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REDUCING CHEMOTOXIC STOMATITIS IN CANCER PATIENTS WITH & SELF-CARE ORAL HYGIENE PROTOCOL

RUTHANN BRINTNALL AND

A THESIS

IN PARTIAL FULFILLMENT OF REQUIREMENTS FOR A MASTER'S DEGREE

GRAND VALLEY STATE COLLEGE

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JULY 1985

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ABSTRACT

A Pretest-Posttest Control Group design was used to examine the effectiveness of a self-care management approach to reduce the severity of chemotoxic stomatitis. Orem's nursing model, Levin's self-care theory, and Magoon's constructivist research methodology were employed as the theoretical framework. Subjects, 24 short-stay or out-patient oncology clients, were all beginning treatment with known stomatotoxic agents. Buccal cultures were taken to determine changes in normal oral flora during stomatitis.

The experimental group received information and direction for a systematic oral hygiene protocol. Post-chemotherapy oral assessment score means of the experimental group were significantly better (p<.01) than those of the control group. <u>Candida</u> was cultured from half of the sample subjects in the pre-chemotherapy specimens; oral cultures taken when stomatitis occurred were similar to initial cultures.

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CHAPTER ONE

Introduction

Statistical tables report the incidence of cancer but cannot hope to reflect the emotional turmoil its victims must endure. As a disease, cancer stands alone in its ability to provoke fear and to stir thoughts of an agonizing death. If current trends continue, cancer will strike one American in four, and two out of three families will see cancer develop in one of their loved ones (Carter, Bakowski & Hellman, 1981). Health care professionals must recognize cancer as a major and terrifying health threat and continually assess care measures for effectiveness in serving the needs of cancer victims. As the largest body of health care professionals, nurses are challenged to evaluate and improve nursing care practices in the light of current scientific knowledge.

The practices and teaching of self-care for patients undergoing chemotherapy is an area in which research is sorely needed. The fairly stable curative potentials of surgery and radiotherapy have encouraged the use of chemotherapy as a single or adjuvant mode of therapy. This trend toward more chemotherapy is both widespread and undisputed because of its relative effectiveness. However, nursing interventions which address self-care practices or aim to reduce known side effects related to chemotherapy have not kept pace with the changing therapies.

Unfortunately, oral side effects linked to chemotherapy are not uncommon, and clients must be educated to recognize them promptly. Stomatitis, an interruption in the integrity of the oral mucosa manifested as redness, swelling, irritation, and/or ulceration, is seen too frequently in cancer patients. In fact, some degree of oral epithelial interruption can be seen in as many as 40% of all clients undergoing chemotherapy (Sonis & Sonis, 1978).

When stomatitis occurs, it is quite painful and interrupts most normal functions of the oral cavity. Additionally, the ocurrence of stomatitis during treatment with an anti-neoplastic agent poses a major health threat to the client by increasing the incidence of nutritional alterations and susceptability to infection. A cancer patient's diminished immune mechanisms and potential for disease-related anorexia make him highly vulnerable to stomatitis at a time when he is unable to respond to the affliction.

Stomatitis is recognized as a dose-limiting factor during the course of commonly prescribed chemotherapy regimens. Those agents identified as stomatotoxic by Dreizen, Bodley, and Rodriquez, (1975) are listed in Table 1. The anti-neoplastic agents included in the list comprise a significant percentage of agents frequently used either alone or in combination with other drugs to treat various cancers.

Thus the cancer patient given chemotherapy is in particular need of effective, supportive nursing interventions that emphasize both oral hygiene and the importance of detecting early signs of side effects. Additionally nurses need to recognize and respond to the trend of treating cancer patients through out-patient or short-stay chemotherapy regimens. Since nurses are conventionally both the monitors and providers of oral care, they are uniquely qualified to respond to these evolving health care needs.

Current mouth-care routines continue to follow traditional practices that are now known to be inadequate and even contrary to measures that promote oral health. Specifically, effective mouth-care measures that encourage oral health and reduce the incidence of stomatitis are badly needed. To date, the research efforts to determine appropriate measures for promoting oral health and limiting this side effect are few in number. This relative void in a subject area that falls within the domain of nursing practice presents a timely challenge to the profession. Table 1

STOMATOTOXIC CHEMOTHERAPEUTIC AGENTS

Antimetabolites:

Baker's antfol Cyclocytidine (Cycol-C) Cystosine arabinoside (Ara-C) 5-Fluorouracil (5-FU) 6-Mercaptopurine (6-MP) Methotrexate (Amethopterin) 6-Thioguanine (6-TG)

Antibiotics:

Actinomycin D (Dactinomycin) Adriamycin (Doxorubicin) Bleomycin Sulfate (Blenoxane) Daunomycin (Daunorubicin) Mithramycin (Mithracin) Mitomycin C (Mutamycin)

Plant Alkaloids:

Vinblastine Sulfate (Velban) Vincristine Sulfate (Oncovin)

Miscellaneous:

Hydroxyurea (Hydrea) Procarbazine Hydrochloride (Matulane)

Adapted from Dreizen, S., Bodley, G.P., and Rodriguez, V. Oral complications of cancer chemotherapy. Postgraduate Medicine, 58, 75-82.

Purpose of the Study

The purpose of this investigation is to focus on two questions relative to mouth-care practices. Can providing educational material and a basic oral care protocol be effective in assisting the client to maintain oral health during chemotherapy? Can a prescribed oral care protocol reduce the incidence of stomatitis in selected self-care cancer patients?

Importance of the Study

A healthy oral cavity is paramount to the overall wellness of an individual. A functioning oral cavity serves nutritional needs, operates as an outlet for emotional expression, and is the center of speech communication (Quinn, 1975). For the cancer patient, one or all of these functions can be interrupted by the side effects of chemotherapy.

Understandably, the goal of chemotherapy is to rid the body of cancer cells and for this to be effective all cancer cells must be eradicated. This onslaught presents a double bind for the patient: the chemotherapeutic agent acting at the cellular level seeks all rapidly proliferating cells and is unable to distinguish rapidly growing normal cells from aberrant malignant cells. Consequently, tissues with normally high proliferation rates such as the mucous lining of the gastrointestinal tract, the bone marrow, and the hair follicles also become prime targets for destruction. An unfortunate result of chemotherapy is that the medication prescribed to cure or palliate, temporarily renders the cancer patient more vulnerable to pain, infection, oral ulceration, and nutritional alterations.

The classic ulcerative lesions of stomatitis begin to appear five to seven days following administration of the stomatoxic agent (Becker, 1981); the lesions usually remain for four to ten days. In fact, the oral cavity may be the first site where effects of the chemotherapeutic agent can be seen. Because of their immunosuppressed state, cancer patients are particularly prone to such inflammatory processes.

Physical injury (trauma, surgery, radiation, irritation from tubings), chemical injury (chemotherapeutic stomatoxic medications), and infectious processes can be significant obstacles for the cancer patient (Daeffler, 1981). Decreased food intake and altered salivary flow further depress the nutritional state; and any diminishment of nutritional status depletes precious body reserves and impairs the healing and rebuilding of damaged tissues.

Lunderquist (1978) described chemotoxic stomatitis as an inflammation and interruption in the oral mucosa which may involve the buccal and labial mucosa, palate, tongue, floor of the mouth, and gingiva. The normal oral epithelial replacement process, characterized by upwardly migrating basal and stem cells, is interrupted by the pharmacologic properties of the anti-cancer agent. Stem cell division can also be altered. As normal sloughing from functional wear and tear continues, inadequate replacement of the sloughed cells leaves areas of denuded oral mucosa. These damaged areas are often seen in conjunction with an inflammatory process. In short, complete replacement of the oral lining occurring approximately every seven days in the healthy individual, cannot take place and varying levels of stomatitis (also termed oral mucositis) occur.

Because of the frequency and potential seriousness of stomatitis, its occurrence as a side effect of chemotherapy must be addressed. Since the onset of stomatitis usually occurs away from professional advice and assistance, the medical community must inform clients about the potential threat and prepare them with practices that can prevent its occurrence or minimize its harmfulness. Chemotherapy-related bone marrow depression, thrombocytopenia, neutrapenia, and lymphopenia are other reasons to urge health professionals and their clients to recognize the potential for a lethal infectious process when the integrity of the oral mucosa is violated by the after effects of chemotherapy.

Operational Definition of Concepts Chemotherapy

Chemotherapy is the use of chemically prepared compounds to treat or to prevent disease. Cancer chemotherapy is the use of chemical compounds as a treatment to cure or palliate the symptoms of cancer. Dose-limiting, a term used in cancer therapy, describes the occurrence of side effects that may compromise the optimal dose of the drug administered. The nadir is the point of time during therapy when the maximal effect of the drug is reached in the body. Stomatitis

Stomatitis, also called oral mucositis, is an interruption in the integrity of the oral mucosa manifesting as redness, swelling, irritation, and/or ulceration. This may occur singly or in combination with interruption on the buccal, gingival, or palatal surface of the mouth. Stomatitis can occur as a side effect of chemotherapy because the anti-neoplastic agents attack cells that are rapidly reproducing and cannot distinguish normal growth from rapid cancer cell growth. Stomatitis is not a permanent condition and disappears after the course of chemotherapy. For this study, stomatitis was determined to be a score on the oral assessment of 150% above the pre-chemotherapy oral score.

