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USE OF COMPLEMENTARY THERAPIES BY PERSONS
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Karen Ann Rosasco

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USE OF COMPLEMENTARY THERAPIES BY PERSONS DIAGNOSED WITH BREAST, LUNG, COLO-RECTAL OR PROSTATE CANCER

Ву

Karen Ann Rosasco

A THESIS

Submitted to
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ABSTRACT

USE OF COMPLEMENTARY THERAPIES BY PERSONS DIAGNOSED WITH BREAST, LUNG, COLO-RECTAL OR PROSTATE CANCER

By

Karen Ann Rosasco

In recent years, there has been an increased interest in the use of complementary therapies for diverse health problems. Cancer patients are no exception; they often use complementary therapies together with conventional medical treatment. This study was a secondary analysis that explored the use of complementary therapies among 587 elderly patients with cancer, who resided in mid-Michigan. The study specifically examined the most frequently used complementary therapies, and the combinations of therapies utilized.

The findings revealed that 22.8% ($\underline{n}=134$) of elderly patients with cancer are using complementary therapies in conjunction with conventional treatments. The therapies used most often were exercise programs, herbal therapy or vitamins, and spiritual healing. Advanced Practice Nurses can use these findings to determine which therapies they should be knowledgeable of, so as to provide education and/or treatment to patients seeking information on complementary therapies.

This study is dedicated with great love to my husband, Thomas, my parents, John and Helen Kozleski, and my loving and caring family.

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INTRODUCTION

Cancer is a family of diseases. It is estimated that in 1996, the United States will witness 1,359,150 new cases of cancer and encounter 554,740 cancer related deaths (Parker, Tong, Bolden, & Wingo, 1996). According to the American Cancer Society (1996), the most common sites of cancer are prostate, breast, lung, and colon/rectal (Parker et al., 1996). The National Cancer Institute (1995) indicates the probability of developing invasive cancer increases as one's age increases, especially when an individual reaches 60 to 79 years of age (Parker et al., 1996). It is estimated that 53% of patients will be alive five years after diagnosis (Murphy, Lawrence, & Lenhard, 1995); however, approximately 50% of cancers remain incurable, with life expectancies of a few months to a few years (Zaloznik, 1994).

Conventional therapies are medical practices that are in conformity with the standards of the medical community. These medical interventions are widely available and practiced throughout the United States (U.S.), and have become the accepted methods of medical care (Lerner, 1994).

Surgery, chemotherapy and radiation therapy have become the conventional treatment approaches to cancer within mainstream American medicine.

Patients may receive a single conventional therapy, or may receive a

combination of conventional therapies, depending on the type and stage of cancer. In recent years, there has been an increased interest in the use of unconventional, alternative or complementary therapies for various health problems. These therapies are defined as "medical interventions not taught widely at United States of America (U.S.A) medical schools or generally available at U.S. hospitals" (Eisenberg et al., 1993, p. 246). Zaloznik (1994) defines unorthodox, unproven or alternative treatments as methods that "have not been objectively, reliably, responsibly, and reproducibly demonstrated in the peer-reviewed literature to be more effective than no treatment" (p. 20).

Previous studies have shown that patients with cancer often use unconventional/complementary therapies in addition to conventional medical treatment, yet frequently do not inform their medical doctor or health care provider (Cassileth, Lusk, Strouse, & Bodenheimer, 1984; Eisenberg et al., 1993: Lerner & Kennedy, 1992). This lack of discussion may indicate a deficiency in patient-provider relations, and could potentially negatively impact patient care and outcomes. This author's study was conducted to determine the use of unconventional/complementary therapies in elderly patients with cancer (age 65 and older) receiving conventional medical treatment for breast, lung, prostate, or colo-rectal cancer. As all elderly patients with cancer participating in this study received conventional medical treatments, the additional therapies they used can be considered complementary. Complementary implies a modality is used in conjunction with conventional therapy, as one complements the other. Therefore the

term "complementary" was used throughout this paper to refer to any therapy not considered conventional.

Statement of the Problem

When a person is diagnosed with cancer, her/his world as once known, is changed. Friends, relatives and colleagues often encourage the patient with cancer to explore all possible modalities for healing, both conventional and complementary. Accounts of successful therapists and therapies are shared in hopes of providing encouragement and optimism for the patient with cancer. Patients with cancer seeking complementary therapies are often reluctant to disclose or discuss such information with their medical care provider because of the fear of disapproval or rejection. According to a survey conducted by Eisenberg et al. (1993), 72% of the respondents who used complementary therapies did not inform their medical doctor that they had used such therapies. This finding was also supported in other studies conducted by Cassileth et al. (1984) and Lerner and Kennedy (1992).

Advance Practice Nurses (APNs) are in a position of providing information about biomedical research and treatment, as well as complementary therapies and practices available to patients with cancer.

Understanding the types of complementary therapies used by elderly patients with cancer, with respect to type and stage of cancer, can assist the APN in knowing which treatments she/he should be well versed in to be able to initiate discussions on the use of such therapies, and suggest specific therapies for patients with cancer. Providers of health care need to

feel comfortable initiating dialogue and addressing issues/concerns with patients with cancer. APNs caring for elderly patients with cancer can play a valuable role in assisting patients to make informed choices about complementary therapies, thereby minimizing potential risks of some complementary therapies, and ensuring that only the benefits are gained.

The purpose of this study was to analyze the use of complementary therapies by elderly patients diagnosed with breast, lung, colo-rectal or prostate cancer. The questions answered in this study were:

- (1) What proportion of elderly patients with cancer receiving conventional medical treatment also used complementary therapies?
- (2) What are the most frequently used complementary therapies among all elderly patients with cancer who use them? What are the most commonly occurring combinations of therapies?
- (3) Are there differences in combinations of complementary therapies which are most often used by elderly patients with one of four types of cancer: breast, lung, colo-rectal or prostate?
- (4) Are there differences in the use of complementary therapies among elderly patients with different stages of cancer?

CONCEPTUAL MODEL

Conceptual Definition of the Variables

The primary concepts under study are complementary therapies, type of cancer, and stage of cancer at diagnosis.

<u>Complementary therapies.</u> Conventional therapies are medical interventions that are in conformity with the standards of the medical

community and are widely available and practiced throughout the U.S. According to Eisenberg et al. (1993), therapies not generally available at U.S. hospitals and not considered as standard components of conventional medicine, yet used in combination with conventional therapies, are considered to be complementary therapies. The American Cancer Society (ACS) has recently changed its terminology when referring to unconventional therapies. In response to changing attitudes about complementary therapies, the ACS renamed what was once termed questionable therapies to alternative and complementary ("American Cancer Society", 1996). Complementary therapies focus on the biological, psychological, social and spiritual integration and evoke healing by an individual, or between two individuals (Dossey, Keegan, Guzzetta, & Kolkmeier, 1995). The term complementary implies a modality is used in conjunction with conventional therapy, as one complements the other. Examples of complementary therapies in this study include but are not limited to: spiritual healing, relaxation techniques, imagery, acupuncture, therapeutic touch, herbal therapy, macrobiotic diet, and homeopathy.

The Workshop on Alternative Medicine (1994), which presented recommendations to the National Institute of Health (NIH) on complementary therapies, categorized complementary therapies into seven broad fields of practice. The fields of practice grouped similar therapies together on the basis of the type of treatment(s) offered by the practitioner. Perhaps these seven broad fields of practice will lend consistency to terms and definitions when discussions take place regarding complementary therapies. The fields

of practice presented by the NIH included the following categories. Mind-Body Interventions are modalities that make use of the extraordinary interconnectedness of the mind and body and power of each to affect the other, and includes therapies such as relaxation, and imagery; Bioelectromagnetics refers to the interaction of living organisms and the electromagnetic fields, and includes thermal and nonthermal applications of nonionizing radiation; Manual Healing Methods are therapies that rely on the practitioner's hands to assess information from and to treat an individual, involving physical touch, pressure, movement, and use of the biofield (or energy field) and includes therapies such as chiropractic manipulation, massage, and therapeutic touch; Pharmacological and Biological Treatments include an assortment of drugs and vaccines that have not been accepted by conventional medicine practitioners, such as cartilage products, and chelation therapy; Diet and Nutrition include diet supplementation with vitamins and minerals, and specific diets such as vegetarian and macrobiotic; Alternative Systems of Medical Practice are those health care systems which do not adhere to the mainstream biomedicine practiced in the U. S., such as acupuncture, and homeopathy; Herbal Medicine includes the use of various plants for medical treatment.

For the purposes of this study, complementary therapies were defined as those therapies not widely practiced in U.S. hospitals or taught in conventional medical schools. Fields of practice were defined as broad categories, using the NIH categories as a model, which grouped similar therapies identified in this study. Six fields of practice were established and

included: mind-body interventions (spiritual healing, relaxation techniques/imagery/yoga, hypnosis, therapeutic audio and video tapes), energy balancing (therapeutic touch), manual healing methods (exercise, massage, osteopathic manipulation, chiropractic manipulation, therapeutic spa, wrap massage with liquid medication), pharmacological and biological treatments (international medications not available in the U.S.), diet and nutrition (lifestyle diets, herbal therapy or vitamins), and alternative medical systems (acupuncture or acupressure, homeopathic practitioners).

Type of cancer. Cancers are defined as having "the properties of uncontrolled growth of cells derived from normal tissues, and of being able to kill the host by the spread of cells from the site of origin to distant sites or by local spread" (Taber's Cyclopedic Medical Dictionary, 1993, p. 297). Research, trends, and statistics discuss and characterize cancer mortality, morbidity and survival rates by cancer sites based on origin of the cancer.

Type of cancer refers to the organ in which the cancer originated.

While cancer can affect any human organ, this study limited the definition of cancer to the four most common types: breast, lung, colo-rectal and prostate, affecting elderly patients 65 years of age and older.

Breast cancer is a disease of the glandular epithelium, and includes carcinoma of the mammary ducts, infiltrating carcinoma, carcinoma of the mammary lobules, and sarcoma of the breast. Lung cancers arise from the epithelium of the respiratory tract and include the broad headings of squamous cell, adenocarcinoma, small cell carcinoma, and large cell carcinoma (McCance & Huether, 1994). Colo-rectal cancer includes tumors

of the right colon, left colon, or rectum, and most commonly are adenocarcinomas (Murphy et al., 1995). Prostate cancer is the most common cancer among males in the United States (Murphy et al., 1995). Most prostate cancers occur in the periphery of the prostate gland, and more than 95% of prostate neoplasms are adenocarcinomas (McCance & Huether, 1994).

