the CIPS, was explained by low income and amount of weight lost 6 months prior to entry into the study (Multiple $R^2$ .55). Comorbidity emerged as the only significant variable in explaining level of physical function at Time 3 (Multiple $R^2$ .52).

Disruptions in the Psychosocial Superscale were poorly explained by variables entered in the regression model. Only low income entered as significant (Multiple $R^2$ .30) at Time 1.

Lower education partially explained poorer communication with the health team at Time 1 (Multiple $R^2$ .19). There were no significant variables associated with problems at Time 3.

No significant explanatory variables were associated in the regression with problems in marital function at either Time 1 or Time 3; or with sexual function at Time 1. Gender (male) explained some of the sexual disruptions at Time 3 (Multiple $R^2$ .29).
Both initial objective (KPS) and subjective (PFS) levels of functional status were partially explained by weight loss. The Multiple R$^2$ for PFS was .18, and for KPS .20. Chemotherapy treatment predicted poorer PFS at Time 3 (Multiple R$^2$ .33). Weight loss and lower education explained poorer KPS rating at Time 3 (Multiple R$^2$ .46).

**Summary**

Quality of life was significantly correlated with functional status. Psychosocial function and increased problems in communication with the health team were related to poorer functional status. Weight loss was correlated with poorer functional status and increased disruptions in physical function. The presence of comorbid disease was important in explaining increased disruptions in quality of life over time, especially physical function.
Chapter 5

DISCUSSION OF FINDINGS

The findings of this study begin to describe how age moderates the impact of chemotherapy on disruptions in the multidimensional aspects of quality of life and functional status in adults with non-small cell lung cancer. Since the initiation of this study, the treatment controversy surrounding non-small cell lung cancer has not abated (see for example, Blumenreich et al. 1987, Evans et al. 1988, Ganz et al. 1989, Hansen, 1987). The central focus of this study and consequent findings was not directed at exploring or resolving these issues. For nursing, the critical importance of data associated with the consequences of treatment decisions is to provide the ability to anticipate problems which may be prevented or ameliorated by nursing action. These findings and the identification of major disruptions in quality of life and functional status begin to provide a clinical base for nursing practice. Interpretation of the results of this study first require assessments of threats to validity and reliability.

Validity Issues

The primary threat to the validity of this study was the small sample size. Initial power calculations had
projected that sample sizes of 24 in each subgroup (younger, older, untreated) would be necessary, in order to make statistically valid comparisons. Problems with accrual have been identified which precluded reaching the target sample size over the period of the study. However, it must be stressed how extremely vulnerable, physically and emotionally, many of these subjects were. They were faced with a life threatening illness and, for the majority, with the initial and often frightening experience of chemotherapy. They exerted an extra effort emotionally, physically and made a time commitment to be involved in this study. The 24 subject sample size was larger than the majority of previous nursing studies in patients with non-small cell lung cancer. It was hoped that some subjects benefited from sharing their feelings and experiences in dealing with lung cancer and a cycle of chemotherapy.

Tests of differences between the treated and untreated group on demographic variables failed to identify any potential biases resulting from inherent group differences, other than a higher incidence of working status in the younger adults. The subgroups for statistical analysis were small, and lack of differences between subgroups may be due to Type II errors. Some trends toward difference in the subgroups were suggested which could have influenced the study findings,
particularly the greater weight loss in the older treated group.

The fact that multiple comparisons were performed in analysis of the CIPS subscals could have potentially created false positives as a statistical artifact. Additionally, no formal statistical corrections were made in comparisons between subgroups based on potentially influencing variables (for example, weight loss).

Limitations

Design

As suggested by Jones et al. (1987) quality of life and functional status data were collected before, during and after an initial cycle of chemotherapy. Baseline data were available for comparison when evaluating disruptions in quality of life and functional status over time, which has been described as essential in quality of life research (Ochs et al. 1988). However, the lack of data describing pre-illness disruptions in quality of life and functional status parameters by the patients limited the interpretation of initial baseline scores. For example, initial scores reflecting disruptions in activity and sexual dysfunction in the older subjects may be related more to changes associated with aging than with cancer. Additionally, assessment of subjects just prior to potentially highly stressful chemotherapy treatment may have inflated some pretreatment scores, such as those of
psychosocial disruptions.

Many researchers, specifically Rapp et al. (1988), and Ganz et al. (1988), have related difficulties with patient compliance with quality of life measures during clinical trials. Subject loss (due to death and relocation) and missing data (of the mailback questionnaire) were problems in this, as in other longitudinal studies, even of short duration. In this study compliance was relatively high because of the personal follow-up by the researcher and assistants. Depression was a cause for drop-out by only one patient.

In future studies, measurement of psychosocial data as uncovered by the CIPS, may need to be performed even at shorter intervals than one month. Kaasa, Mastekassa, and Throud (1988) for example, found that the largest drop in psychosocial well-being in non-small cell lung cancer patients occurred 2 weeks after chemotherapy, but recovery to baseline level was noted at 5 weeks. The acute, short-term toxicities of chemotherapy have abated by 4 weeks, but may be present at an earlier data point.

Setting

There was a serious problem in access to potential subjects in private offices. This occurred despite networking with associates, personal contact, numerous entreaties, and reimbursement for nurse's time involved in data collection. In order to access any potential subject
prior to treatment, the researcher or assistant had to be on location constantly. While office nurses were interested in the research project, heavy clinical schedules limited their abilities to act as research assistants. Even in the case of the university and veteran's hospitals, there did not seem to be an easy way to screen potential subjects both before their clinic appointment, and before they were seen by the physician. Plans for treatment were frequently made at the time of the patients' visit, with the patient receiving chemotherapy that day or shortly thereafter.

**Population**

As mentioned, the small sample size was the most serious limitation and threat to the statistical validity of the findings. Because of the small sample size, discovery of significant differences may be extremely difficult (Type II error). However, the relative homogeneity of the sample was an asset since the majority of studies which have attempted to describe the impact of cancer and cancer treatment on day-to-day activities have been done on heterogeneous (for disease and treatment protocols) samples.

This convenience sample represents a physically healthier population of adults with non-small cell lung cancer because the minimal standard for participation was a Karnofsky Performance Status of 60%, and the absence of
brain metastases. Thus, the study may give a more optimistic and biased view of limitations in activity and quality of life faced by younger and older adults with advanced non-small cell lung cancer. Additionally, the emotional status of those adults involved in the study may be higher than typical patients with lung cancer, especially since there were several refusals by those who complained of depression or anxiety. Those subjects who were treated may represent a more motivated or perhaps more concerned subgroup, independent of their physical status. These factors may all limit the generalizability of the findings to other adults with non-small cell lung cancer, and to other adults with cancer. Additionally, the unique aspects of advanced non-small cell lung cancer make it difficult to generalize these findings to adults with other cancer diagnoses. While there were no statistically significant differences detected between age and treatment patterns in this study, other researchers such as Mor et al. (1985) have noted an age bias resulting in less treatment of the elderly cancer patients.