Self-care Behaviors

Self-care is a voluntary and deliberate act taken by an individual to promote personal health, prevent disease, or treat illness symptoms. Self-care behaviors are a form of self management, carried out by an individual, that contribute to continued existence, health, and well-being (Orem, 1980). The goals of self-care are derived from the individual's perceived needs and preferences.

Mouth Care Protocol

A mouth care protocol is a systematic approach to repeated, consistent care of the oral cavity that promotes and maintains the integrity of oral tissue. For purposes of this study, the protocol is a written explanation of the following items: 1) function and structure of the oral cavity; 2) directions for a self-examination of the mouth; 3) routine for caring for the mouth; 4) changes in the mouth that may occur during chemotherapy; and, 5) directions for caring for stomatitis should it occur.

CHAPTER TWO

Review of the Literature

The current and past literature dealing with mouth care for cancer subjects is limited. While the medical literature clarifies the need for scrupulous care and observation, the clinical research needed to determine effective protocols and to validate assessment tools has not been carried out.

A survey of oral care practices in major cancer research centers conducted by Daeffler (1980) revealed a variety of oral care routines currently in use by care givers. Over half of the 41 institutions responding to the survey reported that no specific procedure or guideline was used for mouth care. Thirty-six centers did not use a guided oral assessment, while five centers had an oral assessment guide or tool in current use. While the importance of oral assessment and mouth care was recognized by the oncology nurses surveyed, only four centers were conducting research to investigate mouth care. This conspicuous void in practice and a need for effective assessments of mouth care were confirmed by Daeffler's work.

Specific research efforts to determine oral care protocols for the cancer patient have been limited.

Beck (1979) provided the single contribution to nursing research on the topic. Using an Oral Assessment Guide that she designed (Appendix A), Beck evaluated the condition of the oral cavity by specifically observing the lips, tongue, gingiva, saliva, teeth, dentures, taste, voice, and eating ability of her subjects. A four-point rating scale was used for each item, with one denoting a normal value and two through four connoting alterations in normal appearance or ability.

Initially, Beck collected oral condition data on a group composed of 25 hospitalized subjects. Ten days later, similar data were collected on an independent sample population of 22 subjects after a systematic oral care protocol was instituted. Subjects in both groups were asked to evaluate the condition of their mouths using an Oral Perception Guide that corresponded to the items assessed by the investigator. The subjective responses to the Perception Guide were also graded on a one to four scale, with one as normal and four as the most undesirable.

A Physical Condition tool rated each subject on: level of consciousness, breathing habits, diet, and self-care ability. The one to four scale was again used to score the observations. Additional information collected from the subjects included an oral culture, an afternoon temperature measurement, a pH of the saliva, white blood cell count, neutraphil count, and platelet count value.

Using the t-test for independent samples, Beck determined that a significant improvement in oral scores (p<0.01) was evident in subjects who followed the protocol. She also found that the Physical Condition values and Subject Perception information did not differ significantly. Beck questioned the use of the Perception tool as an accurate indicator of oral status and discussed several limitations of her work. She recognized that not all subjects included in the study were being treated with anti-neoplastic agents known to be stomatoxic. While Beck did not carry out the oral care routines, she performed all of the oral assessments on the subject pool.

A limitation of Beck's work which was not addressed was the description, or operational definition, of the term "infection" which she used to describe results of oral cultures. The rationale for the purported reduction in infection rates is not clearly stated; several organisms listed as infective micro-organisms are described by Mikat and Mikat (1981) as normal microbial mouth flora (Appendix B). The strength of the microbiological aspects of Beck's study are therefore weakened by this omission.

Nevertheless, Beck's study has provided important

information on a topic relevant to nursing practice. Her thorough and clearly stated assessment tool is especially useful even though its validity and reliability have not been established. The findings from this research lend valuable insight into the importance of mouth care protocols for cancer patients and provide ideas for future research.

Daeffler, another leader in research involving oral-care measures for cancer patients, wrote a descriptive series of articles in 1980. Chemotherapy was described and discussed as a major risk factor for oral interruption. In addition increased incidences of oral disruption caused by reduced capillary permeability, inhibited antibody production, and impaired reticuloendothelial function were found in clients treated with adrenal corticosteriods.

Bacterial, fungal, and viral opportunist infections caused by a variety of organisms are a particular concern in the cancer host because of the weakened defense mechanisms. Daeffler (1980) described the frequent, unexplained occurrence of <u>Candida</u> infections in the cancer patient and stressed the need for prompt treatment to avoid hematologic and esophageal extension. Her work helps define the population at greatest risk for oral lesions.

Herpetic stomatitis is also seen with greater

frequency during treatment with cytoxic and steroid therapy. Rand, Kramer, and Johnson (1981) supported the occurence of this phenomenon but reported that herpes simplex virus should not be implicated in all mucosal lesions.

The most common predisposing factor to oral ulceration is reduced frequency of thorough oral hygiene (Daeffler, 1981; Lane & Forgay, 1981; Lavelle, 1976; Neissen & Jones, 1984). Health care givers should also note additional risk factors such as age, the presence of other chronic diseases, dental caries, gingival disease, smoking, frequent alcohol intake, and chronic low-grade mouth infections that increase the likelihood of chemotoxic-related stomatitis. Plaque, calculus deposits, and food debris collection are other obvious contributors to oral lesions.

In earlier nursing research, DeWalt (1975) compared the effects of toothbrushing with the use of the toothette oral appliance at timed intervals of two, three, and four hours. Two investigators scored 48 geriatric patients on nine dependent variables: salivation, tongue moisture, tongue color, moisture of palates, color of the gingiva, condition of the membranes, lip texture and moisture, and soft tooth debris. Multiple regression analysis revealed an improvement in six variables in the four hour interval group, an improvement in two variables in the four hour interval group. Interestingly, the toothbrush appeared more effective as a tool for stimulating gingival tissue while the toothette proved to be a better appliance for use on the mucous lining.

DeWalt and Haines (1969) found tentative support for their concept that deliberate oral care measures could minimize the detrimental effects of certain oral stressors. Their study revealed that the reversal of symptoms such as dryness and irritation caused by nasal oxygen, mechanical suctioning, mouth breathing, and lack of oral intake was possible. One of the researchers served as the subject in this limited study since creating and observing these conditions in acutely ill patients without implementing relief measures was not viewed as acceptable nursing practice. Replication of this research effort using a sample of hospitalized subjects already exhibiting these symptoms would be desirable and could further define the role of these stressors in oral care.

In a research project described from dental investigation, Lindquist (1978) reported the value of pre-chemotherapy dental scaling and prophylaxis to reduce plaque and thus decrease the incidence of stomatitis. While this effort was a pilot attempt, the role for preventive care is clear. Unfortunately, the statistical measures used for this review are absent. The authors, however, offered a credible evaluation of the whole issue of stomatitis and suggested some relevant ideas for further study.

Attempting to quantify predictive factors and measures of stomatitis, Izutsu, Truelove, Bleyer, Anderson, Schubert, and Rice, (1981) reported finding a mean increase in salivary albumin concentration of 453% in subjects after chemotherapy. Clinical findings of stomatitis were measured, using a standardized form, grading color and tissue changes in the oral cavity. Increased transudation of serum products appeared to be the likely cause of elevated saliva albumin levels, which concur with observed ulcerations and mucosal thinning. Although the sample size was small, findings from this study may have implications as a parameter for scheduling chemotherapy protocols for those with severe stomatitis.

In an earlier study of acutely ill surgical patients, Passos and Brand (1966) reported that the frequency and duration of oral care improved oral hygiene. Although the observed differences among the three rinsing agents used were not statistically significant, the researchers concluded that the effects of hydrogen peroxide were superior to those of milk of magnesia and alkaline mouthwash. Recent reports by McDeVitt (1982), however, indicated that hydrogen peroxide may predispose to <u>Candida</u> infection, thus limiting its use in stomatitis associated with chemotherapy. Daeffler (1980) suggested that peroxide may be useful in removing such patients' oral crusts and debris rather than for routine oral care.

While Passos and Brand's research involved only those subjects who were unable to administer their own care, Dodd (1983) measured self-care behaviors of cancer patients receiving chemotherapy. Subjects who received information regarding side effect management techniques, as opposed to those who received none, reported initiation of self-care behaviors before their side effects became persistant and severe.

In summary, the literature relative to mouth care for cancer subjects is limited. While the need for scrupulous care and observation is widely recognized, the clinical research necessary to determine effective protocols and to validate assessment tools has not been carried out. If nursing is to offer its best to clients, the profession has an obligation to fill this need.

CHAPTER THREE

Theoretical Framework

Introduction

The theoretical framework of this study is based on several concepts and their relationships: self-care, Orem's Nursing Theory, and Magoon's Constructivist research methodology. These three concepts deal with the supportive-educative role of the nurse in informing the cancer patient receiving chemotherapy about self-care actions that can prevent disruption of the oral mucosa.

Self-care

Self-care is a voluntary phenomenon in which an individual deliberately acts on his own behalf to promote personal health, prevent disease, or to treat illness symptoms. Self-care rises from the natural desire to avoid or reduce illness. When viewed as a decision-making process, self-care involves self-assessment including symptom perception, labeling and judgment of severity as well as choice of treatment options (Levin, Katz, and Holst, 1977).