Cancer staging. A classification method for cancer must encompass all attributes of the cancer throughout the tumor's existence. Classification is based on the premise that "cancers of similar histology or site of origin share similar patterns of growth and extension" (Beahrs, Henson, Hutter, & Myers, 1988). Staging of cancer is an evolving science, as many different staging systems have been utilized over the years. Within the last decade, a unified staging system for all primary sites was developed and accepted worldwide. This is the TNM system. Determining the stage of cancer at diagnosis is defined in accordance with the American Joint Committee on Cancer (AJCC) and the TNM classification system. According to the American Cancer Society (1995), TNM classification defines primary tumor size (T), presence and extent of lymph node involvement (N), and distant metastasis (M). This system is based on the biologic concept that a tumor grows locally first, then metastasizes to the regional lymph nodes, and ultimately metastasizes systemically (Scott-Conner, & Christie, 1995). The "T" describes the size and local extent of the primary tumor. As the primary tumor increases in size, local invasion occurs, followed by extension to the regional lymph nodes which drain the area of the tumor (N). Distant

metastasis (M) usually occurs later in the life span of the cancer.

The AJCC system divides all tumors into stages 0 to IV, with mortality rates increasing from one stage to the next. The five stages are described as follows: Stage 0, carcinoma in situ; Stage I, localized carcinoma; Stage II, limited local extension or limited regional lymph node metastases, or both; Stage III, more extensive local extension or regional lymph node metastases; Stage IV, distant metastases (Scott-Conner, & Christie, 1995).

While TNM staging is used for all cancers, prostate and colo-rectal cancer each have an additional staging/grading system that is used. Prostate cancer is also graded according to the Gleason's grading system. This system is based on the tumor's glandular differentiation and growth pattern. Scores range from 2 to 10, and assist in predicting associated lymph node metastases. The Dukes system of staging is used in addition to TNM for colo-rectal cancer. This involves a grading of "A" which relates to TNM stage I (tumor invades submucosa), to "D", relating to TNM stage IV (distant metastasis).

The primary reason for determining the stage of cancer is to allow clinicians to accurately describe the extent of disease. Staging assists in the selection of optimal conventional treatment and planning for an individual with cancer. Staging also assists in the evaluation of treatment modalities, evaluates the outcome of treatment, and estimates the prognosis, as there is a strong correlation between stage of cancer and survival (Scott-Conner, & Christie, 1995). From a patient's perspective, the stage of cancer and

hopes of survival may determine the treatment modalities chosen. For instance, a patient with a Stage 0 or I, with a good prognosis, may choose to augment the conventional treatment by actively participating in and utilizing complementary therapies. Patients with a more advanced cancer, Stage IV, may feel the need to utilize other therapies, in hopes of improving ones prognosis. Staging, in this study, related to severity of cancer, which may impact an individual's decision to use complementary therapies, and consists of Stage 0 through Stage IV.

Conceptual Model

Martha Rogers' conceptual model of nursing, referred to as the Science of Unitary Human Beings, will be applied to the use of complementary therapies by elderly patients with cancer. This model clearly reflects a holistic view of the person and environment which are conceptualized as irreducible, indivisible wholes. The Rogerian model is concerned with patterns of the human and environmental energy fields that are associated with maximum well-being, defined by the individual, and is attentive to the "evolution of change in the direction of wherever human beings think they are going" (Fawcett, 1995, p. 382).

The four basic building blocks of Rogers' model, (energy fields, openness, pattern and pandimensionality), together with the principles of homeodynamics, (helicy, resonancy, and integrality), describe the life process in man and postulates a way of perceiving unitary human beings (Figure 1). The broken lines represent openness and display the continuous and mutual process of the environmental and human energy field.

Rogers proposed that "human beings are dynamic energy fields integral with environmental fields. Both human and environmental fields are identified by pattern and characterized by a universe of open systems" (Marriner-Tomey, 1994, p. 213). Energy fields, both human and environment, are irreducible and indivisible wholes, differentiated by pattern. Pattern is an abstraction that cannot be seen, yet can be observed through its manifestations. Manifestations of pattern, (complementary therapies), represent expressions of the unique relationship of individual human beings

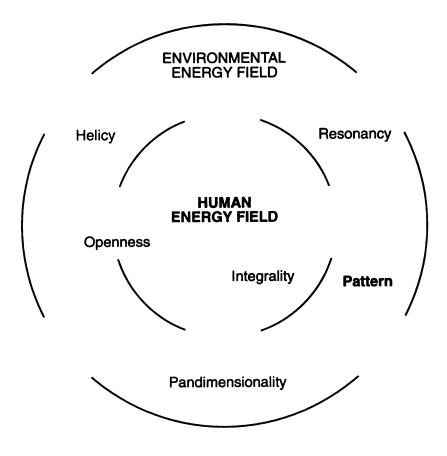


Figure 1. The Science of Unitary Human Beings, adapted from Lutjens (1991) version of Martha Rogers' conceptual model of nursing.

and their environment, and signify the mutual process of the human and environmental energy fields (Lutjens, 1991). Pattern is in bold in Figure 1 and Figure 2, to depict manifestation as the actual use of complementary therapies. Carboni (1991) explains that according to Rogers, humans are sentient, thinking beings who knowingly participate in change. There is active participation in the patterning of ones' field and in reorganizing the environment in accordance with ones' desires. This is accomplished through self-awareness and awareness of the environment. Human beings and their environmental fields are in continuous, mutual process and are always open; they evolve and continuously change at the same time.

According to Rogers (1992), "the purpose of nursing is to promote health and well-being for all persons wherever they are. The art of nursing is the creative use of the science of nursing for human betterment" (p. 28). Marriner-Tomey (1994) explains that according to Rogers "the primary concern for nursing is to view the person as an irreducible, indivisible, pandimensional whole" (p. 216). Within this model, nursing's concern lies with the well-being of the human person in process with his or her universe, and aspires to understand the nature of human evolution and its multiple unpredictable potentialities (Carboni, 1991). As human beings and their universe are in process, so too is knowledge, which cannot remain static. Imaginative and innovative modalities need to be implemented that reflect the rhythmic nature of change and creative emergence of pattern manifestations of the whole.

In applying Rogers' model to this study, one of the basic building

blocks, patterning, is represented by complementary therapies. The principles of homeodynamics and the other three building blocks are schematically reflected in Figure 2, which, by the broken lines, illustrates the two fields as open systems, integral, continuous and in mutual process at all times. While all the building blocks are important to the model, they are not the focus of this study.

The selection and use of complementary therapies depicts a patient's active participation in patterning toward optimum health potential, or human betterment. Patients knowingly participate creatively in the ever-changing process of life, which is a process that is continuously innovative. The Rogerian model emphasizes the use of non-invasive therapeutic modalities to assist patients in designing ways to fulfill their unique rhythmic patterns. Examples of such modalities include therapeutic touch, imagery, and exercise.

The continuous and mutual process of the human and environmental energy fields, together with the use of complementary therapies, is schematically described in Figure 2. The human energy field is the elderly patient with cancer, and the associated stage of cancer. The environmental energy field is the various complementary therapies a patient may chooses to enfold patterning toward harmony, maximum well-being, and therefore human betterment. The two fields are open systems, integral, continuous, and in mutual process at all times, which are depicted by the broken lines.

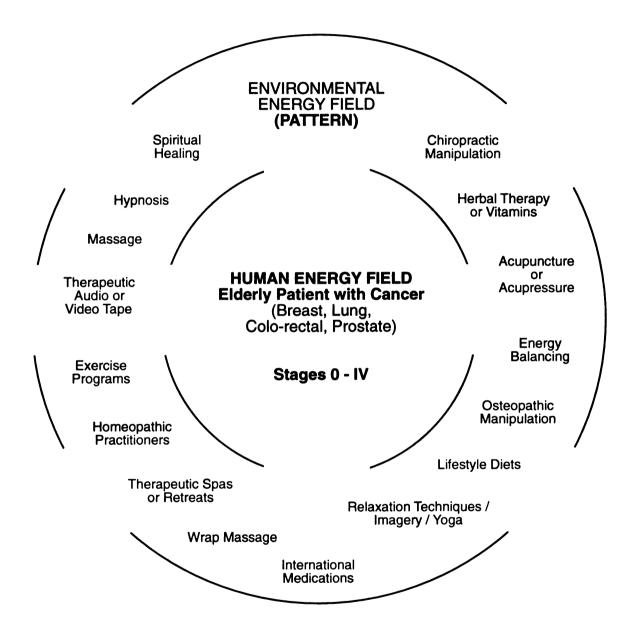


Figure 2. The continuous and mutual process of the human (elderly patient with cancer) and environmental (complementary therapies) energy fields, adapted from Martha Rogers' framework (Fawcett, 1995).

REVIEW OF LITERATURE

Unconventional/complementary therapies are being used by many people throughout the U.S. for various health problems (Eisenberg et al., 1993). The literature refers to these therapies as "unconventional", however as stated earlier in this paper, "complementary" was the term used in this paper. Therefore, for purposes of this review of literature, the terms unconventional, questionable, and complementary are synonymous.

There is a scarcity of studies that examine the use of complementary therapies among the elderly patient with cancer, or relate type and stage of cancer to use of specific complementary therapies. A recurrent topic in the literature review was type and extent of complementary therapies selected for use by patients with cancer (Cassileth et al., 1984; Downer et al., 1994; Lerner & Kennedy, 1992).

Four of the studies reviewed examined survival rates or effectiveness of complementary therapies when specific treatment regimens, selected by the researchers, were used by patients with cancer (Baider, Uziely, & De-Nour, 1994; Bagenal, Easton, Harris, Chilvers, & McElwain, 1990; Cassileth et al., 1991; Troesch, Rodehaver, Delaney, & Yanes, 1993). Fewer studies examined type of complementary therapies selected and used by patients with cancer, without limit to specific treatment regimens (Cassileth et al., 1984; Downer et al., 1994; Lerner & Kennedy, 1992).

Type and Extent of Complementary Therapy Use

Eisenberg et al. (1993) identified the overall prevalence, cost and patterns of use of unconventional therapy in the U.S. Telephone interviews were conducted with 1,539 English-speaking adults 18 years of age and older, (67% overall response rate among eligible respondents), of which 34% were age 50 and older. Results revealed that one in three respondents (34%) used at least one unconventional therapy. Among all the conditions studied, the frequency of use of complementary therapies for cancer and tumors was 24%. Relaxation techniques, chiropractic therapy, and massage were the unconventional therapies used most often.