Instruments

All of the instruments used in this study (CIPS, KPS, PFS) had established psychometric properties and proven reliability and validity with cancer patients. The Cancer Inventory of Problem Situations (CIPS) is not commonly used as a measure of quality of life in nursing
research and in cancer research. However, its problem-specific focus is very appropriate for nursing investigations, as it can identify actual and potential problem areas which may be amenable to intervention. The CIPS goes beyond a single index of quality of life and provides a rich data base for exploration.

The CIPS does share the common domains of emotional, physical, and social aspects of many quality of life tools, as suggested by Aaronson et al. (1988), Spitzer (1987) and others. In addition, it offers descriptions of dimensions of sexuality, and communication with the health care team. These last two domains are included in the global scoring of the CIPS. These domains are unique to this quality of life instrument and must be considered when comparing findings of these instruments with other quality of life tools. The relative weight of questions concerned with physical activity and function is higher than more psychosocially oriented instruments. It does not have the general health perception component which is part of the Ware model (Ware, 1984) or a global quality of life question which is in other tools (e.g. Ferrans & Powers, 1985). The CIPS does have the benefit of proven validity and reliability in an older cancer population (Ganz et al. 1985) and has considered mechanisms for computation of scores for older adults who have retired. In comparison with other assessments of
function in older adults (e.g. Kane & Kane 1981), the CIPS does not assess the so called instrumental activities of daily living: shopping for food and meal preparation.

A significant asset of this tool was its ability to generate relative comparisons with standardized cancer patient norms. However, as suggested by van Dam et al. 1984, a better comparison could be achieved between homogeneous groups. Non-small cell lung cancer patients on chemotherapy are minimally represented in the standardized group norm of the CIPS.

A major limitation in the use of the CIPS was the absence of a way for patients to attribute causality of identified problems to cancer or cancer treatment, as opposed to other causes. Identification of problem areas, despite an identified causative agent is still important for future intervention studies. But, the relationship of specific disruptions to disease or treatment only can be suggested. Other circumstances (e.g. recent death of a spouse) might be equally important in explanations of disruptions. Additionally, the importance or value of the specific disruptions in quality of life was not identified in the CIPS. This did not seem to be an easy questionnaire for self administration for some subjects and the shorter form now available (CARES-SF, Schag & Heinrich, 1988) may be a better form for ill patients in future studies.

Denial can be a significant phenomenon when
interpreting responses to instruments with sensitive questions. A strength of this study was both the subjective and objective evaluations of physical functioning. A "ceiling-floor" effect exists in this and other Likert-type problem focused instruments i.e. some problems may be more severe than the scale indicates. There is not explicit information about levels of wellness in the CIPS, beyond a lack of problems. The sensitivity of the CIPS to the problems of severely compromised patients was demonstrated in this study in the relationship of serious disruptions in quality of life noted by those patients who died during the study.

The lack of assessment of specific symptoms, particularly dyspnea, coughing, and hemoptysis beyond the labels of "local, systemic, and metastatic" was a limitation in the instrumentation of the study. Recently, Moinpour et al. (1989) described the inclusion of the Symptom Distress Scale (McCorkle & Benoliel, 1983) as part of clinical trials in the Southwest Oncology Group. Limited psychometric information about this tool was available prior to the initiation of this study, however it may be a useful adjunct in future studies. Since the beginning of this research, a modular approach to quality of life with disease and treatment appropriate symptoms has been suggested by Aaronson, Bullinger & Ahmedzai, (1988). Inclusion of disease specific symptom experiences
will be an important adjunct to future quality of life studies.

Future assessments of side effects and toxicities might be better performed with the WHO assessment of toxicity (WHO, 1979) rather than the ECOG Toxicity Index because of the more specific descriptors at each level. However, comparisons of the reliability and the validity of these two instruments are not available. Additionally, the ECOG appears to be an interval scale of increasing severity, but, many descriptors in the index appear to be categorical and do not have a linear dimension (e.g. the characteristics of somnolence in Central Nervous System Toxicity Scale).

Interpretations of Results
Disruptions in Quality of Life in Non-Small Cell Lung Cancer

Disruptions in quality of life in adults with non-small cell lung cancer were examined through the overall global score of the CIPS, and through specific disruptions in the superscales of physical function, psychosocial function, sexual function, marital function, communication with health team members, and in miscellaneous categories. The research questions pertaining to quality of life were answered in relation to the overall disruptions in quality of life, and in relation to each of the domains of quality of life as described by the CIPS.
Question #1 asked whether there were differences of disruptions in quality of life in older adults as compared with younger adults with lung cancer. The findings in this study do not support the notion that older age alone is associated with significantly greater overall disruptions in quality of life. This lack of support for increased problems in older adults also was previously reported by the report by Ganz et al. (1985) in a heterogeneous cancer patient sample. The lack of differences in the CIPS global score of quality of life may result from the masking of varied differences in the multiple dimensions of quality of life. A high score indicating disruption in one area can lose its impact on the global score when averaged with a low score in another dimension.

Specifically, the findings supported increased disruptions in specific dimensions of physical activity for older adults. As was expected, older adults had greater problems in ambulation, daily activities, recreation and working. Interestingly, they reported less pain. These findings of increased problems in physical activity and age are similar to those of Mor et al. (1987). Mor et al. (1987) found that 61% of cancer patients living at home needed assistance in at least one area of physical functioning. These findings also are congruent with those of Mettlin et al. (1983) where older adults with lung cancer reported the most impairment in
functioning when compared with other cancer patients. Masiak et al. (1983) also reported problems of immobility as a frequent complaint of older cancer patients. The impact of lung cancer on disruptions in physical activity in older adults are even more dramatic when compared to findings of Branch et al. (1984) where the majority of older adults functioned independently. Disruptions in physical activity may be more an all or none phenomenon in older patients. That is, that when the older adult becomes ill, physical functioning drops at a more dramatic rate than in younger adults.

The findings did not support an age-related difference in psychosocial disruption in adults with non-small cell lung cancer. In fact, older adults had less problems in psychological distress, body image, relations and communications with others, and anxiety in medical situations. This was similar to the findings of other studies (e.g. Cassileth et al. 1985, Ganz et al. 1985). Masiak et al. (1983) reported that older cancer patients were less depressed than younger patients.

The older adults had significantly more problems in sexual function than the younger adults. However, older adults had significantly less disruptions in marital function than younger adults. Perhaps, there was less disruption because of a longer marital experience of older adults. Additionally, role changes associated with illness
may not have been as disruptive to the older adults who have coped with role changes often associated with aging. Older, as compared with younger adults, indicated less problems in communication with members of the health team. Older subjects may have had less conflict because they didn't challenge the authority of the health care team.

