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The motivation for cancer patients to take donated human milk

Susanne M. Rough
San Jose State University

THE MOTIVATION FOR CANCER PATIENTS TO TAKE DONATED HUMAN MILK

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Susanne M. Rough

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APPROVED FOR THE DEPARTMENT OF
NUTRITION AND FOOD SCIENCE

Clarie B. Hollenbeck, PhD

Pauline Sakamoto MS, PHN, RN

Caroline H. Fee, MA

APPROVED FOR THE UNIVERSITY

ABSTRACT

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This represents the first published account from the patient's perspective of the use of human milk as cancer therapy. Purposive sampling was used to select a sample of 10 participants. Five were patients and five were family proxies. Individual interviews were conducted using confirmatory interviewing technique to obtain individual perspectives on the motivation for cancer patients to take donated human milk. Human milk therapy improved the quality of life (QOL) measures in the physical, psychological, and spiritual domains for most patients interviewed. The patients continued their use of human milk despite cost, taste, and discouragement from the conventional medical community. The study results support the theory that QOL may be more important to cancer patients than cancer outcomes and may improve patient medical care overall. These interviews offer information to cancer patients, their practitioners, and donor milk banks on outcomes and symptom relief from this therapy.

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Preface

The following is a publication style thesis. Chapters I and III are written according to the guidelines outlined in the *Publication Manual of the American Psychological Association*, 5th edition, 2001. Chapter II is written according to the format outlined by the American Medical Association and will be submitted to *The Journal of Human Lactation.*

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Chapter I

INTRODUCTION AND REVIEW OF LITERATURE

Introduction

Research Problem

Between 1999 and the present, cancer patients have requested human milk from the San Jose Mother's Milk Bank as a complement or alternative to their conventional biomedical cancer treatment. The basis for this decision is unknown and at this time, no information has been collected from these patients regarding their experience with the human milk therapy. This lack of reporting is not uncommon, according to Caspi, Koithan & Criddle (2004), who noted that no systematic studies have been published which examine the processes patients use to decide on complementary or alternative health care decisions.

A simple online search suggests possible explanations for their request. Human milk provides not only a superior food for human infants, but protective factors as well, such as antibodies, lactoferrin, and oligosaccharides (Hanson et al., 2002). While researching some of these protective factors, Hakansson, Zhivotovsky, Orrenius, Sabharwal and Svanborg (1995) at Lund University, Sweden made the serendipitous discovery that *in vitro*, human milk causes an apoptosis-like effect on several varieties of cancer cells. A few human *in vivo* research studies realized similar apoptosis–like effects on human cancer cells.

Area of Inquiry

This paper will review relevant research related to human milk as a potential cancer treatment including: the human donor milk banking system in North America, components of human milk, protective factors in human milk, cancer reduction in breast

fed infants, and HAMLET-the protein complex in human milk which induces apoptosis in cancer cells. To clarify the potential motivations for adult cancer patients who request human milk, current research on complementary and alternative medicine (CAM) as a decision making process and quality of life (QOL) issues will be reviewed. This will provide background information for interviews with cancer patients who have taken human milk, to determine why they decided to take human milk, their knowledge regarding this therapy, their use of other CAM therapies, their communication with their primary physician regarding this CAM treatment, as well as any effects on their cancer and on their quality of life.

Significance of the Study

Cancer patients' use of CAM is part of an "informed decision making process" (Caspi et al., 2004, p. 64) that allows them to be a partner in their health decisions or to take control of their treatment choices. Human milk therapy may be a viable option worth considering if the cancer patient seeks a non-invasive cancer therapy without side effects. In order to decide whether to complement or replace their traditional cancer treatment with this therapy, the patient requires access to the accumulated research on the subject. This review of literature will present and analyze the results of an online search related to human milk therapy, to facilitate a cancer patient's decision on whether or not human milk therapy is likely to provide the benefit they seek in their cancer treatment.

In addition, information from the interviews conducted for this study with cancer patients taking human milk will provide case-specific information and personal perspectives to donor Milk Banks and cancer patients regarding this therapy. The

research results may help cancer patients and Milk Banks better understand the impact of this novel treatment on the patients' well-being. The research results could also help clinicians understand patient concerns, including the impact of symptoms on their quality of life. This information could improve communication between patients and their clinician. Possible topics for future research may be identified from the provocative insights of the participants.

Research Questions and Definitions

To facilitate an understanding of the research that follows, a few definitions are needed. *In vivo* testing refers to something performed in the body of a living organism. An *in vitro* test, is done in a laboratory and involves isolated cells, or tissues, or organs. Apoptosis, also known as programmed cell death, refers to the disintegration of cells into particles that are devoured by other cells. CAM, as previously defined, stands for complementary and alternative medicine, and is defined in relation to conventional biomedicine. Simply stated, complementary medicine is a treatment added to traditional treatment, while alternative medicine is a treatment in place of traditional medicine.

The research questions addressed in this study regarding human milk as CAM are: What processes do cancer patients use when making decisions about their CAM treatments? What information was pivotal to cancer patients in their decision to take donated human milk? In the course of the interviews, information should be revealed regarding other methods of CAM used by the patient before, during, and after taking the human milk, the patient's relationship with their medical practitioner, and the therapeutic effects of the human milk treatment on the cancer patients' outcome and quality of life.

Background Literature Review

Donor Milk Banking System

The milk used by patients in this study was obtained from the San Jose Mother's Milk Bank, although many patients also acquired milk from private sources. The San Jose Mother's Milk Bank operates under the guidelines of the Human Milk Banking Association of North America (HMBANA), which includes 11 donor human milk banks in the US and Canada. Modern milk banking in the US began in the early 1900's in response to a shortage of wet nurses and as a means of supplying hospitalized sick infants with human milk. Donor human milk reduced the morbidity and mortality associated with non-human milk feeding (Arnold, 2001). Donor human milk banks now provide the service of "collecting, screening, processing and distributing donated human milk to meet the specific needs of individuals for whom it is prescribed" (HMBANA, 2005, p.9). Milk banks provide milk predominantly for preterm and very low birth weight infants and infants with medical problems. Developmentally appropriate preterm or mature milk is provided. Human milk is also ordered for older babies and children with a variety of medical needs including: "metabolic disorders, severe food allergies or feeding intolerance, short gut syndrome secondary to necrotizing enterocolitis, growth failure on formula, intractable rotavirus, as well as during chemotherapy for cancer" (Tully, 2000, p. 235), and for adopted infants without medical problems. Milk Banks are also getting requests for milk for some adult cancer patients.

The donor population is provided education on proper sanitary collection techniques and undergoes intense scrutiny during prenatal care. All donors are screened

verbally and in writing through an extensive medical questionnaire and survey, which includes a statement from the donor's physician and the donor's infant's physician, ensuring that the donor's own child is thriving. In addition, the donor screening includes lab results regarding infectious diseases for HIV 1 and 2, human T-lymphoma virus (HTLV) 1 and 2, Hep B surface antigen (HbsAg), hepatitis B and C, and syphilis. Annually reviewed and revised HMBANA guidelines recommend temporary exclusion of all donors with active herpes simplex or varicella zoster infections, exposure to rubella in their home, or receipt of an "attenuated vaccine" (Ruff, 1994, p.513).

All HMBANA member banks are in full compliance with the Guidelines for the Establishment and Operation of a Human Milk Bank, standards developed in cooperation with the Food and Drug Administration, and the Center for Disease Control and Prevention (Arnold, 2001 and Tully, 2000). Donor milk is thawed and pooled, and each pool is screened for bacteria. Any sign of pathogens renders milk unacceptable. After pooled milk has been aliquoted into clean containers, it is submerged in a water bath for 30 minutes at a temperature of 63° C, followed by quick cooling and frozen storage. One sample from this batch is again tested for bacteria, and any sign of bacterial growth renders the batch unacceptable for recipient distribution, but is acceptable for research (HMBANA, 2005), such as testing for IgA levels, for toxic metals, or determining the components of breast milk for the National Institute of Tables & Standards (P. Sakamoto, personal communication, March 31, 2006). Raw milk deliveries require a signed waiver.

Protective Factors in Human Milk

There is evidence of a protective effect in early infancy from the consumption of human milk. Similar results have been reproduced in adults when a topical application of human milk is applied to skin papillomas resistant to conventional treatment. This research will be discussed in greater depth later in this paper. Human milk protects through the synergy of the component parts and presence of inhibitors or enhancers, which may act differently *in vitro* than *in vivo* (Newburg, 2005). Human milk protects through a combination of anti-inflammatory agents, antimicrobial agents, and immunomodulators (Goldman, 1993). Immunomodulators include secretory antibodies (secretory IgA, G, M, E, and D) and lysozymes (American Dietetic Association (ADA), 2001; Arnold & Larson, 1993), lactoferrin, lipids, carbohydrates, and oligosacharides, as well as macrophages, neutrophils, T and B lymphocytes, and receptor binding inhibitors (Isaacs, 2005) and cytokines (Hanson et al., 2002). Probiotics in milk protect against specific pathogens (Newburg, 2005). These agents in human milk act against infection and may monitor for "aberrant, undifferentiated" tumors (Daniels, Olshan, Pollack, Shah & Stram, 2002, p.403). Lactoferrin and vitamin B-12 binding proteins have a synergistic effect when they bind iron and vitamin B12 so that they are not available to pathogens that require them (ADA, 2001). Human milk oligosaccharides function by preventing mucosal attachment, the first step in most infections (Morrow, Ruiz-Palacios, Jiang & Newburg, 2005). Antioxidants and mucin act as anti-inflammatory agents, and mucin acts by binding E. coli (Goldman, 1993).

Lipids become protective only after human milk is digested in the GI tract, demonstrating antiviral, antibacterial, and antiprotozoal activity as they lyse bacteria and viral particles (Isaacs, 2005). Oleic acid is the main fatty acid released in human milk and has antimicrobial action, but combinations of medium chain saturated fats and long chain unsaturated fats have also shown antimicrobial activity in fatty acid samples (Isaacs, 2005). Various peptides have also shown antimicrobial action and inhibit specific infections when they disrupt pathogen membranes, causing them to become leaky (Newburg, 2005). Often, lipids and peptides in human milk work synergistically or additively to inactivate microbes.

A potential problem regarding the protective nature of human milk is storage. The type of storage container, time, or temperature of storage can all affect the composition and as a result, the function of the milk. This must be taken into consideration when considering the defense system inherent in the milk (Goldman, 1993).

Components of Human Milk

Human milk is very complex, containing both nutritive and protective functions. The nutrients are synthesized in the mammary glands according to the baby's needs, from components in the mother's bloodstream. The nutrients in milk are colloidally dispersed in a thin, bluish fluid (Gunther, 1970). The concentration of substances dissolved in the milk will vary daily, from one mother to another, over the course of lactation and by infant gestational age (Morrow et al., 2005), but mean values of the concentrations of certain nutrients have been estimated. Human breast milk, per 100 mL, contains 7.3 g

lactose, 0.9 g protein, 4.2 g fat, 70 kcals, various vitamins and minerals including 28 mg calcium, 15 mg phosphorus, 3 mg magnesium, 40 μg iron, 166 μg zinc and other minerals. Some of the main proteins are: 161 mg alpha-lactalbumin, 142mg IgA, 167 mg lactoferrin, and 187 mg casein (Casey & Hambridge, 1983).

Water is the major component of milk, and emulsified fat is the second most plentiful component (3-5%) in mature milk. The types, but not the content, of fat in human milk are dependent on the diet of the mother (Brown, 2002). In contrast to cow's milk, human milk contains few short chain fatty acids and contains more long-chain fatty acids (Gunther, 1970). Human milk protein content is also variable, 0.8–1.0 %, and relatively low compared to other mammals. Casein comprises about 20% of the total protein in milk, while the whey proteins make up 80% and include alpha-lactalbumin, secretory IgA, and lactoferrin. Small amounts of other proteins are found in the whey portion of the milk, and these include immunoglobulins, enzymes, lactoferrin, and glycoproteins (Casey & Hambridge,1983). Milk carbohydrates are predominantly lactose, but glucose (Gunther, 1970) and other monosaccharides, neutral and acid oligosaccharides, and protein–bound carbohydrates are also found in milk (Brown, 2002).