Many studies examined the type and extent of complementary therapies used by patients with cancer. Cassileth et al. (1984) conducted interviews with 660 patients with cancer to identify the nature and specifics of unconventional cancer treatments, and the reasons why patients seek unconventional treatments for cancer. Patients ranged in age from 18 to 92 years, with a median age of 57 years. Of the 660 patients, 282 (42%) used conventional therapy only, 325 (49%) used conventional and complementary therapies, and 53 (8%) used only complementary therapies. The clinical characteristics of those patients who used conventional and complementary therapies, revealed that 6% had lung cancer, 32% had breast cancer, 10% had genitourinary cancer, and 11% had gastrointestinal cancer. The most common therapies identified were metabolic therapy, diet therapies, megavitamins, mental imagery, spiritual or faith healing, and immune therapy.

Similarly, Downer et al. (1994) conducted a study to determine what proportion of oncology patients receiving conventional therapy also used complementary therapy, what therapies were used, and the patients' motivation for seeking complementary therapies. A total of 600 patients were sent a questionnaire, and 69% response rate was attained. The results showed that of the number of patients with cancer who returned the questionnaire, 65 (16%) had used complementary therapies, and revealed a mean age of 50 years. Of these patients, 2% had lung cancer, 6% had breast cancer, 18% had gastrointestinal cancer, and 8% had gynecological cancer, (specific prostate or colo-rectal cancer are not described). Of the 65 patients who used complementary therapies, the most common therapies were healing (65%), relaxation (35%), visualization (34%), diet, all types (26%), and homeopathy (25%). Thirty six (75%) patients used two or more therapies, and one patient used 13 therapies.

In another study, Lerner and Kennedy (1992) reported the results of the ACS's Committee on Questionable Methods national survey which assessed the use of questionable (complementary) cancer therapies. A professional public opinion agency conducted telephone interviews of approximately 36,000 households nationwide. 5,047 patients with cancer were identified, 3,272 of which were living. Results from the Lerner and Kennedy study (1992), revealed that 9% of all patients used at least one complementary therapy in addition to conventional treatment. This may appear to be a small percentage of patients with cancer, however, "it can be reasoned that 9% of the 8 million patients with a history of cancer in

America equals 720,000, which is a very large number" (p. 189). Mind therapies (mental imagery, hypnosis, and psychic healing) were used by 49% of the respondents, diets by 38%, and drugs by 33% of the respondents. Diets were used more by women, mind therapies were favored more by men, and drug therapy was used equally by both sexes (specific percentages are not listed in the study). The use of complementary therapies was reported to be influenced by the length of time a cancer persisted after the diagnosis. Complementary therapies were used by 9.2% of the patients with breast cancer, 8.9% of patients with lung cancer, 8.8% of patients with prostate cancer, and by 8.2% of patients diagnosed with colon cancer.

The literature confirms the use of complementary therapies among patients with cancer in general, ranging from a low of 9% (Lerner & Kennedy, 1992) to a high of 57% (Cassileth et al., 1984). Imagery and diet were identified as the therapies used most often (Cassileth et al., 1984; Downer et al., 1994; Eisenberg et al., 1993; Lerner & Kennedy, 1992). Effectiveness of Complementary Therapies

Several studies were also reviewed that examined specific complementary treatment regimens, selected by the researchers, used by patients with cancer. Troesch et al. (1993) conducted a study to determine if the addition of guided imagery to a standard antiemetic regimen decreased nausea, vomiting and retching occurrence and distress in patients receiving cisplatin chemotherapy. A convenience sample of 28 patients with cancer, aged 33-80 years with a mean age of 63 years, participated in the study.

Results showed that the "patients who participated in guided imagery felt significantly more in control, more powerful, more relaxed, and more prepared than did the control group" (p. 1183). The guided imagery experience did not significantly affect the physiologic outcome of nausea, vomiting or retching, but did affect the patient's perception of the experience.

Baider et al. (1994) examined the effectiveness of progressive muscle relaxation and guided imagery in reducing long-term psychological distress in patients with cancer. A total of 86 patients completed the full six weeks of sessions, with a mean age of 53 years. Type of cancer was not defined in this study, however stage of cancer was identified, and was described as 19.7% stage I, 45.3% stage II, 17.4% stage III, and 17.4% stage IV. Of these patients, 58.3% were currently receiving conventional treatment. Results indicated that 94% of the patients revealed a decrease in their psychological distress.

Cassileth et al. (1991) compared length of survival and quality of life in patients with end stage cancer who received conventional and complementary therapies to patients who received only conventional therapies. A total of 156 patients were enrolled in the study (78 matched pairs), aged 24-81 years (median age of 59). Half the patients in each group had colo-rectal cancer, 35% had non-small-cell lung cancer, 10% had pancreatic cancer, and 6% had melanoma. The treatment regimen consisted of injections of bacille Calmette-Guerin and an autogenous immune-enhancing vaccine, vegetarian diet (75% raw), and coffee enemas. Results

showed no difference in length of survival among the two groups of patients, and quality of life was better in the patients undergoing conventional care, whose quality of life was also better at enrollment.

In one study, the results did not reveal a positive effect or patient outcome from the complementary therapies. Bagenal et al. (1990) compared survival and metastasis-free survival in patients treated at the Bristol Cancer Help Center (BCHC) to patients treated at a specialist cancer hospital and two district general hospitals. The study involved women with breast cancer, and included 334 from BCHC, and 461 women in the control group. In the BCHC group, 98.2% were under the age of 65, and 95.2% were under the age of 65 in the control group. All BCHC patients and control group patients were TNM staged and were similar, being stage I in 56% and 56% respectively, stage II in 16% and 20%, stage III in 25% and 22%, and stage IV in 3% and 2%. The BCHC treatments consisted of a stringent diet of raw and partly cooked vegetables, counseling, and "healing". Results suggested that women attending BCHC fared worse than women receiving conventional therapy alone relative to metastasis-free survival and overall survival.

Studies revealed mixed results on the effectiveness of complementary therapies for patients with cancer. A decrease in psychological distress was revealed by 94% of cancer patients utilizing progressive muscle relaxation (Baider et al., 1994), while Troesch et al. (1993) identified that the addition of guided imagery did not decrease the occurrence of nausea or vomiting during chemotherapy administration.

Summary and Critique of the Literature Review

Review of the literature uncovers the paucity of information on use of complementary therapies among the elderly, and the related use of complementary therapies to stage and type of cancer. The literature does confirm, however, the use of complementary therapies among patients with cancer in general, ranging from a low of 9% (Lerner & Kennedy, 1992) to a high of 57% (Cassileth et al., 1984). The mean age of patients with cancer varied widely from 50 years (Downer et al., 1994) to 63 years (Troesch et al., 1993), with only two studies providing percentages for mean age of patients with cancer (Bagenal et al., 1990; Eisenberg et al., 1993), and one study not identifying the age of the patients with cancer (Lerner & Kennedy, 1992).

Each study had different variations of complementary therapies available to patients with cancer. Although the complementary therapies cited were both diverse and numerous, *imagery* (Baider et al., 1994; Cassileth et al., 1984; Downer et al., 1994; Eisenberg et al., 1993; Lerner & Kennedy, 1992; Troesch et al., 1993) and *diet* (Bagenal et al., 1990; Cassileth et al, 1984, 1991; Downer et al., 1994; Eisenberg et al., 1993; Lerner & Kennedy, 1992) were mentioned most often. Relaxation, vitamins, and spiritual/faith/psychic healing followed in frequency of citing (Baider et al., 1994; Cassileth et al., 1984; Downer et al., 1994; Eisenberg et al., 1993; Lerner & Kennedy, 1992).

Limitations of the studies identified in the literature included the lack of correlation between stage and type of cancer, to use of specific

complementary therapies. Of the three studies that identified cancer type (Cassileth et al., 1984; Downer et al., 1994; Lerner & Kennedy, 1992), none linked cancer type to use of a specific complementary therapy. Stage of cancer was only disclosed in two studies (Bagenal et al., 1990; Baider et al., 1994), of which only one identified the cancer type (Bagenal et al., 1990). Bagenal et al. (1990) related breast cancer to the use of complementary therapies that were offered at the treatment center, and identified the percentage of use by stage of cancer. Cassileth et al. (1991) identified the cancer type, and related it to the specific complementary treatment regimen offered at the center, however stage of cancer was not provided. The limitation of these studies lies in the fact that while complementary therapies were identified, the therapies followed a precise treatment regimen, therefore limiting patient selection of therapies.

The literature revealed that patients with cancer who used complementary therapies often did so without informing their medical doctor. Eisenberg et al. (1993) reported that in more than 7 of 10 instances (72%), users of complementary therapy did not inform their medical doctor of their use of such therapies, compared to Cassileth et al. (1984), which reported that only 25% of patients with cancer using complementary therapies did not inform their physician. Lerner and Kennedy (1992) also revealed that only 27% of patients with cancer did not inform their medical doctor. Despite the diverse results regarding patients with cancer informing their health care provider on their use of complementary therapies, it is evident that patients with cancer are not entirely comfortable with revealing

this information. Perhaps this withholding is due in part to the patient's fear of the provider's reaction to such information, but certainly suggests a deficiency in current patient-provider relations. Therefore, it is vital for the health care provider to initiate dialogue on the use of complementary therapies with patients so as to assure that comprehensive care is provided to all patients.

More often than not, complementary therapies are generalized to patients with cancer and cancer types, but the specific type of therapy employed by cancer site was not identified, nor was the stage of cancer described. More information is needed which specifically cites the spectrum of healing modalities that are used for specific cancers. Studies which identify the complementary therapies used by patients with specific types of cancer would assist health care providers in knowing what therapies they need to be well versed in so they could initiate discussion and provide education to patients with cancer.

Discussion of and Rationale for Proposed Study

Based upon the review of the literature, it is clear that few studies identify the specific complementary therapies used by patients diagnosed with breast, lung, colo-rectal or prostate cancer; however, it is recognized that patients with cancer are using various complementary modalities.

Identification of use patterns, and types of therapies utilized by patients with cancer relative to stage and type of cancer, can assist the APN and other health care providers in successfully managing the health care needs of patients with cancer, and providing a comprehensive plan of care.

