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Enzyme Therapy in Oncology Care: A Clinical Scholarship Project

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Abstract

Studies worldwide indicate that oral enzyme therapy (OET) can prevent or reduce the side effects associated with standard oncology care. Yet use of OET is not common in the United States. The ultimate aim of the proposed project is to improve the quality of life of women with breast cancer who are on standard chemotherapy protocols. Achieving this goal can be facilitated by implementation of the proposed feasibility project designed to: (a) enhance the knowledge of oncology care providers and women with breast cancer on use of OET in conjunction with standard oncology care, (b) assess the attitudes of oncology care providers and women with breast cancer regarding use of OET, and (c) establish relationships with providers in the oncology care community and groups for women with breast cancer.

An educational program entitled *"Enzyme Nutrition in Oncology Care"* was developed and implemented in the project setting. Six programs were conducted with women with breast cancer, their support persons and the general public. Four programs were conducted with oncology care provider groups. An enzyme knowledge test was administered to program attendees in a pre-test/post-test fashion. Analysis of scores on the post-test when compared to the pre-test demonstrate that the knowledge base regarding oral enzyme therapy use in conjunction with standard oncology care was increased for all educational program attendees. Additionally scores reveal a favorable shift for use of OET in conjunction with standard oncology care and patient participation in clinical trials. By conducting educational programs with four oncology care provider groups, relationships were established with all of the oncology care provider groups in the project setting.

Acknowledgements

I would like to acknowledge the assistance given to me by my committee chair, Dr. Margaret Barton-Burke, through the numerous submissions and revisions of this proposal. Her kindred spirit, assistance, insistence and encouragement have been invaluable. Additionally I want to thank her for her contributions to the oncology care community at large giving graciously of her time and expertise. Dr. Rick Yakimo proved to be a breath of fresh air and a welcome, willing ear during the most challenging aspects of this graduate program. I believe it imperative for him to know the positive impact he had not only on me but our entire DNP cohort. Somehow thank you seems inadequate for the role he has played. Gratitude is extended to Dr. Sue Farberman for her accepting the challenge of the DNP Program Coordinator role, her willingness to move beyond the box in support of students and for agreeing to be on my committee. Despite the numerous challenges she faces with her DNP program responsibilities she has not been at a loss for time to interact with students in the program which she may not fully realize the value of – to the DNP students this is priceless! Words cannot begin to express the respect, admiration and appreciation I feel for Dr. Dennis Frerking. Over the last several years I have benefited immensely from his clinical education programs on enzyme therapy. More important than his educational savvy is his gentle spirit and humble heart. It seems incomprehensible to me that he willingly serves as a mentor to so many in the healing arts, including myself, in the face of the demanding schedule he faces on a daily basis. I count my interactions with him as pure blessing. Most importantly I want to acknowledge the continued unconditional love and support from my amazing family.

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Introduction

The National Center for Complementary and Alternative Medicine (NCCAM) defines complementary and alternative medical (CAM) approaches as "a group of diverse medical and health care systems, practices and products that are not generally considered a part of conventional/allopathic medicine" (NCCAM, 2010). Complementary and alternative (CAM) approaches are grouped into categories which include: (a) natural products, (b) mind and body medicine, and (c) manipulative and body-based practices. Data from the 2007 National Health Interview Survey (NHIS) reveals that adults in the United States spent 33.9 billion out-of-pocket dollars on visits to CAM practitioners and purchases of CAM products, classes and materials (Nahin, et al, 2009). Additionally the 2007 estimates place overall prevalence of CAM use at 38.3 percent (83 million) of adults in the United States (Nahin, et al, 2009).

Patients seeking relief from the side effects of cancer therapy often turn to approaches outside of the conventional medical model. The debilitating side effects of radiation and chemotherapy, e.g. nausea/vomiting, sore mouth, loss of appetite, pain, fatigue, hair loss, and numbness/tingling in fingers and toes, often are not adequately managed with conventional medical approaches. A survey conducted with patients receiving care at M.D. Anderson Cancer Treatment Center in Houston, Texas, revealed CAM use was common in this patient population (Richardson, et al, 2000).

Use of CAM approaches in lieu of or in conjunction with conventional oncology care appears to be absent in clinical oncology literature published in the United States. Peer-reviewed articles from journals such as the American Journal of Clinical Oncology

and the Oncology Nursing Forum center predominantly on managing standard oncology care, such as radiation and chemotherapy.

Most CAM approaches use natural substances that are not proprietary and to date have not been patented by the U.S. Patent Office. Research and development dollars are not typically spent on CAM products or approaches. Clinical research on CAM approaches is required for sustainability of their use in the current evidence-based medical culture. Meanwhile clinical research on CAM approaches is requisite for sustainability of their use in the current evidence-based medical culture. This poses a dilemma regarding ways to generate evidence-based CAM approaches to treat the side effects of cancer therapy but sets the stage for a well-designed clinical research trial to evaluate the use of CAM approaches in conjunction with or in lieu of conventional oncology care.

Additionally medical and nursing school curricula do not include course offerings on the use of CAM approaches as treatment for health problems making their use in practice challenging. Based on this lack of education, health care providers are challenged to develop an in-depth understanding of CAM approaches. The challenge must be met with the same scientific rigor and discipline that has successfully served the biomedical model.

Extensive clinical experience has been gained by this doctoral student with patients who use CAM approaches. In particular experience has been gained with patients who use oral enzyme therapy (OET) in combination with their standard oncology care. Observations of clinical outcomes for these patients reveal reduction in the severity, and at times prevention, of many of the expected side effects associated with

standard oncology care. Anecdotal observations regarding fatigue, pain, and numbness/tingling of the hands and feet suggest a benefit for patients with cancer who use OET in conjunction with their standard oncology care. Healing damaged skin secondary to radiation therapy has been observed in patients who use OET.

An informal survey among a network of CAM practitioners who recommend OET for their patients receiving chemotherapy or radiation therapy reveals similar anecdotal observations to those cited above.

Yet anecdotal observations do not stand up to scrutiny in today's evidence-based health care culture and CAM approaches must be evaluated in a scientific manner using well-designed clinical trials.

This Doctor of Nursing Practice Clinical Scholarship Project (CSP) is the first step in beginning to quantify data about the effect of OET in a group of women with breast cancer. The population of women with breast cancer is meaningful for two different reasons. The first is personal since my sister died from recurrent, metastatic breast cancer. The second is epidemiologic in that one in eight women will be diagnosed with breast cancer over the course of her lifetime (ACS, 2010). The review of the literature presented later in this paper reveals that the use of OET may prevent, reduce or eliminate the side effects associated with standard oncology care. A reduction or even prevention of the side effects associated with standard breast cancer chemotherapy regimens may improve the quality of life for women with breast cancer. Preventing, reducing or eliminating side effects may result in decreased cost of care for breast cancer patients undergoing chemotherapy.

Project Rationale

This doctoral student conducted a clinical scholarship project (CSP) regarding the use of OET in conjunction with standard oncology care. The CSP aims to uncover the strengths and weaknesses of a proposed venture to determine the interest from the community regarding their involvement in a research study on the topic of OET. This CSP allowed for identification of opportunities and threats presented by the implementation of such a research study and the process of conducting such a research study at some time in the future.

