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Number 78

Best-Case Series for the Use of Immuno-Augmentation Therapy and Naltrexone for the Treatment of Cancer

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We would also like to thank the expert reviewers who helped us abstract the data at these clinics. Thank you Adelaide Coulter, Dr. Jim Gagne, and Dr. Jay Udani.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Acting Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 6010 Executive Blvd., Suite 300, Rockville, MD 20852.

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Structured Abstract

Objectives. The primary objective of this project was to create a best-case series for two CAM therapies for treating cancer patients: Immuno-Augmentation Therapy (IAT) and low-dose Naltrexone.

Methodology. The two CAM providers were asked to identify their best cases. The criteria used for a best-case series were based on those established by the National Cancer Institute (NCI). Promising cases were identified and these patients were contacted to obtain permission for us to abstract their file and to be interviewed by telephone. For cases identified as "best cases" based on NCI criteria, all pertinent clinical data (radiologic scans, pathology slides, etc.) were requested from the original institution to confirm the cancer diagnoses and any progression of the cancer. The cases were then reviewed by the NCI Office of Cancer for Complementary and Alternative Medicine.

Main Results. For both therapies, it was extremely difficult to meet the full documentation requirements of the NCI best-case series criteria. For IAT, nine cases were found that we consider the most complete or appropriate in terms of the NCI criteria for a best-case series. For Naltrexone treatments, only three cases best met the NCI criteria. These cases represent the best that we were able to assemble using the currently accepted best-case method of the NCI.

Conclusions. Assembling documentary evidence for a best-case series through retrospective case analysis for CAM therapy will seldom meet the full NCI criteria. An alternative approach might be to establish a prospective case series.

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Best-Case Series for the Use of Immuno-Augmentation Therapy and Naltrexone for the Treatment of Cancer

Summary

Overview

This report presents an assessment of patients with cancer treated with either of two complementary and alternative medicine (CAM) therapies, immuno-augmentation therapy (IAT) or low-dose naltrexone. Some patients report that these treatments have improved their health-related quality of life. Two clinics that treat patients with these therapies were identified by staff at the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health. In selecting patients' records for review, the researchers used criteria developed by the National Cancer Institute for its "best-case series." These criteria require rigorous and objective evidence of the patient's clinical condition and treatment received. A "best-case series" can provide information on the efficacy of a treatment in the absence of a controlled clinical trial. The researchers judged nine cases in which patients received IAT and three cases in which patients received naltrexone, to best meet the "best-case series" criteria, and these cases are reported in detail herein. The authors also report on the difficulties identifying "best-case series" for these patients.

Methodology

The project's staff visited the two sites and asked the CAM providers to identify their best cases based on their belief that the patients benefited from the treatment. The staff screened these and additional patient files that were identified from the clinic records, based on the criteria for a best-case series established by the National Cancer Institute.

In a "best-case series," cases are not selected randomly and are not representative of the "average" or "typical" case. Furthermore, there are no control cases that would facilitate a comparison of patient outcomes with and without the treatment in question. A best-case series relies on assumptions about patient outcomes in the absence of treatment, and consequently requires very rigorous documentation of the patient's clinical status. This information is then used by clinical experts to make judgments about outcomes in similar patients treated with the best available conventional therapy. This is the basis for conclusions regarding the potential efficacy of the treatment in question. Best-case series are useful to help identify therapies that have sufficient promise of efficacy to justify the time and resources necessary for more rigorous study, such as a clinical trial.

For this study, the researchers used criteria developed by the Office of Cancer Complementary and Alternative Medicine (OCCAM), a part of the National Cancer Institute. These criteria require the following:

- *Documentation of the diagnosis of cancer.* The patient's cancer should be documented by obtaining tumor tissue and having it examined by a pathologist. The pathologist's report should be included in the case summary.
- *Evaluation of the appropriate antitumor endpoint.* The only reliable antitumor endpoint that can be documented in a best-case series is a demonstrable and reproducible reduction of tumor size. Tumor measurements are made before treatment, during treatment, and after treatment is complete. An objective response is considered to be a decrease of at least 50 percent in the area of the tumor (i.e., the cross product of the diameters) with no increase in size of any other lesions.

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- *The patient must not be receiving any other treatment for his/her cancer*. To document an antitumor effect based upon individual patient histories, the patient must have a documented, measurable tumor just before the CAM modalities are given. While the CAM modalities themselves may have multiple components, they must not be given together with any other cancer treatments.
- *A record of previous anti-cancer treatments.*
- *Documentation of sites of the cancer.* At least one recurrent or metastatic cancer should be documented histologically. The date at which recurrence or metastatic disease was first noted should be provided.
- *Description of the patient's general medical condition.* The age, sex, and any other previous or concurrent illnesses or significant medical conditions should be carefully documented.
- *Description of the treatment administered.* The treatment that was felt to result in the antitumor response should be described.

Promising cases were identified, and these patients were contacted to obtain permission for the researchers to abstract their files. After consents were obtained, patients were interviewed by telephone; for deceased patients, their next of kin were interviewed. All data collected from abstraction forms and the interview were summarized on a case report form. The most pertinent clinical data (radiology studies, pathology slides) were identified, and original clinical material was requested from the appropriate institution. If the original clinical material was still available, it was sent to the Southern California Evidence-Based Practice Center (SCEPC).

Several instruments were developed specifically for this project: Cancer Best-Case Series Abstraction Form; Case Report Form; and IAT and Naltrexone Patient Interview Questionnaires. The patient questionnaire includes a health-related quality-of-life instrument, the European Organization for Research and the Treatment of Cancer Quality-of-Life Questionnaire (QLQ-C30).

Findings

For IAT, the researchers reviewed in detail 30 cases (out of 60 promising cases) that had the potential to be included in a best-case series. Of those, nine cases are presented that the researchers consider the most complete or appropriate in terms of the NCI criteria for a best-case series. These cases include the following types of cancer: Hodgkin's lymphoma, non–small-cell carcinoma of the lung, nodular lymphoma (poorly differentiated), peritoneal mesothelioma (two cases), ovarian adenocarcinoma, squamous cell carcinoma of vocal cord (two cases), and adenocarcinoma of the colon.

For naltrexone treatments, three cases of the 21 that the researchers reviewed in depth best met the NCI criteria. These include the following cancers: melanoma, pancreatic cancer, and endometrial adenocarcinoma with a second primary breast adenocarcinoma (single case). These cases represent the best that the authors were able to assemble using the currently accepted NCI best-case method.

Conclusions

With regard to the two best-case series, this review supports the following conclusions:

- The IAT cases provide sufficient indications for the recommendation that IAT warrants further study.
- The naltrexone cases provide insufficient indications to determine the likely benefit for naltrexone at this time.

For IAT, this review suggests there is sufficient evidence to recommend that either a random controlled trial or a prospective case series could be considered. For naltrexone, a prospective cohort case series should be considered.

While the researchers' work demonstrates that a best-case series can be constructed for CAM therapy, it also demonstrates that to do so requires considerable resources, time, and effort. Assembling documentary evidence through retrospective case analysis is difficult, even with a trained research staff. The researchers encountered several difficulties trying to establish a "best-case" series: the quality of the records; confirmation of the diagnosis and the disease; documentation of treatment; self-selection of patients; and use of multiple treatment methods.

Future Research

This review was based on the assumption that a proactive approach by researchers to creating a best-case series might be more productive than relying on practitioners to create their own best-case series. The authors' review established that this work is extremely time consuming and expensive. This lead them to the conclusion that it is not feasible to expect health providers to create such a series—especially CAM providers, who may not be trained in research. An alternative approach might be to establish a prospective case series where the protocol for treatment and the documentation can be established prior to the treatment.

Availability of the Full Report

The full evidence report from which this summary was derived was prepared for AHRQ by the Southern California-RAND Evidence-based Practice Center under contract number 290-97-0001. It is expected to be available in spring 2003. Printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 78, *Best-Case Series for the Use of Immuno-Augmentation Therapy and Naltrexone for the Treatment of Cancer.* When available, Internet users will be able to access the report online through AHRQ's Web site at: www.ahrq.gov.

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Evidence Report

Chapter 1. Introduction

Purpose

Complementary and alternative medicine (CAM) is commonly tried by patients with cancer. However, evidence is lacking for the effectiveness of most CAM therapies for cancer. One of the challenges confronting the Cancer Advisory Panel on Complementary and Alternative Medicine (CAPCAM) is to identify promising CAM therapies that may have received insufficient consideration by the cancer research community. These include therapies that have not been subjected to a controlled trial, as well as those that have been subjected to a controlled trial but whose outcomes have either never been published or have been published only as a case study or a case series. As part of its mission, CAPCAM, in conjunction with the Office of Cancer Complementary and Alternative Medicine (OCCAM), provides a forum for practitioners to report on the outcomes of therapies and provides a resource for them to obtain technical assistance in developing best-case series studies. In best-case series studies, a provider chooses those cases that represent the best outcomes for a given form of treatment, and these cases are then reviewed by experts to determine if the evidence is sufficient to warrant further study. To assist in this effort, NCI has developed a set of criteria for creating a best-case series. For CAM therapies, CAPCAM has been charged with facilitating more rigorous investigation of therapies that show sufficient promise. Despite CAPCAM's efforts to publicize this forum, few case series have yet been presented to the panel. It was therefore decided that a proactive approach might be more productive in generating best-case series. Thus, the purpose of this study was to use the resources of the Southern California Evidenced-Based Practice Center (SCEPC) to create best-case series for therapies identified by the National Center for Complementary and Alternative Medicine (NCCAM).

Our purpose was to abstract patient records of a selected CAM provider and then to create a best-case series by evaluating each of the cases against a set of defined criteria. In addition, we report on the method, effort, and resources required to complete a best-case series and the practicality and feasibility of this method.

Specific Aims

The project had four specific aims, established by the National Center for Complementary and Alternative Medicine (NCCAM) and the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM):

1. To create best-case series for two CAM providers treating cancer patients.

2. To determine if there is sufficient evidence for recommending further study of these therapies.

3. To recommend the type of future study, if any.

4. To describe the technical challenges and difficulties in creating this kind of best-case series.

A Brief Review of the Use of CAM for Cancer Treatment

In the United States, the general public has increasingly sought out CAM therapies; about 40 percent of patients recently reported using some form of CAM (Eisenberg, Davis, Ettner, et al., 1998; Astin, 1998). Between 1990 and 1997, the prevalence of CAM use in the United States increased from 33.8 percent to 42.1 percent, and the number of visits to CAM practitioners increased from 427 million to 629 million visits per year (Eisenberg, Davis, Ettner, et al., 1998).

Among cancer patients, increasing interest in CAM has also been reported. Recent surveys of cancer patients in the United States estimated that 65 to 83 percent have tried some form of CAM therapy for their cancer (Richardson, Sanders, Palmer, et al., 2000; Boon, Stewart, Kennard, et al., 2000; Sparber, Bauer, Curt, et al., 2000). These figures exceed previously reported estimates (Burstein, Gelber, Guadagnoli, et al., 1999; Lerner and Kennedy, 1992; Cassileth, Lusk, Strouse, et al., 1984; Beckrow, Wyatt, Given, et al., 1999; Faw, Ballentine, Ballentine, et al., 1978; Adler and Foskett, 1999). A systematic review of 26 surveys across 13 countries concluded that the mean prevalence of CAM use by cancer patients in these countries was 31.4 percent (range, 7 percent to 64 percent) (Ernst and Cassileth, 1998).

The typical cancer patient using CAM in the United States is reported to be Caucasian, more affluent and better educated than average, 30 to 50 years of age, and suffering from advanced disease (Richardson, Sanders, Palmer, et al., 2000; Paltiel, Avitzour, Peretz, et al., 2001; Lerner and Kennedy, 1992; Cassileth, Lusk, Strouse, et al., 1984; Cassileth, 1986). National surveys of cancer patients found that dietary supplements (including vitamins, herbs, and substances that affect metabolism), electronic treatments, and mind/body approaches were the most popular (Richardson, Sanders, Palmer, et al., 2000; Lerner and Kennedy, 1992; Cassileth, Lusk, Strouse, et al., 1984). Studies report that most cancer patients (60 – 80 percent) who engage in CAM practices are simultaneously receiving conventional treatments (Cassileth, Lusk, Strouse, et al., 1984; Richardson, Sanders, Palmer, et al., 2000; McGinnis, 1991; Lerner and Kennedy, 1992; Bourgeault, 1996).

The growth in use of CAM in the United States is also supported by figures on expenditures for these treatments: out-of-pocket expenditures for 1997 were estimated at $34.4 billion (Eisenberg, Davis, Ettner, et al., 1998), compared with a 1984 estimate of $4 billion spent annually on unproven cancer treatments (U.S. House Select Committee on Aging, 1984). A recent survey of women with breast cancer found that approximately $45 was spent monthly on CAM products and $55 was spent monthly on CAM practitioners (Boon, Stewart, Kennard, et al., 2000).

A variety of factors have prompted the increasing utilization of CAM among cancer patients. CAM use has been strongly associated with the belief among these patients that conventional therapy did not meet their needs (Paltiel, Avitzour, Peretz, et al., 2001). Patients have also reported concerns about the toxicity of conventional treatments, viewing CAM therapies as natural and nontoxic (Paltiel, Avitzour, Peretz, et al., 2001; Astin, 1998; Campion, 1993; Lerner and Kennedy, 1992). Despite this finding, another survey showed that approximately 60 percent of cancer patients who used CAM believed that conventional cancer treatments were more likely to cure their cancer than were CAM therapies (Boon, Stewart, Kennard, et al., 2000), and most patients used conventional medicine concurrently (Cassileth, Lusk, Strouse, et al., 1984; Richardson, Sanders, Palmer, et al., 2000; McGinnis, 1991; Lerner and Kennedy, 1992; Bourgeault, 1996). In a recent survey of cancer patients, the most common reason patients cited for using CAM was to boost their immune system (63 percent) (Boon, Stewart, Kennard, et al.,

2000). Patients who use CAM also report feeling more hopeful (Richardson, Sanders, Palmer, et al., 2000). Although cancer patients often turn to CAM with the hope of improving their quality of life (Paltiel, Avitzour, Peretz, et al., 2001), some evidence suggests that users of CAM do not achieve that goal (Paltiel, Avitzour, Peretz, et al., 2001; Burstein, Gelber, Guadagnoli, 1999; Cassileth, Lusk, Guerry, et al., 1991). However, cancer patients who utilize CAM do report feeling more personal control over their situation (Richardson, Sanders, Palmer, et al., 2000), and patients assert that CAM use provides a feeling of control over their lives (Boon, Stewart, Kennard, et al., 2000).