Knowledge of complementary therapies utilized by patients with cancer can assist the APN in seeking further education regarding specific modalities. This education is needed so that accurate information can be provided to patients. Patients with a specific type of cancer or specific stage of cancer may only use a certain type of complementary therapy. This may be due to ease of use, familiarity with the therapy, or specific likes or dislikes by the patient.

As previously mentioned, discussion of complementary therapies with a health care provider, is often a sensitive issue for many patients with cancer. This insight is important to this study because the hesitancy may also pertain to answering a self administered questionnaire regarding use of complementary therapies, which may then impact the results. Therefore, the APN who is aware that use of complementary therapies exists among patients with cancer, can more readily facilitate open discussion about such treatments, creating an environment of trust and allowing healing to begin.

METHODS

Research Design

This was a nonexperimental descriptive study, derived from survey research. This study was conducted to determine use of complementary therapies in elderly patients (age 65 and older) receiving conventional medical treatment for breast, lung, prostate, or colo-rectal cancer.

This study was a secondary analysis of elderly cancer patient's responses, who agreed to participate in the Family Home Care for Cancer - A Community-Based Model study (Grant #2 R01 NR/CA01915-03A3),

funded by the National Institute of Nursing Research and the National
Cancer Institute. The original study was initiated in 1993 by Michigan State
University researchers Barbara A. Given, PhD, RN, FAAN, Principal
Investigator, and Charles W. Given, PhD, Co-Principal Investigator.

Selection of Subjects

The subjects (elderly patients with cancer) for this study were selected from the point of intake into the original study (Wave I), and provided a sample size of 587 elderly patients with cancer. Elderly patients with cancer were enrolled in the original study if it was within the first eight weeks of their diagnosis.

Selection criteria for elderly patients with cancer in this study was consistent with the original study. The elderly patients with cancer resided in mid Michigan, and were accepted into the original study if they (1) were 65 years of age or older; (2) had a new diagnosis of either breast cancer, lung cancer, prostate cancer, or colo-rectal cancer, and did not have a cancer treated within the last year; (3) signed a human subject consent form.

Field Procedures and Data Collection

The original study gathered data from two instruments (telephone interview and a self administered questionnaire), and the medical record of the elderly patients with cancer. Interviews were conducted at point of intake into the study after written consent was given, then at 6, 12, 24 and 52 weeks. Also at point of intake, a self administered questionnaire was given to the elderly patients with cancer at their first clinic visit and were

instructed to return the questionnaire via a self-addressed stamped envelope. The information obtained was then entered into a computer database.

Data analyzed for this study was gathered during Wave I of the original study, and was obtained from the telephone interview and self administered questionnaire component of the computerized database.

Sociodemographic information (i.e., sex, age, highest level of education, race, marital status, and household income) was obtained from the telephone interviews, (Appendix A). Type of complementary therapy used was obtained from the self-administered questionnaire entitled "Cancer Therapies" (Appendix B). Type and stage of cancer at diagnosis was obtained from the medical record audit of the elderly patients with cancer.

All data provided was maintained on a computer disk. Complete procedures for the original study are provided in Appendix C.

Protection of Human Subjects

The original study, Family Home Care for Cancer - A Community-Based Model, was approved by the Michigan State University Committee of Research Involving Human Subjects (UCRIHS). Data for this study was provided on a disk. The elderly patients with cancer were entered by identification number only; no names were included, therefore, no association can be made with the elderly patients with cancer of this study. Approval to conduct secondary analysis for this study was obtained by Michigan State University's UCRIHS prior to the initiation of data analysis and is provided in Appendix D.

Instrumentation

Several instruments were used initially to collect the study data. A telephone survey was used to collect sociodemographic data (sex, age, educational level, race, marital status, and household income), which was then entered into a computerized database. Reliability (accuracy) of this instrument was tested by comparing the verbal reports provided by the elderly patient with cancer to that information found in the medical record. Validity was not confirmed, as the information came directly from the elderly patient with cancer. This instrument is in Appendix A.

The Cancer Therapies instrument, developed by G. Wyatt, R.N., Ph.D., used a <u>yes</u> or <u>no</u> answer for use of 16 specific complementary therapies. This instrument had not been used before, and reliability or validity were not measured. While the instrument is not an inclusive list of complementary therapies, most of the therapies listed are consistent with those specified in the literature. This instrument is in Appendix B.

The medical record was utilized to obtain the stage of cancer at diagnosis, based on the pathology report. This information was included in the computerized data base of each patient.

Operational Definitions of the Variables

Complementary therapies. Complementary therapies were defined as therapies not generally available at U.S. hospitals and not considered as standard components of conventional medicine, yet used in combination with conventional therapies. Sixteen complementary therapies were specifically defined for this study in the Cancer Therapies instrument, and

included spiritual healing, relaxation techniques/imagery/yoga, massage, herbal therapy or vitamins, exercise, lifestyle diets, acupuncture or acupressure, energy balancing, therapeutic spas, hypnosis, international medications not available in the U.S., wrap massage with liquid medications, therapeutic audio or videotapes, osteopathic manipulation, homeopathy, chiropractic manipulation, and a blank line for patients to write in other therapies not listed.

The Cancer Therapies instrument instructed elderly patients with cancer to circle <u>yes</u> (positive response), if they had used a particular therapy, and to circle <u>no</u> (negative response), if they had not used or were unfamiliar with the therapy. This information was then coded as 1 (<u>yes</u>) or 2 (<u>no</u>) for analysis of frequency of complementary therapy use. Combinations of complementary therapies were defined as an elderly patient with cancer circling "yes" to more than one therapy on the questionnaire.

Type of Cancer. Type of cancer was limited to the four most common sites: breast, lung, colo-rectal and prostate. This information was obtained from the original study's data base.

Cancer Staging. Stage of cancer at diagnosis was defined in accordance with the AJCC staging system utilizing the TNM, Gleason's and Dukes classification system. This information becomes a permanent part of the patient's medical record. Stages were identified as Stage 0, Stage I, Stage II, Stage III, or Stage IV. This information was obtained from the original study's data base.

Research Assumptions

It was assumed that data collected was accurately entered into the data base. It was assumed that the data for this study was accurately and thoroughly extracted from the original study. It was also assumed that all eligible participants were included in the data base for this study. It is further assumed that subjects understood the instructions and the types of complementary therapies listed on the questionnaire.

Research Limitations

Several research limitations are recognized for this study. One limitation is in working with secondary data, it is not possible to contact participants for clarification to responses or missing information, therefore some questions may go unanswered. It is also not possible to extrapolate additional information, as one can only work with the information contained within the limited data set. This study was limited to elderly patients with cancer who resided in mid Michigan, and therefore the findings may not be representative of the general population of elderly patients with cancer. It is also recognized that the number of elderly patients with cancer may vary significantly by type and stage of cancer. The Cancer Therapies instrument had several limitations: (1) reliability and validity was not established prior to using the instrument or prior to analysis of the data; (2) definitions or descriptions of the therapies were not included, therefore therapies may have been interpreted differently by the elderly patients with cancer; (3) the instrument did not inquire if the elderly patient with cancer used the therapy(s) prior to the cancer diagnosis; (4) frequency of use of therapy was not established; (5) effectiveness of therapy was not assessed; (6) the title of the instrument, Cancer Therapies, may indicate these therapies are only used with cancer; (7) not all therapies were listed individually, therefore exact therapy utilized was questionable.

Data Analysis Plan

Frequencies, percentages, mean and standard deviation were calculated for sociodemographic data as appropriate to the level of measurement of the variable.

Question 1: What proportion of elderly patients with cancer receiving conventional medical treatment also used complementary therapies?

Frequency and percents were calculated to answer this question.

Question 2: What are the most frequently used complementary therapies among all elderly patients with cancer who use them? What are the most commonly occurring combinations of therapies? Combinations of therapies were obtained if the elderly patient with cancer reported using more than one therapy. Percentages were calculated and rank ordered from most frequent to least frequent to answer this question.

Question 3: Are there differences in combinations of complementary therapies which are most often used by elderly patients with one of four types of cancer: breast, lung, colo-rectal or prostate? Crosstabulation between type of cancer and combinations of complementary therapy (4 x 29 table) with chi-square analysis was performed to determine any statistically significant differences. The level of statistical significance was established a 0.05.

Question 4: Are there differences in use of complementary therapies among elderly patients with different stages of cancer? Crosstabulation between subjects who used and did not use complementary therapies and the four stages of cancer (2 x 4 table) with chi-square analysis was performed to determine any statistically significant differences. The level of statistical significance was established at 0.05.

Research Hypotheses

Two research hypotheses for this study are derived from research questions three and four respectively.

- (1) There are differences in combinations of complementary therapies used by elderly patients with different types of cancer.
- (2) There are differences in use of complementary therapies by elderly patients with different stages of cancer.

RESULTS

Description of Sample

The sample consisted of 587 elderly patients with cancer, with a mean age of 72 years ($\underline{SD}=5.28$). Slightly more than half were male (53.2%, $\underline{n}=312$). Over nine-tenths (93.3%, $\underline{n}=544$) of the sample was comprised of Caucasian patients, with close to three quarters having a high school education or greater. Slightly more than half (64.1%, $\underline{n}=332$) reported being married. Only 57.9% ($\underline{n}=340$) of the sample reported their combined household income, of which 90% reported income of \$44,999 or less (Table 1).

TABLE 1

Characteristics of Sample (N = 587)

Characteristic	n	%	
Sex			
Female	275	46.8	
Male	312	53.2	
Age (year)			
64 - 70	242	45.0	
71 - 75	161	29.9	
76 - 80	97	18.0	
81 - 85	29	5.3	
86 - 89	6	1.1	
<u>></u> 90	4	0.7	
Missing	48	- 1	
Race			
Caucasian	544	93.3	
African American	34	5.8	
Hispanic	2	0.3	
Native American	2	0.3	
Asian Pacific	1	0.2	
Missing	4	5.2	
Level of Education			
No formal education	1	0.2	
Grade school	38	7.2	
Some high school	119	22.6	
H.S. diploma	161	30.6	
Some college	121	23.0	
College degree	52	9.9	
Graduate degree	25	4.8	
No answer	9	1.7	
Missing	61	1.7	
Marital Status			
Never married	17	3.3	
Married	332	64.1	
Widowed	36	6.9	
Divorced/Separated	133	25.7	
Missing	69	25.7	

(Table continues)

Table 1 (cont'd.)