In Southwest Missouri there is a noticeable lack of use of complementary and alternative medicine (CAM) approaches in health care practice. This fact suggests that conventional health care providers are not recommending the use of OET. The proposed CSP may enhance future efforts in conducting clinical research that includes OET.

Intent of the Clinical Scholarship Project

The major component of the proposed CSP was the development and implementation of an educational program entitled *"Enzyme Nutrition in Cancer Care"*. The educational program was presented to both oncology care providers and women with breast cancer. Goals of presenting the educational program include: (a) increased knowledge on use of OET to prevent/reduce the side effects of standard oncology care, and (b) assessment of the attitude of oncology care providers and women with breast cancer regarding OET use.

The intent of the proposed CSP was to evaluate outcomes of presenting "*Enzyme Nutrition in Cancer Care"*. Several issues have been identified that may impact implementation of OET in conjunction with standard oncology care. Those issues

included: (a) observed lack of implementation of CAM approaches in the project region, (b) an observed lack of knowledge among health care providers and the general public regarding CAM approaches, and (c) the prevailing conventional medical culture. The proposed CSP was designed to: (a) enhance the knowledge of oncology care providers and women with breast cancer on use of OET in conjunction with standard oncology care, (b) assess the attitudes of oncology care providers and women with breast cancer regarding OET use, and (c) establish relationships with the oncology care community and with groups for women with breast cancer.

Stakeholders Identified for the Clinical Scholarship Project

In Springfield, Missouri, there are two large oncology care groups. Oncology Hematology Associates is affiliated with Cox Health Systems, and Hematology and Oncology Clinics is affiliated with Mercy Medical Missions. Each health system has a dedicated cancer resource center: C.H. "Chub" O'Reilly Cancer Center at Mercy Medical Missions, and Hulston Cancer Center at Cox Health Systems. Each of these two large health care systems in Springfield has a dedicated breast cancer center. Additionally the feasibility project included Skaggs Cancer Center in Branson (approximately 35 miles south of Springfield) and Central Care Cancer Center in Bolivar (approximately 40 miles north of Springfield).

Another group includes members of each of the oncology care groups mentioned above who joined forces for purposes of conducting clinical research. This joint venture is known as the Cancer Research for the Ozarks (CRO). While their research efforts focus on standard oncology care protocols, inclusion in the stakeholder discussion is warranted as CRO faces challenges and barriers in conducting clinical research. This

doctoral student anticipates similar challenges and barriers for conducting clinical research on CAM approaches.

Additional stakeholders for this CSP included women with breast cancer who attend support group meetings in the study setting. A cursory survey revealed two such groups that are active at the time of project implementation.

Conceptual Framework

Mior, Barnsley, Boon, Ashbury and Haig (2010) designed a qualitative study aimed at promoting interprofessional collaboration between physicians and chiropractors in a community-based primary care setting in Ontario, Canada. The resultant framework yielded processed-based factors that fell into three categories: (a) communication, (b) practice parameters, and (c) service delivery (Mior, et al, 2010). The emergent framework focused on patient care and attributes promoting a trusting relationship between chiropractors (CAM providers) and physicians in a primary care community setting.

Delineated in the framework are activities to enhance communication. Attendance at formal meetings, which include regular educational programs to share knowledge about relevant aspects of evidence-based patient care, is promoted. Case study discussions are used as the educational format for facilitating discussion. Informal social meetings are used for developing personal relationships and mutual trust and respect (Mior, et al, 2010).

The conceptual framework developed by Mior, et al, (2010) may help promote interprofessional collaboration not only between physicians and chiropractors, but also between other health care providers. The conceptual framework developed by Mior, et

al, (2010) was selected for the CSP and is appropriate for CAM providers to begin establishing relationships with members of the conventional medical community and for facilitating outcomes of the clinical scholarship project (see Figure 1).

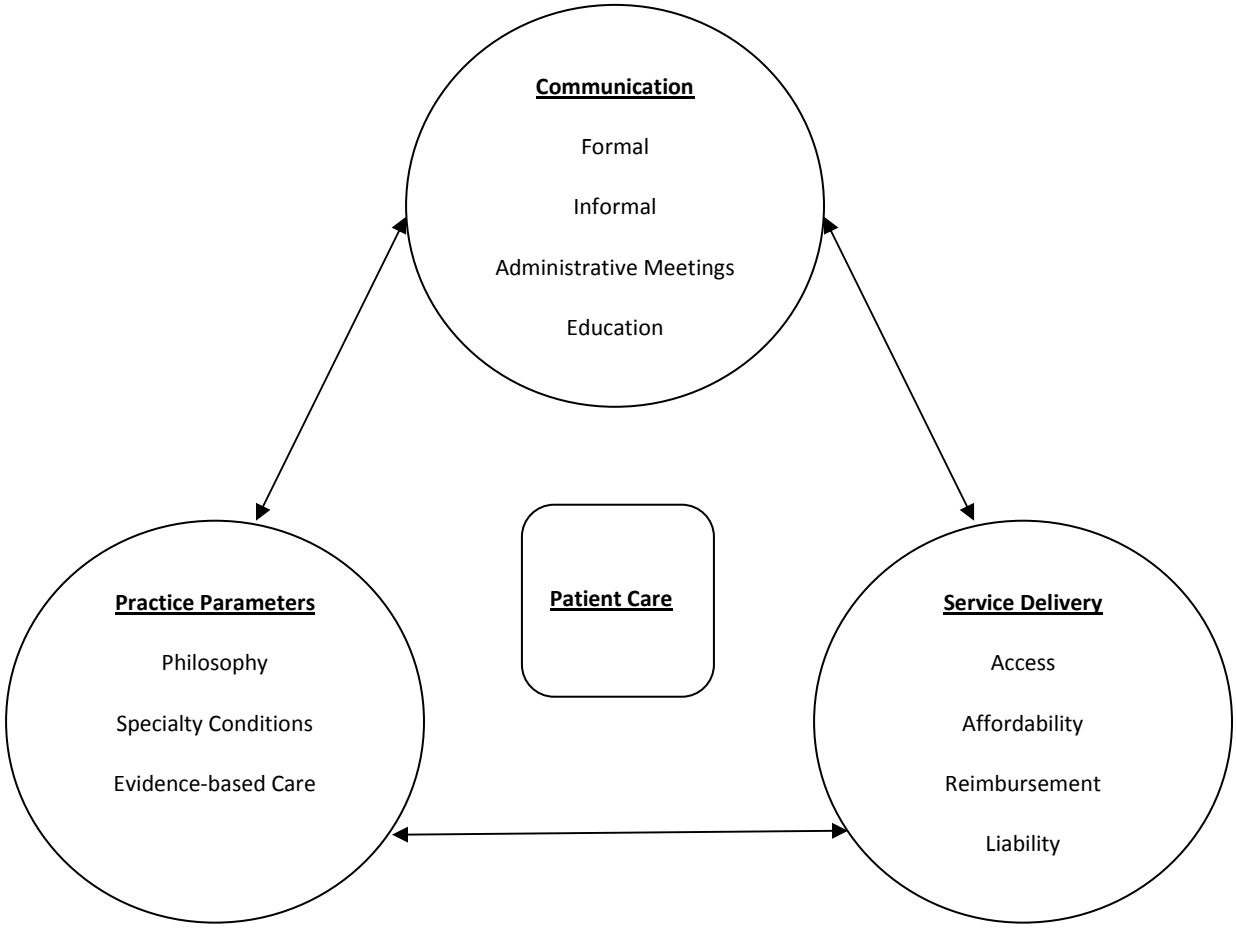

Figure 1. Framework focusing on patient care and promoting collaboration (Mior,et al).