Question #2 asked whether there were increased disruptions in quality of life in adults with non-small cell lung cancer as compared with cancer patients with other diagnoses. The findings of this study support significant disruption in quality of life in adults with non-small cell lung cancer when compared with other adults with cancer. Initially, when examining the low mean baseline Global score of the CIPS, adults with non-small cell lung cancer do not appear to be substantially compromised in their overall quality of life. However, when the global scores were compared with a standardized cancer specific norm, the lung cancer subjects in this study had dramatically more disruptions in quality of life (80th percentile) than other adults with cancer (Figure 5.1). Earlier studies by Ganz et al (1985) have suggested that significant disruptions in day-to-day living occur in both younger and older adults with cancer. Adults with non-small lung cancer, even with a minimum 60% Karnofsky Performance Status, had more disruptions in physical activity than other adult cancer patients (85th percentile
Figure 5.1
Profile of Percentile Disruptions of Adults with Non-Small Cell Lung Cancer*

Percentile of Disruptions

Global                  Physical       Psychosoc      Commun       Marital       Sexual

- Older  N=10
- Younger N=14

*Comparison with Cancer Patient Norm
for older adults, 82nd for younger adults).

Serious psychosocial disruptions in adults with lung cancer were evident when compared with the normative adult cancer sample. The subjects in this study ranked with the 20% of cancer patients with the highest distress. This was similar to findings of high psychological distress reported by McCorkle & Quint-Benoliel (1983) in their comparison of adults with lung cancer with those who had experienced a recent heart attack.

The older adults with non-small cell lung cancer had severe disruptions in sexual function. When this sample was compared with the standardized norm for global sexuality score (which is largely based on an older sample) they fell within the eightieth percentile (the 20% with the most problems). This can be contrasted with the younger adults who were only in the 50th percentile.

The findings indicated that older adults with non-small cell lung cancer who were married seemed to experience less marital disruption (50th percentile) than younger adults (70th percentile). The CIPS, however, only gives the patients's perception of difficulty in family relations. Cooper (1984) reported that the impact of the diagnosis of lung cancer had a profound affect on family relations. In that study spouses were found not to share fears with patients and appeared more stressed than the patients. Heinrich & Schag (1987) did not find a
difference in quality of marital relationships between couples with good health and couples where one spouse had cancer.

The subjects had more than average problems in communications with members of the health care team. They had disruptions in the top 30th percentile. Considering the poor prognoses of the subjects, and the difficult symptoms of the disease, problems in interaction with doctors and nurses are not surprising.

Findings in relation to Question #3 identified the major disruptions in various aspects of quality of life for adults with non-small cell lung cancer. The most common physical disruptions included difficulty with strenuous activities, fatigue and changes in recreational activities. Over 40% complained of difficulty with household chores and pain. Those who went on for chemotherapy treatment appeared to have experienced less physical disruptions prior to treatment than those who remained untreated. The findings of disruptions in physical activity are similar to those indicating extensive disruptions in activities of daily living by adults with a variety of cancer diagnoses (Gordon et al. 1980). Recognition of the importance of the alterations in social (physical) dependency also have been documented by Benoliel et al. (1980). Cain and Henke (1978) reported similar disruptions in leisure activities as those
reported in this study. Heinrich & Schag (1987) have reported that even cancer patients with high KPS scores spent more time in their home than adults without cancer. Disability and changed activity have been two of the greatest sources of personal suffering reported by lung cancer patients at different stages of treatment (Benedict, 1989). Twice as many complaints of serious suffering were associated with physical, as opposed to psychosocial concerns. Frank-Stromborg & Wright (1984) recognized the increased prevalence of physical over psychosocial concerns in a sample of ambulatory cancer patients with multiple diagnoses, and undergoing various treatment.

Worries about cancer prognosis and family coping and frequent anxiety were the most prevalent problems. Over 40% were overwhelmed with their situation. Similar to the findings in this study, Nerenz et al. (1986) found that worry was less of a concern for older adults receiving treatment. Additionally, Ganz et al. (1985) has reported that older cancer adults appear to worry less than younger adults.

Over 50% of the sample had no interest in sex. Serious problems with sexual function were noted. These findings are similar to the findings of significant sexual dysfunction in cancer patients reported by Ganz et al. (1985). There were no major disruptions (affecting 50% of
the sample or more) affecting marital function, however, difficulty in talking about death with one's spouse remained the most prevalent concern. Difficulties with communication with the spouse was the most serious concern after treatment. The most serious disruptions were in the area of feelings of overprotectiveness of the spouse.

In the area of communication with the health care team no major concerns were identified, only 16% of patients had difficulty understanding their medical treatment. The most serious concern by all subjects relative to the relationship with the health team was in the area of control.

Impact of Chemotherapy on Disruptions in Quality of Life

Question #4 asked whether there were increased disruptions in quality of life after a cycle of chemotherapy in treated older as compared to younger adults and, as compared to an untreated cohort of non-small cell lung cancer patients. Older and younger adults appeared to have similar disruptions in overall quality of life after a cycle of chemotherapy. Treatment did not have a substantial impact on decreasing or increasing disruptions in overall quality of life. However, the older treated adults appeared to have less problems prior to treatment (lower baseline) than both the younger treated and older untreated subgroups. The untreated subjects had more disruptions at baseline and increased disruptions
over time than both younger and older treated subgroups. The older adults were most affected by disruptions in physical activity after treatment, but this still indicated less disruption than that experienced by the untreated adults.

Older subjects treated with chemotherapy had more psychological disruptions initially, and over time. Younger adults had minimal changes and less disruption than older adults. The untreated adults had substantially less disruptions both at the beginning and the end of data collection. The improvement of sexual activity after treatment, might suggest a benefit of treatment or perhaps control of pain. The older treated adults experienced less disruptions in marital function than younger adults, but more than older untreated subjects. The findings indicated that older treated adults had substantially less disruptions in communication than younger adults, and than the untreated subjects. However, the untreated subjects had significantly more than the older treated group.

Question #5 asked whether there were increased disruptions in quality of life over time, independent of treatment status in older adults as compared with younger adults. In this study, age alone was not critical in determining disruptions in quality of life over time. The findings indicated that older adults did not experience greater disruptions in overall quality of life over time.
Older adults, independent of treatment status, appeared to have increased disruptions in physical activity over time. A trend for physical deterioration even over a one month time period has important implications for nursing action.

In the psychosocial superscale of the CIPS the older adults had slightly more distress after chemotherapy than younger adults, and much more distress than untreated adults. The older treated subjects were the most worried about their prognosis. Love et al.'s (1989) findings supported the high prevalence of an emotional and social impact during treatment. This was somewhat different than the findings by Ganz et al. (1985), and Cassileth et al. (1984, 1985) that older adults were better equipped emotionally to cope with rigors of treatment. In the untreated cohort the decision not to accept treatment may have occurred because subjects did not have the desire to seek treatment. There was no evidence that the experience of treatment lowered anxiety 4 weeks after treatment. This requires more investigation.