An individual's self-care is influenced by his life style, culture and values. Meaningful self-care involves drawing information from one's personal resources then acting on that data or deciding to seek professional services that can assist the individual to better care for himself. Because the goals of self-care are derived from the individual's perceived needs and preferences, and because the individual decides which risks to avoid and which to take, self-care measures most likely seen to be beneficial are those compatible with one's values.

Orem's Nursing Theory

Orem describes self-care as the "practice of activities that individuals initiate and perform on their own behalf to maintain life, health, and well being" (Orem 1980, p 35). According to Orem, man's ability to engage in self-care is influenced by age, developmental state, experiences, cultural orientation, health status, and availability of resources.

Orem believes that man has three types of self-care needs: universal, developmental, and health-deviation. Universal self-care requisites include maintenance of life processes, or basic human needs. Human developmental events that occur during various stages of the life cycle, such as pregnancy or loss of a family member, comprise developmental self-care needs. Health-deviation self-care requisites are those that arise from disturbances or defects in human structure and function. When the individual is unable to meet his self-care needs, either because of an interruption in his capabilities or a steady decline in self-care capacities, he is in a state of self-care deficit.

Using the Nursing Process, nurses identify the individual's need for self-care action necessary to bring about normal or near normal living despite disabilities that cause self-care deficit. The individuals are assisted by "actions deliberately selected and performed by the nurse to help maintain or change conditions in themselves or their environment" (Orem 1980, p 5).

Orem proposes three nursing systems: (1) wholly compensatory, in which the nurse acts for the patient who is unable to perform self-care actions; (2) partly compensatory, in which the patient can perform some, but not all, self-care actions; and, (3) supportive educative, where the nurse's role is to assist the individual to learn self-care practices by teaching and promoting personal development.

Magoon's Constructivist Research Methodology

Magoon (1977), describing the constructivist approach to research with human subjects, stated that it must be assumed humans are knowing beings and their knowledge has important consequences for their behavior.

The control over such intelligent behavior lies within the individual. Humans build their own reality by developing or "constructing" aspects of existing knowledge and, if behavior is viewed as purposeful, it is more likely to be initiated and repeated.

Self-care Education

To initate and persevere in self-care behaviors, the client must: "possess the necessary knowledge and skills for health care needs; have sufficient motivation and energy to continue such behavior until desired results are achieved; place a high value on health; and perceive that the new health behavior will reduce vulnerability to illness" (Hill and Smith 1985, p 10).

All individuals can and should learn measures of self care to promote health and prevent disease. Changes in internal or external conditions that create new self-care requisites call for adjustments in skills, additional knowledge, and willingness of the individual to participate in self-care activities.

Self-care education relies heavily on the individual's prior knowledge and skills, supplements these with medical concepts and skills not previously used, and focuses the center of health control on the individual. Results may not always conform to professional values, but "does lower dependency and its negative sequelae" (Levin 1978, p172).

Dodd (1982) reported a hesitancy among clients of chemotherapy to report side effects. She found subjects reluctant to complain about treatment aimed at curing their disease. Some clients assumed that side effects were an inevitable consequence of therapy and were to be quietly endured. Even when they were able to identify side effects that had occurred, few self-care behaviors were initiated. Most side effects were not reported at all unless they were unusually severe or debilitating.

The relationship between the lack of self-care behaviors and the lack of knowledge about chemotherapy's side effects is not clear. However, the implication for the role of nursing can be surmised; that is, clients must be better informed about the potential effects of their medications if they are going to initiate self-care behaviors. Nurses can offer that information and support. Some side effects are an inevitable part of chemotherapy, but their occurrence need not unnecessarily compromise the client and detract from his quality of life.

The use of Orem's Nursing model to increase self-care practices in patients of all ages and in various settings stresses evaluating the individual's ability to engage in such efforts. Subjects included in this study received chemotherapy as outpatients or as short stay inpatients discharged after intravenous infusion of the drugs. Using the Karnofsky scale (Appendix C), a guide developed for assessment of the functional ability levels of cancer patients, they were determined to be capable of self-care action at the 80 - 90% level since none was hindered by physical or mental disabilities that would have interfered with performing activities of daily living.

In addition to assessing the individual's ability to engage in self-care practices, the nurse determines his self-care needs in a specific situation by a cognitive approach, the Nursing Process (Figure 1). Assessment of the individual's abilities and resources and identification of the self-care needs are steps in the initial phase of this process. This is followed by diagnosis of the self-care deficit. Once identified, this deficit becomes the focus of the planning phase in which setting goals and establishing methods for their attainment must necessarily involve cooperation between the nurse and the client. The fourth phase of the nursing process is evaluating the effectiveness of the plan as well as determinating modifications that must be made to better meet the client's needs.





The individual functions in a similar process to meet his own self-care needs (Figure 2). The initial phase, self-assessment, is the individual's deliberate identification of a problem in his self-care abilities. This is followed by a phase of self-education during which the individual gathers information before determining his self-care goals. Such activity provides a knowledge base for establishing methods of attaining these goals. Evaluation of the efficacy of the process, which then contributes to information that can be used in making future self-care decisions, is the fourth phase of the process.

The client can practice self-care independently, entering the nursing process periodically for specific assistance. This intermittent input from the nurse increases the client's knowledge without interrupting his self-care process (Figure 3). One of the shortcomings of this process, from a nursing viewpoint, is that the individual, after receiving the information necessary to perform the prescribed behavior, determines the type of self-care activities and the number of times they are repeated. Nurses can assist the individual in gaining the knowledge and skills that are necessary for health care needs but, as resources and not as direct care givers, they cannot control the amount or type of self-care activity generated.









(Adapted from: Hall and Smith, 1985, p 46.)

Providing information that will enable the client to perceive the new self-care behavior as meaningful while contributing to his knowledge base for decision making is essential. However, the individual is ultimately in control, determining what self-care measures he will implement, in accordance with his beliefs, values, motivation, and energy.

In summary, self-care behaviors were operationally defined as voluntary and deliberate actions initiated by individuals to achieve, promote, and maintain health. Benefits from maintaining accountability for certain aspects of one's own care influence feelings of worth and the likelihood of compliance to the treatment regimen. Nursing must accept the client as a thinking, capable being by expanding its role in the assessment of self-care competencies and in educative efforts to reduce knowledge deficits while promoting self-care behaviors.

Hypothesis

This study was undertaken to determine if defined educational instruction including a systematic oral care protocol could improve the oral status of patients receiving stomatoxic agents.

The following hypothesis was tested: subjects receiving information and direction regarding a

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self-care, oral hygiene protocol will have a significant decrease in severity of stomatitis compared to those subjects receiving no prescribed oral care routine.

Additionally, the following research question was addressed: what are the changes that occur in normal oral flora during stomatitis?
CHAPTER FOUR

Methodology

Introduction

In order to examine whether following a specific self-care oral protocol can decrease the incidence and severity of stomatitis in chemotherapy patients, the Pretest-Posttest Control Group Design described by Campbell & Stanley (1963) was employed. Twenty-four subjects were randomly assigned to either a control or experimental group. All oral examinations were performed by the investigators without knowledge of the subject's group placement.

The initial observation, which occurred before the first dose of chemotherapy, was an assessment of each subject's oral status using criteria developed by Beck (1979) and modified by the present investigators. All subjects received their physicians' standard instructions, if any, pertaining to oral maintenance. The experimental group received additional instructions: a combination of written oral hygiene information including a specific protocol and an oral care home management kit. The oral cavity of all subjects was examined after four weeks of chemotherapy. Some subjects were also assessed at weekly or bi-weekly intervals, depending on the individual therapy protocols and drug nadir.

The status of each subject's oral cavity prior to chemotherapy was compared to its condition one month into treatment. The pre- and post-chemotherapy graded scores of the oral examinations were contrasted between the control and the experimental groups.

The independent variable was identified as the combination of written oral care information and the home management kit. The dependent variable was the condition of the mouth as measured by the physical status grade on the oral examination guide, the subject's oral perception guide, and the oral cultures. Socio-demographic variables that were recorded included age, sex, marital status, educational background, dosage and combination of medications, diagnosis of chronic disease, and type and location of tumor.

Protection of Human Rights

Application was made to the Human Subjects Review Committee of Grand Valley State College for permission to conduct the study. Permission was granted on December 19, 1984. Additionally, the Research and Institutional Review Boards of two major local teaching hospitals were successfully petitioned for authorization of on-site data collection. Four group oncology practices also gave the investigators permission to seek subjects for the study in their offices and clinics.

In order for a subject to be qualified for the study, the investigators validated that the inclusion criteria were met. The purpose of the research was reviewed with each subject and the subject's role in the study was thoroughly explained. After their rights were reviewed with them, a written consent (Appendix D) was obtained from all participants. A coded identification number, known only to the investigators, was assigned to each subject to provide confidentiality and anonymity.

Subjects

The sample included adult patients from four private oncology group practices in a large metropolitan area. The subjects were all over 18 years of age with a diagnosis of cancer. All were beginning a series of treatment with a known stomatoxic agent. Other criteria included: a willingness to participate in the study; the ability to read, write and speak English; an anticipated lifespan greater than six months; and no prior or concurrent radiation to the head or neck.