Review of the Literature

Literature on Enzyme Therapy in Oncology Care

Somewhat misunderstood, use of enzyme therapy struggles to gain a legitimate position in medical approaches in the United States. There is limited literature on it in peer-reviewed oncology journals. Yet the foundations of modern enzyme therapy can be found in a book by an English physician, John Beard, DSc, published in 1911 entitled

"The Enzyme Treatment of Cancer and its Scientific Basis" (Beard, 1911). Extending early science on enzyme therapy came when James B. Sumner was awarded the Nobel Prize in Chemistry for his efforts to crystallize the enzyme urease from jack bean meal and identified it as a protein (Sumner, 1946; Zanker, 2001).

Plant extracts with high proteolytic enzyme activity have been used for a long time in traditional medicine (Leipner & Saller, 2000). Therapeutic use of proteolytic enzyme therapy is based partially on scientific studies and partially on empirical evidence. Modern enzyme therapy often includes pancreatic enzymes. Clinical studies to evaluate the efficacy of proteolytic enzyme therapy in oncology have mostly been conducted with an enzyme preparation that contains both plant and pancreatic enzymes.

German researchers designed an epidemiological retrospective cohort analysis with parallel groups to evaluate the impact of OET given complementary to standard oncology care therapy in patients with all stages of colorectal cancer. In a cohort of 1242 patients with colorectal cancer, 616 received complementary treatment with OET while 626 had not received OET. Patients who had undergone primary surgery numbered 1162. For primary surgical patients, 526 received adjuvant chemotherapy and 218 received radiation therapy. Median follow-up time for the OE group was 9.2 months and for the control group 6.1 months. The primary test criterion of efficacy for the OET group was the multivariate effect size of the changes from baseline of the disease-related and therapy-related signs and symptoms of nausea, vomiting, changes in appetite, stomach pain or stomach disorder, tiredness, depression, memory or concentration disorder, sleep disturbance, dizziness, irritability, dyspnea at rest, dyspnea during activity, headache, tumor pain, cachexia, skin disorders and infections. Safety of OET was

analyzed in terms of number and severity of adverse events, their duration, treatment and outcome. Analysis revealed a significant reduction in disease-associated signs and symptoms in patients treated with OET. Adverse reactions to chemotherapy and radiation therapy were diminished in all patients receiving OET. Researchers concluded that treatment of colorectal cancer patients with adjuvant OET reduces the signs and symptoms associated with their disease process and reduces the adverse reactions associated with adjuvant standard oncology care therapies (Popiela, et al, 2001).

Researchers in India conducted a prospective, randomized clinical trial enrolling 120 subjects undergoing radiation therapy for treatment of locally advanced, biopsy proven carcinomas of the cervix (Stages IIa, IIb or IIIb). Patients received 50 Gy of external radiation therapy over a period of 5 weeks, followed by intra-cavitary brachytherapy of 20-30 Gy. Sixty patients who were assigned to the test group received additional OET. Patients were evaluated weekly for acute radiation therapy-related side effects and for an additional 8 weeks after the conclusion of their radiation treatment. Results of the study revealed that the maximum extent of acute radiation side effects was reduced in the enzyme group: a) skin reactions (mean 0.97 vs 1.68 in the control group, $P<0.001$); b) vaginal mucosa reactions (mean 0.55 vs 0.85, $P=0.10$); c) genitourinary symptoms (mean 0.93 vs 1.38, $P<0.001$); and d) gastrointestinal reactions (mean 1.12 vs 1.30, $P=0.12$). Sum scores during treatment were noted to be significantly less in the enzyme treated patients. All observed side effects of radiation therapy were of lower intensity in the enzyme group. Based on study findings the researchers concluded that for patients with locally advanced cancer of the cervix, OET was found to be effective in

significantly reducing radiation side effects such as genitourinary symptoms, subcutaneous changes and reactions of the vaginal mucosa (Dale, et al, 2001).

In Germany an epidemiological, multicenter retrospective cohort study was conducted to evaluate the impact of OET given complementary as a post-operative care approach with breast cancer patients receiving standard anti-neoplastic therapy. A cohort of 2339 breast cancer patients undergoing surgical intervention and radio, chemo- or hormonal therapy were studied in 216 centers. Of the 2339 patients, 1283 received complementary OET and 1056 patients did not. The median follow-up team for the test group was 485 days and for the control group 213 days. The endpoint of the study was to evaluate if complementary OET can reduce typical disease- or therapy-associated signs and symptoms (e.g. gastrointestinal symptoms, mental symptoms, dyspnea, headache, tumor pain, cachexia, skin disorders, infections and side effects associated with standard oncology care protocols) in patients with breast cancer. Analysis of data revealed for all symptoms, except tumor pain, the adjusted mean improvement in symptom scores was larger in the test group than in the control group. The adjusted difference was statistically significant for all symptoms except tumor pain and infections. Results demonstrate that the typical disease- and therapy-associated signs and symptoms for breast cancer patients on complementary OET during postoperative treatment were significantly less (Beuth, et al, 2001).

Patients with invasive breast cancer receiving adjuvant or palliative chemotherapy between 2005 and 2006 who had at least two further cycles of chemotherapy scheduled were studied by researchers in Austria. The hypothesis was that specific toxicities of individual patients would be reduced by the use of OET. The majority of the 57

consecutive patients received palliative chemotherapy. Researchers concluded that OET administered consistent with the study protocol had only a marginal influence in patients with breast cancer who had experienced grade two toxicity in the preceding cycle and who had received two additional identical cycles of chemotherapy (Petru, et al, 2010).

Researchers in the Slovak Republic utilized OET adjunctively with standard combination chemotherapy for patients with multiple myeloma. A cohort of 265 patients with multiple myeloma stages I-III was treated consecutively in two parallel groups. An OET regimen was given to 166 patients receiving standard chemotherapy while 99 patients receiving standard chemotherapy served as the control group. Primary endpoint for this study was disease-specific survival. Secondary endpoints were response to therapy, duration of the first response and side effects. Survival analysis was performed using the Kaplan-Meier method and a multivariate analysis was done with the Cox proportional hazards model. Analysis revealed significantly higher overall response rates and longer duration of remissions for the OET group. Additive therapy with OET for greater than six month duration decreased the hazard of death for patients at all stages of disease by approximately 60 percent. Observation time was not adequate to estimate the median survival for patients with Stage I and Stage II disease; for Stage III patients median survival was 47 months in the control group versus 83 months in the OET group (Sakalova, et al, 2001). Based on these findings, a prospective, randomized Phase III study was initiated in the United States under an orphan drug designation. A search regarding the outcome of the aforementioned Phase III study entitled “Chemotherapy With or Without Wobe-Mugos E in Treating Patients with Stage II or III Multiple

Myeloma" [protocol ID MUCOS-MU 699-501, NCT 00014339] reveals recruitment has closed but final results are not available.