The findings did not support increased problems in marital dysfunction in older patients as compared to younger adults. The older adults appeared to have less disruptions in sexual dysfunction over time. Problems in communication with members of the health team appeared to increase in the older group. However, the older adults had
less problems over time than younger adults.

Question #6 asked whether there were increased disruptions in quality of life after one cycle of chemotherapy in treated as opposed to untreated adults. Overall there was no substantial difference in quality of life over time in those who did and those who did not receive chemotherapy. One could argue that the side effects of a cycle of chemotherapy did not have a devastating impact on quality of life, which is one reason given for not treating adults with non-small lung cancer with chemotherapy. On the other hand, the aggressive treatment did not dramatically improve disruptions in quality of life. Subjects who appeared to have clinical improvement had the least disruptions in global quality of life, but even those subjects who appeared to respond to treatment had an increase in problems identified over baseline (pre-treatment).

The untreated patients demonstrated an increased disruption in physical activities over time. This was especially evident in the older untreated subjects. The untreated subjects appeared to have more disruptions in physical activity at baseline than those who went on for treatment. There were significant differences in pain frequency by treatment status. Pain appeared to decrease over time in the subjects who received treatment, but increased in those who remained untreated.
Independent of age, untreated subjects appeared to experience more disruption in sexual function than adults who received chemotherapy, but there was little change over time. The treated subjects experienced substantially more disruptions in marital dysfunction than the untreated subjects. Kane (1983) has noted that both cancer and aging may be isolating phenomena. Increase in problems in interactions with spouses after treatment was apparent. This may be indicative of the extent of emotional turmoil that families of older lung cancer patients experience as suggested by Wellisch et al. (1983). The risk of under-reporting may be a problem in this subscale because of imagined criticism of a family member. The degree of support for either is unknown. As the reality of the illness continues, and as the anticipation of death occurs, there may be a pulling away by both spouses. Ganz et al. (1985) did report the difficulty that younger adults had with talking about the future.

The subjects who received treatment exhibited more psychosocial distress over time than those who were not treated. However, the treated subjects had more disruptions in psychosocial function prior to treatment. For subjects receiving chemotherapy, the psychosocial dimension of disruption in quality of life was relatively stable over the month of data collection, despite changes in physical status, the experience of side effects, and
response to treatment. Divergent findings about psychosocial distress and treatment status have been reported. Cassileth et al. (1984) found that those adults undergoing active treatment had better psychological status than those on palliative care alone. Hughes's (1985a,b) findings also support greater psychic distress in untreated when compared with treated patients for lung cancer. In her study, depression was correlated with physical disability. Saunders & McCorkle (1987) also suggested that treatment may be a method of coping in their reanalysis of data on lung cancer patients. Viewing treatment as a way of coping with the disease has been supported by the findings of Lewis (1982) that personal control was a consistent correlate of quality of life in terminally ill patients.

Kaasa et al. (1988) found that psychosocial well-being was reduced in chemotherapy (platinol based) patients mid cycle but some recovery was noted after 5 weeks. The findings of Ell, Nishismoto, Morvay, Mantell, and Hamovitch (1989) in a longitudinal analysis of adaptation of 253 cancer patients (8% lung cancer patients) 3 to 6 months and 9 to 12 months post diagnosis support a model of constant psychological deterioration over time for a subgroup of cancer patients. These findings were independent of cancer site or stage. Initial psychological status was the most important predictor of subsequent
adaptation. Greater stress, lower sense of control, and less emotional support characterize the group with the poorest emotional status.

Findings pertinent to Question #7 identified the major disruptions in quality of life after a cycle of chemotherapy. The major disruptions in physical activity after chemotherapy included difficulties with strenuous activities, fatigue and recreation. Work and ambulation were most seriously disrupted. The impact of disease and treatment on work status is seen in this sample. It is surprising that some subjects were even attempting to continue to work after the assault of lung cancer. The complaints of clothing not fitting may have been a proxy for increased weight loss during treatment. These findings of serious physical disruption in non-small cell lung cancer patients are similar to those reported by Kaasa, Mastekassa & Throud (1988). In that study (n=44), subjects receiving chemotherapy did not experience more disruptions than those experienced by a cohort receiving radiation therapy. Tiredness also was an important symptom noted during chemotherapy, this is similar to the findings of lack of energy in this study.

The major psychosocial disruptions experienced after treatment included: worry about family coping with death, worry about cancer progression, and anxiety about the effectiveness of the treatment. It might be postulated
that the major concern about disease progression was a compelling factor which drove the treated subset to accept or seek chemotherapy. Additionally, the timing of data collection, sometimes minutes before chemotherapy may have tapped extremely high anxiety and worry. Conversely, it might be suggested that those with lower psychological distress who remained untreated had no pressing need to seek treatment. Other major problems included decrease in sexual activity, and lack of interest experienced after chemotherapy.

**Impact of Lung Cancer on Disruptions in Functional Status**

Question #8 asked whether there were increased disruptions in functional status in older adults as compared with younger adults. In congruence with the disruptions in the physical activity domain of the CIPS, the impact of lung cancer on diminished physical functioning was obvious with both the objective and subjective measures. The subjective assessments of physical disruptions were not greater in older adults.

An increased acceleration in loss of physical function over time has been related to age by Palmore et al. (1985). However, over 60% of men and women over 65-74 in the community state that they have no activity limitation (Stat Bull. 1988). Feinstien et al. (1986) stressed the importance of patient effort when assessments of physical function are made. Patients who exert greater
effort may appear to be more functional than those with the same physical capacity who do not exert that effort.

Findings relevant to Question #9 identified the major disruptions in functional status over time in adults with non-small cell lung cancer, independent of treatment status. The major disruptions in functional status included limitations in vigorous activities, walking distances, stair climbing, and moderate activities. The most common limitation of physical functioning, strenuous activities, has been significantly associated with increased age alone in studies by Jette & Branch, 1981. Mor (1987) and others have reported that KPS was the strongest correlate of quality of life and an important predictor of longevity in terminally ill patients.

Impact of Chemotherapy on Disruptions in Functional Status

Question #10 asked whether there were increased disruptions in functional status during and after a cycle of chemotherapy in a treated as compared with an untreated cohort of lung cancer patients. Older treated adults exhibited less disruptions in functional status than either younger treated adults or untreated adults. They also had the highest functional status at baseline. This was the case for objective (KPS) and subjective (PFS) measures of functional status. The transient increase in problems during the time of acute side effects of treatment was reflected in scores at mid cycle of the PFS.
The finding of higher quality of life and better physical functioning by subjects who appeared to respond to chemotherapy has been supported by previous studies. Finkelstein et al. (1986) noted the identification of the ability to ambulate as an important predictor of long-term survivors treated with chemotherapy.

**Question #11** asked if there were increased disruptions in functional status after one cycle of chemotherapy in younger as compared with older adults. Older adults had less disruptions mid-point in the data collection.