HAMLET and the Apoptosis – like Effect of Human Milk

A synergistic relationship between antimicrobial lipids and peptides in human milk was studied at an immunology lab at Lund University, Sweden in 1972. Knowing that human milk contains antibodies to bacterial, viral, and protozoal antigens and that glycoconjugates inhibit bacterial adherence to epithelial cells, Hakansson et al. (1995) experimented with human milk to determine why it blocks bacterial adherence on the

human lung cancer cell line. Instead, the breast milk killed all the cancer cells by inducing apoptosis. Cancer cells are often used in experimental models because they can be cultured indefinitely in lab dishes, but otherwise they behave like other human cells. Apoptosis, or programmed cell death, is an ongoing process in the human body and is useful for eliminating useless, abnormal, or unwanted cells. During apoptosis, cells change by shrinking, condensing the chromatin in the nucleus, fragmenting the DNA, and forming cytoplasmic blebs (Hakansson et al., 1995). In cancer cells though, apoptosis is not characteristic. The serendipitous discovery at Lund University that human breast milk caused an apoptosis-like effect in the cancer cells was therefore unexpected. Interestingly, cow's milk did not affect the cytotoxic activity but in subsequent experiments, bovine alpha-lactalbumin was converted to the cytotoxic form (Gustafsson et al., 2005).

So far, over 50 cell lines have been tested (Svensson et al.,2002), and apoptosis was produced in carcinomas of the lung, throat, kidney, colon, bladder, prostate, and ovaries, in melanomas, glioblastomas of the brain, and leukemias (Gustafsson et al., 2005). The tumor cells in the lymph system are the most sensitive to the apoptotic effect of human milk, and 50% of carcinomas are killed within 24 hours (Svensson et al., 2002). Tumor cells in cows, primates, murines, and canines are also affected by HAMLET.

It was determined that the complex that induced an apoptosis-like effect in cancer cells was in the casein portion of the human milk and consisted of a protein-lipid complex which is alpha-lactalbumin and oleic acid (C18:1 n9 cis). Alpha-lactalbumin is the most abundant protein in human milk, and its main known function is as a substrate

of beta-galactosyltransferase, which enables lactose to be synthesized in the mammary gland from the alpha-lactalbumin in whey. Lactose enhances calcium absorption and is important in central nervous system and brain development (Jelliffe, 1978). Oleic acid is the most abundant lipid in human milk. Together, oleic acid and alpha-lactalbumin form a protein–lipid complex (Svanborg et al., 2003) named HAMLET, which stands for Human alpha-lactalbumin made lethal to tumor cells. This complex induced apoptosis in malignant cells but not in healthy, nonmalignant cells (Hakansson et al., 1995), and requires alpha–lactalbumin to alter its usual biological function. A similarity to prions should not be missed. In both cases, an alternate form of the protein changes first to a molten globule form, requires a cofactor for the transition, and serves a different function in its altered form. Both proteins become killer complexes in their altered form (Svensson, Hakansson, Mossberg, Linse &Svanborg 2000).

The first step for HAMLET is that alpha-lactalbumin must partially unfold from its native state to a molten globule–like state which has the same secondary, but a different tertiary structure and requires the release of the Ca++ ion (Svensson et al., 2002). This requires a low pH, which allows the Ca++ ion, which is normally strongly attached to the alpha-lactalbumin, to be released, allowing the alpha-lactalbumin to assume a new shape and expose a new fatty acid binding site. Acidic conditions, such as in the stomach of a breastfed infant or adult cancer patient, also activate pH–sensitive lipases, which release the oleic acid for binding. When the oleic acid fits the binding site exposed by the release of the Ca++, it holds the protein in the partially unfolded

conformation. Only C18:1 n9 cis, the isomer released from human milk, will complex with alpha-lactalbumin and become biologically active (Newburg, 2005).

The HAMLET complex, formed by the binding of oleic acid to alpha-lactalbumin, binds to the cell's surface and enters the cytoplasm of malignant and normal cells, but is only transported to the nucleus in malignant cells where it accumulates. This accumulation induces DNA fragmentation in the malignant cell (Newburg, 2005). HAMLET binds to histones, inhibits histone binding to DNA, and disrupts chromatin assembly, resulting in apoptosis by interfering with protein synthesis required for replication (Svanborg et al., 2003). In the cytoplasm, HAMLET targets ribosomes and may disrupt translation, activates the caspase cascade, and condenses chromatin in the nucleus. (Duringer, Hamiche, Gustafsson, Kimura & Svanborg, 2003). DNA fragmentation increases with concentration of HAMLET (Hakansson et al., 1995). HAMLET induces apoptosis regardless of p53 tumor suppressor status and is not controlled by bcl-2 cell survival regulators (Gustafsson, Leijonhufvud, Aronsson, Mossberg & Svanborg, 2004; Svanborg et al., 2003).

The results illustrate how HAMLET may contribute to the protective effect of human milk against childhood tumors. It is one of many watchful molecules whose role it is to act locally to influence tissue development (Svensson et al., 2002) and help the baby's immature immune system develop. After birth, the baby experiences a period of rapid cell development, which increases the risk of mutation. Any atypical or highly immature cells that breastfeeding eliminates, could reduce the likelihood of cancer in the breast fed baby. Since these pre-malignant cells will not lead to templates for future

tumor development, they may be responsible for long–term effects as well. The presence of HAMLET in the intestine may also help lymph cells to mature without becoming malignant (Svanborg et al., 2003). Also, HAMLET may kill virus-transformed or pre-malignant cells from the baby's GI tract (Gustafsson et al., 2005). It seems likely from these findings that HAMLET lowers the incidence of cancer in breast-fed children by purging the gut of cancer cells. This effect may also be achievable in the gut of adult cancer patients taking breast milk.

The research mentioned thus far has been conducted *in vitro*. *In vivo* research using HAMLET is limited to two effective studies. Glioblastomas (malignant brain tumors) are especially challenging to treatment. They are the most malignant of the gliomas because they have a tendency to become invasive and to spread. Patient survival rates are not improved by treatment, and currently the mean survival rate is less than a year. Treatments are needed which destroy malignant cells without damaging the brain. Research by Fischer et al., (2004) demonstrated that HAMLET prolonged survival when administered intra-tumor in nude rat brains, due to an apoptotic effect. Brain tissue was not affected and no toxic side effects were observed. HAMLET delayed tumor growth in the brain and delayed the onset of pressure symptoms. *In vitro* testing was also done with glioblastoma biopsy spheroids exposed to HAMLET, and only HAMLET induced apoptosis.

Gustafsson et al., (2004) studied the effect of HAMLET applied topically for three weeks on skin papillomas (benign epithelial tumors of the skin or mucous membranes, including warts and polyps). Patients were chosen for the study because

they had lesions that were not responding to conventional therapies. After treatment with HAMLET, it was found that the size of the lesions was reduced in all 20 patients, for 96% of the skin papillomas, while not in the placebo group. In the second phase of the study, the placebo group was treated with the HAMLET complex, and similar results were obtained. Follow–up studies after two years found that all lesions had gone back to normal. Not only did the topical treatment of HAMLET kill the tumor, but it also had a lasting effect. No difference was found between immunosuppressed and immunocompetent patients, even though immunosuppressed patients have an increased rate of papillomas.

These *in vivo* applications of the HAMLET complex combined with results from *in vitro* studies, suggest that HAMLET is active in humans, and human milk contributes a protective effect against cancers. Since human milk kills many varieties of cancer cells *in vitro*, HAMLET should be researched as a novel approach to cancer therapy as it is nontoxic to the tissue and unlikely to have side-effects if used as therapy. Potential uses might be alpha-lactalbumin containing food products to treat or prevent cancer (Sternhagen & Allen, 2001).

Cancer and Breast-Fed Children

Epidemiological studies have been inconsistent over the past 53 years, and have shown opposing results about the association of breast milk and the infant's immune response in carcinogenesis, so the question of whether the HAMLET complex is active in human milk and reduces the risk of childhood cancers is inconclusive. Potential limitations of the studies reviewed were: the evidence is based on observations not on

experimental study; there were a small number of studies for some cancers; there was a reliance on mother's recall in 85% of the studies; and there were changes over the course of five decades of data collection. For example, controls originally received unmodified diluted cow's milk, while more recently controls received formulas that closely resemble breast milk. This change may result in heterogeneity of participants. Most of the control infants were breastfed, suggesting a confounding factor (Kwan et al., 2005). Adjusting for confounding factors has been shown to affect results in both directions, with either a positive or negative association between breastfeeding and cancer.

Despite inconsistent results, though, the overall trends in the studies suggest that human milk may offer a protective effect against childhood cancer, especially with duration > 6months. Martin, Gunnell, Owen, & Smith (2005), Bener, Denic & Galadari (2001), Davis (1998) and Grufferman (1998) found that duration of breastfeeding greater than 6 months seemed to confer greater reductions in childhood cancers than breastfeeding less than 6 months and may protect against childhood acute leukemia, Hodgkin's lymphoma, and non-Hodgkin's lymphoma. Infante-Rivard, Fortier and Olson (2000); Kwan, Buffler, Abrams, & Kiley (2004); McNally and Eden (2004) and Shu et al., (1999) reported a more negative association between longer breast-feeding and acute lymphoblastic leukemia (ALL). Kwan et al. (2004) agree with the earlier study by Shu et al. (1999) which noted a protective association between long–term breast feeding and acute myeloblastic leukemia (AML). Neuroblastomas were significantly reduced, especially as duration of breastfeeding increased (Daniels, 2002). Some studies showed a small reduction in the risk for all childhood cancers combined (Beral, Fear, Alexander &

Appleby, 2001; Davis, Savitz & Graubard 1988). Smulevich, Solionova & Belyakova (1999) found a high increase for all cancers when duration of breastfeeding did not exceed 1 month compared to more than 12 month duration.

The protective effects from watchful molecules was noted in infants, during stages of rapid replication and development, when stimulation of the immune system might increase the response to cancer then and later. Whether a similar cytotoxic effect would be conferred from human milk therapy on fully-developed adult immune systems with cancer is not demonstrated by the results of studies of cancer and the breast fed child. The pH in the adult human stomach is lower than a child's and findings at Lund University determined that a pH of 4 was necessary for alpha-lactalbumin to release Ca++ and adopt the apo conformation (J. Pettersson & A.Mossberg, personal communication, October 17, 2005). But results from HAMLET research *in vivo* suggest that the human body assists in the conversion of harmless milk to a cancer-killing compound in adults as well. Further *in vivo* studies are warranted to test the cytotoxic effect of human milk therapy in adults with cancer.

Complementary and Alternative Medicine (CAM) as a Decision Making Process

The use of CAM for cancer is widespread (Cassileth & Deng, 2004). The American Cancer Society defines "complementary therapies as supportive methods that are used to complement evidence-based treatment, to help control symptoms and to improve well-being and quality of life, and contribute to overall patient care". They define alternative therapies as those therapies used instead of mainstream treatment, and promoted as cancer cures though unproven or scientifically disproved (Mahan & Escott-

Stump, 2004, p.1020, from the American Cancer Society, 1999). The most often referenced definition of CAM is "interventions neither taught widely in medical schools nor generally available in US hospitals" (Eisenberg et al., 1998, p.1569). Harris, Finlay, Cook, Thomas & Hood (2003, p.249) define CAM as a complement which diversifies mainstream medicine, contributes to a "common whole" and satisfies an unmet demand.

The definitions of CAM may need revising, since as a result of its rapid growth in the 1990's, medical schools are often including CAM courses in the curriculum, insurance companies are covering CAM treatments, and many hospitals offer CAM therapies to their patients (Verhoef, Hilsden & O'Beirne,1999). A survey conducted in 1999 of 26 National Cancer Institute Centers revealed that "88% had a CAM practitioner and 54% offered CAM programs, such as support groups and guided imagery (Cassileth & Deng, 2004, p.81). Although many of the practices referred to as complementary or alternative medicine are new to the western world, they have been developing over centuries or millennia in other parts of the world (Barrett et al., 2003). Caspi et al. (2004) refer to the "mainstreaming of CAM" (p.74) and add that many old healing philosophies and techniques are being revisited.