Discussion

Review of this limited scientific literature supports use of OET in conjunction with standard oncology care as a safe and efficacious approach for the prevention or reduction of side effects observed from such therapy. Observation of conventional oncology care approaches in the United States reveals use of OET is not commonplace. A potential explanation includes a lack of knowledge of oncology care providers with regard to OET. A lack of prospective, randomized, controlled clinical trials on the use of OET in the United States may be another factor.

Review of the Literature on Continuing Education Programs

A review of the literature supports the use of an educational program for achieving the ultimate aim of this clinical scholarship project. Studies show that educational programs impact both knowledge and attitudes for both health care providers and patients. Studies cited below demonstrate the impact of educational programs presented to both provider and patient audiences.

Researchers conducted a study to evaluate the impact of a continuing education course on general practitioner knowledge, attitude, practice approach and patient outcomes with regard to the diagnoses of depression and anxiety. A case controlled before-and-after design was used with fourteen general practitioners who participated in the continuing education program. Practitioners who participated in the educational program were matched with fourteen general practitioners who did not participate. Differences between the groups and pre- and post-test measurement of knowledge,

attitude and clinical practice were examined using *t*-tests and chi-square tests for categorical variables and analysis of covariance for continuous variables. Analysis of the data resulted in statistically significant changes in the intervention group of general practitioner's knowledge and attitude regarding the diagnoses of depression and anxiety. Findings reveal attendance at a continuing education program can result in a change in practitioner knowledge and attitudes (McCall, Clarke, and Rowley, 2004).

A randomized controlled trial (RCT) was conducted to investigate the effectiveness of, and satisfaction with, small-group problem-based learning (PBL) versus a didactic lecture approach for disseminating evidence-based guidelines on asthma management. Both groups experienced a significant increase in asthma related knowledge. However PBL participants rated the perceived educational value of the program higher than did lecture participants (4.36 vs 3.93, P=.04) suggesting a more satisfactory learning experience. Small group sessions, such as the PBL sessions used for this study, with participants sitting around a conference table may be preferable for disseminating clinical information to providers in the context of busy schedules and multiple responsibilities (White, et al, 2004).

Investigators sought to evaluate the effectiveness of a community based cervical cancer education program targeting both nurses and women living in rural areas of Honduras. Radio programs were used to deliver the education program to the general public. There were short spot messages that aired at fifteen or thirty minute intervals and an hour long message that aired twice a day. At the nurses' monthly educational session a forty-five minute education program was presented. Structured interviews were used to evaluate the knowledge level regarding the need for screening pap smears among women

in the community before and after the radio broadcasts. Response score increases were statistically significant for all knowledge categories evaluated for the women in the community who had attended the educational program via radio broadcasts. Pre- and post-intervention questionnaires were administered to the nurses. Statistically significant differences were observed in all knowledge categories evaluated for the nurses who attended the program. Researchers concluded that in developing countries, inexpensive community-based educational programs delivered via radio broadcasts and lecture presentations can increase cervical cancer knowledge and impact health care behavior (Perkins, et al, 2007).

A study was conducted to evaluate the effectiveness of a nurse-initiated education program on osteoporosis prevention behaviors. A randomized controlled study was conducted with seventy-six women. A forty-five minute educational program on the four osteoporosis prevention behaviors was conducted with the thirty-eight women randomized into the intervention group. Two follow-up phone consultations were conducted within the month following the program. Pre-, post- and follow-up data were compared regarding attitudes and adoption of osteoporosis behaviors. Results of analysis revealed statistically significant increases for adoption of each of the behaviors by the intervention group when compared to the control group (Chan and Ko, 2006).

Discussion

Central to the CSP design is to present an educational program to members of the oncology care community and to women with breast cancer. Using this approach is well supported based on review of the literature and consistent with the conceptual framework described by Mior, et al, (2010). Continuing education programs delivered in a fashion

similar to the proposed program have been shown to have an impact on the knowledge and attitudes of both health care providers and the general public. Impact on attitudes and enhanced knowledge regarding the use of OET in conjunction with standard oncology care may benefit future clinical research efforts.

The Educational Program

An educational program entitled *"Enzyme Nutrition in Oncology Care"* regarding the use of enzyme therapy in oncology care was developed (see Appendix A) and implemented to facilitate the stated aim of this clinical scholarship project. Topics covered in the educational program include: (a) an overview of enzyme therapy, (b) the history of enzyme therapy use in oncology care, (c) review of the science regarding enzyme therapy used in conjunction with standard oncology care protocols, and (d) presentation of anecdotal observations regarding the use of OET with oncology patients.

A Power- point presentation format was used to aid presenting the educational program. The same program was used with both oncology care provider groups and groups of women with breast cancer, their support persons and the general public. While the program was the same, during the presentation emphasis was placed on different aspects tailored to the target audience. The physiology and biochemistry of proteolytic enzymes was emphasized for provider groups while clinical experiences with OET were emphasized for women with breast cancer, their support persons, and the general public.

Evaluating effectiveness of the educational program was accomplished by use of a pre-test/post-test design. A multiple item knowledge test, containing multiple choice and true/false items, was developed to measure clinical knowledge about basic physiologic enzyme activity and the role of enzyme nutrition in oncology care (see

Appendix B). The test was administered to participants prior to the educational program and again at the conclusion of the program; in a pre-test/post-test design. Participant pre-test/post-test scores were compared as a way of evaluating the effectiveness of the educational program.

Provider attitude and behavior was measured using a student-developed questionnaire specific to this clinical scholarship project (see Appendix C). The questionnaire contains one yes/no item and three Likert-scaled items. The questionnaire was administered in a pre-and post-program fashion. Provider responses completed prior to the educational program are compared with their responses completed after the educational program. Changes in provider attitude and clinical approach with regard to OET were evaluated by comparing these responses. Provider willingness to support patient participation in a clinical research study using OET with standard oncology care was assessed as well.

Attitude and behavior of women with breast cancer, their support persons, and the general public were measured with a student-developed questionnaire using the same process used for the provider groups. The questionnaire contains one yes/no item and three Likert-scaled items (see Appendix D). A change in attitude and stated care approach with regard to OET for women with breast cancer, their support persons, or the general public were evaluated by comparing responses on the pre-program questionnaire with those on the post-program questionnaire. Willingness to participate in a clinical research study using OET with standard oncology care was assessed as well.