Many patients who use CAM for any illness do not reveal that use to their physicians (Eisenberg, Davis, Ettner, et al., 1998; Adler and Foskett, 1999; Begbie, Kerestes, Bell, 1996). In a recent study of 1,221 breast cancer patients, fewer than half informed their physician of their CAM use (Boon, Stewart, Kennard, et al., 2000). Reasons for not disclosing CAM use include anticipating physician negative response, perceiving that CAM therapies are irrelevant to their conventional medical care, and believing that their physician is unable to contribute useful information about CAM (Adler and Foskett, 1999; Begbie, Kerestes, Bell, 1996). Some CAM users have expressed feeling abandoned by their physicians, and others admit having little faith in them (Cassileth, Lusk, Strouse, et al., 1984). Some patients reported a desire for CAM to be part of conventional cancer treatment (Coss, McGrath, Caggiano, 1998). Other reports indicate that cancer patients want more information about CAM from their medical doctors (Richardson, Ramirez, Nanney, et al., 1999).

Oncologists are becoming increasingly aware that patients use CAM, yet few oncologists discuss these therapies with their patients (Richardson, Ramirez, Nanney, et al., 1999; Neogi and Oza, 1998). This finding may stem from a number of factors. Research shows that the established medical community has been seeking evaluation of CAM therapies through traditional clinical trials (Angell and Kassirer, 1998, Levin, Glass, Kushi, et al., 1997), Without the evidence of efficacy such trials may provide, practitioners may be reluctant to broach the subject. Some physicians have expressed concerns about serious health risks associated with CAM and cite poor outcomes for patients who reject proven conventional cancer treatment in favor of CAM approaches (DiPaola, Zhang, Lambert, et al., 1998; Coppes, Anderson, Egeler, et al., 1998). However, since most cancer patients using CAM are receiving conventional treatments at the same time, it may be critical for oncologists to become more informed about use of CAM, because the effects of those conventional therapies may be influenced by concurrent CAM therapies.

Chapter 2. Methodology

Summary

The project involved a survey of two CAM cancer treatment sites identified by the NCCAM. Our project staff visited the two sites and asked CAM providers to identify their best cases. As the visitation team worked with the clinic staff physicians and reviewed the cases the latter had recommended, new cases suggested themselves to the clinic staff. These additional patient files were also screened by the visitation team based on the criteria for a best-case series established by the National Cancer Institute (NCI). The process of identifying the cases therefore was an interactive one. Promising cases were identified, and these patients were contacted to obtain permission for us to abstract their files. After consents were obtained, patients were interviewed by telephone; or if the patients were deceased, their next of kin were interviewed. All data collected from abstraction forms and the interview were summarized in a case report form. Cases identified as "best cases" based on NCI criteria, were further analyzed. All pertinent clinical data (radiologic scans, pathology slides) were identified, and clinical material was requested from the original institution. If the original clinical material was still available, it was sent to the Southern California Evidence-Based Practice Center (SCEPC).

A Best-Case Series

A "best-case series" differs from other forms of clinical evidence in that the cases are purposively selected because they are thought to be the best examples of improved patient outcomes as a result of treatment. In other words, cases are not selected randomly and are not representative of the "average" or "typical" case. Furthermore, there are no control cases that would facilitate a comparison of patient outcomes with and without the treatment in question — making it difficult, if not impossible, to establish a cause-and-effect relationship between treatment and outcome. A best-case series relies on assumptions about patient outcomes in the absence of treatment, and consequently requires very rigorous documentation of the patient's clinical status. This information is then used by clinical experts to make judgments about outcomes in similar patients treated with the best available conventional therapy. The difference in actual outcomes compared to this assessment of expected outcomes provides the basis for conclusions regarding the potential efficacy of the treatment in question. Best-case series are useful to help identify therapies that have sufficient promise of efficacy to justify the time and resources for more rigorous study, such as a clinical trial.

OCCAM Protocol for Best-Case Series

For this study, we used criteria developed by the Office of Cancer Complementary and Alternative Medicine, a part of the National Cancer Institute. These criteria require the following process:

1. Documentation of the diagnosis of cancer. The patient's cancer should be documented by obtaining tumor tissue and having it examined by a pathologist. The pathologist's report should be included in the case summary.

2. Evaluation of the appropriate antitumor endpoint. The only reliable antitumor endpoint that can be documented in a best-case series is demonstrable and reproducible reduction of tumor size. Tumor measurements are made before treatment, during treatment, and after treatment is complete. An objective response is considered to be at least a 50 percent decrease in the area (cross product of the diameters) of the tumor with no increase in any other lesions.

3. The patient must not be receiving any other treatment for his/her cancer. To document an antitumor effect based upon individual patient histories, the patient must have a documented, measurable tumor just before the CAM modalities are given. While the CAM modalities themselves may have multiple components, they must not be given with any other cancer treatments.

4. A record of previous anti-cancer treatments.

5. Documentation of sites of the cancer. At least one recurrent or metastatic cancer should be documented histologically. The date at which recurrence or metastatic disease was first noted should be provided.

6. Description of the patient's general medical condition. The age, sex, and any other previous or concurrent illnesses or significant medical conditions should be carefully documented.

7. Description of the treatment administered. The treatment that was felt to result in the antitumor response should be described.

A complete best-case series should contain:

1. Demographic data:
    a. Age
    b. Sex
    c. Date of primary diagnosis
    d. Date alternative treatment initiated
    e. Listing of all prior therapy and dates of therapy for the malignant disease.

2. Documentation of disease prior to therapy:
    a. Pathology report of primary
    b. Pathology reports documenting recurrent or metastatic disease
    c. Reports of all X-rays, CT scans, bone scans, and MRI or other imaging studies documenting the presence of known sites of tumor(s) prior to alternative treatment

d. Clinical summary denoting all signs and symptoms related to disease, the presence of other malignancies, and all nonmalignant conditions.

3. Documentation of treatment:
    a. Dates and doses of all treatment administered, including supportive care and all other drugs (other than the CAM therapy) that are administered concurrently.

4. Documentation of response:
    a. Date a response is observed
    b. Copies of all x-ray reports or other imaging studies on first date response is observed
    c. Tumor measurements of all known sites of disease that are not demonstrable on the imaging studies (e.g. skin lesions, lymph nodes) to document reduction in tumor size. This information should be provided for each date of patient evaluation
    d. Date of last visit and status and/or date and cause of death
    e. Pathology reports of biopsy of autopsy findings any time after initiation of unconventional treatment.

5. Documentation of highest toxicity during treatment by organ system and grade.

Both objective and subjective outcome measures (including quality of life) can be included.

Study Design

1. The project was conducted according to the following sequence (see Figure 1):

2. NCCAM identified two CAM providers who were treating cancer with a CAM therapy and secured their agreement to participate in the project.

3. The CAM providers were asked to identify their best cases, that is, those patients whom they judged benefited most from therapy.

4. The patients were contacted by the clinics to secure permission for their files to be reviewed, for the research team to contact them for an interview, and for permission to contact their other medical providers and request their patient files and records.

5. A research team from Southern California Evidence-Based Practice Center (SCEPC) visited both clinics to abstract patient files identified as potential best cases.

6. Following review of the patient abstraction records by the research staff, copies of the most promising patient files for inclusion in a best-case series were sent to SCEPC, where summaries of abstracted information were later checked against those files for accuracy.

7. The patients were interviewed to further confirm the medical information obtained from the charts, to identify any relevant medical information or procedures not previously identified, and to complete a Health-Related Quality of Life instrument.

8. Additional medical records were sought from the patients' other providers.

Development of the Instruments

Abstraction Instrument

Several instruments were created for this study. A draft abstraction record was created based on our previous experience assessing the office files of CAM practices. This instrument incorporated the criteria established by NCI for a best-case series (see above). Each clinic was asked to provide examples of their files (de-identified) for the team to test the abstraction form. The abstraction form is shown in Appendix A. This instrument was used in the clinics to record the relevant information from the patient files.

Case Report Instrument

Following the clinic visit and consent of the patients, the SCEPC team received copies of the patients' full files. A second instrument, the case report form (Appendix B), was developed to enable the team to summarize the cases and to arrange the information to establish the chronology of the disease and its treatment. The case report form also allowed identification of the significant events surrounding the treatment and any significant information that was not in the file (x-rays, biopsies etc.). Two versions of this instrument were produced. In the first, the information was described using medical terminology. This version, which also included columns to record information on when records were requested and the status of the request, was intended for the interviewer. A second version, designed for the patient, was written in lay terminology and included only the events and the dates of the events (also shown in Appendix B.) This form was sent to the patient prior to the interview. During the patient interview, the interviewer had both forms.

Interview Instrument

The interview instrument (Appendix C) was developed by the research team to collect the following information: basic demographic data, health related quality of life information, details of the patient's conventional treatment for cancer if applicable, details of the patient's use of CAM therapy, reasons for seeking alternative care, and reasons for choosing this particular CAM therapy. In addition, patients were asked to confirm the treatment events and dates summarized on the case report instrument which they were sent and asked to review prior to the interview.

Health-Related Quality of Life Instrument

The research team reviewed the literature on HRQOL instruments for cancer. Three Cancer Quality of Life surveys appear in the literature most frequently. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30) is cited often both in the United States and around the world. The Functional Assessment of Cancer Therapy – General (FACT-G scale) is cited more frequently in the U.S. literature than the QLQ-C30 and has several sub-scales that have been created for specific cancers. The Functional Living Index – Cancer is also used frequently in the United States. All three surveys have been shown to have valid psychometric properties (Schipper, 1984). We chose the QLQ-C30 because of its

widespread use and ease of administration. The instrument has 7 items on general health status, 21 items that refer to health status in the past week, and 2 general measures of overall physical condition and quality of life (see Appendix C, pages 7 – 9).

Research Staff

Five trained abstractors (three physicians, one oncology nurse, and one medical sociologist) performed the chart abstraction in the clinics. The three physicians are board-certified internists, and two are directors of programs in integrative medicine and have expertise in CAM therapies. The third physician is director of a chronic-pain clinic and manages a multidisciplinary team that includes practitioners of alternative therapies. The nurse has practiced in oncology wards, hospices, and palliative care units in several countries for over 30 years. The medical sociologist is a health services researcher at RAND who has been involved in abstraction studies in chiropractic over the past 10 years. A fourth physician, also trained in integrative medicine and practicing CAM therapies, participated in writing the case reviews and the case reports. This physician and the medical sociologist, who was responsible for training the other staff, conducted all the patient interviews.

Human Subjects

The following procedures were used to ensure patient confidentiality and informed consent:

1. The CAM provider obtained the patient's consent for us to view and abstract the files. When consent could not be obtained prior to the clinic visit, all files were de-identified.

2. The CAM provider sent a letter and three consent forms drafted by SCEPC to the patient for his or her signature:

    a. Consent to review the files and to contact the patient
    b. Consent to complete a short HRQOL interview
    c. Consent to pursue other medical files of the patient from either other providers or institutions.

    In addition, patients were asked to provide verbal consent to receive, by registered mail, a summary of their medical care and to participate in the interview.

3. The patient's signed consent forms were then sent to the provider/medical institutions at which the patient was receiving traditional cancer treatment.

Data Sensitivity

Data collected for this project were private and sensitive. Data abstracted from medical records documenting the patients' cancer and their treatment as well as data collected from telephone interviews (name, phone number, age, gender, quality of life) contained information that could be damaging to the individuals if revealed. Furthermore, patients may not have

wanted their providers of traditional care to know they were also receiving CAM treatment. If released, such information could possibly damage a patient's treatment, employment, and insurability. A data-safeguarding plan was instituted using guidelines established by RAND.

Safeguarding Procedures

A data-safeguarding plan was instituted using guidelines established by RAND. To prevent linkage of data to a patient, the front sheet was removed from the interview and abstraction forms and filed separately from these forms.

The patients' traditional care providers were asked to copy and provide the portions of the patients' medical files that contained information regarding the cancer treatment. This information could include radiographic films, scans, and laboratory reports. Histological slides, if any, were also requested (a detailed list of the information we sought was provided to each physician). The files received from providers were handled identically to the interview and medical record data.

Clinic Visits

Immuno-Augmentation Therapy (IAT)

Immuno-Augmentation Therapy (IAT) was developed by Lawrence Burton Ph.D. It is based on the theory that the immune system attacks cancer cells but also controls the rate of the attack by a blocking protein to prevent toxic damage to the liver. The theory is that cancer cells multiply when four factors of the immune system fail to recognize and destroy them (Center for Alternative Medicine Research in Cancer website, 1999; National Cancer Institute website, 1999; Office of Technology Assessment (Princeton University website), 1990). Cancer occurs not through a deficiency in the immune system but in the controlling mechanism that deals specifically with cancer. The therapy claims to treat the immune system—the competence of the immune system—not the cancer as such (IAT Clinic website, 2001). [Immunosupression occurs and the anti-tumor activity, the inhibitor system must be reactivated.]

The four factors that fail in the immune system are given in the therapy through daily injections of reconstituted blood: a deblocking protein from pooled blood serum of healthy donors, which is said to remove the tumor-blocking factor that prevents the immune system from detecting the cancer; tumor antibody 1, a combination of alpha 2 macroglobulin with other immune proteins (IgG and IgA) derived from pooled blood serum of health donors; tumor antibody 2, an antibody complement that stimulates the antibody, also derived from healthy donors but differing in potency; tumor complement, a substance derived from the blood clots of patients with many types of cancer, that activates the two tumor antibodies.

The therapy consists of two evaluations daily, five days a week, of the immune system to determine the relevant components in the blood by use of a spectrophotometer. The data reveal the relative activity of the tumor kill process and immune response (IAT Clinic website, 2001). The amount of serum is calculated for each patient. Through the use of subcutaneous self-injections, the serum is prescribed in timing and sequence. While all treatment initially is at the clinic and may be over a lengthy period, subsequent treatment may be done at home, interspersed with visits to the clinic for reassessment.

The Immuno-Augmentation Therapy (IAT) Clinic is located in Freeport, Bahamas. A team of four researchers (two physicians, a nurse, and a medical sociologist) spent four days in the clinic identifying and abstracting patient files. Because all the patients had already signed a consent form to allow their records to be reviewed as part of the clinic's normal procedure, no additional consent was necessary at this stage. Although the clinic staff was to have identified the best cases prior to the team's arrival, it proved to be more productive for the team, in discussion with the lead physician in the clinic, to identify likely cases and have staff pull charts during the visit. Because this clinic is dedicated to cancer treatment and because it has been in existence for some time, the number of files was very large. In addition, because many of the patients had been attending the clinic for more than 15 years, their files were rather large. The team reviewed a total of 300 patient card indexes, of which approximately 60 were chosen as possible cases. Each of these case files was independently reviewed by the two physicians on the team and with the clinic physician. Once a case was identified (using the NCI criteria) by the reviewers as a possible candidate, the information was abstracted.