There are estimates that more than 100 healing therapies are considered as CAM (Caspi et al., 2004) and are being used for preventative, curative, and general wellness purposes (Spence & Ribeaux, 2004). Boon et al. (2000) include therapies such as vitamins /minerals, herbal remedies, green tea, special foods/diet, Essiac, body work (e.g., Reiki, massage, therapeutic touch), meditation, shark cartilage, homeopathy, and faith healing as well as practitioners such as chiropractors, herbalists, acupuncturists,

traditional Chinese practitioners, naturopathics, reflexologists, nurses offering therapeutic touch therapy, homeopaths, and spiritual or faith healers as CAM treatments. The Office of Alternative Medicine (OAM) created seven classifications: alternative systems of practice, bioelectromagnetic applications, manual healing methods, mind/body control, pharmacologic and biologic treatments, herbal medicine, and diet/ nutrition/ lifestyle changes (Mahan & Escott-Stump, 2004).

Caspi et al. (2004) report that CAM is most often used for conditions for which no complete cure is offered by conventional medicine (e.g cancer). Boon et al. (2000) report that use of CAM is motivated by attendance in a cancer support group. Truant and Bottorff (1999) interviewed breast cancer patients and found that the decision to use CAM is the result of a relationship with social trends and beliefs and is a dynamic decision, made and revised many times. CAM is a means for an "illusion of control over a disease full of uncertainty" (Truant & Botorff, 1999, p.134). These researchers identified three phases in the CAM decision–making process. Phase one is getting something in place, covering all the bases during the time between diagnosis and surgery. While patients feel overwhelmed, their CAM choice allows them to do something while waiting. In this phase, decisions are quickly made without spending a lot of time doing research. Phase two is hand–picking complementary therapies that fit, i.e. getting a personalized regimen in place. Patients might try different therapies, then evaluate and adjust them to their needs and beliefs. In this post-surgery phase, the patients attempt to improve upon the effects of traditional treatment, control side effects, and boost their immune system. This phase gives them a feeling of control, hope, and a sense of

promoting their healing. Phase three is living with the security of complementary therapies and begins after treatment is completed. It fine-tunes a regimen to live with. Patients feel comfortable that their cancer is under control, but continue to stay informed of new developments in complementary therapies. They will adjust the dose or frequency of complementary therapies, but a core therapy is retained giving them an "illusion of control" over their cancer (Truant & Botorff, 1999, p.134).

CAM users report that their CAM practitioner was a better listener and provided more emotional support than their conventional practitioner (Verhoef et al., 1999). Boon et al. (2000) reported that CAM use is only disclosed to the patient's primary physician by 46% of those surveyed. This increase over previous findings of 30% of individuals informing their physician (Boon et al., 2000) may indicate that cancer patients are more likely to discuss CAM use with their physicians than the general population, or it may indicate a level of acceptability of CAM use by the group surveyed and among the medical profession. Caspi et al. (2004) argue that it is essential to understand patients' use of CAM in order to provide useful information about risks and efficacy to improve the management of patient care, and decrease the risks of oversights. It would be helpful if oncologists were familiar with the most commonly used CAM cancer remedies, so that they could direct their patients to reliable sources of information on the therapy. Many patients reported that although they felt it was important to discuss CAM with their physician, they did not expect their doctor to be knowledgeable about the CAM therapy (Verhoef et al., 1999).

Some patients reported that oncologists may not be supportive of their decision to include CAM in their treatment. Thorne, Paterson, Russell & Schultz (2002) concluded that practitioners attempt to limit or regulate CAM in the name of public safety, due to their belief that cancer patients are using CAM at high and increasing rates because they are unwilling to accept the chronic nature of their condition. Practitioners believe that patients' unwillingness to accept their condition leads patients to seek CAM as curative options. Balneaves, Kristjanson & Tataryn (1999) found that patients believed that CAM use enhanced conventional care, rather than CAM use resulting from disappointment with conventional treatment. They found that the cancer patients were not taking the CAM as a cure for their cancer but rather as additions to conventional therapy. In their discussion of the safety and efficacy of CAM, Verhoef et al. (1999) suggest that there is a useful distinction between "cancer cure and cancer care" (p.95). To date, they cite, there are no proven cancer cures in complementary medicine. Tasaki, Maskarinec, Shumay, Tatsumura & Kakai (2002) believe CAM treatments may be taken to improve general well-being or health (not for anti-cancer effects) and may be giving the patients a sense of hope, responsibility, and control over cancer.

Truant & Bottorff (1999) found that most patients integrate CAM therapies with their conventional treatment. They explained this treatment combination as a patient's decisional control over their health process. Cassileth & Deng (2004) estimate that more than 60% of cancer patients have used CAM. Tasaki et al. (2002) estimate that as many as 50-83% of cancer patients have used at least one CAM therapy. Verhoef et al. (1999) reviewed CAM use in cancer therapy in Western developed countries and found a range

between 7-64%, with variance by types of cancer. Some of this range may be due to a difference in the definition used for CAM among studies

Harris et al. (2003) found that CAM users are more often female, younger, better educated, and have used CAM before. Cassileth & Deng (2004) reported that studies to date have found CAM users to be better educated, of higher socioeconomic status, female, younger and more health-conscious. Verhoef et al. (1999) found that most CAM users are female, younger, employed, and of a higher socioeconomic class (as measured by education). Patients with a more advanced stage of cancer are also more likely to use CAM. Barrett (2001) found that women, with college educations, aged 40-59 are, in general, 10% to 40% more likely to use CAM therapies than their counterparts. He also emphasizes that CAM users are 2-3 times more likely to be people with chronic health problems.

Verhoef et al. (1999) reported estimates that 5% of cancer patients abandon conventional treatments for alternative therapies and that recent studies show that CAM users often employ multiple complementary therapies at once, so another explanation for integrating CAM with conventional treatment or use of multiple therapies may be perceived success rates. In a meta analysis of 26 studies, Chinese herbal medicine combined with chemotherapy increased survival at 12 months (RR1.55; 95%CI 1.39-1.72), 24 months (RR2.15; 95% CI 1.75-2.64), and 36 months (RR2.76; 95% CI 1.95-3.91), while increasing tumor response for patients with hepatocellular carcinoma when compared to chemotherapy alone (Shu, McCulloch, Xiao & Broffman, 2005). In a review of randomized trials comparing Astragalus–based

Chinese herbal medicine combined with platinum-based chemotherapy versus the chemo alone, the combination treatment improved survival, increased tumor response, and reduced chemo toxicity (McCulloch et al., 2006). While these results require controlled trials to confirm results, both studies suggest that integrative, multimodal protocols (i.e. CAM therapies combined with conventional treatments) may increase patient survival rates and drug effectiveness.

The criticism most often leveled against CAM is the lack of peer-reviewed, scientifically conducted research to evaluate its effectiveness. Some methods, such as randomization and blinding, make sense in Western experimental research where the patient is a passive recipient of prescribed therapies. These could seem out of place in a CAM therapy where the patient is actively involved. CAM treatments, which are highly individualized to the patient's needs and characteristics, would be difficult to test in a highly controlled study setting. Some CAM outcomes are more subjective, and as a result might be more difficult to measure (Hilsden & Verhoef, 1999). Also, studies may exist, but CAM therapies for cancer may not be published in English or may be in sources unfamiliar to Western practitioners (Hilsden & Verhoef, 1999). According to Michael Broffman of the Pine Street Clinic, the Chinese have started to computerize their research papers since the 1990's, so it is becoming easier to locate articles related to Traditional Chinese Medicine online especially through the Traditional Chinese Medical Literature Analysis and Retrieval System (TCMLARS), a massive Chinese language/Traditional Chinese Medicine database (personal communication, March 29, 2006).

Quality of Life Issues

Traditionally, only objective end-points (response rate and survival) were considered when the medical establishment evaluated a patient's response to a treatment (Conroy, Bleiberg & Glimelius, 2003), but in many chronic conditions, major differences in survival rates are not expected. For cancer patients, the impact of a treatment on their physical, psychological and social well-being as perceived by that patient, and the easing of their suffering are more telling assessments and are termed quality of life (QOL). Although measurement of QOL is a new concept, the World Health Organization (WHO) defined health in 1948 as "not merely the absence of disease and infirmity, but a state of physical, emotional and social well-being" (Litwin, Fitzpatrick, Fossa & Newling, 1999, p.59).

QOL has been defined as an "individual's subjective perception of their experience in life in the context of the areas that are important to them and in relation to their goals, expectations, standards, and concerns" (Tang & McCorkle, 2002, p.1087). Lindley's definition is: "Quality of life is the patient's appraisal of and satisfaction with their current level of functioning as compared to what they perceive possible or ideal" (1992, p.346). The underlying essence of QOL is whether one's individual needs and desires are fulfilled, "whether life is offering or lacking the right balance of challenges and successes in those areas of personal salience" and whether the patient is experiencing happiness and satisfaction, as expected or desired (Dijkers, 2003, p.S3).

No gold standard exists for assessing health-related quality of life (HRQOL), so no single, agreed–upon checklist of dimensions of HRQOL exists, but nine dimensions

have been identified including: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, mental health, and the "bother" associated with particular dysfunctions (Bostrom, Sandh, Lundberg & Fridlund, 2003; Litwin et al., 1999, p.59; Schapira, Lawrence, Katz, McAuliffe and Nattinger, 2001). The American Society of Clinical Oncology claims that "patient outcomes (health–related quality of life, toxicity, and survival) are more important than cancer outcomes (response rate, duration of response)" (Conroy et al., 2003, p. 2). In patients with cancer, QOL is most influenced by: symptoms and side-effects, social, physical, and psychological functioning. Economic factors and spirituality are also sometimes considered major domains.

QOL assessments are useful if the practitioner's assessment of what would improve QOL does not match the patient's reality. Assessments of patient perceived outcomes may lead to modifications in treatment regimens (Lindley, 1992). The informed decision-making process, according to Caspi et al. (2004) "combines desires (utilities, personal values, goals, ends, etc) and beliefs (expectations, knowledge, means, etc.) to choose a course of action" (p.74). Informed decision-making is enhanced by QOL considerations, and can lead to a more relevant dialogue between physician and patient, which leads to improved patient care. If medical decisions have more than one potential option, the patient's participation in the decision making is necessary to match their preferences with the management decision.

Disease specific modules have been developed for more effective evaluations of patients' well-being during treatment. In their study, Schapira et al. (2001) found that

disease-targeted HRQOL domains showed more change over time than general HRQOL domains. They also concluded that treatment choice significantly affected QOL changes in the prostate cancer patients that they interviewed in the first year after treatment. Consequently, some patients may trade survival advantages for better QOL when offered alternative outcomes. One theme that can be seen from QOL testing is that multiple therapies lead to better results, as was noted in the research by McCulloch et al. (2006). A difficulty in QOL testing is that it is difficult to target QOL issues. Different responses are given upon different modes of questioning with the same patient (Bottomley & Therasse, 2002). Another problem of QOL testing is compliance. Many terminal patients become too ill for questioning and attrition may be high. Missed data may limit the strength of, and lower the confidence in, results. Useful data may be lost when patients are unable to complete the study and can lead to a bias due to selective loss of information (Conroy et al., 2003).

One solution to this loss of information is to employ family proxies for information on terminal cancer patient's treatment. Many family caregivers share the thoughts and feelings of the cancer patient intimately. In a review of 25 QOL studies, Tang & McCorkle (2002) evaluated the agreement between terminally ill cancer patients' assessment of their QOL, compared to their family members' assessments. Questions related to subjective judgments–personal feelings and psychological states–showed poor correlations, while observable and concrete items showed almost perfect agreement. In general, the magnitude of differences was small between groups. One study found that the majority of patients' assessments agreed at least moderately ($r > 0.6$) with what was

provided by their family caregivers, and one study found that assessments were within one response category in either direction from each other. The tendency was for family caregivers to view patient QOL in a more unfavorable perspective than the patients did. Greater agreement was found when the caregiver lived in the same house as the patient. Family proxies can be considered a reliable source of data for terminal cancer patients who are no longer alive (Tang & McCorkle, 2002).