Characteristic	<u>n</u>	%	
Combined Household Inco	me		
\$0 - 14,999	98	29.0	
\$15,000 - 29,999	145	42.6	
\$30,000 - 44,999	64	18.8	
\$45,000 - 59,999	17	5.0	
\$60,000 - 79,999	6	1.7	
≥ \$80,000	10	2.9	
Missing	247		

Those elderly patients with cancer who used complementary therapies (22.8%, $\underline{n}=134$), were demographically similar to the overall group except for gender. Slightly more than half of the elderly patients with cancer using complementary therapies were female (55.2%, $\underline{n}=74$), compared to the overall group in which the majority were male (53.2%, $\underline{n}=312$).

Prostate cancer, the most frequent cancer reported (31.7%, \underline{n} = 186), was followed closely by breast cancer (28.1%, \underline{n} = 165; Table 2).

TABLE 2

Frequency and Percent of Site of Cancer (n = 587)

Site of Cancer	<u>n</u>	%	
Prostate	186	31.7	
Breast	165	28.1	
Lung	138	23.5	
Colo-rectal	98	16.7	

Of all cancers staged ($\underline{n} = 244$), Stage II was most frequently reported (39.2%, $\underline{n} = 96$; Table 3).

TABLE 3

Frequency and Percent of Stage of Cancer by Site (n = 244)

			(Stage	-		
Site of Cancer	1	11		III		IV	
	<u>n</u> %	n	%	n	%	<u>n</u>	<u>%</u>
Breast	36 14.7	11	4.5	8	3.3	1	0.4
Lung	10 4.1	15	6.1	31	12.7	11	4.5
Colo-rectal	4 1.6	16	6.5	12	5.0	2	8.0
Prostate	21 8.6	54	22.1	10	4.1	2	0.8
Total	71 29.1	96	39.3	61	25.0	16	6.6

Answers to Research Questions

Question 1: What proportion of elderly patients with cancer receiving conventional medical treatment also used complementary therapies?

Of the 587 elderly patients with cancer, 22.8% ($\underline{n}=134$) used complementary therapies with conventional treatment.

Question 2: What are the most frequently used complementary therapies among all elderly patients with cancer who use them? What are the most commonly occurring combinations of therapies?

The three most frequently used complementary therapies among elderly patients with cancer were exercise programs (52.2%, $\underline{n}=70$), herbal therapy/vitamins (35.1%, $\underline{n}=47$), and spiritual healing (20.1%, $\underline{n}=27$); Table 4). These therapies are categorized under manual healing

methods, diet and nutrition, and mind-body interventions respectively.

Some therapies had little or no reported use notably energy balancing,

Rank Order of Complementary Therapies by Frequency of Use (n = 134)

nerapy	<u>n</u>	%
Exercise	70	52.2
Herbal therapy/vitamins	47	35.1
Spiritual healing	27	20.1
Massage	14	10.4
Chiropractic manipulation	13	9.7
Diets	9	6.7
Other therapies	9	6.7
Relaxation/imagery/yoga	7	5.2
Therapeutic audio/video tapes	6	4.5
Acupuncture/acupressure	1	0.7
Homeopathic practitioner	1	0.7
Osteopathic practitioner	1	0.7
Energy balancing		
(therapeutic touch)	0	0.0
Hypnosis	0	0.0
International medications	0	0.0
Spas	0	0.0
Wrap massage with liquid		
medication	0	0.0

acupuncture or acupressure, homeopathic practitioner, osteopathic manipulation, hypnosis, international medications, spas, and wrap massage with liquid medications.

A total of 41 elderly patients with cancer (30.6%) of the sample using complementary therapies, reported using more than one complementary therapy. Of those, 56% ($\underline{n}=23$) used a combination of two therapies, 22% ($\underline{n}=9$) reported using three therapies, 15% ($\underline{n}=6$) reported using four

therapies, and 7% ($\underline{n} = 3$) reported using five therapies.

The most frequently used double combination was herbal therapy/vitamins and exercise programs, used by 26% ($\underline{n}=6$) of the total number who reported using a combination of two therapies (Table 5).

TABLE 5

Most Frequently Used Combinations of Complementary Therapies

Combination of 2 therapies ($\underline{n} = 23$)	n	%	
Herbal therapy or vitamins/exercise program	6	26.0	
Spiritual healing/herbal therapy or vitamins	4	17.4	
Spiritual healing/exercise program	3	13.0	
Massage/exercise program	3	13.0	
Spiritual healing/chiropractic			
manipulation	1	4.3	
Massage/chiropractic manipulation	1	4.3	
Spiritual healing/massage	1	4.3	
Exercise program/diets	1	4.3	
Relaxation, imagery, yoga/			
herbal therapy or vitamins	1	4.3	
Exercise/chiropractic manipulation	1	4.3	
Spiritual healing/audio, video tapes	1	4.3	

The most frequently reported triple combination was herbal therapy/vitamins, exercise programs, and diet used by 33.3% ($\underline{n}=6$) of the total number who reported using more than two therapies. This combination was obtained by reviewing the responses of those using three or more therapies. The three therapies which occurred most frequently within these combinations were herbal therapy/vitamins, exercise programs, and diet. Results thus indicated a trend, or pattern, toward using a combination of these three complementary therapies.

Question 3: Are there differences in combinations of complementary therapies which are most often used by elderly patients with one of four types of cancer: breast, lung, colo-rectal or prostate?

Results indicated that elderly patients with cancer did use combinations of complementary therapies; however, few dominant combinations were identified. This resulted in a very small sample size per combination for each type of cancer, which then did not provide a meaningful analysis. A pattern was not identified among combinations of complementary therapies and type of cancer. Therefore, this question as proposed, was not able to be answered. The hypothesis that there are differences in combinations of complementary therapies used by elderly patients with different types of cancer was unable to be answered due to insufficient data.

Question 4: Are there differences in the use of complementary therapies among elderly patients with different stages of cancer?

While elderly patients with different stages of cancer did report using complementary therapies, chi-square analysis did not reveal a statistically significant difference between use of therapies and stage of cancer (Table 6). When data was obtained for this study, staging information was not available for all subjects, accounting for the difference between total sample ($\underline{n} = 587$) and sample with stage of cancer identified ($\underline{n} = 244$). The hypothesis that there are differences in use of complementary therapies by elderly patients with different stages of cancer, was not supported by the data in this study.

TABLE 6

Crosstabulation and chi-square: Use of Complementary Therapies by Stage of Cancer

				Stag	ge			
				11		III	1	
	<u>n</u>	%	n	%	n	%	n	%
Used Therapi	es							
Yes	15	6.1	18	7.4	12	4.9	3	1.2
No	56	23.0	78	32.0	48	19.7	14	5.7

$$\chi^{2}(3, \underline{n} = 244) = 0.195, \underline{p} > 0.05$$

DISCUSSION

Interpretation of the Findings

Complementary Therapies. In this retrospective descriptive study, a total of 587 elderly patients with cancer, age 65 years and older residing in mid Michigan, were questioned regarding their use of complementary therapies. From this sample, 22.8% expressed using one or more complementary therapies. This percentage of use, while not extremely large, is consistent with the literature, which identified 9% (Lerner & Kennedy, 1992) to 57% (Cassileth et al., 1984) of patients with cancer using complementary therapies.

This study identified a slightly older population using complementary therapies (mean age of 72 years) than what the literature revealed, with a mean age of 50 years (Downer et al., 1994) to 63 years (Troesch et al., 1993). The sample in this study was restricted to elderly patients with cancer 65 years of age and older. A broader and larger sample, without limit

to age, may have resulted in a larger number of patients with cancer using complementary therapies, which may have resulted in more statistically significant findings. Eisenberg et al. (1993) has reported the use of complementary therapies to be most common among people 25 to 49 years of age. This finding may be attributed to the different attitudes, beliefs, and values commonly found within different generations.

The primary users of complementary therapies in this study were female (55.2%), which is consistent with much of the literature (Baider et al., 1994; Cassileth et al., 1984; Downer et al., 1994; Lerner & Kennedy, 1992). However, Cassileth et al. (1991) and Eisenberg et al. (1993) identified males as the primary users of complementary therapies, and Troesch et al. (1993) did not identify the gender of the participants.

One can only speculate on the reasons that only 22.8% of the sample used complementary therapies. Age of the patients with cancer may have been a significant factor in the low usage rates. As Eisenberg et al. (1993) identified, complementary therapies are more common among the baby boomers, than among the elderly. Factors such as age of the individual, availability of complementary therapies, lack of educational resources related to complementary therapies, cultural acceptance, coverage by health insurance plans, opinions of family and friends, and lack of a clear understanding of complementary therapies or instructions related to the questionnaire, may have influenced the low usage results. The fact that the questionnaire was administered at the patient's first clinic visit, which was within eight weeks of a cancer diagnosis, may have contributed to the low

reported use of complementary therapies. Perhaps enough time had not elapsed for the elderly patient with cancer to begin considering using such therapies. They may still have been contemplating the meaning of a cancer diagnosis, how this would affect their life, how would they and the cancer respond to treatment, and so forth. Many questions and issues surface with the diagnosis of cancer, and consideration of using complementary therapies may not be the most prevalent issue. Lerner and Kennedy (1992) identified that the use of complementary therapies was strongly influenced by the length of time that a cancer persisted after diagnosis.

The elderly patients with cancer who reported using complementary therapies, may have been using these therapies prior to the cancer diagnosis (exercise and diet for example), and not necessarily after they had been diagnosed with cancer. Perhaps some elderly patients with cancer were unaware that these therapies could be used with conventional treatment.

As previously mentioned in the literature, patients are not entirely comfortable with discussing or informing their health provider of their use of complementary therapies (Cassileth et al., 1984; Eisenberg et al., 1993; Lerner & Kennedy, 1992). While this study did not address this issue, this point should be considered as a possible contributing factor in low reported use of complementary therapies. In addition to this, perhaps the health care providers had not introduced the use of complementary therapies to the elderly patient with cancer.