**Question #12** asked whether there were increased disruptions in functional status after one cycle of chemotherapy in treated as opposed to untreated adults. There were little differences in disruptions in functional status between the treated and untreated subjects over time when subjects were measured by the KPS. However, there were appreciable differences in functional status over time between treated and untreated adults as measured by the PFS. The untreated subjects showed a subjective deterioration in physical functioning. The older subjects had the greatest deterioration. Ganz et al. (1989) also did not note a change in KPS after platinum/velban therapy in non-small cell lung cancer patients. Despite a 22% tumor response reported by Rapp et al. (1988) with cisplatin/velban clinical trial, only a few subjects
exhibited improvement in functional status or weight gain. Similar to Dodd's findings (1982), KPS did not alter significantly during chemotherapy, despite the occurrence of troublesome side effects.

An interesting finding of this study was the uniform serious limitations rated by all of the subjects who died during the study and by the subject who stated he was too depressed to continue. These subjects were clearly in serious distress and in need of nursing support even though their KPS rating did not reflect a serious degree of physical difficulty.

Findings pertinent to Question #13 showed that the major disruptions in functional status during and after chemotherapy continued to include vigorous activities, walking distances and stair climbing, but their prevalence decreased over time. Even with this ill population experiencing advanced lung cancer, 20% of the subjects stated that they were satisfied with their level of activity. Of course, this may be relative; that is the subjects were satisfied that it was not worse than it was. This is in contrast to Aaronson's et al.'s (1987) preliminary report that only 28% of the small cell lung cancer patients were dissatisfied with their activity level. The concern of dissatisfaction with activity level in this study was similar to the primary concern of decreased physical activity expressed by those ambulatory
cancer patients assessed by Frank-Stromborg & Wright (1984).

Linn and Linn (1984) and other researchers have emphasized the importance of personal evaluation of the consequences of physical disruptions due to illness. Despite a diagnosis of advanced lung cancer, 20% of the subjects stated they were satisfied with their level of activity. Feelings about the impact of illness on function has been an understudied problem. The use of denial of severity of disruptions by patients when evaluating their physical abilities can create methodological problems when measuring functional status (Ochs et al. 1988).

Theoretical Considerations

Relationship of Disruptions in Quality of Life and Functional Status in Lung Cancer

Age. In this study, age alone did not serve as a predictor for more disease and treatment related problems. Mor (1987) found that in the National Hospice Study, assessment of physical functioning was a core concept and overall predictor of quality of life and perhaps because of this, age was negatively correlated with quality of life. Not surprisingly, in that study, the greater physical needs of the patient were associated with the greater burden by the caregiver.
George & Bearon (1980) recognized that physical functioning was the foundation for the construct of quality life in the elderly. In some cases the older patients may actually fare better in coping with illness and treatment due to wisdom gained from past experiences. However, this study had a limited number of those over 65.

Treatment. Those subjects who were treated with chemotherapy experienced more problems than the untreated subgroup in most areas, except for disruptions in physical activities. Alterations in cognition due to chemotherapy can be important factors in compromised physical and psychological functioning. Silberfarb et al. (1983) reported differential effects of various chemotherapy protocols on cognition. Kaasa, Olnes and Mastekassa (1988) also reported that non-small cell lung cancer patients receiving chemotherapy (platinum/velban) had reduced cognitive performances when compared with patients who had received radiation alone. Changes in cognition can complicate and perhaps invalidate indications of subjective quality of life without objective assessments.

Severity of side effects and tumor response (disease progression) were viewed as potentially confounding variables in this study, but in future studies they may be viewed as independent variables affecting changes in functional status and quality of life. Substantial advances have occurred in the delivery of cisplatin based
protocols for non-small lung cancer patients and others in outpatient settings, which may have resulted in better control of treatment related side effects (Frogge, 1989). In this study, older adults did not have more side effects than younger adults. Dose reduction due to age, which can affect both side effects and response to treatment, was not evident though it has been reported by others (Bonadonna & Valugussa, 1981). Richardson et al. (1988) have reported that younger patients (n=107) had a more difficult time dealing with side effects of treatment than older patients, particularly: nausea, appetite loss, infection, weakness, and alopecia.

Nausea and vomiting due to chemotherapy were not more serious problems in this sample. The older subjects, as has been shown in other studies (e.g. Nerenz et al. 1986), suffered less nausea and vomiting than the younger adults. While responses to treatment may not be seen until after additional cycles of treatment, the subjective confirmation of early clinical improvement in 50% of the subjects at the end of the initial cycle, was similar to findings by Folman & Rosman (1988) who saw symptomatic improvement within 3 weeks of therapy. The evaluation of clinical response in this study was different from the more rigorous measurement of tumor response in clinical trials, thus those who seemed to have improved may not have been rated as responders in clinical trials.
Correlates of Disruption in Quality of Life and Functional Status

A multivariate model was proposed to guide research in the impact of age on disruptions in quality of life and functional status. Analysis of the disruptions in quality of life (Global CIPS score) along specific demographic variables produced several interesting findings.

Question #14 required examination of the theoretical relationship between functional status and quality of life, independent of treatment over time. The significant correlations of PFS and KPS with the Global score of the CIPS after a cycle of chemotherapy supported the theoretical relationship. In this study the relationship of physical functioning to quality of life was supported by the correlations of KPS and PFS with the global score of the CIPS. The CIPS has a large number of items assessing physical activities, thus the significant correlation between it and the functional status instruments is not surprising. Additionally, the KPS has been correlated previously in validity explorations of the CIPS (Schag et al. 1983). The KPS and PFS also were importantly related to the psychosocial dimension of the CIPS when evaluated in all subjects. Hughes's (1985 a, b) correlation of depression in lung cancer patients with severe physical disability, and Cassileth et al.'s (1984) report of poorer psychological status in functionally
compromised patients with chronic illness, support the relationship of physical and psychosocial functioning.

**Question #15** considered the relationship between quality of life and levels of functional status after a cycle of chemotherapy. After treatment, the correlation between KPS and quality of life did not reach statistical significance. This may have been due to the problem of small sample size since the correlation was relatively high. However, the PFS and CIPS continued to be significantly related.

The relationship between age, weight loss, time since diagnosis and disruptions in quality of life and functional status was investigated to address **Question #16**. Since subjects already had advanced lung cancer, further examination of the impact of the extent of disease on quality of life was not possible. The importance of extent of disease has been demonstrated by Cella et al.'s (1988). Stage of illness was not a major factor in predicting psychological dysfunction in the findings reported by Ell et al. (1989). Similar to findings of this study, Ell et al. (1989) found that those who died during data collection had the lowest psychological scores.