Naltrexone

Naltrexone is an opiate antagonist used for treating heroin addiction and has been used to treat persons with HIV and AIDS. Its primary proponent is Dr. Bernard Bihari (Bihari, 1999). The theory for the use of low-dose Naltrexone for cancer is that it raises the levels of beta-endorphins and metenkephalins that are capable of slowing down cancer growth. Many tissues of the body have opioid receptors on their membranes for endorphins (White, 2000). The immune system is primarily regulated by the endorphins. Since AIDS involves an immune deficiency, Dr. Bihari and his colleagues (Bihari, Ottomanelli, Orbe, et al., 1998) explored using Naltrexone for this condition. In the process, they discovered it shrank malignancies and inhibited their growth, particularly in tissues with opiate receptors (Bihari, 2000). The direct activation of the opioid receptors, if it occurs while the cell is dividing, is thought to kill the cell (Bihari, 2000). It is also postulated that Naltrexone increases the activity of the immune system's natural killer cells and hence prevents newly forming or metastasizing cancer cells.

Taken in large doses, Naltrexone was found to have significant side effects. But taken at bedtime in doses of 3 mg, it doubles endorphin levels but leaves the body within 2 to 4 hours (Bihari, not dated). The endorphin levels and enkephalins remain elevated all the next day. The drug is self-administered by the patient.

Because the clinic selected for us to study was not dedicated solely to cancer treatment, it had far fewer cases to review than did the previous clinic. As a result, we reviewed the cases of nearly all the cancer patients. The research team comprised one physician and two other reviewers (nurse and medical sociologist). Over a three-day period, the team reviewed a total of 21 case files, all of which were abstracted. However, because the patients had not given consent to having their files reviewed prior to our visit, all files and all records within the files were de-identified prior to review, as required by the RAND Human Subjects Protection Committee. De-identification was done in the following manner. The physician was asked to identify the best cases prior to the team's visit. Patients' identifying information was then masked on the entire contents of the patient files, including all the physician's notes, laboratory reports, letters from other providers, and letters from the patients. Files were de-identified prior to abstraction and the determination of whether they represented potential best cases. The abstraction process we followed was the same as that used in the previous site.

Followup

At both clinics, we asked the clinic physician and/or staff to contact by mail those patients we wished to include in a followup interview, that is, those identified as potential best cases based on our abstraction. These patients were asked to sign three additional consent forms: 1) to have their files copied for the team; 2) to have the research team contact them for an interview; and 3) to have the research team contact their other medical providers to obtain ancillary materials such as lab reports, radiographic films, and histological slides.

Once a patient or his/her proxy (e.g., the next of kin in cases where the patient was deceased) consented to be included, we requested the clinic to forward a copy of that patient's entire file to us. The file was then reviewed a second time to develop a chronological record of the care. This record was then reviewed by two members of the team (including a physician) to ensure we had identified the important events and dates in the disease and treatment history, and to identify any additional records we might wish to seek. The patient or proxy was then contacted to establish a time for the interview and to determine if he or she was willing to review the chronology prior to the interview to confirm the events and dates. To ensure confidentiality, this chronology was sent via registered mail. It could be delivered only to the patient or, if the patient was a minor or deceased, to a proxy who had consented to be interviewed.

Interview

An interview designed to last approximately 30 minutes was conducted by members of the research team with the patient or proxy. The interview included demographic questions, a health-status and quality-of-life instrument, and a review of the treatment chronology for both traditional medical care and CAM therapy. A key component of the interview was to confirm the information included in the patient's file and to identify any additional relevant information not previously captured, such as additional surgeries, treatments, or followup studies. A HRQOL instrument was also included, and patients' reported HRQOL status is noted in the case reports. However, whereas some patients had extensive disease progression, no patients reported less than a "good" health-related quality of life, and most reported very good to excellent health-related quality of life.

Assessment of Cases

Using the information obtained from the patient interview and abstracted from the patient chart, one of the research physicians constructed a patient report for each case. The reports included a chronology of the disease course and the therapies used. Each case was reviewed and discussed by the two physicians and the medical sociologist to determine if it should be included. In determining whether a case should be recommended as a best case, we used the following inclusion criteria:

1. Histological, radiographic, or other imaging evidence for the initial presence and diagnosis of the cancer

2. Evidence of metastases, if any

3. If traditional modalities were used, evidence about what was done, the dates these treatments were provided, evidence for tumor response (or lack thereof), and evidence for whether the care was completed

4. Evidence for the start of the CAM therapy

5. Documentation of the CAM therapy

6. If possible, evidence for exclusive use of one CAM therapy

7. Evidence for tumor response following the CAM therapy.

Wherever possible, we requested the histological and imaging confirmations from the relevant institutions. Few cases met all the inclusion criteria.

Chapter 3. Results

Overview of Case Review

For IAT, we reviewed, in depth, 30 cases (of the possible 60 cases) that had the potential to be included in a best-case series. Of those, nine cases are presented that we consider the most complete or appropriate in terms of the NCI criteria for a best-case series. They included the following types of cancer: Hodgkin's lymphoma, non – small cell carcinoma of the lung, nodular lymphoma (poorly differentiated), abdominal mesothelioma (two cases), ovarian adenocarcinoma, squamous cell carcinoma of vocal cord (two cases), and colon cancer.

For Naltrexone only three cases of the 21 we reviewed in depth approximated the NCI criteria. These included the following cancers: melanoma, pancreatic cancer, and endometrial adenocarcinoma with breast adenocarcinoma (single case).

However, the extent to which these cases meet the NCI criteria varied considerably. The most difficult criteria to meet are the histological/imaging confirmations, for two reasons; 1) inadequate information was provided by the file or the patient, or 2) the case was so old that the providers no longer had the specimens or files.

Whereas no institution refused to provide us with the material we requested, we had to rely in some cases on biopsy reports, radiological reports, and other such interpretations of the original material instead of the actual slides and images. Any case older than five years was unlikely to be able to meet the strict criteria of providing actual biopsy material and/or original images. However, we are still actively seeking much of this material for the cases included in this review. The status reports of the requested materials are shown below in Tables 1 and 2.

Cancer Best-Case Series

Patient #1-1
Nodular Sclerosing Lymphoma Stage 1B

Case 1-1

The patient in case 1-1 is a 46-year-old male diagnosed on 12/2/83 with nodular sclerosing lymphoma stage 1B after presenting with superior vena caval obstruction. Palliative radiation therapy was completed on 12/7/83 with a total of 800 RADS delivered to his vena cava. Chemotherapy (MOPP) was started on 12/00/83 and stopped early on 6/00/84. Four cycles of full-dose chemotherapy and two additional courses of a 25% reduced dose were given. On 7/19/94, it was recommended that the patient receive full mantle radiation, which he declined. At the termination of conventional therapy, the patient had no palpable peripheral lymphadenopathy but still had a superior mediastinal mass (CXR 7/10/84). IAT was started on 8/2/84, and 22 courses were completed as of 12/8/00 (the data of chart abstraction). The patient had sporadically taken a variety of dietary supplements in the past. Serial chest x-rays performed during IAT therapy showed a decrease in tumor mass. The most recent MRI for which we have a report (11/4/86) showed inactive disease. The most recent MRI of the chest (1995) revealed no tumor according to the patient. At the last patient contact (interview, 9/26/01), the patient reported that his overall physical condition was excellent.

Pathology

12/2/83	**Biopsy: anterior mediastinal Hodgkin's lymphoma (nodular sclerosing type)**
12/7/83	**Biopsy: bone marrow: normal**

Imaging

4/17/84	**X-ray chest: further improvement of mediastinal mass**
7/10/84	**X-ray chest: mass in chest, no change**
11/4/86	**MRI chest: complete obstruction of superior vena cava. Unchanged anteromediastinal mass suggests inactive disease at this time**
1995	**MRI chest: no evidence of disease per patient**

Conventional therapy

12/7/83	**Radiation: palliative to superior vena cava: 800 RADS: decrease in size of mass**
12/83-6/84	**Chemotherapy: MOPP: 4 cycles: followed by 2 cycles reduced by 25%: Did not complete chemotherapy due to patient preference and low blood counts.**
7/19/84	**Radiation (mantle) recommended; patient declined**

Complementary therapy

8/2/84-12/8/00	**IAT 22 courses**
11/1/84	**Benzaine E, calcium orotate, molybdenum, S.O.D., beta-carotene, glutathione, kyolic, Vitamin C, Vitamin E, lithumorate, Wobenzym, inzellonal, transmutase forte, thymus pills & injections, asterile injections, beriglobin, Vitamin D oil, selenium, carnitine (treatment recorded as provided by patient)**
Date unknown	**Live cell therapy in Germany; did not proceed with entire treatment**

Patient # 1-1						
EVENT	**PERIOD 1** **1st qtr 1983 – 4th qtr 1983**	**PERIOD 2** **1st qtr 1984 – 4th qtr 1984**	**PERIOD 3** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1995 – 4th qtr 1995**	**PERIOD 6** **1st qtr 2000 – 4th qtr 2000**
Biopsy/diagnosis	**12/83**					
Surgery						
Radiation	**12/83**					
Chemotherapy	**12/83**	**6/84**				
IAT		**8/84**				**12/00**
CAM other		**11/84**				
Imaging CXR		**3/84 4/84 7/84**				
Imaging MRI				**11/86**	**1995**	

CAM Therapy:	IAT		
Case:	1-1		
Condition:	Hodgkin's disease, nodular sclerosing type		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/26/01
Comments:	Incomplete chemotherapy with residual tumor		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	12/6/55
Diagnosis:	Hodgkins disease, nodular sclerosing type, involving mediastinum
Diagnosis date:	12/7/83
CAM therapy dates:	8/2/84-12/8/00: 22 courses
Conventional therapy dates:	12/83-6/84 chemo: incomplete 12/7/83 radiation: completed
Last contact date:	12/8/00
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Family history of lymphoma in brother		
12/2/83	Biopsy: anterior mediastinal: Hodgkin's disease (nodular sclerosing)	Slides	Not avail.
12/7/83	Biopsy: bone marrow; normal	Slides	Not avail.
12/7/83	Radiation: palliative to superior vena cava: 800 RADS: decrease in size of mass		
12/83-6/84	Chemotherapy: MOPP: 4 cycles: followed by 2 cycles reduced by 25%: Did not complete chemotherapy due to patient preference.		
4/17/84	X-ray chest: further improvement of mediastinal mass	Films	Not avail.
7/10/84	X-ray chest: mass in chest, no change	Films	Not avail.
8/2/84-12/8/00	IAT 22 courses		
11/1/84	Benzaine E, calcium ortate, molybenum, S.O.D., beta-carotene, glutathione, kyolic, Vitamin C, Vitamin E, lithumorate, wobenzym, inzellonal, tranmusase forte, thymus pills & injections, astenile injections, beriglobin, Vitamin D oil, selenium, carnitine		
11/4/86	MRI chest: complete obstruction of superior vena cava. Inactive disease at this time	Films	Not avail.
1995	MRI chest: no evidence of disease per patient	Films	Pending

Cancer Best-Case Series

Patient #1-3
Squamous Cell Carcinoma of the Right Vocal Cord and Anterior Commissure

Case 1-3

The patient in case 1-3 is a 68-year-old male who was diagnosed with squamous cell carcinoma of the right vocal cord and anterior commissure on 9/3/81. An excisional biopsy was performed at that time, but the resection was not complete. The patient was referred for radiation therapy, which he refused due to patient preference. Thus, the patient received no definitive conventional therapy. He completed 15 courses of IAT from 9/22/81 to 5/19/89. Serial examinations by his otolaryngologist revealed the persistent presence of disease without progression through 2/23/82. An otolaryngologist performed an indirect laryngoscopy on 7/20/94, which did not reveal any abnormal findings. At the last contact (interview, 9/24/01), the patient reported that his overall physical condition was very good to excellent.

Pathology

9/3/81	**Biopsy: squamous cell carcinoma, well differentiated, infiltrating: right vocal cord and anterior commissure: stage T:1 1/2 N:0 M:0**

Imaging

9/22/81	**X-ray chest: normal**
7/20/94	**ENT evaluation visual inspection via indirect laryngoscopy: normal exam**

Conventional therapy

9/3/81	**Surgery: biopsy with debulking; 80–90% bulky tumor mass removed; residual cancer remained**
9/16/81	**Referred for radiation: patient refused**

Complementary therapy

9/22/81-5/19/89	**IAT 15 courses**

Patient # 1-3						
EVENT	**PERIOD 1** **1st qtr 1981 – 4th qtr 1981**	**PERIOD 2** **1st qtr 1984 – 4th qtr 1984**	**PERIOD 3** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1989 – 4th qtr 1989**	**PERIOD 6** **1st qtr 1994 – 4th qtr 1994**
Diagnosis/ biopsy	**9/81**					
Diagnostic procedure						**7/94**
Surgery	**9/81**					
Radiation						
Chemotherapy						
IAT	**9/81**				**5/89**	
CAM other						
Imaging CXR	**9/81**					

CAM Therapy:	IAT		
Case:	1-3		
Condition:	Squamous cell carcinoma right vocal cord and anterior commisure: stage T:1 1/2 N:0 M:0		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	JTF	**Date of Interview:**	9/24/01
Comments:	Surgical debulking, residual cancer; no other conventional therapies		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	7/1/33
Diagnosis:	squamous cell carcinoma right vocal cord and anterior commisure: stage T:1 1/2 N:0 M:0
Diagnosis date:	9/3/81
CAM therapy dates:	9/22/81-5/19/89
Conventional therapy dates:	9/3/81 surgery
Last contact date:	5/19/89
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Family history of gastric cancer in mother		
9/3/81	Biopsy: squamous cell carcinoma, well-differentiated, infiltrating: right vocal cord and anterior commisure: stage T:1 1/2 N:0 M:0	Slides	Not avail.
9/3/81	Surgery: biopsy with debulking- residual cancer remained		
9/3/81	Referred for radiation: patient refused		
9/22/81	X-ray chest: normal		
9/22/81-5/19/89	IAT: 15 courses		
7/20/94	ENT evaluation visual inspection via indirect laryngoscopy		

Cancer Best-Case Series

Patient #1-4
Metastatic Non – Small Cell Carcinoma of the Lung

Case 1-4

The patient in case 1-4 is a 67-year-old woman with a family history of cancer, diagnosed with metastatic non – small cell carcinoma of the lung in July 1992. She initially presented with swelling in the neck, an enlarged supraclavicular lymph node, and a chest mass demonstrated by CT in the area of the aortic notch. A mini-thoracotomy was performed to obtain tissue for diagnosis. Initially, the mass was identified as an anaplastic mediastinal tumor, which subsequent review at the Canadian Reference Lab for Pathology determined to be non – small cell poorly differentiated lung cancer. Subsequently, she was referred for palliative chemotherapy and radiation, which she completed. No response was demonstrated to these treatments, and no further conventional therapy was advised. She initiated IAT in February 1993 and continues on maintenance therapy today. Serial CT scans beginning in September 1994 revealed resolution of the tumor. At the last contact (interview, 12/4/01), the patient reported that her overall physical condition was good.