Exercise (52.2%), herbal therapy/vitamins (35.1%), and spiritual healing (20.1%) were identified in this study as the top three therapies

utilized, unlike the literature which identified *imagery* (Baider et al., 1994; Cassileth et al., 1984; Downer et al., 1994; Eisenberg et al., 1993; Lerner & Kennedy, 1992; Troesch et al., 1993) and *diet* (Bagenal et al., 1990; Cassileth et al, 1984, 1991; Downer et al., 1994; Eisenberg et al., 1993; Lerner & Kennedy, 1992) as most frequently mentioned. Exercise was only reported in one study (Eisenberg et al., 1993), and for those respondents who used exercise, details about this use were not described. Perhaps, to some researchers, exercise is not truly considered a complementary therapy, as more and more people are incorporating exercise in their lifestyle routine.

The inconsistent findings related to the most frequently used complementary therapies may be a result of the different "lists" of therapies used in various studies. It is evident from the various findings, that patients can choose from an assortment of complementary therapies that are available. Age of the patients with cancer may also have been a factor, in that other therapies may not be personally, culturally or socially accepted, or they may be viewed as "new age". Exercise, herbal therapy/vitamins, and spiritual healing may be more readily accepted as complementary therapies, as these appear more "traditional" and socially acceptable. Some therapies (energy balancing, hypnosis, international medications, spas, and wrap massage) were not used at all, perhaps because the therapies were not available in the patients geographic area, or the patient was not aware of the therapy or its use. As each patient is unique, with different attitudes, beliefs and values, so to are their choices for healing, which must be respected.

Of all the individual therapies reported by elderly patients with cancer in this study, the majority were categorized under manual healing methods, which included exercise, massage, chiropractic manipulation, and osteopathic practitioner. Other complementary therapies used by the elderly patients with cancer fell under the categories of (a) diet and nutrition, which contained herbal therapy/vitamins, and diet; and (b) mind-body interventions consisting of spiritual healing, relaxation/imagery/yoga, and therapeutic audio/video tapes. This finding suggests that elderly patients with cancer, in this study, prefer complementary therapies from within these three different fields of practice.

The self administered Cancer Therapies instrument grouped some therapies together, such as herbal therapy or vitamins; relaxation techniques/imagery/yoga; acupuncture or acupressure. This grouping made it difficult to ascertain which therapy the elderly patient with cancer admitted to using. This raises the issue regarding herbal therapy/vitamins as being the second most frequently used complementary therapy. One must question whether the elderly patient with cancer used herbal therapy, vitamins, or both when selecting this response. If the answer was for vitamins, it was not known if that meant taking a multi-vitamin once a day (as many elderly people do), or using megavitamins in hopes of treating or curing one's cancer. One must question the rationale behind this answer in response to the therapy in question.

Combinations of Therapies. Of the elderly patients with cancer who used complementary therapies, the majority (69.4%, $\underline{n}=93$) used only one

therapy. However, the use of two or more therapies was reported by some elderly patients with cancer. Combinations of therapies, use in general and specific to type of cancer, are not detailed in the literature. The literature does, however, refer to patients using more than one therapy. Downer et al. (1994) reported 75% of patients with cancer used two or more therapies, Eisenberg et al. (1993) reported 34% used at least one or more therapies, and Lerner and Kennedy (1992) reported use of at least one complementary therapy (percentage not detailed). Consistent with the literature, this study uncovered that of those elderly patients with cancer using complementary therapies, 30.6% ($\underline{n} = 23$) used two or more. This low reported usage may be due to several factors. Perhaps the elderly patients with cancer were not aware of what the listed therapies were, as there was not an explanation/definition given for each therapy. They may not have been knowledgeable of other therapies, due to lack of discussion about complementary therapies with their health provider. Also, as mentioned earlier, use of complementary therapies is influenced by the length of time that has passed after diagnosis (Lerner & Kennedy, 1992). Perhaps enough time had not elapsed for the elderly patient with cancer to begin thinking about using complementary therapies, as the questionnaire was administered within eight weeks of diagnosis.

The therapies used in combination were both similar yet diverse among those elderly patients with cancer who reported using more than one therapy. Of those combinations that were most frequently reported (double and triple combinations), there were similarities in the therapies identified.

Each combination was a different blend of the most common single therapies of exercise, herbal therapy/vitamins, and spiritual healing. The most frequently reported triple combination, however, was herbal therapy/vitamins, exercise programs, and diet used by 33.3% ($\underline{n}=6$) of the total number who reported using more than two therapies. This combination is not surprising, as diet and exercise often go hand in hand. Similar to diet, is the use of herbal therapy/vitamins, which again, often join a diet regimen. Since there was not a common definition given for each of these therapies, the elderly patients with cancer may have interpreted these therapies as part of their every day routine: taking a vitamin in the morning, using herbs in meal preparation, getting some exercise, and watching what they eat.

The complementary therapies used in combination were primarily selected from three fields of practice: mind-body interventions, manual healing, and diet and nutrition. Elderly patients with cancer who use more than one complementary therapy, may be amenable to other therapies from within the same field of practice. Knowing the different therapies included in each field of practice, furnishes health care providers with an assortment of therapies to offer and suggest to elderly patients with cancer.

Type of Cancer. Little can be said about the relationship between type of cancer and use of combinations of therapies by elderly patients with different types of cancer. Because of the small sample size per combination for each type of cancer, neither a pattern nor a dominant combination was identified. This finding may indicate that elderly patients with cancer choose therapies that are readily available to them, based on the recommendation

from a family member or friend, or ones they are familiar or comfortable with.

Stage of Cancer. When data were obtained for this study, staging information was not available for all the elderly patients with cancer, accounting for the different sample totals between site of cancer ($\underline{n}=587$) and stage of cancer ($\underline{n}=244$). Chi-square analysis did not reveal a statistically significant difference between use of complementary therapies and stage of cancer, indicating these two variables were independent. The distribution between using and not using complementary therapies were similar across stages I, II, and II, however that was not the case in stage IV, largely due to a much smaller sample size ($\underline{n}=16$) than the other stages (Table 3). The hypothesis that there are differences in use of complementary therapies by elderly patients with different stages of cancer, was not supported by the data in this study.

Discussion of Results with the Conceptual Model

While the general use of complementary therapies by patients with cancer support Martha Rogers' Science of Unitary Human Beings model, the results of this study did not fully support the adapted conceptual model. The use of complementary therapies was reported by 22.8% ($\underline{n}=134$) of the elderly patients with cancer, suggesting that the predominant pattern (the emphasized building block for this study) for 77.2% ($\underline{n}=453$) of the elderly patients with cancer, was depicted by the exclusive use of conventional therapy. Differences in combinations of complementary therapies most often used by elderly patients with different types of cancer, was unable to be

determined in this study, and results did not reveal a statistically significant difference between stage of cancer and use of complementary therapies.

Based on the findings of this study, several changes to the adapted conceptual model are necessary. The environmental energy field represents the various therapies an elderly patient with cancer chooses, to enfold patterning toward harmony and maximum well-being. Therefore, this field should include the conventional therapies of surgery, chemotherapy, and radiation therapy; the most frequently used complementary therapies of exercise, herbal therapy or vitamins, and spiritual healing; as well as all the other complementary therapies that can be introduced to elderly patients with cancer. These therapies assist individuals in designing ways to fulfill their unique rhythmic patterns. The human energy field should be represented by the elderly patient with cancer, eliminating the constraints of type and stage of cancer.

These changes in the adapted conceptual model would more accurately reflect the selection and use of conventional and/or complementary therapies (environmental energy field), by the elderly patient with cancer (human energy field), portraying the patient's active participation in patterning toward maximum well-being. Specific therapies can be viewed as a manifestation of pattern, which represents an expression of the relationship of individuals and their environment, and symbolizes the mutual process of the human and environmental energy fields (Lutjens, 1991).

Implications for Advanced Practice Nursing in Primary Care

The two major findings of this study were that some elderly patients with cancer used complementary therapies, and the most frequently used complementary therapies were exercise, herbal therapy/vitamins, and spiritual healing. While the segment of elderly patients with cancer who used complementary therapies was small (22.8%), these patients deserve to be recognized, and their decision to use complementary therapies needs to be respected. As the incidence of cancer continues to rise, especially when an individual reaches 60 to 79 years of age (Parker et al., 1996), it can be expected that APNs practicing in primary care, will provide care to these patients. The APN who is aware that these complementary therapy practice patterns exist among elderly patients with cancer, can more readily facilitate open discussion about such treatments, creating an environment of trust and allowing healing to begin.

Recognizing that there are elderly patients with cancer who utilize complementary therapies, the APN must first become educated about such therapies so as to provide accurate information to patients. Complementary therapies which require in-depth knowledge include exercise, herbal therapy and vitamins, spiritual healing, and lifestyle diets. Knowledge related to these therapies should encompass interventions which are appropriate to the elderly population such as (a) exercise behavior; creative movement plans; and exercise as a social activity; (b) current "popular" herbs highlighted in health oriented magazines; vitamin requirements for the elderly; antioxidant vitamins A, C, and E; (c) distinctions between spirit, spirituality, and religion;

assessment of spirituality; and (d) nutrient requirements of the elderly; macrobiotic and vegetarian diets. Potential benefits and risks (such as toxic levels of fat soluble vitamins or certain herbs; vitamin or nutrient deficiencies) of each therapy are critical for the APN to understand, in order to provide accurate information to patients, and assessment of therapies used by the elderly patient with cancer. APNs have the responsibility to continuously update their knowledge base and remain abreast of new and current modalities available to patients with cancer, both conventional and complementary.

The APN who is cognizant of the specific complementary therapies that are most often used by elderly patients with cancer, can then offer this information to all patients with cancer. The APN, functioning as an educator, assumes the responsibility of teaching and assisting patients in the recognition of various complementary modalities, and in helping patients make informed health care choices regarding the use of complementary therapies. As many therapies are self selected by the patient, the education must include the potential benefits and risks of the various therapies.

Education may take place as one-on-one interactions with an elderly patient with cancer, or in a support group setting. APNs can facilitate cancer support groups, such as the ACS's <u>I Can Cope</u>, for education about use of complementary therapies, as well as providing an opportunity for patients with cancer to discuss their experiences using complementary therapies.

Education expands beyond the boundaries of the elderly patient with cancer. APNs not only have a responsibility to educate the elderly patient

with cancer, but also to teach family members, colleagues, novice nurses, and members of the community about the most frequently used complementary therapies by elderly patients with cancer. Such education is necessary, as many of these groups may be intimately involved with the patient with cancer. Opportunities for providing such education may come through senior citizen groups, retiree clubs, inservices for hospital staff, or as a guest speaker for a formal nursing education program. Topics should include the most frequently used complementary therapies of exercise, herbal therapy/vitamins, and spiritual healing. APNs must seize the opportunity of informing consumers and thus expanding their view and knowledge of health and healing. By sharing this knowledge with others, APNs will empower patients with cancer, families, and others in making decisions regarding comprehensive and holistic health care.