IRB and HIPPA Issues

The proposed clinical scholarship project included implementation of an educational program on the use of OET in conjunction with standard oncology care. A knowledge test and an enzyme use questionnaire were used as a part of the educational program. No personal identifying information or health care information was collected during the project. An IRB submission for exempt approval was initiated by this doctoral student and an exemption was granted in accordance with Title 5 Code of Federal Regulations Part 46.101b. There are no identifiable HIPPA issues, given that no personal identifiers are used and no protected health information was collected from attendees.

Setting and Participants

The setting for this feasibility project was the greater Springfield, Missouri, the location of this doctoral student's clinical practice. Springfield's population is approximately 200,000 people. A brief telephone survey conducted with the two large health care facilities in Springfield revealed an average of 600 – 650 women newly diagnosed with breast cancer annually. The project setting was expanded to include Branson, Missouri and Bolivar, Missouri, both of which are approximately forty miles outside of Springfield. Presence of a designated cancer center in these communities makes their inclusion in the feasibility project appropriate. A brief telephone survey conducted with Bolivar revealed an average of 30-35 newly diagnosed women with breast cancer annually and telephone survey results for Branson revealed a similar number of women diagnosed with breast cancer annually.

Potential participants for the project's educational program included any of the oncology care providers in the project setting and women with breast cancer, their

support persons, or the general public. Staff members of local breast cancer screening programs, breast cancer support groups, breast cancer advocacy groups, and the American Cancer Society local office are also potential participants. While the latter group are not typically involved in clinical decision making regarding treatment they are included in this project because they provide support to women diagnosed with breast cancer.

Implementation Activities

Activities to move the project forward to completion commenced upon receiving approval for the proposed CSP by this doctoral student's committee. After IRB review and approval implementation activities were launched. The main activities included: (a) identifying resources used by women with breast cancer in the project setting, (b) identifying educational resources used by women with breast cancer in the project setting, (c) identifying group or meeting resources utilized by women with breast cancer in the project setting, (d) determining the ability to interface with women with breast cancer as a part of/during group or meeting formats, (e) determining availability of facilities to conduct the proposed educational program with women with breast cancer, (f) identifying educational resources used by oncology care providers in the project setting, (g) determining the ability to interface with oncology care providers in the project setting, (h) identifying appropriate facility use to conduct the educational program with oncology care providers, (i) disseminating information about the scheduled educational programs for women with breast cancer, (j) conducting the proposed educational program with women with breast cancer, their support persons and the general public, (k) disseminating information about the scheduled educational programs for oncology care

providers, and (l) conducting the proposed educational program with oncology care providers.

Identifying resources used by women with breast cancer in the project setting – to include general resources, educational resources and support group resources. Face-to-face, phone, and internet inquiries were conducted in the project area regarding the resources available to/used by women with breast cancer. There is a cancer resource center at the Hulston Cancer Center located in a building on the Cox Health System campus. Individuals with cancer in the project setting, including women with breast cancer, can browse through the resource center and find information about groups, meetings and support services. There is a general retail store located in this center with products that may be of interest and benefit to individuals undergoing standard oncology care, e.g. hats, scarves, special garments, or items to be of assistance to caregivers e.g. personal hygiene assistance devices, safety devices. Also found in this resource center is a wide variety of reading materials/books on the subject of dealing with cancer. A monthly calendar of support and group meetings can be found on the information desk in the resource center.

Typically on the third Thursday of the month there is a breast cancer support group meeting held in the evening at the Hulston Cancer Center. However, with October being breast cancer awareness month, the Pink Ribbon Rally and Luncheon for Breast Cancer was held on October 22nd instead of the usual support group meeting. Informational flyers with dates, times and locations of the OET educational program were handed out at this event.

Extensive networking and investigation revealed that there are no other breast cancer support groups meeting in the project setting at the present time. The Breast Cancer Foundation of the Ozarks sponsors a *Young Survivors* group in Texas County, Missouri. However a phone conversation with the coordinator of this program revealed that active group meetings that had taken place for about the last year.

Contact with the American Cancer Society (ACS) office in the project setting revealed that they do not sponsor any support group activities for breast cancer patients. However the local ACS does sponsor the *Reach to Recovery Program*. The *Reach to Recovery Program* was implemented to assist individuals diagnosed with breast cancer navigate the diagnosis and treatment. The program pairs a trained volunteer who is a breast cancer survivor in a one-on-one relationship with a woman who is newly diagnosed with breast cancer. Conversations with ACS staff members revealed that a full day *Reach for Recovery Program* training class was scheduled for October 29, 2011. A request was made by this doctoral student to be able to attend the training course as an observer. This request was denied.

Determining the ability to interface with women with breast cancer and availability of facilities to conduct the educational program with them. Lack of consistent group and support meetings for women with breast cancer in the project setting resulted in then need to expand activities for successful implementation of the educational program. Facilities in the project setting appropriate for conducting the educational program were surveyed in regard to availability and costs. After extensive surveying it was determined that the most acceptable settings, based on availability, accessibility, and cost were community rooms at the local public libraries.

For the public libraries in Springfield and Bolivar, Missouri, use of community rooms was restricted to not-for-profit activities. Even though presentation of the educational program was a not-for-profit venture, scheduling of rooms at the libraries could not be accomplished without a not-for-profit organization sponsoring the proposed educational program. A not-for-profit health ministry, *High Way Ministries*, founded by this doctoral student in 2003 became the sponsoring organization for the proposed educational program.

Identifying educational resources used by oncology care providers. Phone contact was made with oncology care provider groups in the project setting. Practice managers and/or advanced practitioners from each of the groups were queried as to the continuing educational approaches used most often for dissemination of information regarding patient care approaches. This inquiry revealed that a common approach used across multiple practice settings was a breakfast or lunch presentation in the office. Other approaches included attendance at grand rounds, journal review/journal club activities and attendance at continuing education programs.

Determining the ability to interface with oncology care providers and availability of facilities to conduct the educational program with them. Contact was made with each of the oncology care provider groups mentioned in this document as stakeholders with the exception of CRO, as members there were represented in other stakeholder groups. Another contact was made with the American Cancer Society Office in the project setting.

An educational program was conducted with each of the stakeholders with the exception of the ACS, whose administrative representative declined the invitation to

participate in the project. All of the oncology provider groups determined that the best setting to conduct the educational program was in the oncology clinic or oncology infusion center so as to minimize the disruption of the work flow of the providers who might possibly attend the program.

Disseminating information about the scheduled educational programs for women with breast cancer. Implementation of the CSP was planned to coincide with national breast cancer awareness month. It was discovered that the Breast Cancer Foundation of the Ozarks was sponsoring and promoting "Breastfest" on October 1st. Event activities included mini-educational programs on topics related to the experience of breast cancer. Several health and wellness organizations in the project setting served as both vendors and presenters. The event was attended with the express purpose of distributing flyers to event vendors and attendees with dates, times and locations that the OET educational program was going to be held for women with breast cancer, their support persons, and the general public. Nearly fifty flyers were distributed at this event.