Radiation therapy poses an additional risk of xerostomia, stomatitis, dental decay, taste loss, osteoradionecrosis, and trisus (Daeffler, 1980; Dreizen et al, 1977). Xerostomia often begins early during radiation treatment, and is irreversible, while stomatitis can subside after radiation is stopped. Because many of these side effects will permanently alter the functional ability of the oral cavity or precipitate nutrition-deficient stomatitis, subjects receiving prior or concurrent head and neck radiotherapy were not included in the study.

To ensure that all subjects would be capable of implementing the self-care protocol, the investigators determined that all participants were ranked at or above 70% on the Karnofsky functional level scale for assessment of self-care levels (Appendix C). This scale was used because a strong correlation has been reported between functional status and response to chemotherapy (Burns, 1982). The investigators determined this level of self-care at each contact with the subjects.

During a four month period from February through May 1985, 35 subjects were identified and interviewed after it was determined that they met the inclusion criteria. All eleven who declined to participate were females. The most common explanation for refusal to participate was the inability to cope with anything else during this stressful period in their lives. The remaining twenty-four subjects comprised the sample.

Instrumentation

A thorough search of the literature failed to reveal an established instrument capable of testing the study hypothesis. While Beck's (1979) model for oral assessment is widely cited, it has not yet been validated. A relatively high degree of content validity for the tool was assumed, however, based upon the literature findings of the investigators. The reliability of a tool as a measurement is equated with the stability, consistency, or dependability of the tool in repeated measures (Polit & Hungler, 1983). Again, insufficient research is available to verify reliability of Beck's instrument.

Interrater reliability was established between the investigators prior to data collection of this study. Using the oral assessment tool, ten oral examinations were conducted on acutely ill inpatients on a 30 bed oncology unit at a major teaching hospital. The graded scores from the oral evaluations were compared for similarity. An analysis of the scores revealed less than 0.4% difference between the items scored by the investigators.

In order to improve congruence with the self-care model, Beck's tool was modified for the data collection process. Because of the inability to detect subtle changes in tone and quality in spaced assessments, the examination of the voice was omitted from the tool. However, voice assessment was retained in the subjects' Oral Perception Guide. To reduce complexity of the tool, a combined score for color and moisture in each category was employed rather than using separate scores. With these changes in Beck's rating system, possible scores on the adapted scale ranged from seven to twenty-eight.

For this study, posttest scores on the modified scale greater than 150% of the pre-chemotherapy baseline scores were considered indicative of stomatitis. An increase of this magnitude was important because notable variation in at least two catagories of the scale or visible oral lesions were required to reach this level. Subjects with such elevated scores would manifest obvious symptoms of stomatitis.

Procedure

Potential subjects for the study were identified with the assistance of nursing personnel from the participating hospitals, outpatient clinics, and oncology offices. The investigators performed a pre-chemotherapy oral assessment of each subject using the adapted model (Appendix E) and a buccal culture was also obtained at that time. Demographic data (Appendix F) and laboratory determination of the complete blood count (CBC) were also recorded. Additionally, information regarding the diagnostic and treatment history of the cancer was collected by the investigators. Subjects were asked to complete the Lifestyle and Health Habits Assessment tool to determine individual self-care habits and to focus on wellness-oriented self-care behaviors (Appendix G).

The subjects were randomly assigned to either the control or the experimental group by nursing personnel at each site. The written oral care information and home care management kit were given to the experimental subjects by their chemotherapy nurses. The nurses also kept records of the subjects' group assignments and revealed them to the investigators only at the conclusion of data collection.

Experimental Treatment

Subjects in the experimental group were given educational information including directions regarding an oral care protocol (Appendix H) and an oral care home management kit. The written information explained the need for thorough mouth care during chemotherapy and, with diagrams of the mouth, included techniques for examining the oral cavity. Because of findings that cancer patients on chemotherapeutic regimens had consistently poor recall of information provided at the time of consent to treatment, the educational material was given to the subjects in written form (Dodd & Mood, 1981).

The intent of this information was twofold: to educate the client about the risks of oral side effects associated with chemotherapy; and, to provide a systematic approach to mouth care during the course of treatment. A glossary was included to clarify the terminology used in the presented material and terms the client might encounter during treatment. A protocol to promote oral health and help detect early manifestations of side effects was presented in a step-by-step guide.

The oral care home management kit contained the following oral care products: fluoride toothpaste; a four-row, round bristle, adult-sized toothbrush; unwaxed dental floss; a penlight; two plastic dental mirrors; lip balm; and disclosing tablets. The toothpaste and toothbrush were included to increase consistency in the oral care products. Because of its value in tooth cleansing and gingival stimulation, dental floss was placed in the kit (Ariaudo, 1971). As a supplemental light source during self-examination of the mouth, a penlight was supplied and its use encouraged. Because of the frequent complaint of rough or dry lips reported by many chemotherapy patients, a lip balm was included to soften the lips and to reduce dryness. Subjects were encouraged to keep oral care

products in one place and request more of the kit supplies from the office or clinic nurse if necessary.

While the value of using disclosing tablets has been questioned by some researchers (Ariaudo, 1971), tablets and instructions for their use were enclosed in the kit. The most common objection to using these tablets as a cleansing tool is the obvious fact that the intended purpose of the product, an increased visualization of missed areas of oral care, cannot be viewed without the aid of mirrored appliances. The dental mirrors supplied in the kit were intended to promote visibility while allowing the client to see areas of debris build-up.

Control subjects received no specific instruction in oral care procedures from the nurses before beginning treatment with the anti-neoplastic drugs. A pre-treatment oral assessment and buccal culture were obtained and the identical routine for oral assessment as the experimental subjects was followed during treatment. Control subjects who reported alterations in oral mucosal integrity during therapy were told by the office or clinic nurses how to care for the discomfort after stomatitis had developed. This was the normal protocol of these offices.

Data Collection

The researchers collected all of the data during

the five month period from February through June of 1985. Using the adapted assessment tool, each subject's oral cavity was inspected to determine a baseline pre-chemotherapy assessment. The condition of the lips, tongue, gingiva, saliva, teeth and/or dentures, and swallowing ability was graded.

Following the format of the Oral Care Program (Appendix H), the mouth was examined systematically by one of the two investigators including: the roof of the mouth, the gums surrounding the teeth, the top and underside of the tongue, and the mucous membrane lining of the oral cavity. Subjects were asked to note and report areas of discomfort or alteration. A graded number scale from one to four was utilized to evaluate each area of the mouth observed during the examination. A score of one was considered normal for each item; scores of two through four were considered less desirable and variations of normal.

At the time of the initial assessment, a buccal culture was taken from each subject. Using Amie's transport medium, cultures were transported to the microbiology laboratory at Grand Valley State College. All cultures were managed and interpreted by a graduate student in Health Sciences under the supervision of a doctorally prepared clinical microbiologist.

Using aseptic technique, the culture swabs were

subcultured to each of the following four agar plates: 1) Columbia agar with 5% deep red blood cells (blood agar); 2) Colistin nalidixic acid agar with 5% sheep red blood cells; 3) MacConkey agar; and, 4) Sabarrhoud's dextrose agar. These plates were then incubated aerobically at 37[°] C for 48 hours and were then observed for growth.

Growth was evaluated by the following method: when the predominant organism was other than normal flora as defined by Mikat and Mikat (1981), it was identified to species. Identification was based upon the definitions of genus and species, using procedures recommended by Lenneto, Balows, Hausler, and Schadomy (1985) with the following exceptions: 1) isolates from the Enterobacteriaceae were identified using the API 20E (Analytab Products, Plainview, New York); 2) Streptococci other than Streptococcus pyogenes and S. pneumoniae were identified using the API 20S (Analytab Products, Plainview, New York); 3) Staphylococci were identified using the Staph-Ident (Analytab Products, Plainview, New York); and, 4) yeasts were identifed using the API 20C (Analytab Products, Plainview, New York).

After the inital assessment, subjects were evaluated during their return visits to their oncologist. Depending on the schedule protocol of their chemotherapy, subjects were evaluated with graded oral examinations weekly, bi-weekly, or monthly. As previously stated, oral assessment scores greater than 150% of the baseline assessment were considered indicative of stomatitis. Repeat oral cultures were then taken to determine if there were any changes in the oral flora concurrent with these visible changes in the condition of the oral cavity.

Data Analysis

Initial assessment scores of the experimental and control groups were compared to determine if the oral conditions of the subjects were significantly different before chemotherapy. The Mann Whitney U, a non-parametric statistical test, was chosen because of the relatively small sample size of the study group and the ordinal measurement scaling. The purpose of this test is to determine whether the two independent groups were drawn from the same population. If the two groups were not shown to be significantly different by this initial assessment, the control and experimental post-chemotherapy scores were compared to determine if there was a difference after the intervention. The significance level of p<.05 was established for this study.

A parametric statistical test for comparing the differences of group means, the t-test, was used in

comparing interval level data such as age and laboratory reports of blood component counts between groups to determine if there was significant difference in the groups. Such a difference would indicate a sampling variation. The Spearman rank correlation coefficient, a non-parametric statistical test, was used to determine correlation between oral assessment scores and lab values because of the two levels of data involved.