The APN, working in primary care, is responsible for providing longitudinal care, regardless of the type of health problem (Starfield, 1992). Through this attribute of primary care, the APN comes to know patients over time and the development of a knowing and trusting relationship begins. As mentioned in earlier studies, (and possibly a factor in this study), patients are not entirely comfortable with sharing their use of complementary therapies with their health care provider (Cassileth et al., 1984; Eisenberg et al., 1993; Lerner & Kennedy, 1992). Therefore, careful assessment regarding use of complementary therapies, such as exercise, herbal therapy/vitamins, and spiritual healing, should be included in discussions between the APN and every patient. These discussions will

more easily occur if the APN gives the patient with cancer permission to discuss the use of complementary therapies. The APN should first explore what the elderly patient with cancer routinely does for their health (natural routines that took place even prior to the diagnosis of cancer). Further assessment should include the patient's attitude, beliefs and values (personal and cultural), towards complementary therapies.

Inquiring about the use of complementary therapies by elderly patients with cancer must become a routine component of the history taken at each clinic or office visit, as patient behaviors can change over time. APNs must assume a leadership role by taking responsibility in establishing this assessment as a standard of practice. Strategies to bring about this change include (1) assessing the health care system's attitudes and beliefs towards complementary therapies; (2) discussing how including this assessment will better meet the needs of the elderly patients with cancer, based on research findings related to the use of complementary therapies; (3) demonstrating this change by implementing the assessment into the APN's practice; and (4) championing the change. These activities will assist in bringing about a positive change in the health care system, thus contributing to reshaping health care delivery for the future.

The APN who establishes open and trusting communication with cancer patients can continuously appraise conventional and complementary therapy interactions. Lifestyle diets which may be used by elderly patients with cancer, must be supervised to assure nutritional needs are being met.

Proper diet and nutrition, for instance, must be maintained throughout any

type of therapy, but is especially important during administration of chemotherapy. The APN, working together with the elderly patient with cancer, can establish meal plans, assuring adequate intake of essential nutrients. Herbal therapy/vitamins, when taken in standard or mega doses, may interact with conventional therapy, as well as potentially becoming toxic to the body. Thorough assessment, management and evaluation is needed by the APN who possesses advanced clinical skills and judgement.

The APN, as patient advocate, recognizes the patient's values and facilitates decision making which is congruent with those values. Specific therapies, such as the most frequently used therapies identified in this study, as well as other similar therapies within the same field of practice, should be discussed as possible complements to conventional care. The APN can also suggest other complementary therapies to expand the options available to the elderly patient with cancer who uses complementary therapies.

APNs who are knowledgeable of complementary therapies can facilitate the development of clinical pathways or standards of care which include specific complementary therapies, and can be used by the entire interdisciplinary team caring for the elderly patients with cancer. Many of the complementary therapies are well within the scope of advanced practice nursing, and may therefore provide a more holistic, and comprehensive approach for patients. According to Daniels and McCabe (1994), patients must have a choice of interventions, therefore APNs who draw on the complementary therapies as part of their clinical repertoire need to be

recognized and encouraged. Examples of therapies often incorporated into the APN's practice include nutritional and exercise counseling, spiritual guidance, relaxation exercises, and imagery.

Spiritual healing, which was identified by 20.1% of those using complementary therapies, is one example of an interdisciplinary modality. According to Snyder and Mirr (1995), the APN provides a type of spiritual advocacy by interacting with the patient to determine the personal meaning the health experience has for that individual. In addition, the APN may collaborate with clergy or counselors to assist the patient in their healing journey.

Some elderly patients with cancer, who choose certain complementary therapies (e.g. acupuncture), many need to be referred to specialists. In collaboration with the elderly patient with cancer, the APN identifies the community resources available to provide a comprehensive plan of care. When patient referrals to specialists are required, the APN functions as a case manager, assuring that all aspects of a patient's plan of care are met. As the case manager, the APN must be cognizant of community resources and competent health care professionals who offer the specific therapies. The APN has a pivotal role in coordinating both the conventional and complementary therapies the elderly patient with cancer may be receiving, so as to assure open communication between health providers, and facilitate the continuity and appropriateness of care.

The APN guided by Rogers' model focuses on human beings as unique energy fields, integral and in mutual process with the environmental

energy field. The focus of the APN's practice is recognizing a patient's pattern, assisting the patient to knowingly participate in change (repatterning), harmonize the person-environment rhythm, and promote self-healing and well-being through the use of various complementary therapies. Deliberative mutual patterning strategies are utilized to enhance a patient's knowing participation in change. Such strategies include the use of complementary therapies (Martin, Forchuk, Santopinto, & Butcher, 1992). Repatterning occurs when the elderly patient with cancer chooses different complementary therapies, or when the elderly patient with cancer first chooses to use a complementary therapy (changing from non-user to user). Professional nursing practice flows from the application of knowledge; knowledge flows from the APN's understanding of diverse modalities used by human beings.

APNs have the opportunity to use the role of change agent, and join consumers in advocating for the incorporation of complementary therapies, such as nutritional counseling, in health care plans. Managed care companies are receiving growing pressure from consumers to have access to complementary therapies through their managed care plans (Moffet, 1994). According to Pfeil (1994), nurses are among the most suitable professional group to help complementary therapies attain their rightful place in health care. By actively participating in professional nursing organizations, APNs can begin to dialogue with insurers on behalf of individuals, groups, and society as a whole, so that changes in reimbursement policies can occur. Public speaking and supporting APN membership on health policy

making boards and councils are other examples of appropriate political activities.

Research with complementary therapies needs to be the focus of future studies for APNs. According to Hoekstra (1994), potentially expensive invasive and drug therapies may by minimized with the use of complementary therapies, thereby reducing and containing the overall cost of patient care. As this study revealed, exercise was used by 52.2% of elderly patients with cancer who reported using complementary therapies. According to Lerner (1994), no studies exist that assess the effect of exercise on a patient with an existing cancer, only on cancer prevention. However, there is evidence that physical exercise is beneficial to health such as decreasing anxiety and depression, enhancing psychologic well-being, and increasing circulating leukocytes. Research is needed to determine the possible positive outcomes of exercise on the elderly patient with cancer.

APNs, with their knowledge base of research methodologies, can conduct outcome based research which addresses use, safety, efficacy, cost effectiveness, and patient satisfaction with complementary therapies. APNs, together with other health professionals, have the opportunity to incorporate complementary therapies in the design of future studies to further the goals of understanding the experience of human healing (Cleaveland & Biester, 1995). Results of these studies would assist health care providers in adopting specific therapies, and adapting their services to better meet the needs of elderly patients with cancer. APNs who conduct research focusing on health care cost reduction, together with the voice of

consumer demand, will help bring acceptance of complementary therapies into the health care plans offered by managed care companies.

Recommendations for Further Research

According to Lenhard (1996), virtually any aspect of research which focuses on complementary therapies for patients with cancer will be of benefit, as cancer mortality is increasing at a pace that parallels increasing incidence. Further research is needed which would assist APNs and other health care professionals in providing recommendations of therapies to elderly patients with cancer, and ensuring a comprehensive plan of care. Suggestions for future research, using a larger sample size, include:

- (a) What proportion of elderly patients with cancer use complementary therapies with conventional treatments? Assessment of complementary therapy use should be conducted one year (or longer) after diagnosis to allow time for an individual to adjust to the diagnosis. The instrument used should have reliability and validity established prior to using; the fields of practice should be identified, with specific therapies listed individually under the respective field of practice; explanations of each therapy should be provided; each therapy listed should include the question of when the therapy was used: before or after the diagnosis of cancer.
- (b) Is there a relationship between stage and type of cancer, to use of specific complementary therapies? This may be done by an analysis of individual type of cancer including all stages.

- (c) What complementary therapies are used simultaneously (combinations) by elderly patients with specific types of cancer? Predetermined groups could be described for patients to select from, as well as patients identifying their own combinations.
- (d) What are the reasons a patient with cancer uses complementary therapy(s)? This qualitative data would provide insight into current patient-provider relationships.
- (e) Examine the effectiveness (as perceived by the patient) of the particular complementary therapy(s) used. Examples of outcomes include reduction in pain, nausea or vomiting; hastened healing post-operatively; and increased feeling of relaxation.
- (f) Survey the incidence and knowledge of APNs guiding cancer patients in the use of complementary therapies.

The next step, as follow-up to this study, would be to resurvey the 587 elderly patients with cancer who participated in this study, to identify any changes in the use of complementary therapies. It would be expected that reported use of complementary therapies would be higher than 22.8% (as reported in this study). As Lerner and Kennedy (1992) have stated, use of complementary therapies is influenced by the length of time that has elapsed since diagnosis.

Summary

This study analyzed the use of complementary therapies by elderly patients with breast, lung, colo-rectal or prostate cancer. The principal finding of this study supports other studies in the literature, indicating that

some elderly patients with cancer (22.8%) use complementary therapies in conjunction with conventional treatments. The top three complementary therapies most frequently used were exercise programs, herbal therapy or vitamins, and spiritual healing. As more and more information is available to consumers regarding complementary therapies, and awareness and practice of these therapies increases, one may expect more patients to inquire about and begin utilizing complementary therapies.

APNs are uniquely prepared and competent to provide the services requested by elderly patients with cancer. APNs must seize the opportunity and augment their knowledge about the pros and cons of complementary therapies, so as to provide the education and information elderly patients with cancer need in order to make informed health care decisions.

Complementary therapies can, and should be, incorporated into the practice of APNs in primary care. Each therapy, both complementary and conventional, must be recognized for the value both modalities bring to elderly patients with cancer, as each has a rich heritage to be acknowledged and used as a resource (Cohen, Huey & Neims, 1995). The integration of complementary and conventional therapies, can enhance the APN's ability to meet the health care needs of others. By responding to the needs of consumers and elderly patients with cancer, APNs are assured of contributing to the comprehensive and holistic service all patients deserve.