QOL measures may be useful in clinical practice by helping physicians understand patient concerns. Also, QOL data may advise physicians regarding when to modify doses or switch to palliative care or to less toxic agents. QOL study results have been instrumental in approval of new anti-cancer agents. QOL measures may predict patient survival, thus preparing family members for impending consequences. QOL research results, when compared between a diseased and healthy population, can profile a disease and predict other medical services needed by the diseased population. For example, QOL study results have suggested that advanced lung cancer patients have psychological and emotional issues that are of primary concern to these patients and need to be managed for proper care and treatment. Comparing cross-sectional and longitudinal scores can help researchers understand the impact of a new cancer treatment on patient QOL. Although the treatment might increase survival, long-term negative effects on QOL may decrease the advisability of the treatment for some patients. QOL research results may also help insuring agencies decide contract decisions for future coverage options (Soni & Cella, 2002).

One example of a survival decision that may be overshadowed by QOL effects was a study by Schapira et al. (2001), who reported that prostate cancer patients who underwent radical prostectomy experienced significant declines in urinary and sexual function and "bother." The study found that some prostate cancer patients may trade an alternative treatment with a better QOL over survival. Results were collected up to 12 months after treatment (the duration of the study). A suggestion was made by Conroy et al. (2003), that claiming an improvement in QOL results may require the maintenance of these results for two months or more. They also suggest that a useful method of reporting results should include how many patients benefit, how many perceive no change, and how many get worse.

The goal of QOL research is to improve medical care overall and to assist patients in their informed decision making process. Incorporating QOL choices into the decision making process increases patient satisfaction regarding their care overall, allows patients to feel better about their choices of treatment, and helps them feel less regret about their medical care. When treatments are equal in other regards, QOL considerations may be the determining factor in the patients' choice for cancer therapy. A standard, internationally validated instrument is needed, though, for measuring the QOL of cancer patients. Following this, making the results available to individual patients is an issue that must also be addressed (Litwin et al., 1999).

Designing Health-Related QOL Instruments

Interview process.

No gold standard exists for assessing health-related quality of life (HRQOL), so an instrument appropriate to the purpose of the HRQOL study may need to be selected or designed. For cancer patients, making treatment decisions is a dynamic rather than a static process, as the nature of their condition progresses and changes. Decisions are influenced by many factors, including the patient's beliefs and lifestyle (Truant & Bottorff, 1999). Most data collection methods limit the patient's description of their cancer treatment to answers about their level of functional limits, rather than to the meaning these limits have for them. This approach may limit understanding of the effect of a cancer treatment on a patient's QOL (Dijkers, 2003). In order for a QOL measurement to capture the voice of the individual, and represent the patient's perspective, the instrument must attempt to be individualized. QOL measurements must broadly question the participants in order to identify unexpected trends. Tasaki et al. (2002) found that an open-ended interview format is the most effective for capturing people's unique perspectives. Truant & Bottorff began their interview with an open-ended question, and maintained the open-ended interview format throughout to allow the subject to determine the content of the interview. To focus and stimulate the discussion in the open-ended interview, trigger or prompting questions were used by Caspi et al. (2004). Such questions are useful when little is known about the topic being researched, and they may uncover a greater breadth of information. Confirmatory interview technique, in which the interviewer periodically summarizes the content of the interview, is used to clarify information heard, without biasing the participant's answers. Montbriand (1998) utilized a cyclic process by asking each new interviewee about issues

mentioned in previous interviews, after the participant finished telling his personal story. Truant & Bottorff (1999) used information gathered in each interview to determine the categories of their emerging theory, then expanded and validated the emerging categories and themes in subsequent interviews.

Item pool.

Most instruments test the patient's health, which is in fact only a part of QOL ratings. The domains which need to be included in HRQOL assessments are physical, emotional and social functioning (Lindley, 1992). Soni & Cella (2002) also include the effect of an illness on the psychological well-being as perceived by that patient, and their study included factors such as financial status, job satisfaction and living conditions. Age, gender, marital status, socioeconomic level, type of occupation, hobbies and any other factors a person cares about will determine the QOL domains the person considers important (Dijkers, 2003, p.S3). Tasaki et al. (2002) included questions related to: personal background, satisfaction with health-care providers, satisfaction with conventional treatments received, types of CAM used, CAM providers, communication with providers about CAM use, perceived effectiveness of the cancer treatment received, costs for CAM used, and frequency and duration of CAM use. Boon et al. (2000) tested their questionnaire on six focus groups, and from that data determined variables for inclusion in an instrument. They included reasons for using CAM, barriers to use of CAM, disclosure of the use of CAM to physicians, demographic information, and attitudes about CAM and conventional medicine. Lindley (1992) advises using a short item pool (20-30 questions) which can be answered in a short time, when constructing a

QOL instrument. Individualized instruments may place a burden on the subject and the investigator, both in time and effort, and will require more skill in deciphering the results (Dijkers, 2003).

Psychometric properties.

A measure must be reliable, valid, and responsive. Reliability refers to the reproducibility of the instrument. Tasaki et al. (2002) revised their instrument after pilot-testing it on cancer survivors. Validity refers to how well the instrument measures what it intends to measure. The validity of the instrument can be tested on a separate group of patients. Invalid items can be removed when statistical methods identify the items showing the most variance. Validity could be tested by an ad hoc panel of advisers including researchers, clinicians, statisticians and psychologists with expertise in oncology (Efficace et al., 2002). It is advised that a researcher avoid picking and choosing items from different instruments to construct a new instrument, since this would create an instrument that has not been psychometrically validated. Responsiveness refers to how sensitive the scales are to change over time, to detect meaningful changes in QOL over time. Standardized instructions and completion procedures ensure adequate data quality and minimize bias.

Analysis.

In his research, Montbriand (1998). utilized qualitative data analysis software to organize the data into common themes, words or phrases, even when they occurred in other parts of the interview Caspi et al. (2004) used thematic and content analysis strategies to identify core concepts and categories in order to determine the patient's

motivation for choosing a treatment option. Massive amounts of data are generated in a qualitative research study. Concise, interpretable analysis is difficult. Ease of data interpretation and comparison should be taken into account when designing an instrument. This tool should allow for easy interpretation and comparison of data (Soni & Cella, 2002).

Theoretical Perspective / Conceptual Framework

Since 1999, cancer patients have requested human milk from the San Jose Mother's Milk Bank. It is assumed that these patients have read the results of *in vitro* and a few *in vivo* studies, conducted primarily at Lund University on the apoptosis–like effect of human milk on various cancer cells, and chose to use the therapy based on the established safety and benefit of human milk, despite a dearth of large-scale, experimental research. It is assumed that these patients were willing to try this untested cancer treatment due to being in later stages of cancer, or had a life-threatening condition for which conventional medicine did not have an acceptable answer. This assumption would be in line with the findings reported by Spence & Ribeaux (2004), that in more targeted surveys, patients used CAM because conventional medical treatment (CMT) did not effectively treat their condition.

In order to clarify the patients' motivation for requesting human milk, and to determine if the human milk had any effects on their cancer and on their quality of life, a qualitative, interview based–study was conducted. The study sought to determine why the participants decided to take human milk, their knowledge regarding this therapy, their use of other CAM therapies, their communication with their primary physician regarding

this CAM treatment, as well as any impact on their well-being. It will provide case-specific information and personal perspectives to donor Milk Banks and cancer patients regarding this therapy. The research results may illustrate the processes cancer patients use when making decisions about human milk therapy and clarify what information is pivotal in deciding upon human milk as a cancer therapy. The research results could also help clinicians understand patient concerns, including the impact of symptoms on their quality of life. This information could improve communication between patients and their clinician. Possible topics for future research may be identified from the provocative thoughts of the participants.

The research is somewhat applied and retrospective and used primary analysis. No instrument was available for surveying cancer patients taking human milk, so an instrument was designed and tested for this study. HRQOL and CAM studies were researched to determine the basic and essential issues that the QOL instrument should include for this population. The main categories were determined to be: conceptual, measurement, methodology, and interpretation, with specific questions related to human milk therapy. Existing QOL instruments were reviewed for guidance, to design open-ended questions specific to human milk therapy, which would yield the largest pool of usable information. An individualized interview format with prompting questions along with a confirmatory interview technique would guide the interview in order to capture the unique perspectives of each respondent. The instrument questions would be validated with a group of scholars, health professionals, and cancer patients. Thematic and content

analysis strategies identified core concepts and categories. The research results will be presented in a narrative format that captures the perspective of the participant.

The model used here is borrowed from Carl Rogers' counseling theory, and is called the patient-centered model. It considers the patient's perspective in the decision-making process and includes consideration of the patient as a person. This study hopes to capture how the patient applied the person-centered model, to explore new possibilities and actively participate in their illness management, rather than passively accept their prescribed treatment (Nystul, 2006). The purpose of this study is to capture each patient's highly individualized and participatory healing process, by obtaining the patient's perspective related to taking human milk as cancer treatment. The conversations will be recorded in terms of the decisions the patient made and why they made these choices. Milk Banks and interested cancer patients may benefit from this information by better understanding the impact of human milk therapy on other cancer patients. The information may clarify the treatment's impact on the QOL of cancer patients and may illustrate some of their concerns. In addition, the information gathered may suggest future research topics related to human milk therapy.

CHAPTER II

JOURNAL ARTICLE

Title: The Motivation for Cancer Patients to Take Donated Human Milk

Susanne M.Rough, MS, RD[1], Pauline Sakamoto, MS, PHN, RN[2], Caroline H. Fee, MA[3], Clarie B. Hollenbeck, PhD[4]

[1]Graduate student, Department of Nutrition and Food Science, San Jose State University, San Jose, California

[2] Director, San Jose Mother's Milk Bank, San Jose, California

[3] Lecturer, Department of Nutrition and Food Science, Associate Director Division of Health Professions San Jose State University, San Jose, California

[4] Professor, Graduate Research Coordinator, Department of Nutrition and Food Science, San Jose State University, San Jose, California

Address all correspondence and reprint requests to:

Susanne M. Rough, MS, RD
c/o Clarie B. Hollenbeck, PhD
Department of Nutrition and Food Science
San Jose State University
One Washington Square
San Jose, CA 95192-0058
Tel: (408) 924-3100
FAX: (408) 924-3114
Email: ragbiter@att.net

Running title: Donated Human Milk and Cancer

Biographical Paragraph

[1]Susanne Rough MS, RD.

[2]Pauline Sakamoto MS, PHN, RN is the Executive Director of the Mother's Milk Bank at Valley Medical Center, San Jose, CA and the Vice-President of the Human Milk Banking Association of North America.

[3]Caroline H. Fee, MA is Associate Director for Health Professions and Lecturer in the Department of Nutrition and Food Science at San Jose State University.

[4]Clarie B. Hollenbeck, PhD, Professor, Graduate Research Coordinator, Department of Nutrition and Food Science, San Jose State University, San Jose, California

ABSTRACT

THE MOTIVATION FOR CANCER PATIENTS TO TAKE DONATED HUMAN MILK

This represents the first published account from the patient's perspective of the use of human milk as cancer therapy. Purposive sampling was used to select a sample of 10 participants. Five were patients and five were family proxies. Individual interviews were conducted using confirmatory interviewing technique to obtain individual perspectives on the motivation for cancer patients to take donated human milk. Human milk therapy improved the quality of life (QOL) measures in the physical, psychological, and spiritual domains for most patients interviewed. The patients continued their use of human milk despite cost, taste, and discouragement from the conventional medical community. The study results support the theory that QOL may be more important to cancer patients than cancer outcomes and may improve patient medical care overall. These interviews offer information to cancer patients, their practitioners, and donor milk banks on outcomes and symptom relief from this therapy.

Keywords

Human milk, adult cancer treatment, Complementary and Alternative Medicine (CAM), Quality of Life (QOL), breastfeeding & risk of cancers.