Weight loss has been reported in many studies as strongly correlated with functional status. This study continued to support the finding that weight loss prior to entry onto the study was negatively correlated with both
subjective and objective evaluations of functional status. Additionally, weight loss was positively correlated with increased disruptions in the physical activity domain of quality of life. The finding of increased weight loss in older subjects in this study was different from that reported by De Maria and Cohen (1987) in which older subjects were not at greater risk for weight loss. The pattern of weight loss was not measured in this study over time, thus it is not known if there were differential changes by age. Additionally, weight loss prior to treatment was assessed by patient report, not actually measured.

The findings of this study did not report a significant relationship between the time since diagnosis and psychosocial disruptions. This was different from Cassileth et al.'s (1984) work where diagnosis of less than 3 months was associated with higher psychic distress. McCorkle and Benoliel's (1983) findings also suggested assimilation of the diagnosis. They found an improvement in mood in subjects one month after an initial assessment (despite lack of change in symptom distress).

Specific symptoms of lung cancer could have directly contributed to disruptions in physical activity, but the findings in this study were not able to support that relationship. Types of symptoms were not specifically related to levels of functional status and disruptions in
quality of life in this study. Diminished activity over time due to dyspnea was noted by Brown et al. 1986. More symptom distress was linked with greater awareness of life threatening disease (Germino & McCorkle, 1985). The findings of frequent pain in the overall sample of this study is not unlike the serious pain control problems with men with lung cancer reported by Austin et al. (1986). In that study, similar to these findings, older patients reported less problems with severe pain. The trend for improvement in pain after chemotherapy can be an important implication of the benefit of treatment. It also can be an indication of a closer assessment or commitment for symptom relief for the patient undergoing treatment by the physician and nurse.

Question #17 asked which combination of moderator variables of gender, income, time since diagnosis, education, symptoms, and comorbidity best predicted disruptions in quality of life and functional status in adults with non-small cell lung cancer over time. In the multiple regression, low income was an important predictor for increased disruptions, a lower global quality of life, and physical and psychosocial disruption. Gender (male) was associated with increased disruptions in sexual function.

Financial status was an indirect measure of the patient's care environment. Those subjects in a lower
socioeconomic group may have had less access to resources. When analyzed by income, those with the highest income had the least problems and the highest quality of life. Only one subject in this study lived alone, thus statistical comparisons by living situation were not possible.

Level of education emerged as an important variable to consider in future studies. It was not surprising that low education correlated with problems in communication with medical personnel. The significant relationship with functional status was puzzling. Additionally, the subjects with the lowest education (Jr High School) identified the least problems and thus emerged with the highest global quality of life scores. Because only 2 subjects fell in this category, it was difficult to make theoretical conclusions about the relationship of education to disruptions in quality of life. Interestingly, this finding of low income and higher quality of life also was reported by Love et al. (1989). Perhaps the subjects with lower income were focused on the day-to-day basics and not the more abstract issues of quality of life included in the assessment.

Comorbidity was the most powerful predictor of disruptions in quality of life and physical dysfunction, but this was not clearly related to age. The impact of cancer, along with the impact of other chronic illnesses, may be an interactive phenomenon accelerating disruptions
in various dimensions of quality of life in a domino-like fashion. Ganz et al. (1985) did not find significant comorbid disease as a major factor in differentiating disruptions in quality of life in older subjects. Pearlman & Uhlman (1988) reported that perception of overall health was significantly linked with measures of quality of life in elderly adults with chronic illness. Mor (1987) suggested that poor physical function leads to decreased interpersonal support that may lead to reduction in quality of life. Taylor et al. (1985) theorized that there may be a threshold effect before physical disability affects day-to-day activities and then disrupts psychosocial function and ultimately overall quality of life.

Implications for Nursing

The findings of severe disability and physical limitation in younger and older adults with non-small cell lung cancer give this study important implications for nursing, especially in light of Brown and Kesslers's (1988) projections of increasing incidence of lung cancer in older adults. As Mor et al. (1987) have previously suggested, there is a need for concrete services and assistance in day-to-day activities for adults with cancer that must go in concert with psychosocial interventions. Specific programs for minimizing symptoms, and physical and psychosocial disruptions in this population are vital.
A pragmatic, function oriented approach to building a science of quality of life is essential (Schipper & Levitt, 1985).

Impact of disease and treatment on disruptions in quality of life and functional status, particularly as operationalized in this study, suggest specific targets for practice based on disruptions of specific behaviors of daily living such as walking. The compromised physical ability noted in the findings may limit the participation of these patients in elaborate self-care programs.

Knowledge of patterns, severity and kinds of disruptions in the multidimensional aspects of quality of life experienced during treatment can help the nurse to counsel and prepare patients prior to chemotherapy. The findings that there were minimal differences in disruptions in quality of life by age may be important to share with older adults and their families.

**Recommendations for Future Research**

This study is one of but a few documenting the impact of cancer on older adults. As Given and Given (1989) have noted, there were no research articles related to older adults with cancer in their survey of gerontological nursing. The recognition of the necessity of the investigation of age related similarities and differences in cancer care is just being recognized (Ershler & Yarbo, 1989).
As Padilla et al. (1985) have suggested, dimensions of quality of life can be important outcome variables for nursing interventions. Currently, this is occurring in nursing research related to cancer pain management (Ferrel, Wisdom & Wenzl, 1989) and in assessments of quality of life of adults with a variety of diagnoses (Ferrens, 1989). Measures which assess the impact of nursing interventions on the patients' quality of life need to be constructed as rigorously as those which are being used to compare efficacy in clinical trials. These assessments may help to screen patients who may be at increased risk for dysfunction in multiple aspects of day-to-day life. This study used a detailed and comprehensive description of dimensions affected by disease and treatment, but other areas, most importantly specific measures of symptom distress, should be included in future studies.

In a recent review of cancer nursing research priorities (Funkhouser & Grant, 1989), less than 1% of respondents who returned the survey (203/1060) rated quality of life as a top research priority. Only one respondent rated problems with immobility as an important research area for cancer nursing. Using a pragmatic behavioral approach to disruptions in quality of life and functional status, changes over time were monitored in this study which could give direction for future nursing
interventions. Additionally, there is a need for extensive nursing research to describe and delineate aspects of the course of illness (specifically lung cancer) and of treatment from a nursing perspective to direct prevention and intervention efforts. Age specific inquiries into needs for differential nursing care are essential. The establishment of patterns of activity and immobility, especially in older adults with cancer, can help nurses prescribe actions to prevent unnecessary suffering.

Another contribution of this study is the careful and homogeneous subject selection. The numerous research studies with heterogeneous samples (age, diagnosis, and stage) make applications of findings difficult. Focused studies, controlling for disease and treatment variables, will allow for valid generalizations in planning care for adults faced with lung cancer. Additionally, this study focused on changes over time, which were rarely considered in previous investigations of disruptions in day-to-day activity. The prospective approach is essential in considering both causal relationships. A distinct advantage of this study was the multivariate perspective of physiologic data (describing disease and treatment) and psychosocial data (describing emotional responses to disease and treatment) along with the behavioral manifestations affecting function in everyday life.