APPENDIX A

	Sociodemographic Information for Cancer Patient - Instrument
1.	Sex of patient: (check one)Male (1)Female (2)
2.	What is your birth date? (write in) Month Day Year
3.	What is your highest level of education completed? (check one)
	 No formal education (1) Completed grade school (2) Completed some high school (3) Completed high school (4) Completed some college or technical training (5) Completed college (6) Completed graduate/professional degree (post baccalaureate degree) (7) NA/Refused (9)
4.	What is your race or ethnic background? (check one) Caucasian/White (1) African American/Black (2) Mexican American/Hispanic/Chicano (3) Native American/Alaskan (4) Oriental/Asian/Pacific Islander (5) Other (6) (specify) NA/Refused (9)
5.	What is your marital status? (check one) Never married (1) Married (2) Divorced/Separated (3) Widowed (4) NA/Refused (9)

APPENDIX A (cont'd.)

Sociodemographic Information for Cancer Patient - Instrument

6. What was the combined household income of all household members in 1994? (check one)

Household Income Categories:
0 - 4,999 (1)
5,000 - 9,999 (2)
10,000 - 14,999 (3)
15,000 - 19,999 (4)
20,000 - 24,999 (5)
25,000 - 29,999 (6)
30,000 - 34,999 (7)
35,000 - 39,999 (8)
40,000 - 44,999 (9)
45,000 - 49,999 (10)
50,000 - 59,999 (11)
60,000 - 69,999 (12)
70,000 - 79,999 (13)
80,000 - 89,999 (14)
90 000 and over (15)

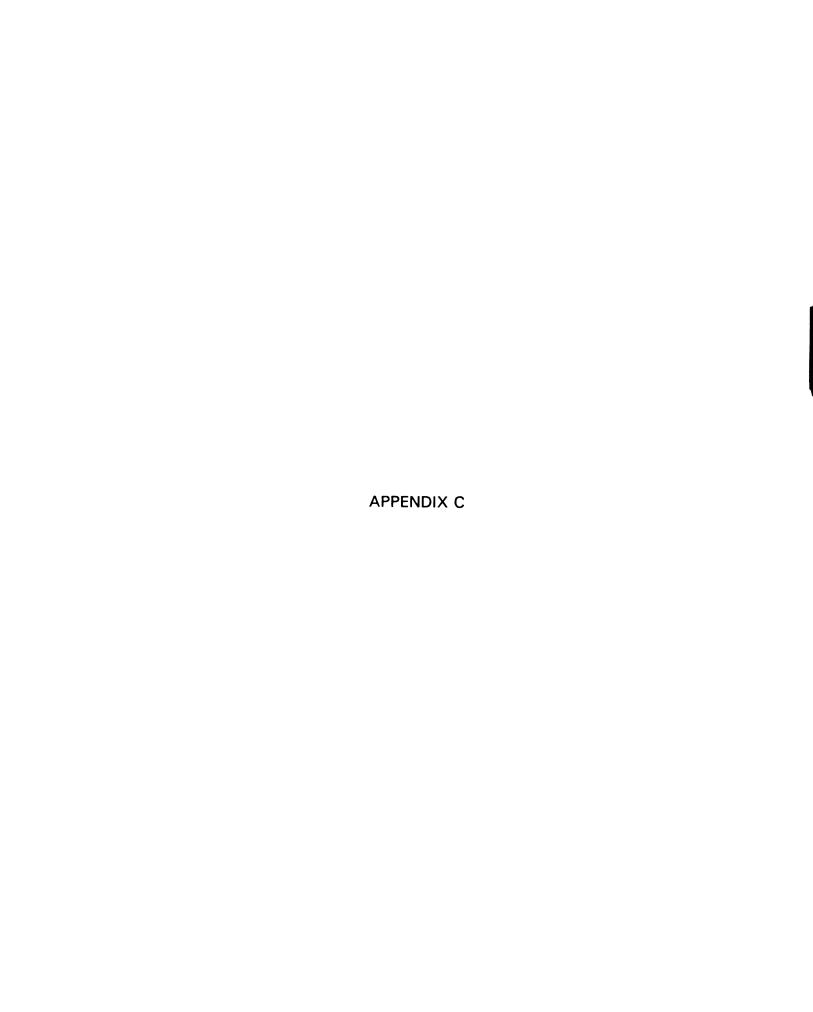


APPENDIX B

Cancer Therapies - Instrument

There are many therapies available to people. Some people choose therapies that they believe will compliment the care given by health care professionals for cancer. We realize that you may not be familiar with some of these therapies. If you have used this therapy please circle YES. If you have not used or are unfamiliar with the therapy circle NO and go to the next therapy.

CANCER THERAPIES	DO YOU USE THIS THERAPY? (CIRCLE ONE)	
1. Spiritual healing or therapy	YES	NO
2. Relaxation techniques/imagery/yoga	YES	NO
3. Massage	YES	NO
4. Herbal therapy or vitamins	YES	NO
5. Exercise programs	YES	NO
6. Lifestyle diets (Macrobiotic, trace mineral)	YES	NO
7. Acupuncture or acupressure	YES	NO
8. Energy balancing (Therapeutic touch)	YES	NO
9. Therapeutic spas or retreats	YES	NO
10. Hypnosis	YES	NO
11. International medications that cannot be attained in the United States	YES	NO
12. Wrap massage with liquid medication	YES	NO
13. Therapeutic audio or videotapes	YES	NO
14. Osteopathic manipulation	YES	NO
15. Homeopathic practitioners	YES	NO
16. Chiropractic manipulation	YES	NO
17. Other	YES	NO



APPENDIX C

The Family Home Care for Cancer - A Community-Based Model
Field Procedures and Data Collection

The data for this study was gathered from two types of instruments (telephone interview and self administered instruments), and the medical records of the subjects. Subjects were informed of the goal of the study, and that the study involved telephone interviews that would last from 40-50 minutes each. These interviews took place shortly after written consent was given, then at 6, 12, 24 and 52 weeks. The self administered questionnaire was given to subjects at their first clinic visit after written consent was obtained. The subjects completed the questionnaire and returned it via a self-addressed stamped envelope. Two telephone numbers were printed on the questionnaire for subjects to call if questions arose.

Telephone interviews were conducted by trained staff, who were given a manual of over 200 pages of references and information. Included in this manual was a list of study contacts, general background information for the study itself, a large section on verbal interviewing which included the interviewer's personal job description, procedures for confidentiality, general interviewing procedures, interview rules, guidelines for appropriate feedback, techniques for clarification and probing, and special situations. Procedures for paper questionnaires received and articles by the study investigators were also included.

The telephone interview gathered personal information including

sociodemographics and household income. Results of the telephone interview were entered directly onto a computer or taken on paper and later entered into the computer system. Quality assurance was conducted regularly on the interviews and on the paper questionnaires that were received. This was done by comparing paper information to the information in the computer system.

Reliability of this instrument was tested by comparing the verbal reports provided by the patient to the information found in the medical record. Validity was not confirmed, as the information came directly from the patient.



APPENDIX D

The University Committee on Research Involving Human Subjects - Approval

MICHIGAN STATE

June 11, 1996

TO:

Karen Rosasco 17345 W. Spring Lake Rd. Spring Lake, MI 49456

RE:

IRB#:

96-390

USE OF COMPLEMENTARY THERAPIES BY PERSONS DIAGNOSED WITH BREAST, LUNG, COLO-RECTAL, OR

PROSTATE CANCER

REVISION REQUESTED: CATEGORY:

APPROVAL DATE:

N/A 1-B 06/10/96

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed above. above.

REMEMBL:

UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/

CHANGES:

Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

DEFICE OF RESEARCH AND GRADUATE STUDIES

(UCRIÀS)

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

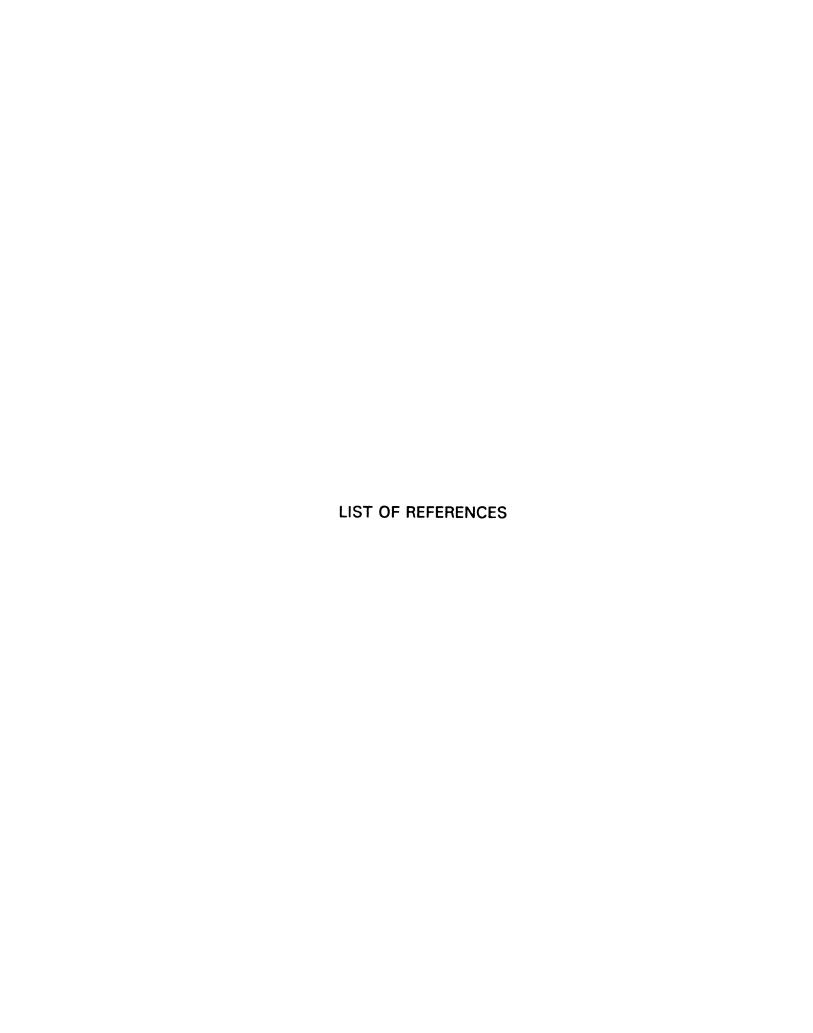
niversity Committee on Research Involving man Subjects

Michigan State University 232 Administration Building East Lansing, Michigan 48824-1046

wid B. Wright, Ph.D. UCRIHS Chair

DEW: bed

517/355-2180 FAX: 517/432-1171



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