Introduction

Human milk offers an easily digested and well-tolerated form of calories in a complete food, which is safe enough for infants. Research supports that human milk provides not only a superior food for human infants, but protective factors as well. While researching some of the protective factors in human milk, at Lund University in Sweden, Hakansson et al.[1] made the serendipitous discovery that *in vitro*, human milk causes an apoptosis-like effect on several varieties of cancer cells. A few human *in vivo* research studies realized similar apoptosis–like effects on human cancer cells.[2, 3] Because of this knowledge, people with cancer are requesting human milk. Between 1999 and the present, cancer patients have requested human milk from the San Jose Mother's Milk Bank as a complement or alternative to their conventional biomedical cancer treatment. However, at this time, no information has been collected from these patients regarding their experience with the human milk therapy. Access to this information may facilitate further research for those interested in learning more about this unique therapy.

Complementary and alternative medicine (CAM) addresses these research issues while conventional medicine does not. Cancer trials generally measure tumor response, overall survival, toxicity and level of disease-free status. Complementary and alternative medicine (CAM) [4] is most often used for conditions such as cancer for which no complete cure is offered by conventional medicine. Its use is part of a patient's informed decision–making process which, according to Caspi et al.[4] "combines desires (utilities,

personal values, goals, ends) and beliefs (expectations, knowledge, means) to choose a course of action" (p.74). Informed decision-making is enhanced by quality of life (QOL) considerations, and can lead to improved patient care through a more relevant dialogue between physician and patient. The Journal of Clinical Oncology found that only 10% of cancer studies include some measurement of health-related quality of life (HRQOL) as an outcome [5]. QOL may be more important than cancer outcomes because it measures the benefits perceived by the patient [6] and it may contribute to self-healing by improving the psychological or physical well-being of the patient.

The purpose of the present qualitative study is to interview cancer patients who have taken human milk, to determine their motivation, the effect it had on their quality of life and how it fits into their use of CAM. Included in the study will be their use of other CAM therapies and their communication with their primary physician regarding human milk therapy. These patients have taken an active role in the decision making process related to their healthcare. Information from the interviews will provide case-specific information and personal perspectives to donor milk banks and cancer patients, giving them a preliminary description of this CAM therapy. Medical care can be improved by the insights from patients who take an active, participatory role in their health care. Topics for future research will also be identified.

Methodology

Research Subjects, Sampling, Setting

Since the goal of this study was description and exploration of human milk as a therapy for cancer, purposive sampling was used, to access subjects able and willing to describe their experience with human milk therapy.[4] Subjects were limited to cancer

patients, aged 18-80 years old, who had requested and were receiving human milk from the San Jose Mother's Milk Bank from 1999 to the present. Any patient who received donor milk was contacted by US mail and asked to participate. Only those recipients who responded with signed consent forms were included for a total of 10 participants from the SJMMB, with 5 represented by proxy. (See Table 1 for a breakdown of responses).

Personal interviews were conducted between the primary researcher and the human milk recipient in their home or a convenient place of their choosing. Each interview lasted approximately 1-1.5 hours. One interview was conducted with each participant. If person–to–person interviews were not feasible, interviews were conducted by phone. If the recipient was no longer alive, interviews were conducted with a family member or primary caregiver as proxy, following the same format. Five of the participants were represented by proxy. All responses were included in the study analysis.

Instrument Design

No gold standard exists for QOL testing. A review of literature suggested that 3 approaches[4] are used to measure quality-of-life (QOL) in cancer patients. One is the self-administered questionnaire, another is the structured interview, and a third is modeling. Since no previous studies have been conducted with cancer patients taking human milk therapy, no pertinent guidelines exist regarding which factors to consider. The self-administered questionnaire requires established contributing factors. Mathematical modeling considers a specific group of patients in comparison to time without symptoms

of disease and toxicity, and time with symptoms. This is not the primary concern regarding cancer patients and a human milk therapy. The third method of measuring QOL is the structured interview. This method is useful when no previous data have been collected regarding a specific cancer therapy, since the interviewee determines the breadth of information related to human milk therapy by his responses. The structured interview was the most appropriate data collection method for this study.

To allow the participant adequate opportunity for explanation and presentation of potentially complex responses, the interview was initiated with a general open-ended question. Although the interviewee determined the content and direction of the interview, an instrument which would provide a standard set of prompting questions, was needed to focus the interview and to ensure consistency between interviews. Standard generic, general cancer-specific, and site-specific instruments were evaluated, but none were appropriate for human milk therapy administered to a diverse cancer population. A unique instrument specific to human milk therapy was needed.

Instruments usually contain items or questions, organized into scales,[9] which each measure a different aspect or domain of HRQOL. Lindley reports[5] that the QOL domains most influenced in patients with cancer are: symptoms and side-effects, social functioning, physical functioning and psychological status. Economic factors and spirituality are often included. For this study, the items aimed to be multi-dimensional by assessing the psychological, social, and physical domains. Prompting questions in the psychological domain included the effectiveness of the human milk treatments as perceived by the patient. Social domain questions assessed the patient's communication

with health care providers, perceived barriers to use of this treatment, as well as cost for the milk, duration and dose of human milk treatment, and sources for locating information on human milk therapy. Physical domain questions assessed the patient's symptoms before, during and after taking the human milk therapy and the patient's response to all therapies. Demographic information was gathered for comparison to other HRQOL measures, and the patient's stage and type of cancer before, during and after human milk therapy was recorded. The instrument included 24 questions, to avoid fatigue of the participant before completion.

The instrument was pilot-tested before use with 3 cancer patients not participating in the study, 2 healthcare providers, 2 donor milk bank directors, and 2 nutritional science professors. The feedback of the group was used to revise the questionnaire (Table 2).

Research Procedures

Each interview was personally conducted by the researcher, and was initiated with a broad, general question[10] about the patient's cancer and treatment choices. Each participant was encouraged to explain their motivation for requesting human milk as CAM. Prompting questions were asked in order to focus the interviews. The content and direction of the interviews were determined, in part, by the participant's responses, but a consistency between all interviews was established and maintained by a common set of structured questions. Since little was known about this form of cancer therapy, and the goal was to reveal a breadth of information on the therapy, a non-structured interview with prompting questions was useful.

Confirmatory interviewing technique[5] was used in the present study. At relevant points throughout each interview, the interviewer read a summary of the participant's key concepts to determine if the notes accurately reflected the participant's experiences, or to see if there were any additional important points or changes the participant wanted to add. In this way, the interviewer could clarify unclear areas without biasing the participants' answers. The information obtained in one interview also helped guide the direction of subsequent interviews. The interviews did not seek to prove or disprove a set theory. However, a pattern about human milk and its association to cancer treatment emerged as the interviews were conducted.

When necessary, additional information was obtained from medical records or laboratory tests related to the patient's cancer. This afforded the researcher the opportunity to use triangulation. The questionnaire and the data collection protocol were approved by the San Jose State University Institutional Review Board, for use of human subjects.

Analysis Method

Categories were defined for reporting results, and relevant themes were combined. Data was analyzed descriptively and is presented using frequency, median, and range. Non-numerical data gathered was analyzed conceptually, and the analysis method was determined after the data was collected when themes and content were analyzed and core concepts were identified from the responses. Ten responses for each of the 24 questions were recorded and analyzed for trends and core concepts. Similar responses were tallied for each question, and personal comments or differences that did

not fit a pattern were maintained in the narrative format. When responses overlapped more than one category, they were included in the most relevant category. All responses were included in the study.

Results

Participants' Characteristics

Eleven of the 39 recipients of donor human milk agreed to participate, but 1 relapsed before the interview took place and the patient declined to be interviewed. Five of the 10 respondents are alive and answered the interview on their own behalf, while 5 of the 10 were family or friends answering for a deceased recipient. Participants were equally divided between male and female, ranged in age from 44-86 years, and were well-educated. (Table 3) The participants were not of Hispanic or African-American ethnicity. The primary cancer was lung (n=4), followed by breast (n=2), prostate (n=2), colon (n=1), lymphoma (n=1).

Patient Progress

Two patients were in the early stages of their cancer when they started the human milk treatment, 3 were at stage 2 or 3, three were stage 4 and died within a year of initiating human milk treatment, and two stages were unknown but the patients died within 2 months of initiating treatment. After they stopped consuming the human milk therapy, 3 patients were in remission, 2 had advanced stages of cancer, and 5 had died (Table 4).

Source of Information

All of the patients in this study acquired information about human milk therapy from internet research. Four had some connection to a person in a lactation related field. One patient learned of the treatment through his prostate cancer support group. And 2 patients were also under the care of alternative therapy clinics, which included human milk as part of their CAM treatment plan. The web research was conducted by spouses and other family members and led them to studies conducted mainly by Lund University in Sweden which documented the apoptotic–like effect of human milk on 50 types[11] of cancer cells.

Dose & Duration

Prescriptions were obtained from a physician of choice by each patient to initiate human milk treatment. No optimal dose has been determined experimentally, so doses varied from 59-355mL (2 to 12 ounces) per day. Patients received total quantities between 3 L-174 L (100–5891 ounces) over the course of treatment which varied from 6 to >338 weeks, amounting to a total of 584 L (19,733 ounces or154 gallons) of human milk for the entire study group. However, the total quantity of 584 L delivered to the 10 recipients in this study over a period from September 1999–December 2005 amounts to less than 2% of the total 28,389 L (958,936 ounces) delivered to all recipients from SJMMB during this same period (Figure 1). The average amount of milk received by adult cancer patients from all 11 HMBANA milk banks in 2005 was 4.0-4.5% (Figure 2, noted as Adult Illness).

Dose and duration varied between participants, but were related to stage of cancer at initiation of human milk treatment. The 5 patients who died during treatment were at

terminal stages of cancer when they initiated human milk treatment, and they received the smallest overall quantity of milk for less than 3 months. Four patients continue to take human milk for prophylactic purposes. Two of the patients who are in remission and are taking the milk for prophylactic purposes have received the largest overall quantity of human milk, for the longest period of time.

There is no way to know how much of this milk the patient actually consumed, because patients were self-treated. Four patients reduced their dose to ≤ 8 ounces (237 mL) per day due to the cost of the milk. At US $3.00 per ounce (plus shipping), human milk is expensive, and 2 patients commented that it was the most expensive supplement they took. Only 1 patient was able to bill his insurance, and 1 paid for it with disability payments.

All participants received human milk from the SJMMB, but three also received milk from other donors. One commented that it added spiritual value when the milk was a gift. Human milk from additional donors is not included in this study. Two recipients were refused milk from 5 other sources including other milk banks. The reason given was that human milk is not a proven cancer treatment. Time of day for consuming the milk varied among participants, with 3 not taking it on a regular schedule, 4 taking it on an empty stomach at night, 1 taking it on an empty stomach in the morning, 1 taking it between meals, and 1 taking it after dinner.

Other Therapies

Seven participants took other CAM therapies in addition to the human milk, including Vitamin C (n=2) and acupuncture (n=2). Some of the other therapies included

shark's cartilage, bird's nest soup, milk thistle, turmeric, wheatgrass, chiropractic, homeopathy, naturopathy, music, herbs, and vitamins. Two participants were being treated by alternative clinics, which planned a complementary regimen compatible with the chemicals in the conventional medical treatment and based on their laboratory results and symptoms. The clinics recommended a holistic plan including: music, prayer, and, exercise to enhance the chemotherapy; appetite stimulants, hydration tips and soothing supplements, with a stated goal of achieving peace of mind.

While 5 of the 10 participants were receiving both conventional biomedicine and CAM treatment, 5 patients opted out of conventional treatment: 2 because of "watchful waiting" during the early stage of their cancer; 2 because radical surgery was the only other option; and 1 because she expected a decrease in quality of life from conventional biomedicine. Two patients planned to continue all multiple therapies since something was helping them improve, though they were not sure what it was. One patient asked, "How much does belief help?"

Barriers to Use of Human Milk

Although all cancer patients informed their medical practitioners of their desire to take human milk, some met resistance from a medical professional who felt the therapy was clinically unproven or refused to look at the *in vitro* research study results and told the patients that they were silly, naïve, or misled. Some family members were skeptical, but were aware of others taking the same treatment, and did not interfere with this novel treatment. One patient anticipated resistance from her radiologist and chose not to tell him. When the cancer patients met resistance, they reported finding a more supportive

practitioner to write their prescription. They wondered aloud how the milk could hurt them or what they had to lose by eating a food safe enough for infant consumption.