Obvious methodological improvements would be possible
in larger studies. Sampling by stratified age subgroups (young-old 65-74, mid-old, 75-84, and old-old, > 85) would give a better description and analysis of age-related nursing care needs. A larger sample size would be possible through a multi-institutional effort, or as part of a larger clinical trial (which allows for carefully controlled and documented medical and treatment variables). Additionally, subjects need to be followed over a longer time frame. Further statistical analysis in larger studies might use education, comorbidity, and weight loss as covariates in analysis of change in quality of life over time. As Schipper & Leavitt (1985) have suggested, changes in quality of life are complex and may not necessarily follow a linear pattern.

The impact of the experience of treatment is important from a family perspective, particularly from the perspective of the primary care giver, as they might suggest the need for different types of nursing support. No subjects who lived alone were accrued in the convenience sample. But, because of current demographic trends, older adults living alone may be an important target group for further studies. With the increase of lung cancer in minorities, there is a need for data about the differences and similarities of the impact of the disease and treatment in these groups. The proportion of older Black men and women reporting very good physical
well being was only one fourth, as compared to over one third of older white men and women (Stat Bull, 1988). Analyses using multiple regression are very sample dependent. Even though the predictor variables associated with change in functional status and quality of life confirmed theoretical predictions, a larger sample might reveal a different pattern of predictor variables. Since the subjects who were felt to have subjectively improved went on to receive additional cycles of treatment, future studies should include assessment during the entire treatment phase to describe adequately treatment related toxicity.

The newly revised shortened version of the CIPS (CARES-SF) may be a better tool to use in this and other physically compromised patient populations. It also may serve better as a repeated measure during treatment.

A qualitative dimension to quality of life research along with the quantitative approach may reveal important information about the personal assessment of the meaning of changes in physical and psychosocial function (Bennet, 1985). On the other hand, objective assessments of changes in ambulation during cancer and cancer treatment (for example, gait, speed, endurance) may give specific data to focus interventive nursing programs for prevention and support (Engle 1986). Bedridden patients have been routinely excluded from clinical trials (Livingston,
1988), and limited information is available for these subjects.

In conclusion, the findings of this study demonstrated that serious disruptions in quality of life and functional status occur in adults with lung cancer. Differential disruptions in quality of life, based upon age alone did not support differential nursing care needs. Subjects who received an initial cycle of chemotherapy for non-small cell lung cancer did not suffer more problems in quality of life and functional status than those who were not treated but there did appear to be a decrease in disruptions of psychosocial, physical, and marital function over time. Comorbid disease emerged as a powerful predictor for higher disruptions in quality of life and lower functional status after a cycle of chemotherapy.
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APPENDICES
Name: 
ID No.: 
Date: 
Site: 

Medical Summary

PLEASE COMPLETE THE FOLLOWING INFORMATION ABOUT THE STUDY PATIENT

1. Type of Lung Cancer
   ___ Squamous (epidermoid)  ___ Anaplastic
   ___ Adenocarcinoma  ___ Other

2. Extent of Disease
   ___ Limited (disease limited to one hemithorax and ipsilateral or suprACLavicular nodes: disease encompassed within a single radiation port)
   ___ Extensive (advanced disease beyond "limited" parameters)

3. Type of Metastasis:
   ___ Brain  ___ Liver  ___ Other Lung
   ___ Bone  ___ Lymph Nodes  ___ Other

4. Type of symptoms
   ___ Local (local effects of lung cancer e.g. cough)
   ___ Systemic (remote from the primary lung cancer site, but not anatomically related to tumor spread e.g. anorexia)
   ___ Metastatic (due to distant spread of the lung cancer e.g. bone pain)
   ___ None

4. Date of initial diagnosis ____________

5. Amount of weight lost in previous 6 months ____________
6. Previous Radiation within last 6 months ___

7. Previous surgery for lung cancer treatment
   Type________________________ Date_______________

8. Previous chemotherapy treatment for lung cancer
   Type of RX____________________ Dates___________

9. Current chemotherapy Regimen for lung cancer
   Type (Drugs, dose, schedule)

10. Presence of Concurrent Diseases
    Check existing illnesses and mark the severity of the illness with the appropriate number

    1=no impairment
    2= some impairment
    3= severe impairment

    Respiratory disease 1__ 2__ 3__
    Cardiovascular disease 1__ 2__ 3__
    Renal disease 1__ 2__ 3__
    CNS disease 1__ 2__ 3__
    Musculoskeletal disease 1__ 2__ 3__
    Hearing 1__ 2__ 3__
    Eyesight 1__ 2__ 3__

11. Creatinine clearance (24 hr urine) within last 6 months (if available)
    Level_________ Date____
Patient's Current Karnofsky rating of Performance status*

___ 100 Normal, no complaints: no evidence of disease
___ 90 Normal activity: minor signs or symptoms of disease
___ 80 Normal activity with effort: some signs or symptoms of disease
___ 70 Cares for self, unable to carry on normal activity or do active work
___ 60 Requires occasional assistance but is able to care for most personal needs
___ 50 Requires considerable assistance and frequent medical care
___ 40 Disabled: requires special care or assistance
___ 30 Severly disabled: hospitalization indicated
___ 20 Very ill: hospitalization mandatory: requires active support
___ 10 Moribund: fatal process progressing rapidly
___ 0 Dead

*Consider the following in making your assessment (from Schag et al 1984)

Has the patient experienced any weight loss or weight gain?
Has the patient experienced any reduction in energy or increase in fatigue?
Has the patient had any difficulty with grooming or bathing?
Has the patient had any difficulty in walking or moving around?
Has the patient had any difficulty driving?
Has the patient had any difficulty working full or part time?
Background Information
Please complete the following information about yourself.
This information will be kept confidential.

1. Sex
   ☐ Male
   ☐ Female

2. Age ______

3. Check one of the following that best describes your current and primary employment status.
   ☐ 01 Employed Full-time for pay
   ☐ 02 Employed Part-time for pay
   ☐ 03 Employed Full-time, currently on Sick Leave
   ☐ 04 Employed Part-time, currently on Sick Leave
   ☐ 05 Unemployed and Not-seeking employment
   ☐ 06 Unemployed and seeking employment
   ☐ 07 Retired
   ☐ 08 Homemaker
   ☐ 09 Other: please specify

4. What is (or was) your occupation? ________________________

5. Check one income range that best describes your family's current level of economic support (including salary, social security, benefits, etc.)
   ☐ 00 to $10,000
   ☐ $10,001 to $25,000
   ☐ $25,001 to $40,000
   ☐ Over $40,000

6. Please mark the category that best represents your educational experience.
   ☐ 1. Completed graduate/professional training (e.g. M.D., Ph.D.)
   ☐ 2. College degree
   ☐ 3. Partial college training
   ☐ 4. High school graduate
   ☐ 5. Partial high school (10-11 grades)
   ☐ 6. Junior high school (7-9 grades)
   ☐ 7. Under 7 years of schooling