Community resources that offered avenues to announce/promote the educational program were explored. It was determined that three local publications had a community announcement service available that would allow publishing, at no cost, information about the educational program to include the following: (1) dates, times and locations of presentations, (2) a brief description of information that would be presented, and (3) the sponsoring organization for the presentations. As noted earlier in this document, use of community rooms at local public libraries required that the presentations be sponsored by a not-for-profit organization and they required that all flyers and postings contain the name of the sponsoring organization. Announcements were placed in the available

community publication resources three weeks in advance of scheduled presentations of the educational program. Flyers were placed on community boards at local health food stores, specialty book stores, and organic markets.

Conducting the educational program with women with breast cancer, their support persons and the general public. Eight sessions were scheduled in which to present the educational program to women with breast cancer, their support persons and the general public. Programs were presented in community rooms at public libraries in the project setting. Programs were conducted in Bolivar, Springfield and Branson. Attendance at the programs varied from location to location. Larger attendance was observed at programs held in Springfield where the general population is about six times the population of each of the two smaller municipalities.

Presentation of the educational program varied from approximately forty minutes to sixty minutes. The longer times were observed in programs with the larger attendance numbers as there was more discussion during the presentation. A question and answer session was conducted at the conclusion of each program which lasted as long as necessary to insure all questions had been adequately addressed.

Disseminating information about the scheduled educational programs for oncology care providers. Reliance on administrative staff members of the oncology care provider groups was the vehicle used to disseminate dates and times for presentation of the continuing education program to the oncology providers. Avenues reported to have been used included: (a) break room bulletin/announcement boards, (b) flyers posted on entry/exit doors, (c) flyers posted in restrooms, (d) flyers placed in staff internal mailboxes, and (e) intra and inter-departmental email communications.

Conducting the educational program with oncology care providers. A total of four presentations of the educational program were scheduled. Each of the oncology care provider groups had conference rooms in or near the clinical services area making it convenient for providers to attend the educational program. Presentation of the educational program varied from approximately thirty minutes to forty minutes. A question and answer session was conducted at the conclusion of each program which lasted as long as necessary to insure all questions had been adequately addressed.

Deviations from Proposed Plan and Rationale

The original project design was to conduct the educational program with oncology care provider groups and women with breast cancer. Project implementation activities quickly revealed the lack of routine/recurrent gatherings of women with breast cancer. The decision to launch study activities during national breast cancer awareness month did lead to the ability to market the proposed program to women with breast cancer. However it was determined that attendance at the educational programs would have to be open to support persons of women with breast cancer and the general public in order to make the activity a meaningful one, thus reaching a wider audience. This was not part of the original design but the inclusion of these additional individuals in no way altered the educational program. Presenting the educational program to the wider audience may potentially have a greater impact on knowledge of OET in the study setting. In retrospect, it would have been logical to include support persons of women with breast cancer as a part of the original target audience. Often these individuals are the guiding force for women with breast cancer who navigate complex treatment modalities.

Barriers and Challenges

Based on observed lack of implementation of CAM approaches by oncology care providers in the project setting, lack of support for implementation of same in conjunction with standard oncology care was anticipated. Such lack of support could have an adverse effect on implementation of the clinical scholarship project. Initial inquiry regarding scheduling of the educational program was received with responses such as: (a) not sure the providers will have time, (b) don't think the providers will be interested in an education program on the use of enzyme nutrition, and (c) not sure the providers would be in favor of patients taking any supplements during their course of standard oncology therapy. Permission to conduct the educational program was obtained only after introducing the topic of the possibility of a funded research study in the future. Once the topic of potential clinical research was introduced greater receptivity was observed. The ability to schedule the educational program with oncology care provider groups suggests partially overcoming the anticipated barrier that the prevailing conventional medical culture may adversely affect implementation of the proposed feasibility project.

The challenge of time was not anticipated to be such a barrier when designing the project. In the oncology care provider groups, the individual scheduling the educational program was mindful about the amount of time involved for the educational activity. The scheduler wanted to insure that there would be no inconvenience to the personal schedules of the providers and that there would be no negative impact on delivery of patient care services. This challenge was overcome by scheduling the oncology care

provider programs early in the morning when providers would typically be arriving at the clinical site and just prior to beginning of patient care activities.

Conducting the educational program took, on average, fifty minutes when presented to the public audience, the provider programs needed to be streamlined for delivery in thirty minutes. Accomplishing this task was facilitated by the fact that the educational preparation of providers was such that the language and physiologic concepts were not foreign and did not require in depth explanation. This allowed for progression through aspects of the program at a much faster pace than for the general public. That is not to say that questions that arose from providers were not adequately addressed; in fact they were addressed as they arose during the presentation. However more questions arose from the general public attendees regarding the physiologic concepts presented during the program.

Clinical Scholarship Project Outcomes

Analysis of Data

As outlined in the Educational Program Section of this paper, enzyme knowledge tests and enzyme use questionnaires were administered prior to the educational program and then again after the program. Pre-program enzyme use questionnaire responses and enzyme knowledge test scores were compared to the post-program responses and scores. Discussion is summarized separately for the general public and the oncology care providers. Table 1 presents a summary of the results for general public participants and Table 2 presents a summary of the results for oncology care provider participants.

Table 1: General Public Participants (N=36)	% of Participants
Knowledge test - total increased scores from pre-test to post-test	69%*
Use Questionnaire # 2: selected a higher number on the post-program survey for the Likert-scale response question with regard to their likelihood of taking OET along with chemotherapy	40%**
Use Questionnaire # 3: selected a lower number on the post-program Likert-scale response question with regard to their likelihood of stopping OET if their health care provider recommended they do so	40%**
Use Questionnaire # 4: selected a higher response on the post-program Likert-scale response question with regard to their likelihood of participating in a research study where OET was used in conjunction with standard chemotherapy	40%**
*31% of general public participants scored 100% on the pre-test, resulting in no change between pre-test and post-test scores **46% of general public participants did not demonstrate a change because their initial responses were in the affirmative	

For the general public enzyme knowledge test, analysis of pre-test/post-test scores reveals increased scores for 69% of participants. It should be noted that the remaining 31% of general public attendees scored 100% on the pre-test so there was no change in post-test scores. Based on these findings the educational program was effective in increasing the general public attendees' knowledge of the use of OET.

The enzyme use survey administered in a pre-program/post-program fashion was used to evaluate if the educational program could impact participant's attitudes regarding use of OET in conjunction with oncology care protocols. Analysis of the responses on the pre-test survey revealed that 23% of participants were already taking OET. Analysis of the remaining data will not include data from these participants as their current use of OET is demonstrative of their attitude with regard to its use. Comparison of the data with respect to the remaining participants reveals the following: (a) 40% selected a higher

number on the post-program survey for the Likert-scale response question with regard to their likelihood of taking OET along with chemotherapy, (b) 40% selected a lower number on the post-program Likert-scale response question with regard to their likelihood of stopping OET if their health care provider recommended they do so, and (c) 40% of participants selected a higher response on the post-program Likert-scale response question with regard to their likelihood of participating in a research study where OET was used in conjunction with standard chemotherapy. These responses suggest the educational program impacted the attitude of participants with regard to OET.