Four of the 5 terminal patients did not meet resistance. The patients reported that their practitioner supported the human milk therapy because they knew their patient was terminal and felt that this could not hurt them and might help.

Other potential barriers to the use of human milk were the cost, media censure, and taste. The average cost of human milk from the SJMMB was $3.00/ounce, and each recipient was responsible for shipping costs for distances < 30 to >2800 miles from the SJMMB. When interviewing one cancer patient regarding human milk therapy, a newscaster criticized her for taking milk away from babies. Some participants found the taste of the pasteurized milk to have an oily undertaste, a gamey taste, a slightly cooked taste, and a thick taste, while they reported that raw milk tastes delicious, sweet, and lively. One patient held her nose and swallowed the milk while reminding herself that it was healing. Two recipients could drink the human milk but reported being allergic to other milk. Other participants were limited to receiving human milk only when a particular caretaker was present, because of food safety issues related to the milk product (Table 5 for complete results).

Cancer Symptoms

When asked about symptoms, 6 had no symptoms before taking the human milk treatment, 4 patients had decreased appetites, 3 had difficulty swallowing, 1 was extremely ill and unable to work and 2 suffered GI distress related to chemotherapy. Of the 6 patients that felt no symptoms before initiating treatment, 2 patients felt the milk

improved their immune system. They judged this by a lower incidence of colds and fever. One cancer patient felt energized by the milk and said it improved his energy level. Three patients felt no change in symptoms while taking human milk.

Two of the patients with decreased appetite before taking human milk felt it settled their stomach, and they were able to keep the milk down. They did not push it away like other food. Human milk offered the patients more nutrients, and liquids were better tolerated than solids, especially for 3 patients having difficulty swallowing. The extremely ill patient felt stronger after taking human milk, her cough decreased, and her ability to exercise increased. She gained weight, reported improved respiratory function, and increased appetite while being treated. Two patients felt that the side-effects from conventional biomedicine, especially to their GI tract, were minimized by consuming human milk since they did not experience nausea, weakness, and general lethargy after initiating chemotherapy. They felt the milk made them stronger and helped them feel well, not ill.

One patient noted that his levels of prostate–specific antigen (PSA), a widely performed screening blood test for prostate cancer, tested lower while taking human milk. He graphed his PSA levels and found that they dropped when he was taking human milk, and they rose when he discontinued the human milk. Although not considered a perfect screening exam for prostate cancer, PSA is a widely used reference. (Complete results of cancer symptoms in Table 6)

Expectations

When asked to recall their expectations at the initiation of human milk therapy, and to determine if these expectations had been met, 6 cancer patients reported that they had no expectations. Two hoped it would strengthen and support their immune system, and they felt that it had. One had hoped for a reversal and that did not happen, and 2 thought it was a long–shot and did not expect that it would cure their cancer and it didn't. For 3 patients it offered hope, either that things would change or that their digestion would improve. One patient was looking for anything that helped. It was seen as a last-ditch effort when nothing else worked. One patient expected it to taste good and was not prepared for the taste she encountered.

Quality of Life (QOL) Effects

When considering the more radical, invasive treatments, which might have prolonged her survival, 1 patient opted for the human milk therapy, since it had the potential to improve her QOL, even though perceived to be an unproven cancer treatment. Another patient noted that although his cancer had not improved, it also had not progressed, and frankly there were no other options. Two other patients noted that although human milk did not cure their cancer, their energy did increase. One patient believed the human milk would speed up and positively affect the healing process. Another expected that the human milk therapy would improve his cancer stage, while others believed the milk maintained one's health, and cited examples of human milk taken for prophylactic use or for stomach ulcers.

Personal Motivators

Only 1 patient felt the human milk therapy had no health impact and would not use human milk treatment again unless testing proved its efficacy; 2 had no response, 3 had no comment, and 1 would take human milk if the taste were improved. One participant described the human milk therapy recipients as desperate people looking for desperate measures–anything that helps. Another participant did not feel desperate, but he "did not want to die", either. He felt that if there is "a possible million to one chance that it might help," a patient might want to try it. He proposed the unanswerable question: "Even if the human milk did not cure the cancer, did it stop it from progressing?" Without evidence, "the only benefit (of human milk therapy) is psychological. People are looking for hope. This is a pathway for hope and gives the patient something positive when most things about cancer are negative"

Human Milk Distribution

From 2000-2005, the SJMMB delivered a total of 28,839 L of human milk for all client services (Figure 1), and in 2005 the Human Milk Bank Association of North America (HMBANA) records indicated that an average of 4.0- 4.5% of their total distribution was delivered to adult cancer patients (Figure 2, noted as Adult Illness).

Discussion

Comments

Family proxies were needed for half of the responses in this study. According to the findings of Tang and McCorkle,[12] cancer patients and their caregivers agree moderately well ($r > 0.60$) on the patient's QOL and can be considered reliable alternates as sources of data for terminal cancer patients. Two of the 5 patients lived with the

family proxy. The other 3 were in frequent contact with the patient, so it can be expected that they shared their thoughts and feelings. Due to this close contact, their answers were likely to be in strong agreement for observable questions. Proxies provided a reliable, alternative source of data for this study.

Demographics of the respondents were typical of previous CAM research findings[13-16]in terms of socio-economic characteristics (as measured by education) and ethnicity, but were atypical because the respondents were older and not predominantly female. The patients were in more advanced stages of cancer, and previous studies [16] have found that patients in more advanced stages are more likely to use CAM. Additionally, people with chronic health problems [13] are 2-3 times more likely to use CAM therapies.

In all cases, internet research led to the research done at Lund University, which is provocative and suggests that human milk therapy has the potential for success as a cancer therapy. Information about CAM therapies is readily available on the internet, but it is difficult for readers to separate reputable sources[14] from unproven treatments. Human milk therapy has a long history of safe use with premature and medically challenged infants. These factors may have accounted for its recommendation, despite a dearth of large-scale, *in vivo*, scientific studies.

Human milk use also has a long history in Traditional Chinese Medicine (M. Broffman, personal communication, March 29, 2006). It is considered a kidney tonic for cold weather and a liver and spleen nutrient and tonic for the spring. Its purpose as a tonic is to strengthen deficiencies in these organs. It is prescribed because it is

substantive, nutrient dense, and is a cytotoxic chemical. The dose of human milk, typically 177-355 mL (6-12 ounces/day), is based on the patient's degree of deficiency and on supply. Raw milk is preferred to pasteurized milk, to maximize enzymes present in the milk, although quality control is a possible issue in the use of raw milk. Multiple therapies are prescribed along with the human milk to treat the deficiencies identified by the patient's lab results and by screening at the alternative treatment center. Most patients in this study used multiple therapies in addition to human milk. Two recipients, whose cancer advanced to stage 4 after initiation of human milk therapy, are being treated by practitioners at alternative treatment centers. At least 8 alternative centers operate in the San Francisco Bay Area, prescribing complementary treatment plans based on the client's blood tests. Patients report that these centers offer individualized treatments, and practices are more holistic and empowering [17] to patients than conventional modalities. Patients in previous research studies reported that CAM practitioners may be better listeners and provide more emotional support [16] than conventional practitioners.

Five of the patients did not use conventional cancer treatment while taking the human milk therapy. Although earlier studies[18,19] found that CAM is taken more to enhance conventional biomedicine rather than resulting from disappointment with the primary therapy or for anti-cancer effects, Verhoef et al. found that 5% of cancer patients[16] abandon conventional therapy for alternative methods. Health care decisions require trade-offs, and different priorities determine patients' decisions. Terminally ill patients are reported [20] to be more likely to take unproven, untested substitutes. For 5 of

the terminally ill patients in this study, conventional therapies had been exhausted [21] or had side-effects or significant risks. Patients used CAM because their particular condition[20] could not be treated effectively with conventional medical treatment. Some of the patients in this study reported that the conventional treatment would have decreased their QOL, and their priority was QOL over the possible benefits of conventional treatment with negative side-effects.

Nonetheless, all participants were honest with their practitioner about taking the human milk therapy unlike previous studies, [7] which reported that CAM use is only disclosed to physicians by 46% of cancer patients. The 100% disclosure rate in this study is likely because a prescription is required for receipt of human milk from donor milk banks. Five of the 10 recipients met resistance from medical professionals when seeking a prescription, especially from oncologists and surgeons. The resistance was selective, and determined by the stage of cancer. When patients in earlier stages of cancer met resistance, they were told that human milk therapy is an unproven treatment. Terminally ill patient's choice to take human milk was supported by medical professionals who stated that the therapy could not hurt and might help.

An important theme that emerged in this study was the patients' involvement in their informed decision-making process and an emphasis on improving or preserving their QOL through their health care choices. Each of these patients was involved in the process of self-determination and control, as outlined in the person-centered counseling theory[22] of Carl Rogers. The process of researching and selecting a complementary or alternative treatment for their cancer therapy offered hope for a different outcome and

reflected a strong will to live. Patients felt it was worth trying for a "1 in a million chance of success." The therapy offered an "illusion of control"[8] in a mostly negative disease. Also, in the person-centered model, patients are interested in exploring new possibilities. Thus, human milk therapy may have offered hope for a potential treatment for their cancer, self-determination and improved quality of life.

Beyond the measurable stage changes (tumor response and survival) related to cancer treatments, an important consideration for cancer patients is quality of life decisions. Lindley reports[5] that the QOL domains most influenced in patients with cancer are: symptoms and side-effects, social functioning, physical functioning and psychological status. Economic factors and spirituality are often included. In this study, one patient suggested that the primary benefit of human milk therapy is psychological as a pathway for hope. Physical improvements listed by patients as positive effects of the treatment, were numerous: increased energy, immune support, strengthening, respiratory function and as an appetite stimulant. Three participants noted the nutritional support that human milk offered through nutrient and calorie density and that it eased the effects of chemotherapy on their GI tract. The spiritual function of human milk therapy was mentioned when one patient asked "How much does belief help?" Patients in this study agreed with results[23] found by Shapira et al. that "some patients may trade survival advantages for better QOL when presented with the choice of alternative outcomes" (p.252). Taking human milk therapy is an attempt by these cancer patients to be a part of their informed decision-making process, in order to improve their medical care and QOL.

A criticism by physicians and newscasters made to the participants in this study regarding the use of human milk for cancer treatment was that milk destined for premature babies and infants must be sacrificed for cancer patients. This is an incorrect opinion not supported by data. The milk given to adults is mature milk and does not impact premature babies. Neither the total amount (584 L) of milk delivered to all recipients from SJMMB (Figure 1), or the combined amount of 4-4.5% of total requests (Figure 2) from all HMBANA Milk Banks represents a significant impact on infants receiving milk from Milk Banks. More importantly, the SJMMB average amounts represent total amounts requested and delivered, and do not reflect the amount of milk available.

The cost of the milk including shipping was mentioned as a reason for reducing the dose or seeking alternate sources of human milk by 6 cancer patients in this study.[24] Eisenberg found [21] that 58% of CAM users paid for alternative therapy entirely out of pocket. Even though 9 recipients could not bill their insurance for the human milk, they continued to use this therapy. Previous studies[14,15,21] also suggest that cost is not a deterrent to CAM use. The findings in this study suggest that some cancer patients were determined to use human milk therapy despite the high cost, lack of insurance coverage or discouragement by the conventional medical community. Barrett reports [13] a national trend toward coverage of CAM therapies by insurers, mainly because of consumer demand. The insurers' main concern[13] was lack of research on efficacy and lack of standards of practice. Experimental studies of human milk therapy are needed to qualify this non-invasive treatment for consideration by insurance companies in their cancer

treatment and quality of life programs, and to establish standards of practice for dose and duration of human milk therapy.

Study Limitations

There are some limitations to this study design. The study is retrospective and subjective and depends on the patient's memory and on the mode of questioning. Although the sample size of 10 may seem small, the data from participants was very rich. QOL measurement and open ended questioning generate large amounts of data. Combining this data in a concise way may have affected the interpretation of the results, and the process of tabulating subjective responses may introduce human errors.