Pathology

7/31/92	**Surgical biopsy: mediastinum (multiple bite biopsy via mediastinotomy): discrepancy of pathological diagnosis: first diagnosis lymphoma, second diagnosis metastatic giant cell carcinoma, third diagnosis lung carcinoma poorly differentiated (9/4/92)**
7/31/92	**Biopsy: left supraclavicular lymph node final pathology revealed lung carcinoma poorly differentiated**
8/12/92	**Biopsy: bone marrow: negative for malignancy**

Imaging

July, 92	**CT scan thorax: tumor 5cm mass in the area of the aortic notch**
7/31/92	**X-ray chest: no change compared with prior**
8/4/92	**Bone scan whole body: no metastatic bone disease**
9/9/93	**CT scan thoracic: tumor decreased in size, residual tumor or post treatment fibrosis**
11/30/93	**X-ray chest/ left shoulder: right lung clear; no tumor; increase left hemi-diaphragm**
4/13/94	**X-ray chest: no significant changes compared with previous**
9/26/94	**X-ray chest: lungs clear**
9/26/94	**CT scan thoracic: no evidence of tumor; Remission based on CT scan of thorax revealing no evidence of tumor**
6/24/93	**Ultrasound abdomen: normal**
11/11/96	**CT scan thoracic: no evidence of tumor; post radiation changes in left thorax**
11/25/97	**CT scan thoracic: no evidence of tumor**
12/7/98	**CT scan thoracic: no evidence of tumor**
12/15/00	**CT scan thoracic: no evidence of tumor; no change compared with 12/7/98**

Conventional therapy

7/31/92	**Left anterior mediastinotomy; mediastinal mass biopsy**
8/00/92	**Chemotherapy: cytoxan, adriamycin, vincristine, prednisone; stopped early due to change in tissue diagnosis**
9/00/92	**Chemotherapy: VP16 190mg, cisplatinum 48 mg : 3 days every 3 weeks: completed recommended course: no tumor response**
10/21/92	**Radiation: palliative: mediastinum/ left perihilar/ supraclavicular: 4,000cGy; no tumor response**
11/92-12/92	**Chemotherapy: VP16 190mg, cisplatinum 48 mg: 3 days every 3 weeks: completed recommended course: no tumor response**

Complementary therapy

2/8/93-present	**IAT; still on maintenance therapy**

Patient # 1-4						
EVENT	**PERIOD 1** **1st qtr 1992 – 4th qtr 1992**	**PERIOD 2** **1st qtr 1993 – 4th qtr 1993**	**PERIOD 3** **1st qtr 1994 – 4th qtr 1994**	**PERIOD 4** **1st qtr 1995 – 4th qtr 1995**	**PERIOD 5** **1st qtr 1996 – 4th qtr 1996**	**PERIOD 6** **1st qtr 1997 – 4th qtr 1997**
Diagnosis/biopsy	**7/92, 8/92**					
Surgery	**7/92**					
Radiation	**10/92**					
Chemotherapy	**7/92-9/92** **12/92**					
IAT		**2/93**				
CAM other						
Imaging CXR	**7/92**	**11/93**	**4/94** **9/94**			
Imaging CT	**7/92**	**9/93**	**9/94**		**11/96**	**11/97**
Imaging bone scan	**8/92**					

EVENT	PERIOD 7 1st qtr 1998– 4th qtr 1998	PERIOD 8 1st qtr 1999 – 4th qtr 1999	PERIOD 9 1st qtr 2000 – 4th qtr 2000	PERIOD 10 1st qtr 2001 – 4th qtr 2001
Diagnosis/biopsy				
Surgery				
Radiation				
Chemotherapy				
IAT				
CAM other				
Imaging CXR				
Imaging CT	12/98		12/00	
Imaging bone scan				

CAM Therapy:	IAT		
Case:	1-4		
Condition:	Large cell lung carcinoma--metastatic		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	12/4/01
Comments:	Giant cell carcinoma later diagnosed as large cell lung carcinoma, no response to chemotherapy or radiation		

Criteria for inclusion:	**(check all that apply)**		
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	6/15/44
Diagnosis:	Large cell lung carcinoma-metastatic
Diagnosis date:	8/12/92
CAM therapy dates:	2/8/93-still on maintenance therapy
Conventional therapy dates:	Chemotherapy: 8/00/92-1/6/92 Radiation: 10/11/92
Last contact date:	5/1/01
If deceased, date of death:	

Date	Description of Events	Requested
no date	Family history: sister lung cancer, maternal aunt breast cancer, mother urinary cancer	
7/31/92	Surgical biopsy: mediastinum (multiple bite biopsy via mediastinotomy): discrepancy of pathological diagnosis: first diagnosis lymphoma, second diagnosis metastatic giant cell carcinoma, third diagnosis lung carcinoma poorly differentiated (9/4/92)	Slides
7/31/92	Biopsy: left supraclavicular lymph node final pathology revealed lung carcinoma poorly differentiated	Slides
7/31/92	X-ray chest: no mass	
8/4/92	Bone scan whole body: no metastatic bone disease	
8/12/92	Biopsy: bone marrow: negative for malignancy	
8/00/92	Chemotherapy: cytoxan, adriamycin, vincristine, prednisone; stopped early due to change in tissue diagnosis	
9/00/92	Chemotherapy: VP16 190mg, cisplatinum 48 mg : 3 days every 3 weeks: completed recommended course: no tumor response	
10/21/92	Radiation: palliative: mediastinum/ left perihilar/ supraclavicular: 4,000cGy; no tumor response	
1/6/93	Chemotherapy: VP16 190mg, cisplatinum 48 mg : 3 days every 3 weeks: completed recommended course: no tumor response	
2/8/93-present	IAT; still on maintenance therapy	
6/24/93	Ultrasound abdomen: normal	
9/9/93	CT scan thoracic: tumor decreased in size, residual tumor or post treatment fibrosis	Films
11/30/93	X-ray chest/ left shoulder: right lung clear; no tumor; increase left hemi-diaphragm	
4/13/94	X-ray chest: no significant changes compared with previous	

Date	Description of Events	Requested	Status of requests
9/26/94	X-ray chest: lungs clear	Films	Pend.
9/26/94	CT scan thoracic: no evidence of tumor		
11/11/96	CT scan thoracic: no evidence of tumor; post radiation changes in left thorax		
11/25/97	CT scan thoracic: no evidence of tumor		
7/12/98	CT scan thoracic: no evidence of tumor	Films	Pend.
12/15/00	CT scan thoracic: no evidence of tumor; no change compared with 12/7/98	Films	Pend.

Cancer Best-Case Series

Patient #1-6
Poorly Differentiated Nodular Lymphoma

Case 1-6

The patient in case 1-6 is a 49-year-old male who was diagnosed in 1983 with poorly differentiated nodular lymphoma after presenting with an enlarged node on his chin, fever, night sweats, and generalized pruritus. Although the patient was not found to have significant demonstrable adenopathy outside of the neck at diagnosis, he was felt to represent stage II disease. Local radiation was not recommended, and chemotherapy was deferred awaiting progression of disease. By 2/1/84, he had palpable adenopathy in both axillae and demonstrated anergy in skin testing. The patient elected to try unconventional therapy. He started IAT on 2/14/84 and had completed twelve courses by 7/19/90. He is currently in remission. At last contact (interview, 11/07/01), the patient reported that is overall physical condition was excellent.

Pathology

12/5/83	**Biopsy: pathology: lymph node: poorly differentiated lymphocytic nodular lymphoma**
12/21/83	**Biopsy: bone marrow: negative for malignancy**

Imaging

12/4/83	**Chest x-ray: within normal limits**
12/21/83	**Chest x-ray: within normal limits**
12/21/83	**Ultrasound abdomen: within normal limits**
2/14/84	**Ultrasound abdomen: within normal limits**
2/14/84	**Chest x-ray: within normal limits**
3/23/88	**Ultrasound abdomen: within normal limits**

Complementary therapy

2/14/84-7/19/90	**IAT: 12 course s**

Conventional therapy

	None

Patient # 1-6						
EVENT	**PERIOD 1** **1st qtr 1983 – 4th qtr 1983**	**PERIOD 2** **1st qtr 1984 – 4th qtr 1984**	**PERIOD 3** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1988 – 4th qtr 1988**	**PERIOD 6** **1st qtr 1990 – 4th qtr 1990**
Diagnosis/biopsy	**12/83**					
Surgery						
Radiation						
Chemotherapy						
IAT		**2/84**				**7/90**
CAM other						
Imaging CXR	**12/83, 12/83**	**2/84**				
Imaging ultrasound	**12/83**	**2/84**			**3/88**	

CAM Therapy:	IAT		
Case:	1-6		
Condition:	Lymphoma; poorly differentiated lymphocytic nodular lymphoma		
Abstractor:	1,2	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	11/7/01
Comments:	no conventional therapy except excisional biopsy		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	4/7/52
Diagnosis:	lymphoma: poorly differentiated lymphocytic nodular lymphoma
Diagnosis date:	12/5/83
CAM therapy dates:	2/14/84-7/19/90
Conventional therapy dates:	none
Last contact date:	7/26/90
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
no date	Family history of cancer: mother died age 32 melanoma; father died age 57 of lung cancer		
12/5/83	Biopsy: diagnostic excisional biopsy: poorly differentiated lymphocytic nodular lymphoma	Slides	Not avail.
12/21/83	Bone marrow: negative for malignancy		
12/21/83	Ultrasound abdomen: within normal limits	Films	Not avail.
12/4/83	Chest x-ray: within normal limits	Films	Not avail.
12/21/83	Chest x-ray: within normal limits	Films	Not avail.
2/14/84	Chest x-ray: within normal limits	Films	Not avail.
2/14/84-7/19/90	IAT: 12 courses		
3/23/88	Ultrasound abdomen: within normal limits	Films	Not avail.
6/20/98	Physical exam: peripheral lymphadenopathy resolved by 1988: negative radiological studies		

Cancer Best-Case Series

Patient #1-7
Peritoneal Mesothelioma

Case 1-7

The patient in case 1-7 is a 50-year-old Caucasian female with a history of peritoneal mesothelioma. She was initially misdiagnosed with ovarian cancer on 7/1/99 after peritoneal biopsies were obtained from an exploratory laparoscopy with excision of left pelvic mass, left colectomy, colostomy, and omentectomy. Given the diagnosis of ovarian cancer, chemotherapy was initiated with taxol and carboplatin on 7/28/99. She had an anaphylactic reaction to taxol, and chemotherapy was stopped. On 8/5/99, the biopsies were again reviewed at the Armed Forces Institute of Pathology, and a diagnosis of peritoneal mesothelioma was made. No other conventional therapy was pursued due to patient preference. IAT was started on 12/1/99 and continued, with her most recent treatment on 6/6/01. Serial pelvic CT scans reveal a gradual diminution of pelvic densities, with the most recent pelvic CT scan on 5/24/01 revealing no evidence of progressive tumor or other abnormality. On 10/24/01, an attempt was made to reverse the patient's colostomy. Reversal was not possible due to adhesions, and the patient's small bowel was nicked, leading to a complicated post-operative course. However, according to the patient, the surgeon reported a decrease in the tumor bulk based on visual inspection. At last contact (interview, 9/26/01), the patient reported that her overall physical health is good.

Pathology

7/1/99	**Pathology: ovarian carcinoma vs. mesothelioma melanoma**
8/5/99	**Pathology: final diagnosis: malignant mesothelioma (same tissue specimen)**

Imaging

2/29/00	**CT scan of abdomen and pelvis: no associated definitive soft tissue mass to suggest progression or recurrence of disease, no evidence of lymphadenopathy**
5/19/00	**CT scan of abdomen and pelvis: abdomen-no recurrent mass, no definite associated soft tissue mass effect, pelvis-increase in fluid collection L>R c/w 2/29/00.**
8/10/00	**X-ray chest: normal**
8/30/99	**CT scan of pelvis: decrease in soft tissue density and fluid c/w 6/28/99**
9/12/00	**CT scan of abdomen and pelvis: small nodular densities adjacent to the spleen, fluid collection right side of pelvis not decreased, left side extension no longer identified**
11/14/00	**Bone scan whole body: prominent activity in right renal pelvis similar to 2/98**
12/15/00	**US RUQ: no abnormality, no change from prior**
1/16/01	**CT scan of abdomen and pelvis with contrast: no bowel abnormalities, fluid collection on right side has increased to 4.5x3cm, now fluid to lower pelvis left side, findings nonspecific but recurrence possible**
1/23/01	**CT scan of pelvis: increased size of 2 rounded densities in pelvis, right lateral pelvic wall 4.5x3x0.15cm**
1/23/01	**CT scan of abdomen: mild prominence of left adrenal unchanged**
3/9/01	**CT scan of abdomen and pelvis with contrast: abdomen unremarkable, pelvis with loculated fluid collection in inferior pelvis in midline and on right, slight reduction in size**
5/24/01	**CT scan of abdomen: no pathologically enlarged lymph nodes or free fluid**
5/24/01	**CT scan of pelvis: no evidence of progressive tumor or abnormality; significant interval reduction of irregularly loculated fluid collections compared with 3/9/01 consistent with response of mesothelioma**
8/15/01	**CT scan of abdomen: no upper abdominal mass compared with 5/24/01**
8/15/01	**CT scan of pelvis; further reduction in small amounts of fluid. No evidence of progressive neoplasm compared with 5/24/01**

Tumor markers

7/23/99	**CA[a] 125 = 22 (<35)**
5/16/00	**CA 125 = 13 (<35)**

[a]Cancer Antigen.