A non-parametric test, chi-square, was used to determine whether a significant difference existed between an observed number of responses and the expected or chance number of responses in a catagory. The chi-square statistic compares two sets of frequencies: those observed in the study and those expected if there were no relationship between the two variables (Polit & Hungler, 1983). Chi-square was used with educational level responses and the scores on the general self-care index of the Lifestyle and Health Habits Assessment tool to test the differences in proportions of cases that fell into the various catagories between groups.

Summary

Twenty-four oncology patients from four group practices in a large metropolitan area served as the subjects for this study. Using a Pretest-Posttest Control Group Design, the subjects were randomly assigned to either the control or the experimental group. All subjects received an initial oral assessment and had a buccal culture taken at the beginning of the study. The experimental group received educational material and directions regarding an oral care protocol and a home oral care management kit. All subjects received stomatotoxic chemotherapeutic agents for treatment of their cancer. After four weeks of chemotherapy, all subjects again had an oral evaluation performed by the investigators. The means of the initial and post-therapy oral assessment scores were compared between groups to determine if using the protocol made a significant difference in the condition of the mouth.

CHAPTER FIVE

Results

Introduction

The purpose of this study was to determine if nursing intervention, in the form of written educational instruction including a specific self-care oral hygiene protocol, could assist individuals receiving stomatotoxic agents maintain their oral health status. The directional hypothesis proposed that the graded oral scores for subjects receiving self-care education would reveal a significant decrease in the occurrence and severity of stomatitis compared to control subjects. The ordinal level data obtained from the graded oral scores were analyzed using the non-parametric Mann-Whitney U test for independent samples. A p<.05 level of significance was established for analysis of data.

Characteristics of the Sample

The subject sample of 24 patients ranged in age from 30 years to 79 years with a mean of 56.5 (Table 2). The age of the control group was not significantly different from the age of the experimental group (p = >.05).

The primary sites and frequencies of the malignancies for both subject groups are listed in

Table 2

Subjects' Sociodemographic Information

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	Group	
	Control	Experimental
Age		
range	30 to 73	30 to 79
mean	62	51
standard deviation	14.516	12.083
Sex		
males	6	6
females	6	6
Number of Subjects	12	12

Table 3. Three subjects lived alone, while 20 subjects lived either with a spouse or a spouse and unmarried children. One subject lived with a relative other than spouse or child. Only one subject in the study reported that financial resources were inadequate to support health care needs and was referred to a social service agency for assistance.

Educationally, ten subjects completed less than high school level. Six subjects received no formal education after high school graduation and eight participants reported some type of post-secondary education. Table 4 reflects the frequencies in each educational level in both control and experimental groups. The educational differences between groups were not significant at the p<.05 level.

Laboratory Determinations

Laboratory data collected from the medical records of all subjects included: white blood count (WBC), hemoglobin level, and platelet count (see Table 5). Using the t-test for independent samples, there were no significant differences between the control and experimental groups for these laboratory values either initially or at four weeks.

Buccal cultures taken at the onset of chemotherapy reflected the predominant resident microorganism found in the oral cavity at the time of the culture (Table Table 3

Primary Cancer Site

Site	Number of	Subjects
	Control	Experimental
breast	1	2
chondrosarcoma	0	2
colon	1	0
fallopian	0	1
esophagus	0	1
Hodgkins	1	0
GI tract	1	2
lung	5	2
ovarian	1	0
pancreas	1	0
testicular	0	1
undetermined	1	1
Total	12	12

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Table 4

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Educational Level of Subjects According to Group

Level	Control	Experimental
less than high school	7	3
high school graduate	2	4
post-secondary	3	5

Number of Subjects

Chi Square = 2.77 2 degrees of freedom p = N.S.

Table 5

Laboratory Data

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Lab Test	Control	Experimental	p
Initial Results		·····	
White Blood Cells	11,325	7,541	N.S.
per cu. mm			
Hemoglobin	12.68	12.03	N.S.
in gm/100ml			
Platelets	389,166	313,583	N.S.
per cu. mm			
Results at 4 weeks			
White Blood Cells	6,767	6,942	N.S.
per cu.mm			
Hemoglobin	10.30	10.96	N.S.
in gm/100ml			
Platelets	231,000	255,416	N.S.
per cu. mm			

N.S. = non-significant

6). Culture results demonstrated that all subjects except one had organisms described in the literature as normal flora of the mouth (Mikat & Mikat, 1981). However, yeasts which are normally residents of the mouth were isolated at predominant levels in half of the subjects. Other organisms in typical numbers, listed as normal resident flora (Appendix B), occurred in a similar frequency in both groups.

Only four subjects exhibited visible changes in oral mucosa and an increase on oral assessment scores to at least 150% of the baseline scores to indicate stomatitis at the fourth week of chemotherapy. These individuals' buccal mucosa were recultured. Three of the stomatitis subjects were in the control group; one was in the experimental group. The predominant organisms found in the pre-chemotherapy culture are listed along with the one identified in the reculture in Table 7.

Chemotherapeutic Agents

In order to meet the inclusion criteria of the study, participants had to be receiving an initial round of chemotherapy or beginning a new series with a known stomatotoxic agent. These drugs were given alone, in combination with other non-stomatotoxic agents, or, frequently, combined with other drugs known to cause stomatitis. Table 8 lists only the

Oral Hygiene 51

Table 6

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Pre-Chemotherapy Oral Culture Results

Predominate Organism	ganism Group	
	Control	Experimental
-	·····	
Yeast		
Candida albicans	4	6
Candida tropicalis	1	0
Candida paratropicalis	1	0
Normal Flora	4	5
Other		
Enterobacter cloacae	2	0
Acinetobacter lwoffi	0	1
Total	12	12

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Table 7

Recultures

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	Predominat	e Organism
Subjects	Initial Culture	e Reculture
Control		
1	Enterobacter	Actinobacter
	cloacae	species
2	Candida albicans	Candida albicans
3	Enterobacter	Enterobacter
	cloacae	cloacae
Experimental		
1	Candida albicans	Normal flora

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Table 8

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Stomatotoxic Agents received by Sample Subjects

Agent	Number of Subjects		
	Control	Experimental	
<u></u>	·		
5 Fluorouracil (alone)	6	4	
with Adriamycin	1	3	
with Mitomycin C	1	0	
	0		
Adriamycin (alone)	2	1	
with Vincristine	1	2	
Vinblastine (alone)	0	1	
with Bleomycin	1	Ó	
Procarbazine with			
Vincristine	0	1	

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stomatotoxic agents used in the subject sample.

Oral Assessment Scores

The test for the hypothesis compared the oral assessment scores of the experimental group with those of the control group. Although the control group had a higher mean rank for initial oral assessment scores than did the experimental group, the Mann-Whitney U test demonstrated no significant differences in the probability corrected for ties (p = .3085). When the oral assessment scores of the groups at the fourth week of chemotherapy were analyzed, the mean rank of the experimental group was actually lower than it was before the chemotherapy. The control group showed substantial increase in mean rank (from 13.92 to 16.29) and the Mann-Whitney U test, corrected for ties, revealed a very significant difference in the means between the groups (p = .01). The hypothesis was supported (Table 9).

Correlation between the oral assessment scores and laboratory blood values was tested using the Spearman Rank Correlation Coefficient. In all three catagories of lab tests, this statistical test revealed no significant relationship. The blood factors tested did not predict the condition of the oral cavity.

Table 9

Comparison of Oral Assessment Score Means

Measurement	Initial	Fourth week	
Mean			
Control	13.92	16.29	
Experimental	11.08	8.71	
"U"	55	26.5	
p	N.S.	.01	

To test whether the reported scores on the self-care portion of the Lifestyle and Health Habits Assessment tool were related to the condition of the mouth, the Spearman Correlation Coefficient was again used. No significant relationship was found to indicate that these self-care scores could predict oral health.

Summary

To test the hypothesis, the mean of the oral assessment scores of the experimental group was compared to that of the control group using the Mann-Whitney U-test. The value of U obtained for the initial assessment comparison was 55; after the experimental treatment, the value of U was 26.5. A U value of 28 or less was significant at the .01 level. The .05 level of significance was established for analysis of data in this study. Thus, the difference between the group means after treatment was very significant and the hypothesis was supported: self-care instruction can reduce chemotoxic stomatitis. Other statistical tests revealed no other significant differences in the composition of the groups. No relationships were found between laboratory values or reported scores on the self-care assessment and the condition of the oral cavity.

CHAPTER SIX

Discussion

Hypothesis

This study was designed to explore the value of educational materials, including a self-managed oral care protocol, in reducing the severity of chemotoxic stomatitis. Oncology patients treated with recognized stomatotoxic agents composed the sample. An experimental design facilitated the testing of the directional hypothesis: subjects receiving information and direction regarding a self-care, oral hygiene protocol will have a significant decrease in severity of stomatitis compared with those subjects receiving no instruction in a prescribed oral care routine. The experimental subjects, given educational material and an oral care protocol to follow, showed a significant improvement in oral assessment scores compared to the control group which did not receive this information. This supported the study hypothesis and seemed to demonstrate the value of a conscientious and informed approach to mouth care. This finding correlates with previous research by Beck (1979) which demonstrated significant improvement in oral assessment scores when care givers followed a systematic mouth care protocol.