Although the amount of milk delivered to the patients is known, the amount of milk consumed, and the amount shared or received from other sources is not certain. As a result, no quantitative measurement of milk consumption is included in the study results. The amounts presented in this study may or may not be accurate, so it is difficult to draw conclusions based on them. Some patients took other treatments concurrently with the human milk, and all conventional cancer treatments varied. Multiple therapies were taken also, so no results can be specifically attributed to human milk therapy.

Some data were obtained directly from the patient receiving the treatment, while other information was from a proxy. Tang & McCorkle found[12] that proxies matched perfectly on objective type questions, while they showed moderate to poor agreement on subjective questions. Since the quality of life answers in this study are subjective, these responses may or may not reflect the feelings the patient would have expressed.

Conclusions

Ten cancer patients requested human milk from the San Jose Mother's Milk Bank after reading the results of *in vitro* and a few *in vivo* studies, conducted primarily at Lund University, Sweden, on the apoptosis–like effect of breast milk on 50 different cancer cells. Cancer is a condition for which no cure has been found. Cancer patients in this study opted to try an unorthodox cancer treatment when they were dissatisfied with the conventional options offered, and in an attempt to improve the effects of their conventional treatment, as part of a multimodal treatment plan. They chose to use the therapy based on the established safety and benefit of human milk, despite a dearth of large-scale, experimental research on the efficacy of human milk as a cancer treatment. Half of the patients were in advanced stages of cancer, and chose to try human milk rather than conventional treatment with side-effects which decreased QOL.

The subjects in this study were willing to experiment with this unproven treatment despite the high cost of the human milk plus shipping costs, lack of insurance coverage for the milk, an off-taste to some and discouragement from the conventional medical establishment for others. Though the patients did not initially request the human milk for its therapeutic effects, they found that it did ease the side effects of cancer treatment and the ill-effects of their condition. Dosage was reduced by some participants due to the high cost of the milk, possibly diluting the effect longer dose and duration might have had on their results.

Human milk was found by cancer patients in this study to be well-tolerated, nutrient dense, and soothing to the GI tract. Some found it eased their difficulties

swallowing. It reduced the nausea, weakness, and general lethargy after initiating chemotherapy. Patients reported an improved level of function and physical improvements. They listed increased energy, immune support, strengthening, respiratory function and an appetite stimulation as some physical improvements. Their recovery was full of uncertainty, and they sometimes felt like things were out of their control. This treatment option offered them hope, and a sense of control and responsibility in their treatment plan. And one patient posed the question whether the human milk might have stopped the progression of his cancer, even if it did not cure it. This question cannot be answered by this study.

Satisfaction with one's quality of life may be more important than cancer outcomes, and may improve a patient's medical care overall. Participants in this study who were in moderate to advanced stages of multiple cancers reported improvements in their quality of life measures in the physical, psychological and spiritual domains compared to what they experienced before taking the human milk treatment. Patients in early stages of cancer or in remission continued to take the human milk for prophylactic purposes because they felt it had improved their general well-being. In these cases, the human milk therapy was associated with a perception of improved QOL for the cancer patients.

Larger samples are needed. Surveys of area clinics and social organizations are needed to determine a more representative number of total requests for human milk by cancer patients. More data would determine a trend of the total number of requests for human milk, and would clarify whether total requests for human milk are increasing,

decreasing, or staying the same. This larger pool of data would offer a clearer picture of cancer patients' value for this human milk therapy, and confirm whether there is a need for large-scale, *in vivo*, scientific studies on the effects of human milk therapy on cancer patients' QOL. Further experimental research is advised to assist insurance companies in determining whether to include coverage for human milk therapy, considering the potential benefits to the quality of life of their clients with cancer.

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Table 1 Summary of Cancer Patients' Responses to Request for Participation in Human Milk Therapy Study

	Initial Solicitation	Follow-up Request Sent 1 month after original mailing
	Total number	Total number
Participation offer	39	23
Letters undeliverable	4	0
Refusal to participate	1	0
No response	23	0
Total: cancer patients who agreed to participate in study	11	0
Patients too ill to continue study	1	0

Table 2 Instrument

Probing Questions Used in Interviews with Cancer Patients Taking Human Milk Therapy

1) Name 2) Age Gender M F
3) Level of education: High School College Graduate School
4) Type of cancer diagnosis:
prostate breast colon colorectal leukemia lymphoma lung liver
5) What therapies have you used for your cancer and when did you use them?
6) What stage was your cancer when you started on the human donor milk program?
7) Did it change while you were taking the donor milk?
8) Between what dates did you receive human milk?
9) Did you take the human milk with or without meals, or at a special time of day?
10) What was the prescribed dose? Did it ever change?
11) What were your sources for the human milk?
12) What was your cost for the human milk?
13) Was your physician aware of you taking donor milk treatment? If not, why not?
14) How honest can you be with your physician about taking human milk treatment?
15) Did you experience any barriers to using human milk as cancer treatment?
16) What were your symptoms before initiating human milk treatment?
17) What changes did you experience when using human milk therapy?
18) Did you experience any change after stopping human milk treatment?
19) If effective, in what ways was the breast milk effective as a treatment for your cancer? In what ways did it not do what you expected?
20) If effective, how long were you on the donor milk before changes were noted?
21) Did you notice any other health impacts while taking breast milk?
22) Where did you first learn about human milk as a treatment for cancer?
23) What did the information claim about using human milk as a treatment for cancer?
24) Would you ever use donor milk treatment again?

Table 3 Clinical and Demographic Characteristics of Individuals Using Human Milk Therapy for Cancer

- Gender: 5 male, 5 female
- Age range: 44-86 Mean age: 65.7
- Education: All received some higher education; half post-graduate.
- Ethnicity: Non-Hispanic, non-African American.
- Health status when treatment began: 5 Terminally ill
  3 Moderately ill
  2 Early stage of cancer
- Health Status after human milk therapy: 5 deaths
  2 advanced
  3 in remission

Table 4 Comparison of Patient's Stage of Cancer Before and After Initiating Human Milk Therapy

Participant	Cancer Type	Cancer stage at initiation of Human Milk Therapy	Cancer stage at conclusion of Human Milk Therapy
A	Breast	Moderate	Advanced
B	Lung	Advanced	Death
C	Prostate	Early	Remission
D	Lung	Moderate	Advanced
E	Lung	Advanced	Death
F	Prostate	Early	Remission
G	Lung	Advanced	Death
H	Lymphoma	Advanced	Death
I	Colon	Advanced	Death
J	Breast	Moderate	Remission

Key: A-J: Indicates a study participant by letter for purposes of comparing stage of cancer for the same participant at two different points in time: before taking human milk and after taking human milk.
This is intended to illustrate the progression of individual participant's cancer during the course of human milk therapy.

Table 5 Barriers to Use of Human Milk by Individuals Consuming Human Milk Therapy

Barriers-medical professionals	**YES**	**NO**
Informed medical practitioner	10	**0**
Resistance from medical profession	**6**	**4**
Reputation at stake/clinically unproven	**5**	
Anticipated disapproval	**1**	
Terminal patients	**1**	**4**
Read research results offered by cancer patients related to human milk therapy		**3**
Refused to write prescription	**1**	
Concerned with bacteria contamination	**1**	
Other Barriers		
Cost including shipping	**4**	
Media censure	**1**	
Food safety: provision by specific caretaker	**2**	
Taste		
Reduce dose	**1**	
Refuse to drink	**1**	
Waiver for raw milk	**5**	
Mask with chocolate	**2**	
Mask with fruit and tofu	**2**	
Mask with bitter flavor (coffee, Chai tea, coconut ice cream)	**1**	
Held nose and swallowed	**1**	

Table 6 Perceived Cancer Symptoms Before and After Taking Human Milk Therapy

Before Human Milk therapy		After Human Milk therapy	
# of patients	Symptom	# of patients	Symptom
4	Decreased appetite	2	Didn't push human milk away like other food
		2	Stomach settled; Kept milk down
3	Difficulty swallowing	3	Tolerated liquid better than solids; Human milk offered nutrient density
1	Too ill to work	1	Felt stronger, increased exercise ability, weight gain, decreased cough, improved respiratory function, increased appetite
2	Side-effects especially to GI tract from conventional medicine	2	Stronger well not ill. No nausea, weakness, lethargy after initiating chemotherapy
6	No symptoms	2	Improved immune system, fewer colds & fever
		1	Energized by milk. Improved energy level
		3	No change in symptoms
1	PSA levels rose	1	PSA levels dropped