Conventional therapy

7/1/99	**Exploratory laparoscopy with excision of left pelvic mass, left colectomy, colostomy, omentectomy, and multiple peritoneal biopsies**
7/28/99	**Taxol, carboplatin (initially thought to be ovarian cancer) stopped due to anaphalaxis**
10/24/01	**Surgery: attempted reversal of colostomy: decrease of tumor bulk based on visual inspection**

Complementary therapy

12/1/99-6/6/01	**IAT 6 courses over this time interval**
12/1/99-present (intermittent)	**MGn3, noni juice, colostrum, vitamin E, green tea, vitamin C, beta carotene, cat's claw, homeopathic miasms**
1/30/01-present (intermittent)	**Homeopathic –Haelan (fermented soy product), cat's claw, lyperinol**
2/2/01-present (intermittent)	**Illumination: multiherbal combo, Universal Complex (echinacea mix), Circu-Plus (gingko, ginseng), Mg/K aspartate, alpha-oxzyme, LSK Plus (granular liver, spleen, kidney)**

Patient # 1-7						
EVENT	**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 3** **1st qtr 2001 – 4th qtr 2001**			
Diagnosis/biopsy	**7/99**					
Surgery	**7/99**		**10/01**			
Radiation						
Chemotherapy	**7/99**					
IAT	**12/99**		**6/01**			
CAM other	**12/99**		**1/01, 2/01**			
Imaging CT scan		**2/00 5/00 9/00**	**1/01, 3/01 5/01 8/01**			
Imaging CXR		**8/00**				
Imaging ultrasound		**12/00**				
Tumor marker		**5/00**				

CAM Therapy:	IAT		
Case:	1-7		
Condition:	Malignant peritoneal mesothelioma		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/26/01
Comments:	Chemotherapy stopped when anaphylaxis from taxol, and second review of pathology specimen revealed malignant peritoneal mesothelioma		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	7/12/52
Diagnosis:	Malignant peritoneal mesothelioma
Diagnosis date:	8/6/99
CAM therapy dates:	12/1/99-6/6/01
Conventional therapy dates:	7/28/99
Last contact date:	6/11/01
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
6/28/99	CT scan of pelvis: 3.5cm cystic left adnexal mass	Films	Rcvd.
7/1/99	Exploratory laparoscopy with excision of left pelvic mass, left colectomy, colostomy, omentectomy, multiple peritoneal biopsies.		
7/1/99	Pathology: Ovarian carcinoma vs. malignant melanoma		
7/23/99	CA 125 = 22 (<35)		
7/28/99	Taxol, carboplatin (initially diagnosed with ovarian cancer)		
7/28/99	Adverse event: anaphylaxis from taxol		
8/5/99	Pathology: final diagnosis: malignant mesothelioma (same tissue sample)	Slides	Pend.
8/30/99	CT scan of pelvis: decrease in soft tissue density and fluid c/w 6/28/99	Films	Rcvd.
9/24/99	PET scan of whole body: no specific findings to suggest residual tumor in torso, increased activity small area in neck		
2/29/00	CT scan of abdomen and pelvis: no associated definitive soft tissue mass to suggest progression or recurrence of disease, no evidence of lymphadenopathy		
5/16/00	CA 125 = 13 (<35)		
5/19/00	CT scan of abdomen and pelvis: abdomen-no recurrent mass, no definite associated soft tissue mass effect, pelvis-increase in fluid collection L>R c/w 2/29/00.		
8/10/00	X-ray chest: normal		
9/12/00	CT scan of abdomen and pelvis: small nodular densities adj. to spleen, fluid collection right side pelvis not decr., left side extension no longer identified	Films	Not avail.
11/14/00	Bone scan of whole body: no change c/w 2/98		
11/14/00	X-ray chest: within normal limits		

Date	Description of Events	Requested	Status of requests
12/15/00	US RUQ: no abnormality, no change from 6/29/99		
1/16/01	CT scan of abdomen and pelvis with contrast: no bowel abnormalities, fluid collection on right side has increased to 4.5x3cm, now fluid to lower pelvis left side, findings nonspecific but recurrence possible		
1/23/01	CT scan of pelvis: increased size of 2 rounded densities in pelvis, right lateral pelvic wall 4.5x3x0.15cm		
3/9/01	CT scan of abdomen and pelvis with contrast: abdomen unremarkable, pelvis with loculated fluid collection in inferior pelvis in midline and on right, slight reduction in size		
5/24/01	CT scan of abdomen: no pathologically enlarged lymph nodes or free fluid	Films	Rcvd.
5/24/01	CT scan of pelvis: no evidence of progressive tumor or abnormality		
12/1/1999-6/6/01	IAT 5 courses		
12/1/1999-present (intermittent)	Mgn3, noni juice, colostrum, vitamin E, green tea, vitamin C, beta carotene, cat's claw, homeopathic miasms		
1/30/2001-present (intermittent)	Homeopathic – not specified, Haelan (fermented soy product), cat's claw, lyperinol		
2/2/2001-present (intermittent)	Illumination: multiherbal combo, Universal Complex (echinacea mix), Circu-Plus (ginko, ginseng), Mg/K aspartate, alpha-oxzyme, LSK Plus (granular liver, spleen, kidney)		
8/15/01	CT scan abdomen: no upper abdominal mass compared to 5/24/01.	Films	Rcvd.
8/15/01	CT scan of pelvis; further reduction in small amounts of fluid. No evidence of progressive neoplasm compared with 5/24/01	Films	Rcvd.
10/12/01	CT scan of abdomen and CT scan of pelvis with contrast: high grade partial small bower obstruction. No discrete mass is visualized, however, there is free intraperitoneal air with an air fluid level.	Films	Rcvd.
10/17/01	CT scan of abdomen and CT scan of pelvis with contrast: small bowel dilation slightly less prominent than previously seen, otherwise basically unchanged compared to previous examination.	Films	Rcvd.
10/24/01	Surgery: attempted reversal of colostomy: decrease of tumor bulk based on visual inspection		

Cancer Best-Case Series

Patient #1-9
Ovarian Cyst Adenocarcinoma

Case 1-9

The patient in case 1-9 is a 54-year-old woman with ovarian cyst adenocarcinoma diagnosed on 5/3/80. She had a total abdominal hysterectomy with bilateral salpingo-oophorectomy with debulking at that time. Subsequently, she was referred for chemotherapy but refused due to patient preference. Her only therapy has been 34 courses of IAT from 6/3/80 to 6/12/99. In June 1987, a CT scan revealed lesions in her liver suspicious for metastatic disease. A liver biopsy was recommended, but since a needle biopsy was not possible due to adhesions, none was performed. Subsequent followup did not reveal progression of disease. A pelvic mass was noted on 8/6/00 and found to be increasing over the next year to a maximal dimension of 2.8cm x 2.8cm. An exploratory laparotomy with resection of left pelvis mass and biopsy of right pelvis was performed on 6/29/81. Pathology from the surgery was negative. Tumor markers have also been negative. Routine gynecologic care has not revealed any abnormalities. At last contact (interview, 10/09/01), the patient reported that her overall physical health was good.

Pathology

5/3/80	**Biopsy: right ovary: papillary cyst adenocarcinoma, left ovary: same diagnosis**
6/29/81	**Biopsy: excision of pelvic mass—no tumor**
6/14/90	**Pap smear cytology: negative for malignancy**
6/12/91	**Pap smear cytology: negative for malignancy**

Imaging

5/1/80	**Ultrasound: pelvis mass 9cm x 7cm**
5/21/80	**Liver scan: normal**
5/23/80	**Bone scan whole body: normal**
8/6/80	**Ultrasound: pelvis cystic left adnexal mass 2cm x 2.5cm, no fluid in pelvis**
9/24/80	**Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 unchanged**
12/10/80	**Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 slightly smaller**
1/28/81	**Bone scan whole body: new area of increased uptake left iliac crest since 5/23/80**
4/20/81	**Ultrasound: pelvis cystic left adnexal mass 2.3cm unchanged c/w 12/10/80**
4/22/81	**Bone scan whole body: diffuse uptake in skull; increased uptake lumbar spine consistent with osteoarthritis: no evidence of metastases**
6/8/81	**Ultrasound: pelvis cystic left adnexal mass 2.8cm x 2.8cm, increased since 4/20/81**
9/8/81	**Ultrasound: pelvis no adnexal mass present, no fluid present**
6/1/83	**Ultrasound: pelvis no adnexal mass present, no fluid present**
1/15/86	**Ultrasound: pelvis no adnexal mass present, no fluid present**
6/10/87	**CT scan abdomen: suspicious for liver metastases; focal areas of low attenuation throughout liver**
3/4/91	**X-ray chest no change c/w 8/9/89**
5/31/91	**Mammogram breast: normal**
5/27/92	**Mammogram breast: normal**
8/6/1993	**MRI thoracic spine: osteoporosis**

Tumor markers

5/30/90	**CA[a]-125: <7.5 (normal 0-35)**
5/29/91	**CA-125: 6.3 (normal 0-35)**
5/6/94	**CA-125: <8.0 (normal 0-35)**
6/10/97	**CA-125 = 5.0 (0-35); CEA[b] = 0.3 (0-3)**
6/11/01	**CA-125 = 6.0 (0-35)**

[a]CA: Cancer Antigen.
[b]CEA: Carcinoembrionic Antigen.

Conventional therapy

5/1/80	**Surgery: TAH/BSO with appendectomy**
5/3/80	**Chemotherapy recommended: never started**
6/29/81	**Surgery: exploratory laparotomy with resection of left pelvic mass and biopsy**

Complementary therapy

6/3/80-6/12/99	**IAT: 34 courses over this time period; no home maintenance after 16 courses**

Patient # 1-9						
EVENT	**PERIOD 1** **1st qtr 1980 – 4th qtr 1980**	**PERIOD 2** **1st qtr 1981 – 4th qtr 1981**	**PERIOD 3** **1st qtr 1983 – 4th qtr 1983**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1987 – 4th qtr 1987**	**PERIOD 6** **1st qtr 1989 – 4th qtr 1989**
Diagnosis/biopsy	**5/80**	**6/81**				
Surgery	**5/80**	**6/81**				
Radiation						
Chemotherapy						
IAT	**6/80**					
CAM other						
Imaging CXR						
Imaging ultrasound	**5/80** **8/80, 9/80** **12/80**	**4/81, 6/81** **9/81**	**6/83**	**1/86**		
Imaging CT					**6/87**	
Tumor markers						
Bone scan	**5/80**	**1/81** **4/81**				
Pap smear						

Patient # 1-9, cont'd						
EVENT	PERIOD 7 1st qtr 1990– 4th qtr 1980	PERIOD 8 1st qtr 1991 – 4th qtr 1991	PERIOD 9 1st qtr 1994 – 4th qtr 1994	PERIOD 10 1st qtr 1997 – 4th qtr 1997	PERIOD 11 1st qtr 1999 – 4th qtr 1999	PERIOD 12 1st qtr 2001 – 4th qtr 2001
Diagnosis/biopsy						
Surgery						
Radiation						
Chemotherapy						
IAT					6/99	
CAM other						
Imaging CXR		3/91				
Imaging ultrasound						
Imaging CT						
Tumor markers	5/90	5/91	5/94	6/97		6/01
Bone Scan						
Pap smear	6/90	6/91				

CAM Therapy:	IAT		
Case:	1-9		
Condition:	Bilateral cystadenocarcinoma of the ovaries		
Abstractor:	mh	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	10/16/01
Comments:	recurrence then disappearance of pelvic mass		

Criteria for inclusion:	**(check all that apply)**		
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	8/11/47
Diagnosis:	bilateral cystadenocarcinoma of the ovaries
Diagnosis date:	5/3/80
CAM therapy dates:	6/3/80-6/12/99
Conventional therapy dates:	surgery 5/80; 6/81
Last contact date:	6/21/01
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Mother-carcinoma of the uterus, grandmother-lung cancer, grandfather-cancer of tongue, brother-leukemia		
5/1/80	Ultrasound: mass in pelvis 9cm x 7cm	Films	Not avail.
5/3/80	Surgery: TAH/BSO with appendectomy		
5/3/80	Biopsy:right ovary: papillary cystadenocarcinoma ; left ovary same diagnosis	Slides	Not avail.
5/3/80	Chemotherapy recommended: never started		
5/21/80	Liver scan: normal		
5/23/80	Bone scan whole body: normal		
6/3/80-6/12/99	IAT: 34 courses over this time period; no home maintenance after 16 courses		
8/6/80	Ultrasound: pelvis cystic left adnexal mass 2cm x 2.5cm, no fluid in pelvis	Films	Not avail.
9/24/80	Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 unchanged		
12/10/80	Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 slightly smaller		
1/28/81	Bone scan whole body: new area of increased uptake left iliac crest since 5/23/80		
4/20/81	Ultrasound: pelvis cystic left adnexal mass 2.3cm unchanged c/w 12/10/80	Films	Not avail.
4/22/81	Bone scan whole body: diffuse uptake in skull; increased uptake lumbar spine consistent with osteoarthritis: no evidence mets		
6/8/81	Ultrasound: pelvis cystic left adnexal mass 2.8cm x 2.8cm, increased since 4/20/81		

Date	Description of Events	Requested	Status of requests
6/29/81	Surgery: exploratory laparotomy with resection of left pelvic mass and biopsy	Slides	Rcvd.
6/29/81	Biopsy: excision of pelvic mass- no tumor		
9/8/81	Ultrasound: pelvis no adnexal mass present, no fluid present		
6/1/83	Ultrasound: pelvis no adnexal mass present, no fluid present		
1/15/86	Ultrasound: pelvis no adnexal mass present, no fluid present	Films	Not avail.
6/10/87	CT scan abdomen: suspicious for liver mets; focal areas of low attenuation throughout liver	Films	Not avail.
Jun-87	Biopsy of liver lesions recommended but not performed; needle biopsy not possible due to adhesions		
5/30/90	CA-125: <7.5 (normal 0-35)		
6/14/90	Pap smear cytology: negative for malignancy		
3/4/91	X-ray chest no change c/w 8/9/89		
5/29/91	CA-125: 6.3 (normal 0-35)		
5/31/91	Mammogram breast: normal		
6/12/91	Pap smear cytology: negative for malignancy		
5/27/92	Mammogram breast: normal		
8/6/93	MRI thoracic spine: osteoperosis		

Date	Description of Events	Requested	Status of requests
5/4/94	CA-125: <8.0 (normal 0-35)		
6/10/97	CA-125 = 5.0 (0-35); CEA = 0.3 (0-3)		
6/11/01	CA-125 = 6.0 (0-35)		
present	Routine physical exams/ serial CA-125 normal per patient during interview		

Cancer Best-Case Series

Patient #1-11
Peritoneal Mesothelioma

Case 1-11

The patient in case 1-11 is a 59-year-old male with a family history of breast cancer, diagnosed in May, 1980 with peritoneal mesothelioma after presenting with a history of right lower quadrant abdominal pain and dyspepsia. His work-up included a cholangiogram, upper GI series with a small bowel follow-through, and an intravenous pyelogram of the GU tract. After these tests returned normal, a small bowel obstruction was the leading diagnosis until an exploratory laparotomy revealed peritoneal mesothelioma. According to the operative report (5/8/80), there was widespread disease throughout the pelvic and abdominal cavities. A partial omentectomy was performed, and as much bulk disease was removed as possible. A second opinion was obtained at MD Anderson (6/16/80 – 6/23/80), and it was recommended that additional tissue be obtained to confirm the diagnosis of mesothelioma via electron microscopy, which was done on 6/25/80. Due to the lack of a definitive curative therapy, no specific recommendations for chemotherapy, radiation, or future surgery were made. The patient started IAT therapy on 7/22/80 and completed the course in 5/84. At last contact (interview, 9/19/01), the patient reported that his overall physical condition is very good.