While it is difficult to measure, promoting free

choice as a means of preserving control over some aspect of the illness was felt by the investigators to be of value to the subjects and may have influenced the results. A self-care approach presented early in the disease process promoted the client as a willful decision maker capable of weighing past choices in the light of new knowledge. The written educational material given to the experimental subjects served to reinforce positive oral habits and present new information for improved self-care. This information, gained from the educational guide, could be reviewed leisurely at home, away from the stresses of the treatment procedure. The home management kit presented the client with a convenient, standardized supply of oral care tools to carry out the protocol.

While the combination of educational material and the oral care protocol could be construed as two separate independent variables, the value of combining them to meet self-care deficits of the individual outweighed the possibilities that one had more effect on the subjects than the other. From their clinical experience with the self-care model and support from the literature, the investigators believed that giving information without direction or vice versa would be less likely to motivate the subjects to deliberately act to prevent oral side effects. Therefore, the educational material and the protocol were viewed as a single entity.

Research Question

The microbiological findings of the pre-chemotherapy buccal cultures are of interest. One half of the subjects exhibited <u>Candida</u> species as the predominant oral organism prior to treatment with anti-neoplastic agents. These results were unexpected. Data collection was insufficient to rule out antibiotic therapy as a cause of such colonization of otherwise normal flora. Possibly, this may have been a reflection of the status of the immune system of these oncology patients due to the disease process itself. Because only those subjects with visible stomatitis were recultured after chemotherapy, there were not follow-up cultures on all subjects.

The small sample size prevents generalizations about these cultures but indicates the need for further investigation. While the literature reveals that yeast commonly occurs in the oral cavity after chemotherapy, this study demonstrates that the organism was predominant before treatment in the sample subjects. The implication that the client was already compromised before chemotherapy presents a dilemma that may only be answered by a study focused on microbiological concerns.

Limitations of the Study

While the seven inclusion criteria were designed to control known variables, they limited the accessible subject pool. The subject sample was drawn from the group practices of seven oncologists and represented a large proportion, but not the total available population, of oncology clients in the geographical area. However the investigators believe that the client population did provide a good representation of oncology clients treated locally.

The newness of nursing research to the geographical area in which the study was conducted also appeared to have a negative influence on the sample size and the referral pattern. The use of multiple data collection sites necessitated referral from hospital and office nursing personnel who may have consciously or unconsciously limited the referral of clients. Participating subjects were randomly assigned to either an experimental or control group by the nursing personnel in the cooperating facilities by a chance draw. The manner and nature of the verbal message given to the experimental subjects by the nursing personnel who distributed the educational material and the home oral care kits may have influenced the participation either negatively or positively. The number of nurses involved in this distribution made this variability difficult to control.

The research design employed by the investigators cannot be purported as the functional equivalent of a laboratory experimental design. The complexity of human subjects has made achieving the same level of order and discipline over the research situation difficult. Additionally, the self-care framework of the study lends itself to variability between subjects in the use of the protocol.

Bias related to a client's inclusion in a clinical study may have influenced the degree of subject involvement. Many subjects expressed the desire to assist in any way if others would not have to suffer from the effects of cancer or chemotherapy. The effects of the client-interviewer encounter must also be considered to have influenced the amount of participation in the study protocol. The investigators' interpersonal skills as clinicians might have been viewed as therapeutic by the subjects and their families and may have increased compliance.

Unfortunately, no tool was available that could test the research hypothesis. Reliability had not previously been rigorously demonstrated on Beck's Oral Exam Guide. In addition, the investigators adapted the instrument to better reflect the self-care format of the study. However, the results of this investigation cannot be ignored or minimized. While the modified tool served to provide guided, consistent oral assessments, at some point, data must be gathered to validate a satifactory instrument.

Implications

The goal of this study was not the truth or untruth of the hypothesis, but rather a gathering of knowledge that could facilitate the oral hygiene of oncology patients. The prevalent use of chemotherapy demands that adaptable mouth care measures meet the changing needs of the oncology client. While the literature strongly supported the need for routine assessment and rigorous hygiene during chemotherapy, empirically tested nursing interventions responding to these needs have not ensued. The time is right for nursing to assume a leadership role in health care practices within the domain of its expertise. The national trend toward out-patient chemotherapy protocols were presented as further documentation of nursing's opportunity to develop and implement positive health measures for clients already compromised and now at further risk.

In addition, research efforts are needed that test effective ways to teach and motivate the client to participate in self-care activities that fit the changing therapy patterns. Development of nursing interventions which stress the client's right and ability to participate in care decisions is necessary as the individual assumes more control and interest in self-care. After accurate information and self-care methods are provided, clients have the right to participate in activities and decisions that promote and maintain health as well as those that detect and manage illness.

Recommendations for Further Research

The following recommendations for further research about chemotoxic stomatitis have been generated by this study:

 development and validation of a more satisfactory instrument for oral assessment;

 investigation into the effects of educational material on self-care behaviors;

3. identification and comparison of oral flora in cancer patients before and after chemotherapy;

 replication of this study using a larger sample size.

Summary

Results of the study supported the directional hypothesis: subjects receiving information and direction regarding a self-care oral hygiene protocol will have a significant decrease in severity of chemotoxic stomatitis compared with those subjects receiving no instruction in a prescribed oral care routine. Initially, there were no significant differences between the groups in any of the observed variables. Post-treatment oral assessment scores revealed statistically significant improvement in the oral condition of the experimental subjects compared to that of the control group thus indicating the importance of promoting self-care management techniques. Educative protocols that are empirically sound must be established to better meet the self-care needs of the short-stay or out-patient chemotherapy client.

Although not the focus of this study, the microbiological findings of the pre-chemotherapy buccal cultures raised questions regarding previous reports of the effects of chemotherapy on normal oral flora. Further research specifically designed to study this phenomenon appears warranted.

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APPENDIXES

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APPENDIX A

ORAL EXAM GUIDE

NUMERICAL AND DESCRIPTIVE RATINGS				
CATEGORY	1	2	3	4
LIPS				
Texture	smooth, soft	sl. wrinkled	rough	cracked, bleeding, ulcerated
Color	pink	one/more reddened areas	inflammatory line of demarcation	entire lip inflamed, bleeding
Moisture	moist	slightly dry	swollen, dry blistered	cracked and very dry
TONGUE				
Texture	firm without fissures or prominent papilli	basal papilli prominent; med. lingual groove deep	peppered appearance coating at base	engorged, deep grooves thicker than normal
Color	pink	pink with reddened	entirely red but tip and	tip very red demarcated &
		areas or coated	papilli are redder	coated; sides are blistered
Moisture	moist	slightly dry	very dry and swollen	intensely dry with indentations
MUCOUS MEME	BRANES			
Color	pink	pale	red and inflamed; may have white coating	very red; may have pinpoint brown spots/ ulcerations
Moisture	moist	slightly dry	dry and swollen	blistered/ ulcerated

ORAL EXAM GUIDE (cont.)

NUMERICAL AND DESCRIPTIVE RATINGS				
CATEGORY	1	2	3	4
GINGIVA				
Color	pink	pale; may have reddened areas, white pustules	red with ulcerations	very red and shiny
Moisture	moist	slightly dry	dry and edematous	edematous with ulcers & bleeding
TEETH				,
Shine	shiny	slightly dull	dull	very dull
Debris	no debris	slight debris	debris clining to half of enamel	covered with debris
Dentures	well-fitting	slightly loose	loose and ill-fitting; areas of irritation	unable to wear due to irritation
SALIVA	thin, watery	increased in amount	scanty; mouth dry	thick, ropy viscid or mucid
VOICE	normal tone and quality	slight change voice lower	deep and raspy	difficulty talking noticeable
ABILITY TO SWALLOW	normal gag reflex; swallows without difficulty	discomfort swallowing	diminished gag reflex and/or pain on swallowing	no gag reflex or inability to swallow

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APPENDIX B

NORMAL FLORA OF THE MOUTH

- 1. <u>Alpha-hemolytic streptococci (viridans group)</u>
- 2. Branhamella catarrhalis
- 3. Neisseria mucosa
- 4. <u>Staphylococcus epidermidis</u>
- 5. Haemophilus hemolyticus
- 6. <u>Streptococcus pneumoniae</u>
- 7. Nonhemolytic streptococci
- 8. Diphtheroids
- 9. <u>Coliforms</u>
- 10. Beta-hemolytic streptococciother than group A
- 11. Micrococci
- 12. Veillonella
- 13. Treponemas
- 14. Fusobacterium
- 15. Actinomyces israelii
- 16. Yeasts (Candida albicans, geotrichum)
- 17. Leptotrichia buccalis
- 18. Eikenella corrodens

Adapted from : Mikat and Mikat, 1981, A Clinician's Guide to Bacteria and Fungi, 4th edition, p 58.