It should be noted that 46% of participants did not demonstrate a change on the three enzyme use survey Likert-scale questions as their initial responses were at the end of the scale demonstrating an affirmative attitude regarding: (a) use of OET in conjunction with standard chemotherapy, (b) not stopping OET use with chemotherapy if their health care provider advised them to do so, (c) and opting to participate in a research study where OET was used in conjunction with standard chemotherapy.

Table 2: Oncology Care Provider Participants (N=32)	% of Participants
Knowledge test - total increased scores from pre-test to post-test	100%
Use Questionnaire # 2: selected a higher number on the post-program survey for the Likert-scale response question with regard to their likelihood of recommending the use of OET with chemotherapy	90%
Use Questionnaire # 3: selected a higher number on the post-program Likert-scale response question with regard to their likelihood of not advising a patient to discontinue OET in conjunction with chemotherapy	70%
Use Questionnaire #4:selected a higher response on the post-program Likert-scale response question with regard to their likelihood of supporting a patient's participation in a research study where OET was used in conjunction with standard chemotherapy	80%

For the oncology care provider enzyme knowledge test, analysis of pre-test/post-test scores reveals increased scores for 100% of participants. Based on these findings the educational program was effective in increasing the oncology care providers' knowledge of the use of OET. Unlike analysis of the general public knowledge test results, no oncology care provider scored 100% on the pre-test. A possible explanation for this phenomenon is that general public attendees self-selected to attend an education program on a CAM modality as they have sought or are seeking solutions to health care problems outside of the conventional medical approach.

The enzyme use survey administered in a pre-program/post-program fashion was used to evaluate if the educational program could impact participant's attitudes regarding use of OET in conjunction with standard oncology care protocols. Analysis of the responses on the pre-test survey revealed that 0% of the oncology care providers were already discussing the use of OET in conjunction with standard oncology care approaches. Analysis of the data with respect to oncology care providers' responses reveals the following: (a) 90% selected a higher number on the post-program survey for the Likert-scale response question with regard to their likelihood of recommending the use of OET with chemotherapy, (b) 70% selected a higher number on the post-program Likert-scale response question with regard to their likelihood of not advising a patient to discontinue OET in conjunction with chemotherapy, and (c) 80% of participants selected a higher response on the post-program Likert-scale response question with regard to their likelihood of supporting a patient's participation in a research study where OET was used in conjunction with standard chemotherapy. These responses suggest the educational program positively impacted the attitude of oncology care providers with regard to OET.

Discussion of Findings

In order to adequately discuss the findings cited above, a review of the anticipated outcomes for the feasibility project is presented below:

Short Term Outcomes.

- Increase awareness of the scientific body of knowledge regarding use of oral enzyme therapy in conjunction with oncology care.
- Increase oncology care provider and women with breast cancer's knowledge of oral enzyme therapy use in conjunction with standard oncology care.
- Initiate networking activities with oncology care providers and groups of women with breast cancer.

Intermediate Outcome.

- Establishment of relationships with providers in the oncology care community and groups of women with breast cancer by overcoming anticipated and identified barriers.

Long Term Outcome.

- Improve the quality of life of women with breast cancer by maximizing the relationships developed through this feasibility project which may facilitate implementation of a clinical research study using OET in conjunction with standard breast cancer chemotherapy.

Short term outcomes. Review of the change in scores from pre-test to post-test administration of the enzyme knowledge test demonstrates that the short term outcome was met. The enzyme knowledge test encompassed information gleaned from the scientific body of knowledge regarding use of OET alone or in conjunction with standard

oncology care. Questions and conversations that took place in conjunction with presenting the educational program demonstrate increased awareness of OET in addition to the increased knowledge demonstrated by testing. These evaluations and observations hold for both the oncology care provider groups and group that included women with breast cancer, their support persons, and the general public.

As previously described, networking activities were central to the successful implementation of the clinical scholarship project. Networking activities were conducted with oncology care provider groups and groups of women with breast cancer. However networking activities with women with breast cancer did not take place in the context and setting as anticipated.

Intermediate outcome. A challenge existed for establishing relationships with groups of women with breast cancer. Group meetings thought to be in existence based on initial assessment of resources in the project setting were discovered to be for the most part inactive. The one support group that would typically have met during the most time intensive period of project implementation altered their group meeting format for alternate breast cancer awareness activities.

Long term outcome. The length of time for project implementation and evaluation does not allow for evaluation of the stated long term outcome. Expanding upon and nurturing of the relationships established with the oncology care provider community during project implementation may prove to facilitate the desired long term outcome. Additional requirement for achievement of the long term outcome would include a funding source for a clinical research study to evaluate the use of OET in conjunction with standard oncology care.

Cost to Benefit Analysis and Ethical Concerns

Cost for implementing the clinical scholarship project included: (a) costs of printed materials, writing instruments, and miscellaneous office materials for organizing study documents; (b) cost of laptop computer and video projector to conduct the education program; and (c) cost of light refreshments for program participants. It is difficult to conduct an actual cost/benefit analysis regarding this CSP since the project did employ some minimal costs yet the benefit of an educational program is not able to be determined in such a small project.

One of the issues examined in this clinical scholarship project was the establishment of relationships between this doctoral student and the oncology care provider community. There was no relationship evaluation tool or instrument selected for use as a part of this project, making it impossible to analyze data to come to a conclusion for this question. Personal observation and reflection regarding the stated question reveals: (a) use of a CAM approach, specifically OET, in conjunction with standard oncology care for prevention/reduction of side effects was favorably received and (b) this doctoral student, as a CAM provider, was favorably received by the members of the provider community as well as the public. In the project setting's conventional medical culture, these observations are priceless.

Ethical concerns surrounding implementation of the project included the potential lack of concern by conventional medical providers for women with breast cancer. That concern was based on the observed lack of implementation in the project setting of CAM approaches that have evidence-based efficacy. Implementation and evaluation of the clinical scholarship project does not allow for an opinion or a conclusion to be formulated

with regard to this ethical concern. Only case reviews and time will allow for evaluation of the impact of this feasibility project with regard to the ethical concerns in the project setting.

Application to Practice

As previously stated, implementation of the CSP will not result in any change in clinical practice for this doctoral student. Protocols using OET are presently in use in this doctoral student's practice setting. Findings of this clinical scholarship project indicate an increased knowledge base and a change in oncology care provider attitudes surrounding the use of OET with cancer patients. Additionally implementation of the CSP launched relationship building between the oncology care community and this doctoral student. Perhaps a result of this relationship building will facilitate implementation of clinical research using OET in conjunction with standard oncology care. Furthering the science on use of OET in conjunction with standard oncology care here in the United States may result in better quality of life for women with breast cancer by prevention, reduction, or elimination of the side effects of chemotherapy.

While the focus population of this project was women with breast cancer, benefits of OET in conjunction with standard oncology care have been observed with a wide range of cancer types and therapies. Future projects may focus on the use of OET with individuals diagnosed with other types of cancer. A project design focused on women with breast cancer, implementing of the project to coincide with national breast cancer awareness month, and establishment of relationships with the oncology care community may enhance this doctoral student's ability to co-manage oncology patients and conduct clinical research.