Pathology

5/8/80	**Pathology of cysts on peritoneum: mesothelioma of peritoneum, multiple sites**
6/25/80	**Pathology: electron microscopy: multiple cystic mesothelioma of peritoneum**

Imaging

4/11/80	**IVP of GU tract: within normal limits**
4/12/80	**IV cholangiogram: within normal limits**
4/12/80	**UGI with SBF: within normal limits**
4/14/80	**Barium enema: within normal limits**
4/16/80	**CT scan of abdomen: within normal limits**
4/20/80	**X-ray chest: collapse of portion LLL, air containing structure posterior to sternum; nodular density adj. to left hilum**
4/22/80	**Tomogram of left lung: possible mass adjacent to hilum is "distorted branch of pulmonary artery"**
5/10/80	**X-ray chest: left ventricular enlargement**
5/16/80	**Bone scan of total body: within normal limits**
5/17/80	**Liver and spleen scan: within normal limits**

Conventional therapy

5/8/80	**Surgery: exploratory laparoscopy, excision of multiple cysts, subtotal omentectomy for palliative: most of peritoneal cavity lined with cysts. Debulking done. Tumor is cystic, grape-like, no ascites.**

Complementary therapy

7/22/80-7/20/84	**IAT 16 courses**

Patient # 1-11						
EVENT	PERIOD 1 1st qtr 1980 – 4th qtr 1980	PERIOD 2 1st qtr 1981 – 4th qtr 1981	PERIOD 3 1st qtr 1982 – 4th qtr 1982	PERIOD 4 1st qtr 1983 – 4th qtr 1983	PERIOD 5 1st qtr 1984 – 4th qtr 1984	PERIOD 6 1st qtr 1985 – 4th qtr 1985
Diagnosis/biopsy	5/80					
Surgery	5/80					
Radiation						
Chemotherapy						
IAT	7/80				7/84	
CAM other						
Imaging CXR	4/80					
Imaging tomogram	4/80					
Imaging CT scan abdomen	4/80					
Imaging liver spleen scan	4/80					
Imaging bone scan	5/80					

CAM Therapy:	IAT		
Case:	1-11		
Condition:	Peritoneal mesothelioma		
Abstractor:	IDC, JLG	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/19/01
Comments:	Surgical debulking is only conventional care		

Criteria for inclusion:	**(check all that apply)**	
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
		Tumor size
	x	Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	1/23/42
Diagnosis:	peritoneal mesothelioma
Diagnosis date:	5/8/80
CAM therapy dates:	7/22/80-7/20/84
Conventional therapy dates:	5/8/80
Last contact date:	7/1/87
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
4/11/80	IVP of GU tract: within normal limits		
4/12/80	IV cholangiogram: within normal limits		
4/12/80	UGI with SBF: within normal limits		
4/14/80	Barium enema: within normal limits		
4/16/80	CT scan of abdomen: within normal limits		
4/20/80	X-ray chest: collapse of portion LLL, air containing structure posterior to sternum; nodular density adj. to left hilum		
4/22/80	Tomogram of left lung: possible mass adjacent to hilum is “distorted branch of pulmonary artery”		
5/8/80	Exploratory laparoscopy, excision of multiple cysts, subtotal omentectomy for palliative: most of peritoneal cavity lined with cysts. Debulking done. Tumor is cystic, grape-like, no ascites.		
5/8/80	Pathology of cysts on peritoneum: mesothelioma of peritoneum, multiple sites	Slides	Not avail.
5/10/80	X-ray chest: left ventricular enlargement		
5/16/80	Tomogram of chest: volume loss LLL, unknown etiology		
5/16/80	Bone scan of total body: within normal limits		
5/17/80	Liver and spleen scan: within normal limits		
6/25/80	Pathology: electron microscopy: multiple cystic mesothelioma of peritoneum		
7/22/80-7/20/84	IAT 16 courses		

Cancer Best-Case Series

Patient #1-19
Sigmoid Carcinoma (Dukes Stage C2)

Case 1-19

The patient in case 1-19 is a 50-year-old male with a family history of colon cancer. He was diagnosed with sigmoid carcinoma (Dukes stage C2) in March1985 after presenting with hematochezia, lower-left quadrant abdominal pain, and a normal CEA. Biopsies obtained during colonoscopy verified the diagnosis. He underwent a sigmoid resection, and 6 of 14 nodes were positive for metastases, but no gross residual disease was left in the abdomen. No other conventional therapy was pursued. He started IAT on 5/85 and completed 11 courses by 5/91. Serial colonoscopies have remained normal, with the last exam conducted on 9/8/00. At the last contact (interview, 10/12/01), the patient reported that his overall physical condition was excellent.

Pathology

3/18/85	**Biopsy: mucinous producing adenocarcinoma, mod well diff, associated with adenomatous polyp, sigmoid colon, 6/14 nodes positive for mets, mesocolon and mesentery of colon.**
9/8/00	**Biopsy: colon polyp: no evidence of malignancy**

Imaging

3/22/85	**Liver spleen scan: normal**
1/8/1987	**CT abdomen pelvis: no evidence of recurrent tumor**
3/27/87	**Sigmoidoscopy: normal to 25cm**
9/26/88	**Colonoscopy: colon fully visualized to the cecum**
4/13/89	**CT scan abdomen; normal exam, no change compared with 1/8/87**
10/5/89	**Colonoscopy: normal exam**
11/13/92	**Colonoscopy: no evidence of recurrent colorectal polyps or cancer**
12/2/94	**Colonoscopy: normal exam**
2/10/98	**Sigmoidoscopy: normal to 40cm, normal anastamosis**
5/7/98	**Colonoscopy: normal exam**
7/27/99	**Sigmoidoscopy: normal to 70cm**
9/8/00	**Colonoscopy: sessile polyp (3mm) near anastamotic site**

Tumor markers

3/17/85	**CEA[a] <1.0 (normal)**
2/25/86	**CEA <2.5 (normal)**
7/8/1986	**CEA 1.9 (normal<2.5)**
2/1/1987	**CEA 1.8 (normal)**
7/14/87	**CEA 1.1 (normal <2.5)**
3/9/88	**CEA 1.9 (normal<2.5)**
4/24/89	**CEA 1.2 (normal)**
10/4/89	**CEA 2.0 (normal)**
9/26/90	**CEA 1.4 (normal)**

[a]Carcinoembryonic Antigen.

Conventional therapy

3/18/85	**Surgery: sigmoid resection**

Complementary therapy

5/21/85-5/7/91	**IAT 11 courses**

Patient # 1-19						
EVENT	**PERIOD 1** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 2** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 3** **1st qtr 1987 – 4th qtr 1987**	**PERIOD 4** **1st qtr 1988 – 4th qtr 1988**	**PERIOD 5** **1st qtr 1989 – 4th qtr 1989**	**PERIOD 6** **1st qtr 1990 – 4th qtr 1990**
Diagnosis/biopsy	**3/85**					**9/90**
Surgery	**3/85**					
Radiation						
Chemotherapy						
IAT	**5/85**					
CAM other						
Imaging CT scan			**1/87**		**4/89**	
Colonoscopy				**9/88**	**10/89**	
Sigmoidoscopy			**3/87**			
Tumor markers	**3/85**	**2/86** **7/86**	**2/87** **7/87**	**3/88**	**4/89**	**10/89** **9/90**
Liver spleen scan	**3/85**					

Patient # 1-19, cont'd						
EVENT	**PERIOD 7** **1st qtr 1991– 4th qtr 1991**	**PERIOD 8** **1st qtr 1992 – 4th qtr 1992**	**PERIOD 9** **1st qtr 1994 – 4th qtr 1994**	**PERIOD 10** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 11** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 12** **1st qtr 2000 – 4th qtr 2000**
Diagnosis/biopsy						
Surgery						
Radiation						
Chemotherapy						
IAT	**5/91**					
CAM other						
Imaging CT						
Colonoscopy		**11/92**	**12/94**	**5/98**		**9/00**
Sigmoidoscopy				**2/98**	**7/99**	
Tumor markers						

CAM Therapy:	IAT		
Case:	1-19		
Condition:	Adenocarcinoma of the colon		
Abstractor:	MH, IDC	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/26/01
Comments:	No other conventional therapy except surgery; serial colonoscopies normal		

Criteria for inclusion:	**(check all that apply)**	
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
		Tumor size
	x	Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	12/2/51
Diagnosis:	Adenocarcinoma of the colon, Duke C2
Diagnosis date:	3/18/85
CAM therapy dates:	5/21/85-5/7/91
Conventional therapy dates:	Surgery 3/18/85
Last contact date:	9/8/00
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Family history of colon cancer in uncle		
3/17/85	CEA <1.0 (normal)		
3/18/85	Biopsy: mucinous producing adenocarcinoma, mod well diff, associated with adenomatous polyp, sigmoid colon, 6/14 nodes positive for mets, mesocolon and mesentery of colon.	Slides	Rcvd.
3/18/85	Surgery: sigmoid resection	Oper. Rpt.	Not avail.
3/22/85	Liver spleen scan: normal		
5/21/85-5/7/91	IAT 11 courses		
2/25/86	CEA <2.5 (normal)		
7/8/86	CEA 1.9 (normal<2.5)		
1/8/87	CT abdomen pelvis: no evidence of recurrent tumor	Films	Not avail.
2/1/87	CEA 1.8 (normal)		
3/27/87	Sigmoidoscopy: normal to 25cm		
7/14/87	CEA 1.1 (normal <2.5)		
3/9/88	CEA 1.9 (normal<2.5)		
9/26/88	Colonoscopy: colon fully visualized to the cecum		
4/13/89	CT scan abdomen; normal exam, no change compared with 1/8/87	Films	Not avail.

Date	Description of Events	Requested	Status of requests
4/24/89	CEA 1.2 (normal)		
10/4/89	CEA 2.0 (normal)		
10/5/89	Colonoscopy: normal exam		
9/26/90	CEA 1.4 (normal)		
11/13/92	Colonoscopy: no evidence of recurrent colorectal polyps or cancer		
12/2/94	Colonoscopy: normal exam		
2/10/98	Sigmoidoscopy: normal to 40cm, normal anastamosis		
5/7/98	Colonoscopy: normal exam		
7/27/99	Sigmoidoscopy: normal to 70cm		
9/8/00	Colonoscopy: sessile polyp (3mm) near anastamotic site		
9/8/00	Biopsy: colon polyp: no evidence of malignancy	Slides	Rcvd.

Cancer Best-Case Series

Patient #1-22
Squamous Cell Carcinoma of the Tongue

Case 1-22

The patient in case 1-22 is an 80-year-old male who was diagnosed in February 1999 with squamous cell carcinoma of the tongue accompanied by a benign parotid cyst. He subsequently completed the recommended course of radiation. Definitive surgery was recommended, but the patient refused, due to personal preference. IAT was initiated in June 1999, and he continues on maintenance therapy today. An MRI in October 2001 revealed no evidence of a discrete mass in the oropharynx and a decrease in right cervical lymph node. At the last contact (interview, 9/26/01), the patient reports that his overall physical condition is good.

Pathology

2/12/99	**Biopsy left side tongue: squamous cell carcinoma, invasive, moderately differentiated**
2/18/99	**Biopsy (fine needle) right parotid lymph node: cystic contents; inconclusive**
4/20/99	**Biopsy (fine needle) right parotid lymph node: abscess with Strep species, acute suppurative inflammation with cocci**
5/6/99	**Biopsy aspiration of cyst in right parotid lymph node: cyst contents; acute inflammation**

Imaging

2/17/99	**CT scan left neck and tongue: invasive carcinoma of tongue extends to tonsillar fossa, parapharyngeal space, and beyond inferior margin of mandible into cervical subcutaneous tissue: large contralateral node metastasis**
2/25/99	**MRI of neck: ill-defined enhancing mass at base of tongue with extension into left piriformis sinus, highly suspicious for squamous cell carcinoma; cystic structure in submandibular space/ jugulodiagastric space**
3/4/99	**MRI neck: 2.26cm x 3.60cm x 3.50cm enhancing mass base of left tongue extending into hypopharynx, to level of epiglottis piriformis sinus; no extension past midline; cystic structure 3.2cm x 6.5cm x 7.80cm in jugulodiagastric region**
12/8/99	**CT scan neck: Resolution of left tongue base/lateral pharyngeal mass; pleomorphic adenoma or necrotic lymph node (right parotid cystic mass)**
4/7/00	**X-ray chest: emphysematous changes, otherwise normal**
4/7/00	**MRI of brain: normal**
6/14/00	**CT scan abdomen: bilateral lower lobe fibrosis consistent with UIP; possible nephrolithiasis involving left kidney**
7/11/00	**CT scan thorax: linear interstitial fibrosis consistent with UIP; bilateral apical fibrosis**
7/23/00	**CT scan neck: low attenuation of lesion on along right anterior border of right parotid gland; 2.2cm x 2.3cm; suspicious for metastatic necrotic lymph node**
10/3/01	**CT scan chest: bilateral interstitial lung disease**
10/3/01	**MRI neck: no evidence of discrete mass in oropharynx or oral cavity. Diffuse enhancement in dorsal aspect of hypopharynx could represent post-radiation changes. Interval decrease in right lymph node now measures 1.2cm**

Conventional therapy

3/5/99-4/15/99	**Radiation: upper neck, total rads 7200: 30 fractions over 41 days: completed full course: residual disease present after radiation**

Complementary therapy

6/22/99-present	**IAT (5 courses); still on maintenance therapy**

Patient # 1-22						
EVENT	**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 3** **1st qtr 2001 – 4th qtr 2001**			
Diagnosis/biopsy	**2/99, 2/99 4/99, 5/99**					
Surgery						
Radiation	**3/99**					
Chemotherapy						
IAT	**6/99**					
CAM other						
Imaging CT scan	**2/99** **12/99**	**6/00, 7/00**	**10/01**			
Imaging CXR						
Imaging MRI	**2/99, 3/99 4/99**		**10/01**			