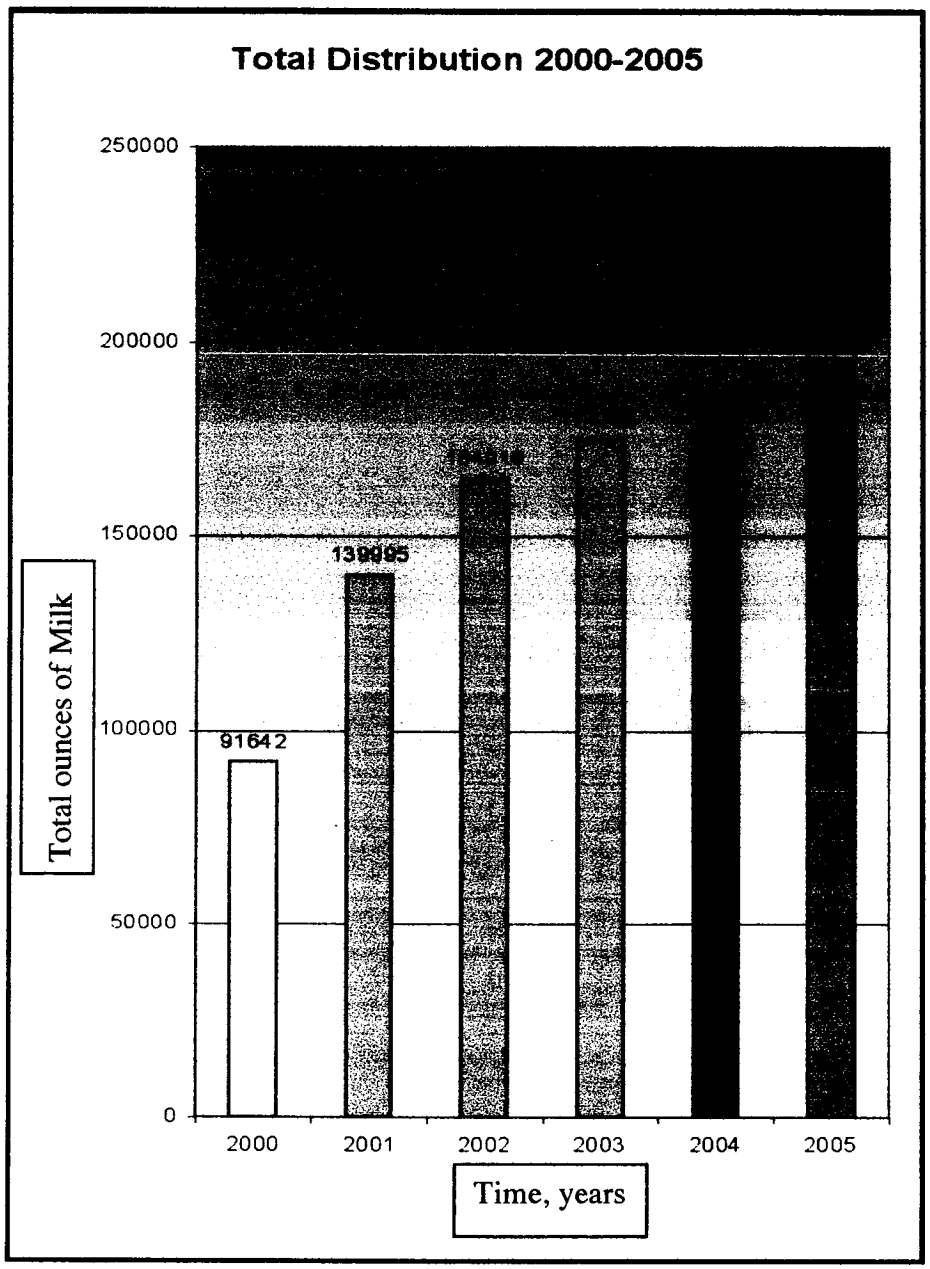

Figure 1

Total Ounces of Milk Distributed Each Year by SJMMB

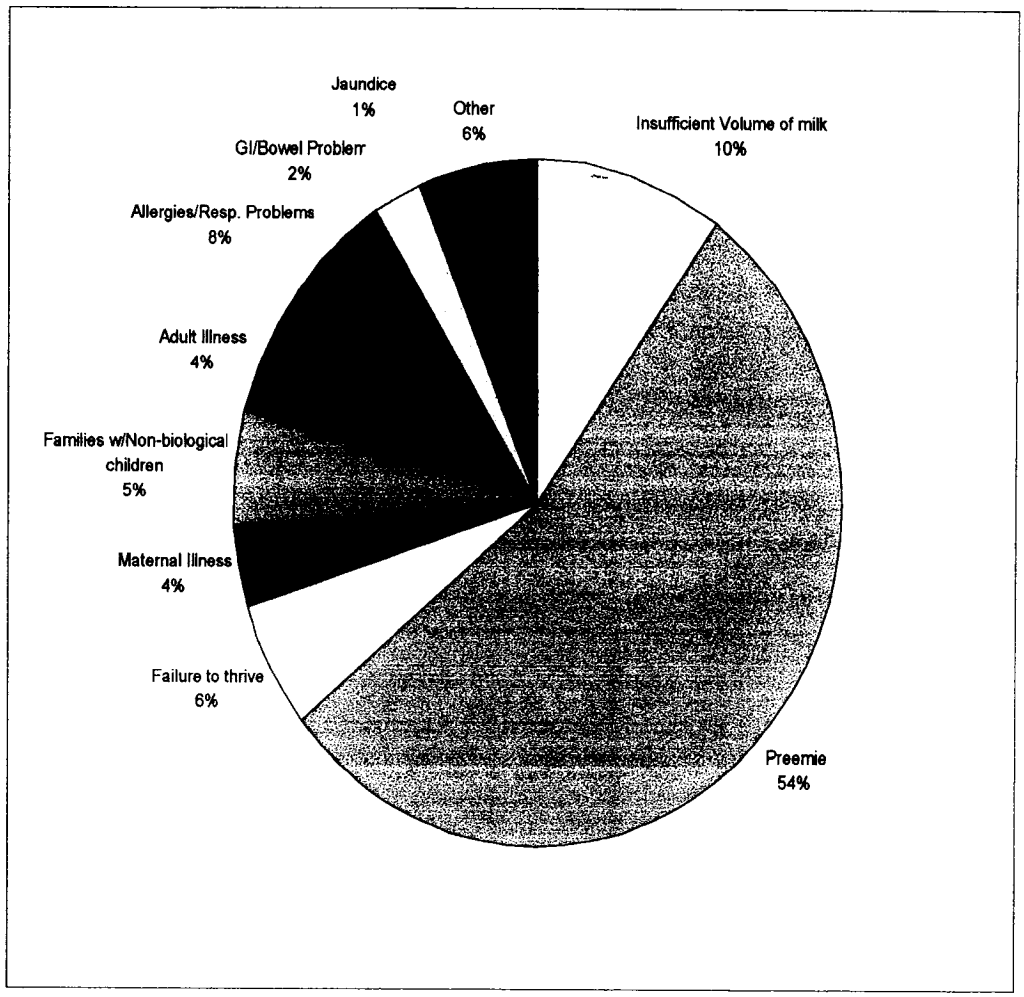

Figure 2

Percentage by Diagnosis of Human Milk Distributed in 2005 by all North American Milk Banks Combined

Chapter III

SUMMARY AND RECOMMENDATIONS

Summary

Ten cancer patients requested human milk from the San Jose Mother's Milk Bank after reading the results of *in vitro* and a few *in vivo* studies, conducted primarily at Lund University, Sweden, on the apoptosis–like effect of breast milk on 50 different cancer cells. Cancer is often a condition for which no cure has been found. Cancer patients in this study opted to try an unorthodox cancer treatment when they were dissatisfied with the conventional options offered, and in an attempt to improve the effects of their conventional treatment, as part of a multimodal treatment plan. They chose to use the therapy based on the established safety and benefit of human milk, despite a dearth of large-scale, experimental research on the efficacy of human milk as a cancer treatment. Half of the patients were in advanced stages of cancer, and chose to try human milk rather than conventional treatment with side-effects which decreased QOL.

The subjects in this study were willing to experiment with this unproven treatment despite the high cost of the human milk plus shipping costs, lack of insurance coverage for the milk, an off-taste to some and discouragement from the conventional medical establishment for others. Though the patients did not initially request the human milk for its therapeutic effects, they found that it did ease the side effects of cancer treatment and the ill-effects of their condition. Human milk was found by cancer patients in this study to be well-tolerated, nutrient dense, and soothing to the GI tract. Some found it eased their difficulties swallowing. It reduced the nausea, weakness, and general lethargy after initiating chemotherapy. Patients reported an improved level of function and physical improvements. They listed increased energy, immune support, strengthening, respiratory

function, and an appetite stimulation as some physical improvements. Their recovery was full of uncertainty, and they sometimes felt like things were out of their control. This treatment option offered them hope, and a sense of control and responsibility in their treatment plan. And one patient posed the question whether the human milk might have stopped the progression of his cancer, even if it did not cure it. This question cannot be answered by this study.

Recommendations

Satisfaction with one's quality of life may be more important than cancer outcomes, and may improve a patient's medical care overall. Participants in this study who were in moderate to advanced stages of multiple cancers reported improvements in their quality of life measures in the physical, psychological, and spiritual domains compared to what they experienced before taking the human milk treatment. Patients in early stages of cancer or in remission continued to take the human milk for prophylactic purposes because they felt it had improved their general well-being. In these cases, the human milk therapy was associated with a perception of improved QOL for the cancer patients.

Larger samples are needed. Surveys of area clinics and social organizations are needed to determine a more realistic number of total requests for human milk. More data would clarify whether total requests for human milk are increasing, decreasing, or staying the same. This larger pool of data would offer a clearer picture of cancer patients' value for this human milk therapy, and confirm whether there is a need for large-scale, *in vivo*, scientific studies on the effects of human milk therapy on cancer patients' QOL.

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APPENDIXES

Appendix A: SJSU Institutional Review Board Approval

San José State
UNIVERSITY

Office of the Academic Vice President
Academic Vice President Graduate Studies and Research
One Washington Square
San José, CA 95192-0025
Voice: 408-924-2480
Fax: 408-924-2477
E-mail: gradstudies@sjsu.edu
http://www.sjsu.edu

To: Susanne M. Rough
CCB 200

From: Pam Stacks, AVP Robert Cooper for Pam Stacks
Graduate Studies & Research

Date: July 19, 2005

The Human Subjects-Institutional Review Board has approved your request to use human subjects in the study entitled:

"The Motivation for Cancer Patients to Take Donated Breast Milk as Complementary or Alternative Medicine ."

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity when they participate in your research project, and with regard to all data that may be collected from the subjects. The approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Pam Stacks, Ph.D. immediately. Injury includes but is not limited to bodily harm, psychological trauma, and release of potentially damaging personal information. This approval for the human subjects portion of your project is in effect for one year, and data collection beyond July 19, 2006 requires an extension request.

Please also be advised that all subjects need to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate, or withdrawal will not affect any services that the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact me at (408) 924-2480.

Cc: Dr. Clarie Hollenbeck

Appendix B: Agreement to Participate in Research

San José State
UNIVERSITY

College of Applied Sciences and Arts
Nutrition and Food Science
Central Classroom Bldg. 200
One Washington Square
San José, CA 95192-0058
Voice: 408-924-3100
Fax: 408-924-3114

Agreement to Participate in Research

Responsible Investigators: Susanne Rough, Clarie Hollenbeck, PhD, and Pauline Sakamoto, RN MS

Title of Protocol:

1. I have been asked to participate in a research study investigating the effects of Human breast milk supplementation on cancer
2. I will be asked to allow access to my medical records specifically pertaining to the treatment of my cancer with human breast milk.
3. I understand that there are no risks anticipated with this study beyond those encountered in everyday life.
4. I understand that there may be no direct benefit to me as a result of participation in the study.
5. I understand that although the results of this study may be published, no information that could identify me or any of the subjects will be included.
6. I understand that there is no monetary compensation for participating is this study.
7. Questions about this research may be addressed to the principle investigators, Susanne Rough, or Dr. Clarie Hollenbeck at San Jose State University (408-924-3106) or Pauline Sakamoto, RN, MS at the Mother's Milk Bank (408-998-4550). Complaints about the research may be presented to the Department of Nutrition and Food Science Chairman of San Jose State University, Dr. Lucy McProud (408-924-3100). Questions about research, subjects' rights, or research-related injury may be present to Pam Stacks, PhD, Associate Vice President for Graduate Studies and Research at San Jose State University (408-924-2480).
8. I understand that no service(s) of any kind, to which I am otherwise entitled, will be lost or jeopardized if I choose to "not participate" in the study.

Patient's initials_____
Date

Patient's Proxy initials_____

Date_____

9. I understand that my consent is being given voluntarily, and that I may refuse to participate in the entire study or in any part of the study. If I decide to participate in the study, I am free to withdraw at any time without negative effect on my relations with San Jose State University, Mothers Milk Bank or with any other participating institutions or agencies

10. At the time that you sign this consent form, you will receive a copy of it for you records, sign and dated by the investigator.

- **The signature of a subject on this document indicates agreement to participate in the study**
- **The signature of the researcher on this document indicates agreement to include the above named subject in the research and attestation that the subject has been fully informed of his or her rights.**

_____ _____

Signature **Date**

_____ _____

Investigator's Signature **Date**

Appendix C: Instrument

Probing Questions for Interviews with Cancer Patients Taking Human Milk Therapy

1) Name 2) Age Gender M F
3)Circle level of education: High School College Graduate School
4) Circle type of cancer diagnosis:
prostate breast colon colorectal leukemia lymphoma lung liver
5) What therapies have you used for your cancer and when did you use them?
6) What stage was your cancer when you started on the human donor milk program?
7) Did it change while you were taking the donor milk?
8) Between what dates did you receive human milk?
9) Did you take the human milk with or without meals, or at a special time of day?
10) What was the prescribed dose? Did it ever change?
11) What were your sources for the human milk?
12) What was your cost for the human milk?
13) Was your physician aware of you taking donor milk treatment? If not, why not?
14) How honest can you be with your physician about taking human milk treatment?
15) Did you experience any barriers to using human milk as cancer treatment?
16) What were your symptoms before initiating human milk treatment?
17) What changes did you experience when using human milk therapy?
18) Did you experience any change after stopping human milk treatment?
19) If effective, in what ways was the breast milk effective as a treatment for your cancer? In what ways did it not do what you expected?
20) If effective, how long were you on the donor milk before changes were noted?
21) Did you notice any other health impacts while taking breast milk?
22) Where did you first learn about human milk as a treatment for cancer?
23) What did the information claim about using human milk as a treatment for cancer?
24) Would you ever use donor milk treatment again?

Appendix D: Letter of Collaboration Between Pauline Sakamoto of the SJMMB & Primary Researcher

MMB
MOTHERS' MILK BANK

Pauline Sakamoto, R.N., M.S.
Executive Director

at Valley Medical Center
established 1974

Ron Cohen, M.D.
Medical Director

July 2004

Susanne Rough

Dear Susanne

I would be please to collaborate with you on your masters thesis in the Department of Nutrition and Food Science at San Jose State University entitled: "The effectiveness of human breast milk in the treatment of cancer and the alleviation of symptoms of cancer". Currently we have about 30 adults who have been or are being treated with breast milk for a variety of cancers.

Sincerely

Pauline Sakamoto, RN, MS
Director
Mothers Milk Bank
San Jose, CA

751 S. Bascom Avenue • San Jose, CA 95128 • 408-998-1550 • Fax 408-297-9208 • MothersMilkBank@hhs.co.santa-clara.ca.us
Member of the Human Milk Bank Association of North America
non profit 77-0131926