APPENDIX C

KARNOFSKY SCALE

GRADE	SCALE	STATUS
1.	100%	Normal; no complaints, no evidence of disease
2.	90%	Able to carry on normal activity minor signs or symptoms of disease
3.	80%	Normal activity with effort; some signs or symptoms of disease
4.	70%	Cares for self. Unable to carry on normal activity or to do active work
5.	60%	Requires occasional assistance, but is able to care for most of needs
6.	50%	Requires considerable assistance and frequent medical care
7.	40%	Disabled; requires special care and assistance
8.	30%	Severely disabled; hospitalization is indicated, death not imminent
9.	20%	Hospitalization necessary; very sick, active supportive treatment
10.	10%	Moribund; fatal processes progressing rapidly

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Adapted from: Burns, N., 1982, Nursing and Cancer, p 178

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APPENDIX D

CONSENT FORM

We would like your help in conducting a study involving the occurrence and effective management of certain oral side effects associated with chemotherapy. Our goal is to improve patient education and ability to care for these symptoms should they occur.

No extra costs will be added to your bill as a result of participation. We know of no detrimental side effects of any proposed treatment. A thorough examination of your mouth will be made during your treatment times by one of the researchers for a length of up to six weeks. Participation is voluntary and refusal to participate will not effect your care.

You are free to withdraw from the study at any time without penalty. Confidentiality and anonymity will be maintained by coding of information. For your protection, this study has been approved by the Human Subjects Review Board of Grand Valley State College. It is funded by a grant from the American Cancer Society, Michigan Division.

Your signature below signifies that this study and your participation in it has been explained to you and that you freely consent to participate. A copy of the results of this study will be provided for you if you so desire.

Thank you.

Jerilyn Binder RN Ruth Ann Brintnall RN

Signature

Date

I would like to be informed of the results of this study. Yes____ No

APPENDIX E

ORAL ASSESSMENT WORKSHEET

SUBJECT # DATE Lips: smooth, moist
 rough, slightly dry
 rough, swollen
 cracked, ulcerated Mucous Membrane 1. pink, moist 2. red, slightly dry 3. red, dry 4. inflammed, ulcerated Gingiyae: pink, moist pale, slightly dry red, shiny, edematous shiny, ulcerated $\frac{1}{2}$. 3. 4. Teeth: shiny, no debris
 slightly dull, debris
 dull, debris
 very dull, much debris . Dentures: 1. well-fitting 2. loose 3. areas of irr areas of irritation under unable to wear due to irritation à. Tongue: pink, moist
 reddened areas, dry
 mostly red, swollen
 dry, red, sides blistered Saliva: 1. thin, watery 2. increased in amount 3. scanty, mouth dry 4. thick, viscid Swallow: 1. no difficulty 2. discomfort upon swallowing 3. pain on swallowing 4. inability to swallow

Total

APPENDIX F

Patient

PATIENT INFORMATION SHEET

Would you please help us by answering the following questions? A code number rather than your name will be used during the study and your answers will be kept confidential.

Please try to answer each question to the best of your ability.

- Sex: 1) female 2) male 1.
- Your age in years on your last birthday 2.
- 3.
- Martial status: <u>1)</u> married <u>2)</u> single separated divorced 4 widowed
- Ethnic background: 4.
 - 1) Asiañ
 - Black
 - Causcasian
 - ÷4í
 - Hispanic Native American -5) -6)
 - other
- 5.
 - $\frac{1}{2}$
- Living situation: 1) live alone 2) live with spouse
 - live with spouse and unmarried children live with relatives live with unrelated persons
 - 4
- 6.
- Residence: 1) City of Grand Rapids 2) within Kent County 3) within 25 miles of Grand Rapids
- Education: please check the highest level completed 1) did not complete grammar school 2) completed grammar school 3) completed 1-2 years of high school 4) graduated from high school 5) attended vocational school 6) completed 1-2 years of college 7) graduated from college 8) attended graduate school 9) hold post-graduate degree 7.

and

8. If you are taking any medication prescribed by your physician other than your chemotherapy, list the name of the drug or drugs and how often they are taken.

Are you	on a special diet prescribed by your doctor s, please check the appropriate number
1 2 3 4 5 6 7) salt restricted calorie restricted) low cholesterol) high fiber) high carbohydrate) bland) other
). Do you	have any other diagnosed illness?
2) Ye	s, please check the appropriate number) asthma
3) allergies (list)
5) epilepsy
7 8) high blood pressure) kidney disease

- medications that you need to stay well? 1) No 2) Yes

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APPENDIX G

Lifestyle and Health-Habits Assessment

Please place an X before each statement that is true regarding your **present** way of life or personal habits. That is, what you generally do.

GENERAL COMPETENCE IN SELF-CARE (14)

Take 12-15 deep breaths at least three times daily
Drink 6-8 glasses of water each day besides other liquids
Do not smoke
Read articles or books promoting health
Know my body contours and physical sensations well
Do not take laxative medications
Know what my blood pressure and pulse should be
Protect my skin from excessive sun exposure
Know the seven danger signs of cancer
Observe my body monthly for cancer danger signs
Understand how to correctly examine my breasts (women only)
Conduct monthly breast self-examination (women only)
Use soft toothbrush regularly
Dental floss regularly

Total number of items checked Percent checked

NUTRITIONAL PRACTICES (16)

Know about the "basic four" food groups
Plan or select meals to meet nutritional needs
Eat preakrast dally
Lat three hears a day
 Avoid between meal shacks Drink less than three cups daily of caffeinated beverages (coffees, teas, or colas) Do not consume alcohol or do so in very limited amounts Limit intake of refined sugars (junk foods or desserts) Frequently use unprocessed foods (without preservatives) Maintain adequate fiber in diet(whole grains, raw fruits and vegetables) Read labels for nutrients in packaged foods Eat more poultry and fish than red meat Chew food thoroughly and eat slowly Add little or no salt to food when cooking or during eating Keep weight within recommended limits for my height
Avoid fréquent consumption of charcoaled foods
Total number of items checked Percent checked
PHYSICAL OR RECREATIONAL ACTIVITY (9)
Walk up stairs rather than riding the elevator Exercise vigorously for 30-40 minutes 4 times a week Regularly engage in recreational sports (swimming, bicycling) Perform stretching exercises at least 4 times per week Participate in individual sports for the pleasure of movement

Total number of items checked Percent checked SLEEP PATTERNS (9) Get 7 hours of sleep per night (not 2 hours more or less) Wake up feeling fresh and relaxed Take some time for relaxation each day Fall asleep easily at night Sleep soundly Systematically relax voluntary muscles before sleep Sleep on a firm mattress Use a small pillow that maintains head and neck in natural position Allow thoughts and worries of the day to leave my mind, concentrating on passive but pleasant thoughts at bedtime

Total number of items checked Percent checked

STRESS MANAGEMENT (11)

Can laugh at myself	
Frequently laugh out loud with others	
Maintain adequate Vitamin C intake when experiencing high	
stress	
Practice relaxation or meditation for 15-20 minutes daily	
Understand the relationship between stress and illness	
Create relaxed atmosphere at meal times	
Forget my problems and enjoy myself when immediate solutio	ns
are not possible	
Enjoy spending time in unstructured activities	
Consider it acceptable to cry, feel sad, angry, or afraid	
Have attended training classes to gain relaxation skills	

Total number of items checked Percent checked

SELF-ACTUALIZATION (12)

Maintain an enthusiastic and optimistic outlook on life Enjoy expressing myself in hobbies, the arts, exercise or play Like myself and enjoy occasional solitude Continue to grow and change in positive directions Am happy most of the time Am a member of one or more community groups Feel fulfilled in my work Aware of personal strengths and weaknesses Am proud of my body and personality Respect my own accomplishments Find each day interesting and challenging Look forward to the future

Total number of items checked Percent checked

SENSE OF PURPOSE (4)

Aware of what is important to me in life Have identified short-term and long-term life goals Am realistic about the goals that I set Believe that my life has purpose

Total number of items checked Percent checked

RELATIONSHIPS WITH OTHERS (11)Have persons close to me with whom I can discuss personal problems and concerns Perceive myself as being well accepted by others Maintain meaningful, fulfilling interpersonal relationships Communicate easily with others Recognize accomplishments and praise other people easily Recognize accomptishments and project cutif people cutif Enjoy my neighbors Have a number of close friends Thoughtfully consider constructive criticism rather than reacting defensively Enjoy being touched and touching others close to me Find it easy to express concern, love, and warmth to others Enjoy meeting new people and getting to know them Total number of items checked Percent checked ENVIRONMENTAL CONTROL (6)When possible, prevent overwhelming changes in my environment Avoid purchasing aerosol sprays Seldom listen to loud rock music Do not permit smoking in my home or car Provide resources to meet my own personal needs Maintain safe living area free from fire or accident hazards Total number of items checked Percent checked USE OF HEALTH CARE SYSTEM (8) Report any unusual symptoms to a physician Question my physician or seek second opinion when I do not agree with the recommended treatment Expect prompt, helpful, and courteous personalized service from health care personnel Discuss health concerns or problems with professional most qualified to provide meaningful assistance Have breast examined at least once a year by nurse/physician Have a pap smear at recommended intervals Have a rectal examination at recommended intervals Attend classes on personal health care provided within the community

community

Total number of items checked Percent checked SCORING: calculate the percentage of items checked in each category by dividing the number of items that you checked by the total number of items listed in the category (total number of items in each category is listed in parentheses by category title). Record below the percentage of items checked from each category.