CAM Therapy:	IAT		
Case:	1-22		
Condition:	Squamous cell carcinoma at the base of the tongue: Stage 1, T2-3, N0		
Abstractor:	IDC, MH	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/30/01
Comments:	Squamous cell carcinoma at the base of the tongue, declined surgery, experimental chemotherapy. Had aggressive radiation with residual disease.		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	11/24/21
Diagnosis:	Squamous cell carcinoma at the base of the tongue: Stage 1, T2-3, N0
Diagnosis date:	2/12/99
CAM therapy dates:	6/22/99-5/4/01
Conventional therapy dates:	3/5/99-4/15/99
Last contact date:	5/4/01
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
2/12/99	Biopsy left side tongue: squamous cell carcinoma, invasive, moderately differentiated	Slides	Pend.
2/17/99	CT scan left neck and tongue: invasive carcinoma of tongue extends to tonsillar fossa, parapharyngeal space, and beyond inferior margin of mandible into cervical subcutaneous tissue: large contralateral node	Films	Pend.
2/18/99	Biopsy (fine needle) right parotid lymph node: cystic contents; inconclusive		
2/25/99	MRI of neck: ill-defined enhancing mass at base of tongue with extension into left piriformis sinus, highly suspicious for squamous cell carcinoma; cystic structure in submandibular space/ juglodiagastric space		
2/25/99	MRI of brain: normal		
3/4/99	MRI neck: 2.26cm x 3.60cm x 3.50cm enhancing mass base of left tongue extending into hypopharynx, to level of epiglottis piriformis sinus; no extension past midline; cystic structure 3.2cm x 6.5cm x 7.80cm in juglodiagastric region		
2/18/99	Definitive surgery recommended: patient refused		
3/4/99	MRI neck: 2.26cm x 3.60cm x 3.50cm enhancing mass base of left tongue extending into hypopharynx, to level of epiglottis piriformis sinus; no extension past midline; cystic structure 3.2cm x 6.5cm x 7.80cm in		
4/20/99	Biopsy (fine needle) right parotid lymph node: abscess with Strep species, acute suppurative inflammation with cocci		
5/6/99	Biopsy aspiration of cyst in right parotid lymph node: cyst contents; acute inflammation		
3/5/99-4/15/99	Radiation: upper neck total rads 7200: 30 fractions over 41 days: completed full course: residual disease present after radiation	Rpt. After treatment	Pend.
12/8/99	CT scan neck: Resolution of left tongue base/lateral pharyngeal mass.pleomorphic adenoma or necrotic lymph node (right parotid cystic mass)	Films	Pend.
4/7/00	X-ray chest: emphysematous changes, otherwise normal		
4/7/00	MRI of brain: normal		
6/14/00	CT scan abdomen: bilateral lower lobe fibrosis consistent with UIP; possible nephroliathiasis involving left kidney		

Date	Description of Events	Requested	Status of requests
7/11/00	CT scan thorax: linear interstitial fibrosis consistent with UIP; bilat apical fibrosis		
7/23/00	CT scan neck: low attenuation of lesion on along right anterior border of right parotid gland; 2.2cm x 2.3cm; suspicious for metastatic necrotic lymph node		
10/3/01	CT scan chest: bilateral interstitial lung disease	Films	Pend.
10/3/01	MRI neck: no evidence of discrete mass in oropharynx or oral cavity. Diffuse enhancement in dorsal aspect of hypopharynx could represent post-radiation changes. Interval decrease in right lymph node now measures 1.2cm	Films	Pend.

Cancer Best-Case Series

Patient #2-10
Pancreatic Cancer Involving the Bile Duct

Case 2-10

The patient in case 2-10 was a 55 year-old female with pancreatic cancer involving the bile duct. Her diagnosis was made in July 1999, after presenting with low back pain and a gastrointestinal bleed. No conventional therapy was pursued, as she was considered terminally ill at the time of her diagnosis and palliative drainage. Naltrexone was initiated on 11/11/99, and by July 2000, a CT scan showed a 90% reduction of her tumor mass. On August 8, 2000, she died from overwhelming septicemia, after three episodes of gram-negative sepsis secondary to loosening of her biliary stent. According to next of kin, no autopsy was performed.

Pathology

7/1/99	**Biopsy of body of pancreas; carcinoma of pancreas (per physician's notes)**

Imaging

Jul-00	**CT scan abdomen: residual pancreatic lesions <1cm: 90% reduction of tumor mass; per physician's notes**

Liver enzymes

10/22/99	**Alk Phos- 1646; ALT 93; AST 159**
10/23/99	**Alk Phos- 1471; ALT 74; AST 108**
11/21/99	**Alk Phos- 2262; ALT 126; AST 180**

Conventional therapy

7/1/99	**Laparoscopy**
Dec-99	**Metenkephalin IV**

Complementary therapy

11/11/99	**Naltrexone 3mg qHS**

Outcome:

8/5/00	**Death—due to septicemia secondary to loosened stent in bile duct**

Patient # 2-10						
EVENT	**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**				
Biopsy/diagnosis	**7/99**					
Surgery	**7/99**					
Radiation						
Chemotherapy						
Naltrexone						
Imaging CT scan		**7/00**				
Liver enzymes	**10/99,10/99, 11/99**					
Death		**8/00**				

CAM Therapy:	Naltrexone		
Case:	2-10		
Condition:	Pancreatic cancer with bile duct involvement stage IV		
Abstractor:	AC IC JU	**Date of Abstraction:**	7/11/01
Interviewer:		**Date of Interview:**	10/11/01
Comments:	Regression without chemo/XRT/surgery, no diagnosing pathology report		

Criteria for inclusion: (check all that apply)			
	Diagnosis confirmed		
x	Documented start date for CAM therapy		
	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
		Tumor size	
	x	Longevity	
	x	Quality of Life	
		Other:	need confirmation

Other Relevant Information:	
Sex:	female
DOB:	9/14/46
Diagnosis:	Pancreatic cancer with bile duct involvement
Diagnosis date:	7/1/99
CAM therapy dates:	11/11/99- started Naltrexone
Conventional therapy dates:	surgery, date unclear
Last contact date:	8/5/00
If deceased, date of death:	8/5/00

Date	Description of Events	Requested	Status of Requests
7/1/99	Laparoscopy; diagnosis of pancreatic cancer per physician's notes	Slides	Pend.
10/22/99	Alk Phos- 1646; ALT 93; AST 159		
10/23/99	Alk Phos- 1471; ALT 74; AST 108		
11/21/99	Alk Phos- 2262; ALT 126; AST 180		
11/11/99	Naltrexone 3mg qHS		
Dec-99	Metenkephalin IV		
Jul-00	CT scan abdomen: residual pancreatic lesions <1cm: 90% reduction of tumor mass; per physician's notes	Films	Pend.
8/5/00	Death--due to septecemia secondary to loosened stent in bile duct		

Cancer Best-Case Series

Patient #2-21
Melanoma

Case 2-21

The patient in case 2-21 is a 67-year-old male who was diagnosed with melanoma in July 1996. The melanoma was resected from his right shoulder at that time, and no further therapy, other than close surveillance, was recommended. In April 1998, a lymph node dissection of his right axilla revealed metastatic disease in 1 of 15 lymph nodes. No conventional therapy was pursued. After presenting in August 1999 with proprioceptive changes in his left lower extremity, he had an MRI that showed a small brain lesion. This proved in fact to be a small bleed. During the course of 1999, the patient reported trying but not sustaining treatment with a variety of alternative therapies (see below). Also, he reported participating in a vaccine trial. Naltrexone was initiated in January 2000. At the last contact (interview, 10/10/2000), the patient reported that his overall physical condition was very good.

Pathology

7/23/96	**Pathology from excision: malignant melanoma focally filling to papillary dermis (level III), vertical thickness 0.78mm. No abnormal melanocytes at margins of specimen**
9/10/99	**Biopsy brain: revealed no evidence of malignancy (per patient report)**

Imaging

4/15/98	**CT scan brain, chest, abdomen, and pelvis: no evidence of metastasis**
8/1/99	**MRI brain: proprioceptive changes in left lower calf and foot: diagnosed with cranial metastasis (per patient report) (this proved to be incorrect as the patient was later diagnosed to have had a small bleed**

Conventional therapy

7/23/96	**Surgical excision of pigmented skin lesion on right shoulder**
8/13/96	**Surgical excision after melanoma diagnosis confirmed**
4/1/98	**Surgery: lymph nodes: 1 of 15 nodes positive for malignancy**
1999	**Clinical trial: vaccinia melanoma cell lysates (VMCL) (per patient report)**

Complementary therapy

1/00-present	**Started Naltrexone 4.5mg**
1999	**Melatonin 3mg q.d. MVI q.d.; antioxidant q.d.; green tea; ginseng; vegetarian diet; selenium; milk thistle; pancreatic enzymes**

Patient # 2-21						
EVENT	PERIOD 1 1st qtr 1996 – 4th qtr 1996	PERIOD 2 1st qtr 1997 – 4th qtr 1997	PERIOD 3 1st qtr 1998 – 4th qtr 1998	PERIOD 4 1st qtr 1999 – 4th qtr 1999	PERIOD 5 1st qtr 2000 – 4th qtr 2000	PERIOD 6 1st qtr 2001 – 4th qtr 2001
Biopsy/diagnosis	7/96			9/99		
Surgery	7/96, 8/96		4/98			
Radiation						
Chemotherapy						
Clinical trial				1999		
Naltrexone					1/00	
CAM other				1999		
Imaging-MRI brain						
Imaging-CT scan abdomen			4/98	8/99		

CAM Therapy:	Naltrexone		
Case:	2-21		
Condition:	Melanoma, malignant		
Abstractor:	JTF	**Date of Abstraction:**	10/5/01
Interviewer:		**Date of Interview:**	10/10/01
Comments:	Unclear if patient had conventional therapy, or dates of initiating Naltrexone		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
x	Documented endpoint:		
		Tumor size	
	x	Longevity	
		Quality of Life	
		Other:	

Other Relevent Information:	
Sex:	male
DOB:	12/12/38
Diagnosis:	Malignant melanoma
Diagnosis date:	7/23/96
CAM therapy dates:	1/00-present Naltrexone
Conventional therapy dates:	7/96 surgery; 4/98 surgery
Last contact date:	1/20/00
If deceased, date of death:	

Date	Description of Events	Requested	Status of Requests
7/23/96	Surgical excision of pigmented skin lesion on right shoulder		
7/23/96	Pathology from excision: malignant melanoma focally filling to papillary dermis (level III), vertical thickness 0.78mm. No abnormal melanocytes at margins of specimen	Slides	Pend.
8/13/96	Surgical excision after melanoma diagnosis confirmed		
4/1/98	Melanoma metastasized to right axilla with lymph node involvement (per patient report)	Slides	Pend.
4/15/98	CT scan brain, chest, abdomen, and pelvis: no evidence of metastasis (per patient report)	Films	Pend.
4/1/98	Surgery: lymph nodes: 1 of 15 nodes positive for malignancy		
year '99	melatonin 3mg qd; MVI qd; antioxidant qd; green tea; ginseng; vegetarian diet; selenium; milk thistle; pancreatic enzymes		
year '99	Clinical trial: vacinia melanoma cell lysates(VMCL) (per patient report)		
8/1/99	Proprioceptive changes in left lower calf and foot (per patient report)		
8/1/99	MRI brain: diagnosed with cranial metastasis (per patient report)	Films	Pend.
9/10/99	Biopsy brain: revealed no evidence of malignancy (per patient report)		
1/00-present	Started Naltrexone 4.5mg		

Cancer Best-Case Series

Patient #2-22
Adenocarcinoma of the Endometrium With Extension into the Peritoneum

Case 2-22

The patient in case 2-22 is a 58-year-old female diagnosed in May 1998 with adenocarcinoma of the endometrium with extension into the peritoneum. She completed four cycles of chemotherapy with adriamycin, cytoxan, and cisplatin. After her initial round of chemotherapy, adriamycin was withheld due to an equivocal multigated radionuclide (MUGA) scan and a past history of pericarditis. A course of radiation was completed. A CT scan (1/22/99) after chemotherapy and radiation showed a decrease in the pelvic mass. In July 1999, she was diagnosed with a second primary malignancy, intraductal carcinoma of the right breast with negative axillary nodes. Subsequent CT scans of her thorax revealed bilateral pulmonary nodules consistent with metastatic disease. She was referred to a thoracic surgeon, but a biopsy was not performed because the procedure was felt to be too difficult. She initiated Naltrexone in January 2001. In March 2001, a CT scan showed fewer abdominal and intrathoracic nodules compared to 1/3/01. A subsequent CT scan in June 2001 revealed a further reduction in peritoneal carcinomatosis. Her oncologist continues to follow her with serial CT scans. Currently, she reports her overall condition over the past week as excellent.