7. Current Marital Status
   ☐ 1. Single
   ☐ 2. Married
   ☐ 3. Separated
   ☐ 4. Divorced
   ☐ 5. Widowed
   ☐ 6. Living together

8. How many people live in your immediate household? ________
9. Are any of the people in your immediate household seriously ill or do they have a chronic illness?
   Yes ☐
   No ☐

10. What is your religious preference?
    ☐ 1. Catholic
    ☐ 2. Protestant
    ☐ 3. Jewish
    ☐ 4. None
    ☐ 4. Other: Specify

11. How often do you attend religious services?
    ☐ 1. Never
    ☐ 2. A few times a year
    ☐ 3. Once or twice per month
    ☐ 4. About once a week or more

12. What is your ethnic background?
    ☐ 1. White
    ☐ 2. Black
    ☐ 3. Hispanic
    ☐ 4. Asian American
    ☐ 5. Native American
    ☐ 6. Other: Specify

13. Do you have a valid driver's license?
    Yes ☐
    No ☐

14. Do you have any other illnesses or conditions which affect your day-to-day activities?
    Yes ☐
    No ☐

15. If yes, please list the illnesses (e.g. heart disease) or conditions (e.g. difficulty hearing) and mark by each one the amount of difficulty they cause in your day-to-day life.

   1. ________________ ☐ 1. no problems
                           ☐ 2. some problems
                           ☐ 3. serious problems

   2. ________________ ☐ 1. no problems
                           ☐ 2. some problems
                           ☐ 3. serious problems

   3. ________________ ☐ 1. no problems
                           ☐ 2. some problems
                           ☐ 3. serious problems
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These consist of pages:

330, Physical Functioning Scale
331-337, Cancer Inventory of Problem Situations (CIPS)
ECOG Toxicity Criteria

INSTRUCTIONS:

PLEASE PLACE THE APPROPRIATE NUMBER INDICATING PRESENCE AND DEGREE OF TOXICITY EXPERIENCED BY THE PATIENT DURING THE CYCLE OF CHEMOTHERAPY.

PLEASE PLACE A CHECK BY THE APPROPRIATE BOX DESCRIBING TUMOR RESPONSE AFTER THE CYCLE OF CHEMOTHERAPY.

______ RESPONSE=CLINICAL INDICATION OF A POSITIVE CHANGE IN DISEASE STATUS

______ PROGRESSION=CLINICAL INDICATION OF AN INCREASE IN TUMOR SIZE OR NEW EVIDENCE OF DISEASE

______ NO RESPONSE=NO CHANGE IN TUMOR SIZE OR DISEASE STATUS
<table>
<thead>
<tr>
<th>Criteria</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukopenia</td>
<td>10^-5</td>
<td>10^-6</td>
<td>10^-6</td>
<td>10^-6</td>
<td>10^-6</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>1.9</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Thromboembolism</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Anemia</td>
<td>11</td>
<td>9.5</td>
<td>9.5</td>
<td>9.5</td>
<td>9.5</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>0.9</td>
<td>0.9</td>
<td>0.9</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>None</td>
<td>Minimal</td>
<td>Mod.-Not debilitating</td>
<td>Debilitating</td>
<td>Life threatening</td>
</tr>
<tr>
<td>Infection</td>
<td>None</td>
<td>None</td>
<td>No active Rx</td>
<td>Requires active Rx</td>
<td>Debilitating</td>
</tr>
<tr>
<td>GU</td>
<td>&lt;20</td>
<td>&lt;12</td>
<td>&lt;12</td>
<td>&lt;12</td>
<td>&lt;12</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Proteins</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
</tr>
<tr>
<td>Hematuria</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>Should be graded under infection, not GU.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematuria resulting from hematuria is graded under hematocrit.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N &amp; Y</td>
<td>None</td>
<td>Nausea</td>
<td>N &amp; Y</td>
<td>Nausea</td>
<td>Nausea</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>None</td>
<td>None</td>
<td>No dehydration</td>
<td>Dehydration</td>
<td>Grossly bloody</td>
</tr>
<tr>
<td>Pulm</td>
<td>PFT</td>
<td>Clinical</td>
<td>25-50% decrease in</td>
<td>Deco or VC</td>
<td>&gt;10% decrease in</td>
</tr>
<tr>
<td>Cardio</td>
<td>ST-T changes</td>
<td>Sinus tachycardia &gt;110</td>
<td>Atrial arrhythmias</td>
<td>Multifocal PVCs</td>
<td>Multifocal PVCs</td>
</tr>
<tr>
<td>Neuro</td>
<td>DTR's</td>
<td>Mild paresthesias</td>
<td>Mild constipation</td>
<td>Absent DTR's</td>
<td>Sensation loss</td>
</tr>
<tr>
<td>CNS</td>
<td>Mild anxiety</td>
<td>Mild depression</td>
<td>Mild headache</td>
<td>Leptagry</td>
<td>Severe anxiety</td>
</tr>
<tr>
<td>Pain &amp; Mucosa</td>
<td>None</td>
<td>Transient erythema</td>
<td>Pigmentation</td>
<td>Subcutaneous</td>
<td>Ulceration</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>None</td>
<td>Soreness</td>
<td>Ulcers-can eat</td>
<td>Ulcers-cannot eat</td>
<td>Ulcers-cannot eat</td>
</tr>
<tr>
<td>Alopecia</td>
<td>None</td>
<td>Alopecia-mild</td>
<td>Alopecia-severe</td>
<td>Alopecia-severe</td>
<td>Alopecia-severe</td>
</tr>
<tr>
<td>Allergy</td>
<td>None</td>
<td>Transient rash</td>
<td>Drug fever</td>
<td>Urinary</td>
<td>Drug fever</td>
</tr>
<tr>
<td>Fever</td>
<td>&gt;100 F</td>
<td>&gt;100 F</td>
<td>&gt;100 F</td>
<td>&gt;100 F</td>
<td>&gt;100 F</td>
</tr>
</tbody>
</table>

1. The toxicity grade should reflect the most severe degree occurring during the evaluated period, not an average.
2. When two criteria are available for similar toxicities, e. g. leukopenia, neutropenia, the one resulting in the more severe toxicity grade should be used.
3. Toxicity grade = 5 if toxicity caused the death of the patient.
DISEASE STATUS

INSTRUCTIONS:

PLEASE PLACE A CHECK BY THE APPROPRIATE BOX DESCRIBING DISEASE STATUS DURING THE PAST MONTH.

____ CLINICAL INDICATION OF A POSITIVE CHANGE IN DISEASE STATUS

____ CLINICAL INDICATION OF AN INCREASE IN TUMOR SIZE OR NEW EVIDENCE OF DISEASE

____ NO CHANGE IN TUMOR SIZE OR DISEASE STATUS