CATEGORY	PERCENTAGE	RATING
COMPETENCY IN SELF CARE		·····
NUTRITIONAL PRACTICES		
PHYSICAL/RECREATIONAL		
SLEEP PATTERNS		
STRESS MANAGEMENT		
SELF-ACTUALIZATION		
SENSE OF PURPOSE		
RELATIONSHIPS WITH OTHERS		
ENVIRONMENTAL CONTROL		
USE OF HEALTH CARE SYSTEM		

For each category, the following scale may be used to evaluate the extent to which the client's lifestyle and health habits maintain or promote personal health.

RATING

PERCENTAGE OF ITEMS CHECKED

Excellent Good	Greater than 85% 75-84% 65-74%
Fair	55-64%
Poor	Below 55%

(Used with permission from Pender, N.J., Health Promotion in Nursing Practice, Appleton-Century-Crofts, 1982)

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APPENDIX H

ORAL CARE PROTOCOL

MOUTH CARE DURING CHEMOTHERAPY

WHY MOUTH CARE?

This information was prepared to assist you in maintaining optimal oral health during your course of chemotherapy. Some anti-cancer drugs may cause stomatitis, a temporary disruption in the lining of the mouth. Not everyone undergoing chemotherapy will develop these changes; only about 40% of people will report some awareness of mouth irritation during chemotherapy. By being more aware of this potential condition as well as measures to promote your own oral health, it is hoped that you will be better able to recognize and manage this side effect if it occurs.

EXPLANATION OF TERMS

CHEMOTHERAPY - the use of medications (chemicals) as a treatment to kill cancer cells. Chemotherapy may be administered in the form of tablets or injections. Some chemotherapy may be given directly into the vein. The purpose of chemotherapy is to destroy rapidly multiplying cancer cells.

SIDE EFFECT - results of a medication that are not the intended outcome of the therapy. Some medications have side effects that occur quite regularly during the course of therapy; while some of these side effects cause little trouble, others can be quite bothersome.

STOMATITIS - changes in the lining of the mouth that appear as redness and irritation; this may progress to swelling and ulceration with breakdown of the lining of the mouth. Stomatitis occurs as a side effect of chemotherapy because the nature of the drug is to attack cells in the body that are rapidly growing. Cells in the lining of the mouth normally grow and are replaced rapidly. The anti-cancer drugs cannot distinguish this normal rapid growth from rapid cancer cell growth. Stomatitis is not a permanent condition and disappears after the course of chemotherapy.

GINGIVA - also called the gums, the soft mucous membrane lining around the teeth.

MUCOUS MEMBRANE - the thin layer of cells that form the lining of the mouth and other body openings; these membranes are kept moist by the secretions of glands.

DEBRIS - material that deposits and collects on the surface of gums, teeth, and mucous membranes that serves as a growth place for bacteria.

 $\tt UICERATION$ - an interruption in the surface of the mucous membrane of gingiva. The base of the ulcer is usually swollen and it may be sensitive to the touch.

ROUTINE FOR MOUTH CARE

1. Keep regular appointments with your dentist for cleaning and maintenance of your teeth and gums.

2. Brush your teeth regularly after each meal with a soft tooth brush.

3. Thoroughly floss your teeth twice a day.

4. Avoid trauma to your mouth -- that is, very hot and very cold liquids and foods that might scrape or injure your gums.

5. Eat regular and nutritious meals to help maintain your health.

6. Use a soft washcloth to help you better clean your mouth if you are unable to use your toothbrush.

7. Don't skip your mouth care; research has shown that the benefits of good oral care are quickly lost when you omit care.

8. Examine your mouth daily according to the guide enclosed. Call your doctor if you have questions or concerns.

EXAMINATION OF THE MOUTH

It is important for you to learn to examine your mouth at regular intervals during chemotherapy. Your mouth serves as one of the first barriers for any bacteria that enter your body. It is most important that your mouth remain healthy. Some chemotherapy may cause you to be less able to fight infection. Your healthy mouth will help you maintain a normal intake of food; a nutritious food intake will maximize your wellness during your course of chemotherapy.



FIGURE 1: ORAL CAVITY

Yasko, J.M., ed. (1983) Nursing Management of Symptoms Associated with Chemotherapy. Reston, Va.: Reston Publishing, p. 54.

HOW TO EXAMINE YOUR MOUTH



BEFORE YOU BEGIN

1. Find a room with a good light source and a mirror; try to do your exam in the same room each day at about the same time.

2. Remove all dentures or dental appliances.

3. Find a flashlight as an additional source of light; a penlight is especially good because of its small size.

4. Allow yourself sufficient time to do your best job.

5. Do use the guide and determine the number value that best describes your mouth. This will help you better see changes in your mouth.

6. Place your oral care products in one place. Don't allow yourself to be "out" of dental floss, toothpaste or other needed supplies.

ORAL EXAMINATION GUIDE

CATEGORY	DESCRIPTIVE RATINGS
Lips	 My lips feel moist and comfortable My lips feel slightly dry My lips are dry & burn especially at the corners My lips burn intensely; they are cracked & it hurts to open my mouth
Tongue	 My tongue is moist and comfortable My tongue is slightly dry & sticks to the roof of my mouth My mouth feels like cotton & my tongue feels numb My tongue feels thick, dry with an intense burning at the tip
Gingiva	 My gums feel moist and comfortable My gums are a little sore but I am hardly aware of it My gums are sore and it is annoying My gums are sore & I am constantly aware of the pain
Saliva	 My mouth feels moist I feel like my saliva has increased I feel like my saliva has decreased My mouth is very dry & my saliva is very thick
Teeth	 My teeth feel clean There is a small amount of debris on my teeth There is moderate debris on my teeth My teeth are covered with debris
Dentures	 My dentures fit well; there is no discomfort I have slight discomfort when I wear my dentures but I am hardly aware of it It is annoying & painful to wear my dentures & I take them out frequently It hurts so much that I can't wear my dentures
Taste	 There is no change in my taste Things taste slightly different Nothing tastes right I can't taste anything
Voice	 My voice sounds normal My voice sounds lower My voice sounds deep & raspy It is difficult to talk my mouth is so dry; it hurts when I try to speak
Eating	 I have no difficulty eating because of my mouth It is harder to eat because of my mouth Certain foods, especially hot & spicy foods burn my mouth It hurts so much to chew & swallow that I can't eat

ORAL CARE PROGRAM

Please read the accompanying information carefully. Feel free to ask questions if you are unsure of the instructions. You will be given a kit to assist you in the management of your home mouth care. Please use only the supplies in the kit; let us know if you feel you need something that is not available in the kit. Extra supplies are available if you run out.

EXAMINATION:

1. Carefully examine your mouth once daily at a convenient time for you; try to make it about the same time each day.

Do use your penlight and dental mirror and look at: a. the roof of your mouth 2.

a. the fool of your mouth
b. your gums surrounding your teeth
c. your tongue - top and underneath
d. the mucous membranes on both sides of your mouth
e. any area of your mouth that feels different or
uncomfortable

3. Consider each question on your Oral Assessment Guide and determine a number value. Record that number at least once a week on the sheet provided. Recording that number is especially important 5-14 days after you begin your treatment. Your nurse will also check your mouth each week when you are given your chemotherapy.

DAILY CARE

a. thorough flossing at least twice a day.
b. brushing with the brush provided after each meal.
c. avoiding commercial mouth washes as they contain a
relatively high percentage of alcohol which might cause drying of

your mouth. d. use "disclosing tablets" once a week which will help you determine the areas of your mouth where debris is forming. e. avoiding very hot and cold food or foods that might traumatize your mouth.

IF STOMATITIS OCCURS

The earliest symptoms you may notice are a dry mouth or generalized soreness in your mouth after drinking citrus juice. The lining of your mouth may look red, shiny, and swollen.

CARING FOR STOMATITIS

1. Before using your toothbrush, soak it in warm water for a few minutes to soften it. A disposable foam stick may be used in place of a toothbrush.

2. Rinse your mouth every two hours during the day with warm salt water and every six hours at night. Continue to rinse also after meals and snacks.

3. Drink plenty of fluids with and between meals.

4. Smoking and drinking alcoholic beverages may irritate your mouth and throat. Sugar-free gum may be chewed instead.

5. Eat soft foods. Avoid hot or spicy foods, and citrus juices. Cold foods and liquids such as ice cream, liquid nutritional supplements, and popsicles may help ease the soreness.

6. Use vaseline or lip balm to moisten your lips every two to four hours.

7. If the discomfort interferes with your ability to eat, please notify your doctor; he may prescribe medication for you to use before meals.

RECIPE

Salt water rinse:

1 teaspoon table salt 4 cups warm water

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CORRESPONDENCE

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Northern Illinois University DeKalb, Illinois 60115

School of Nursing Montgomery Hall 815 753 1231

January 18, 1985

Ruthann Brinthall, R.N., B.S. Jerilyn Binder, R.N., M.A. 655 Plymouth, SE Grand Rapids, MI 49506

Dear Ms. Brinthall and Binder:

As author of Health Promotion in Nursing Practice, you have my permission to use the clinical form of the "Lifestyle and Health Habits Assessment" that appears in the book. My colleagues and I are working on a research form of the instrument that has been tested for reliability. It will be available by March 1, 1985. If you would prefer to use the research form, contact us <u>after</u> <u>that date</u> and we will send the revised form to you. Good Luck with your research.

Cordially,

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Nola J. Pender, Ph.D., R.N., F.A.A.N. Professor Community Health Nursing

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