The application of findings of this CSP outside of the project setting is not anticipated. The project was designed, implemented and evaluated specifically for a given oncology care community. Perhaps the application of this project to nursing practice will be forthcoming in the form of publications that may stem from designing, implementing, and evaluating this clinical scholarship project.

Impact of the Clinical Scholarship Project on Evaluation of the DNP Role

A case can be made for representation of some aspect of each of the eight Essentials of Doctoral Education for Advanced Nursing Practice by designing, implementing, and evaluating the feasibility project. However a stronger correlation of project activities to four of the essentials is observed. The discussion that follows will explore those corollaries.

A review of the essentials of doctoral education for advanced nursing practice reveals that development of this project is grounded in the first essential: scientific underpinnings for practice. According to AACN (2006), to achieve the highest level of nursing practice the DNP program prepares the graduate to integrate nursing science with knowledge from ethics, the biophysical, psychological, analytical, and organizational sciences. Exploration of literature from the organizational sciences ultimately facilitated successful design, implementation and evaluation of this clinical scholarship project (Asprey, 2004). Concepts of a pilot study to determine if such a project is feasible are found in the nursing literature (Polit & Beck, 2004, Zust, 2000).

The ultimate goal of this CSP was to facilitate the conduct of future clinical work. Future clinical work would be linked directly to the third essential: clinical scholarship and analytical methods for evidenced-based practice. With respect to this essential, a

correlation cannot be made between conducting this CSP and the tasks that AACN delineates for the graduate of a DNP program since. Correlation cannot be made as this doctoral student finds the seven tasks outlined for this essential limit the role of an advanced practice nurse.

Given the wide range of provider types represented in the oncology care community this project encompasses the sixth essential: interprofessional collaboration for improving patient and population health outcomes. According to AACN (2006), the DNP program prepares the graduate to use leadership skills with both intraprofessional and interprofessional teams to create change in health care. Conducting the clinical scholarship project resulted in development of interprofessional relationships. The primary object of establishing such relationships is to enhance patient care outcomes and when possible by the addition of CAM approaches with standard oncology care.

Developing, implementing and evaluating this project serves as the hallmark of the eighth essential: advanced nursing practice. Of the seven tasks delineated for this essential, conducting the feasibility project most closely relates to the second task: design, implement, and evaluate therapeutic interventions based on nursing and other sciences. Undertaking the clinical scholarship project is the first step on the journey to enhance patient outcomes by implementing a CAM approach proven to prevent, reduce or eliminate the side effects of standard oncology care.

Influence on Practice

The culmination of this doctor of nursing practice education is the further shoring up of a solid clinical foundation for delivery of advanced practice activities. The experience of the clinical scholarship project allowed this doctoral student to make

inroads into a community of providers that often consider CAM providers as outsiders. Relational foundation and a view of collegiality can only stand to accelerate the goal of conducting clinical research studies on the use of CAM approaches in conjunction with standard oncology care. More importantly, relationships established with members of the oncology care community have paved the way for greater acceptance of CAM approach use by patients with cancer. Such action may have a positive impact on patient outcomes which is the ultimate goal of the healing arts.

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Appendices

A. Enzyme Therapy Educational Program Outline

B. Enzyme Knowledge Test

C. Provider Enzyme Survey

D. Enzyme Use Survey

Appendix A

Oral Enzyme Therapy Educational Program Outline

1. Introduction

2. Pre-test/Survey (unique identifier – middle initial and house number – with a capital A)

3. Overview of enzyme therapy - a nutritional therapy
    a) role of enzymes in the body
        i. role of enzymes in the digestive system (demonstration with food)
        ii. role of enzymes in the immune system
        iii. role of enzymes in the body
    b) historical overview of enzyme use in cancer care

4. Overview of the Literature
    a) study 1 – OET, colorectal cancer
    b) study 2 – OET, cervical cancer
    c) study 3 – OET, breast cancer
    d) study 4 – OET, breast cancer
    e) study 5 – OET, multiple myeloma (emphasis on remission and survivability)

5. Anecdotal observations, questions and answers
    a) case study examples – breast cancer (pain, energy, wound healing, anemia)

6. Post-test/Survey (unique identifier – middle initial and house number – with capital B)

Appendix B

Enzyme Knowledge Test

Identifier:_____ Location:_____

Please answer the following questions (place a check mark on the line next to your answer):

1. Digestive dysfunction is a risk factor for cancer.

___ True

___ False

2. Which of the following are actions of proteolytic enzymes?

___ A. reduce tumor size

___ B. digest proteins

___ C. decrease inflammation

___ D. reduce the toxic effects of chemotherapy and radiation

___ E. prevent metastasis (spread of cancer)

___ F. facilitate detoxification

3. Enzymes taken by mouth are destroyed in the stomach by hydrochloric acid.

___ True

___ False

4. Protein is used in which of the following physiologic activities?

___ A. energy

___ B. growth and repair

___ C. maintenance of homeostasis

5. Use of enzyme therapy can increase survivability for cancer patients?

___ True

___ False

Appendix C

Provider Enzyme Questionnaire

Identifier:_____ Location:_____

Please answer the following questions (place a check mark or circle your answer):

1. Do you presently discuss the use of oral enzyme therapy with patients receiving chemotherapy?

___ Yes

___ No

If the answer to #1 above is No, please answer questions below – thank you.

2. With your current knowledge regarding oral enzyme therapy, what is the likelihood that you would recommend oral enzyme therapy to your patients receiving chemotherapy?

0	1	2	3	4	5	6	7	8	9	10
Would Not Recommend										Would Recommend

3. With your current knowledge regarding oral enzyme therapy, if a patient reported using oral enzyme therapy along with their chemotherapy would you advise them to stop taking them?

0	1	2	3	4	5	6	7	8	9	10
Would Advise To Stop										Would Not Advise To Stop

4. With your current knowledge regarding oral enzyme therapy, what is the likelihood that you would support your patient participating in a research study using oral enzyme therapy adjunctively with chemotherapy?

0	1	2	3	4	5	6	7	8	9	10
Would Not Support										Would Support

Appendix D

Enzyme Use Questionnaire

Identifier:_____ Location:_____

Please answer the following questions (place a check mark or circle your answer):

1. Are you presently taking any oral enzyme therapy?

___ Yes

___ No

If the answer to #1 above is No, please answer questions below – thank you.

2. With your current knowledge regarding oral enzyme therapy, what is the likelihood that you would use enzyme therapy along with your chemotherapy?

0 1 2 3 4 5 6 7 8 9 10

Would Not Use — Would Use

3. With your current knowledge regarding oral enzyme therapy, if you were taking enzyme therapy and your health care provider advised you to stop them what is the likelihood you would you stop them?

0 1 2 3 4 5 6 7 8 9 10

Would Not Stop — Would Stop

4. With your current knowledge regarding oral enzyme therapy, what is the likelihood that you would participate in a research study using oral enzyme therapy with your chemotherapy?

0 1 2 3 4 5 6 7 8 9 10

Would Not Participate — Would Not Participate