Pathology

5/8/98	**Biopsy endometrium: pathology- adenocarcinoma, endometroid moderately to well-differentiated with 33% invasion of the myometrium: extension into peritoneum and left pelvic sidewall**
7/29/99	**Biopsy breast (right) pathology intraductal carcinoma well differentiated**

Imaging

10/30/98	**CT scan 2.5cm mass in lymph nodes on left side of pelvis (MD's notes only-no full report)**
1/22/99	**CT scan abdomen and pelvis: improvement in pelvic mass**
4/9/99	**CT scan abdomen and pelvis: improvement in pelvic mass**
5/10/00	**CT scan chest, abdomen, and pelvis: no abdominal or pelvic lesion. No evidence of metastatic disease. 1cm inguinal node unchanged**
8/2/00	**CT scan chest compared to 5/10/00 upper lobe anterior segment nodule 10mm; 3 new nodules 5mm left apex, 5mm lingula, 7mm right middle lobe. Progression of metastatic disease**
9/29/00	**CT scan chest: no adenopathy (mediastinal)-multiple small nodules; no change c/w 8/2/00**
11/9/00	**CT scan chest, abdomen, and pelvis: bilateral pulmonary nodules some cavitated. New peritoneal carcinomatosis**
3/14/01	**CT scan chest, abdomen, and pelvis: compared to 1/3/01; abdominal and intrathoracic nodules decrease in number**
6/11/01	**CT scan chest, abdomen, and pelvis: compared to 3/14/01; no new adenopathy, interval decrease in peritoneal carcinomatosis. Small superior mediastinal lymph node unchanged**

Conventional therapy

7/15/98-9/24/98	**Chemotherapy: cisplatin and AC; adriamycin held due to equivocal MUGA scan; four cycles**
11/9/98-12/24/98	**Radiation: 5400 cGy to para-aortic lymph nodes; CT scan on 1/22/99 showed improvement of pelvic mass**
9/1/1999	**Surgery: lumpectomy with sentinel node dissection: 1.7cm with clear margins and lymph nodes: ER + PR positive**

Complementary therapy

1/9/01	**Naltrexone 4.5mg daily**

Patient # 2-22						
EVENT	**PERIOD 1** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 2** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 3** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 4** **1st qtr 2001 – 4th qtr 2001**		
Diagnosis/biopsy	**5/98**	**7/99**				
Surgery		**9/99**				
Radiation	**11/98-12/98**					
Chemotherapy	**7/98 9/98**					
Naltrexone				**1/01**		
CAM other						
Imaging CXR						
Imaging tomogram						
Imaging CT scan	**10/98**	**1/99 4/99**	**5/00 8/00. 9/00 11/00**	**3/01 6/01**		

CAM Therapy:	Naltrexone		
Case:	2-22		
Condition:	Adenocarcinoma of endometrium stage III and right breast intraductal carcinoma		
Abstractor:	AC	**Date of Abstraction:**	11/13/01
Interviewer:	IDC	**Date of Interview:**	12/12/01
Comments:			

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	4/6/43
Diagnosis:	adenocarcinoma of endometrium stage III and right breast intraductal carcinoma
Diagnosis date:	5/8/98 adenocarcinoma of endometrium 9/99 breast intraductal carcinoma
CAM therapy dates:	1/9/01 Naltrexone
Conventional therapy dates:	Chemotherapy: 7/15/1998-9/24/98 Radiation: 11/9/98-12/24/98
Last contact date:	
If deceased, date of death:	

Date	Description of Events	Requested	Status of Requests
5/8/98	Biopsy endometrium: pathology- adenocarcinoma, endometroid moderately to well-differentiated with 33% invasion of the myometrium: extension into peritoneum and left pelvic sidewall	Slides	Pend.
7/15/98-9/24/98	Chemotherapy: cisplatin and AC; adriamycin held due to equivocal MUGA scan		
10/30/98	CT scan 2.5cm mass in lymph nodes on on left side of pelvis (MD's notes only--no full report)	Films	Pend.
11/9/98-12/24/98	Radiation: 5400 cGy to para-artic lymph nodes; CT scan on 1/22/99 showed improvement of pelvic mass		
1/22/99	CT scan abdomen and pelvis: improvement in pelvic mass	Films	Pend.
4/9/99	CT scan abdomen and pelvis: improvement in pelvic mass	Films	Pend.
7/29/99	Biopsy breast (right) pathology intraductal carcinoma well differentiated	Slides	Pend.
9/1/99	Surgery: lumpectomy with sentinel node dissection: 1.7cm with clear margins and lymph nodes: ER + PR positive		
5/10/00	CT scan chest, abdomen, and pelvis: no abdominal or pelvic lesion. No evidence of metastatic disease. 1cm inguinal node unchanged.	Films	Pend.
8/2/00	CT scan chest compared to 5/10/00 upper lobe anterior segment nodule 10mm; 3 new nodules 5mm left apex, 5mm lingula, 7mm right middle lobe. Progression of metastatic disease		
9/29/00	CT chest: no adenopathy (mediastinal)-multiple small nodules; no change c/w 8/2/00		
11/9/00	CT chest, abdomen, and pelvis: bilateral pulmonary nodules, some cavitated. New peritoneal carcinomatosis	Films	Pend.
1/9/01	Naltrexone 4.5mg daily		
3/14/01	CT scan chest, abdomen, and pelvis: compared to 1/3/01; abdominal and intrathoracic nodules decrease in number	Films	Pend.
6/11/01	CT scan chest, abdomen, and pelvis: compared to 3/14/01; no new adenopathy, interval decrease in peritoneal carcinomatosis. Small superior mediastinal lymph node unchanged	Films	Pend.

Chapter 4. Conclusions

With regard to the two best-case series, our review supports the following conclusions:

- The IAT cases provide sufficient indications for the recommendation that IAT warrants further study.

- The Naltrexone cases provide insufficient indications to determine the likely benefit for Naltrexone at this time.

For IAT, this review suggests there is sufficient evidence to recommend that a random controlled trial could be considered. For Naltrexone, a prospective cohort case series should be considered.

Limitations of the Study

This study suffers from several limitations. First, as noted earlier, a best-case series is inherently a weak form of evidence to draw conclusions about a cause-and-effect relationship. Secondly, we encountered several difficulties trying to establish a best-case series. While the cooperation of the two clinics and patients was excellent, problems we encountered include the following:

1. *The quality of the records.* Because the study involved retrospective analysis of existing patient files, the records were not constructed with the view that they would be used for research studies. They were frequently incomplete and, as shown by the patient interview, on occasion incorrect. In many instances, the research team was unable to abstract the needed information from the files.

2. *Confirmation.* An essential component of the NCI best-case series is confirmation, both pathological and/or visual, of the diagnosis, the history of the cancer, and the outcomes. Most patients were willing to give consent for us to obtain the necessary information (pathological tissue samples, slides, x-rays, etc.), and the institutions were willing to deliver it. However, for the most part, these crucial pieces of evidence no longer existed. While long-term survival is an important outcome, it complicates the collection of data because most institutions do not keep pathological tissue and/or radiographic films beyond five years.

3. *Documentation of treatment*. Many of the patients experienced a long period of various conventional treatments, and a smaller group of patients underwent a variety of CAM therapies. When the treatment chronology cannot be clearly documented and/or confirmed by the patient, it becomes impossible to attribute an outcome to any particular therapy. An additional problem is that once the CAM therapy starts, the documentation of other (usually conventional) care largely ceases. Furthermore, the CAM therapy itself is often not clearly documented.

4. *Self-selection.* Individuals who choose to attend a CAM clinic do so through a self-selection process. Related to this issue is the potential role of patients' belief systems in the healing process.

5. *Multi-care*. The patients whose cases we reviewed tended to use multiple treatment methods. In addition to receiving a CAM therapy, most had also received conventional care (although in some instances they had refused such care). Frequently, the patients had also employed a range of alternative therapies. In these cases, pinpointing the therapy that might have led to a particular outcome is impossible.

Chapter 5. Future Research

This review was based on the assumption that a proactive approach to creating a best-case series might be more productive than relying on practitioners to create their own best-case series. While our work demonstrates that a best-case series can be constructed for CAM therapy, it also demonstrates that to do so requires considerable resources, time, and effort. Assembling documentary evidence through retrospective case analysis is difficult, even with a trained research staff. For a CAM provider without a trained research staff, such an undertaking is probably not feasible. An alternative approach might be to establish a prospective case series where the protocol for treatment and the documentation can be established prior to the treatment.

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Appendixes

Appendix A:
CANCER - Best-Case Series Abstraction Form

Appendix A: CANCER - Best-Case Series Abstraction Form

Patient's ID Code: _____

Case # _____

Description: _____

_____

_____

CRITERIA FOR INCLUSION (check all that apply)	
1.	Diagnosis – Histological/pathology report (i.e., biopsy)
2.	Documented start point for CAM therapy
	If not 1 AND 2, then stop
3.	Documented previous anti-cancer therapies
4.	Exclusive CAM treatment: No other therapies used during CAM treatment
5.	Documented endpoint (tumor size, longevity, etc.) (check all that apply)
	Tumor size
	Longevity
	Other: _____
	Improved Quality of Life

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

A. TEAR SHEET

6. Patient’s ID Code: _____

7. Date abstracted: _____/_____/_____
   mm dd yyyy

8. Patient’s Medical Record #: _____

9. Patient’s Social Security #: _____-_____-_____

10 Patient’s Name:

(Last)_____ (First)_____ (MI)____

11. Patient’s Date of Birth: _____/_____/_____
    mm dd yyyy

Patient's ID Code: _____

B. IDENTIFICATION DATA

12. Patient's ID Code: _____

13. Site Code: _____

14. Practitioner Code: _____

15. Abstractor Code: _____

C. PATIENT CHARACTERISTICS

16. Date of Birth: _____/_____/_____
mm dd yyyy
(If date of birth is missing, give the patient's age at the time of the first visit and date of first visit, if available.)

_____

_____

17. Race/Ethnicity: (check all that apply)

American Indian/Alaskan Native ..... ☐
Asian/Pacific Islander ..... ☐
Black, not Hispanic ..... ☐
Hispanic ..... ☐
White, not Hispanic ..... ☐
Other (specify: _____) ..... ☐
Other (specify: _____) ..... ☐
Other (specify: _____) ..... ☐
No data ..... ☐

18. Sex: M / F / No Data (circle one)

19. Marital status: Married / Not married / No data (circle one)

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

D. PAST MEDICAL HISTORY

20. **Concurrent medical problems (comorbidities):** _____

_____

_____

_____

21. Previous cancer history? Y / N / No Data

22. If yes, when? _____

23. Diagnosis: _____

Treatment: _____

_____

_____

24. **Medications administered concurrently?** Y / N / No Data *(if yes, list)*

	Start Date mm / dd / yyyy	End Date mm / dd / yyyy	Name	Regimen
A	___/___/____	___/___/____		
B	___/___/____	___/___/____		
C	___/___/____	___/___/____		
D	___/___/____	___/___/____		
E	___/___/____	___/___/____		
F	___/___/____	___/___/____		
G	___/___/____	___/___/____		
H	___/___/____	___/___/____		

Patient's ID Code: _____

E. CANCER HISTORY

25.	**Primary malignancy**: _____ (First histological confirmation)
26.	Date of first diagnosis of cancer: _____/_____/_____ mm dd yyyy
27.	Primary site biopsy proven? Y / N / No Data
28.	Original site of tumor location: _____
29.	Slide available? Y / N / No Data
30.	Type: _____
31.	Stage: _____
32.	Grade:
33.	**Other primary malignancies?** Y / N / No Data *(if no or no data, go to 54)*
34.	Date of diagnosis of cancer: _____/_____/_____ mm dd yyyy
35.	Primary site biopsy proven? Y / N / No Data
36.	Original site of tumor location: _____
37.	Type: _____
38.	Stage: _____
39.	Grade:
40.	**Other primary malignancies?** Y / N / No Data
41.	Date of diagnosis of cancer: _____/_____/_____ mm dd yyyy
42.	Primary site biopsy proven? Y / N / No Data
43.	Original site of tumor location: _____
44.	Type: _____
45.	Stage: _____
46.	Grade:

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

E. CANCER HISTORY (cont'd)

47. **Other primary malignancies?** Y / N / No Data

48. Date of diagnosis of cancer: _____/_____/_____ (mm dd yyyy)

49. Primary site biopsy proven? Y / N / No Data

50. Original site of tumor location: _____

51. Type: _____

52. Stage: _____

53. Grade:

54. **Family history of cancer?** Y / N / No Data

55. If yes, document family member(s), type of cancer, outcome: _____

_____

_____

56. Carcinogen exposure? Y / N / No Data

57. If yes, what kind? Smoking Job exposure Other:_____

58. **Metastases?** Y / N / No Data *(if no or no data, go to #62)*

59. Date of first metastatic diagnosis: _____/_____/_____ (mm dd yyyy)

60. How was the diagnosis of metastatic disease made? (check all that apply)

Biopsy Imaging Other:_____

61. Site(s) of first metastases: _____

_____

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

E. CANCER HISTORY (cont'd)

62. Has **remission** from the primary malignancy occurred? Y / N / No Data

63. If yes, how documented? _____

64. If no, response to conventional therapy? _____

65. Has there been recurrence of cancer? Y / N / No Data *(if no or no data, go to #69)*

66. Date of recurrence: _____/_____/_____
mm dd yyyy

67 How was the recurrence proven? (check all that apply)

Biopsy Imaging Other:_____

68. Site(s) of recurrence: _____

Pathology

69. Pathology report included: Y / N / No Data

70. Pathology report discussed, not included: Y / N / No Data

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

E. CANCER HISTORY (cont'd)

71. **Biopsy Table**

	Site	Date (mm/dd/yyy)	Method	Tissue Type	Markers
A					
	Final Pathology:				
B					
	Final Pathology:				
C					
	Final Pathology:				
D					
	Final Pathology:				
E					
	Final Pathology:				
F					
	Final Pathology:				
G					
	Final Pathology:				

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

F. PRIOR CONVENTIONAL TREATMENT

72. **Surgeries?** Y / N / No Data *(if no or no data, go to #85)* *(copy this sheet for additional dates)*

73. Procedure: _____

74. Intent of surgery: Cure Palliative Other:_____

75. Date of surgery: _____/_____/_____
mm dd yyyy

76. Results: _____

_____

77. Procedure: _____

78. Intent of surgery: Cure Palliative Other:_____

79. Date of surgery: _____/_____/_____
mm dd yyyy

80. Results: _____

_____

81. Procedure: _____

82. Intent of surgery: Cure Palliative Other:_____

83. Date of surgery: _____/_____/_____
mm dd yyyy

84. Results: _____

_____

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

85. **Chemotherapy**? Y / N / No Data *(if no or no data, go to 86)*	Drug	Dose	Start/end dates (mm/dd/yyyy)	# of cycles	Results	(check all that apply) Complications/Reasons for discontinuation
Regimen A					Course: Completed 1, Stopped early 2; Tumor response: Yes 1, No 2	Adverse reaction, Patient preference, Toxicity, Ineffective, Other: _____
Cycle:					Course: Completed 1, Stopped early 2; Tumor response: Yes 1, No 2	Adverse reaction, Patient preference, Toxicity, Ineffective, Other: _____
Regimen B					Course: Completed 1, Stopped early 2; Tumor response: Yes 1, No 2	Adverse reaction, Patient preference, Toxicity, Ineffective, Other: _____
Cycle:					Course: Completed 1, Stopped early 2; Tumor response: Yes 1, No 2	Adverse reaction, Patient preference, Toxicity, Ineffective, Other: _____
Regimen C					Course: Completed 1, Stopped early 2; Tumor response: Yes 1, No 2	Adverse reaction, Patient preference, Toxicity, Ineffective, Other: _____
Cycle:					Course: Completed 1, Stopped early 2; Tumor response: Yes 1, No 2	Adverse reaction, Patient preference, Toxicity, Ineffective, Other: _____

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

F. PRIOR CONVENTIONAL TREATMENT (cont'd)

86. **Radiation?** Y / N / No Data *(if no or no data, go to #102)*

87. Dates of radiation: _____/_____/_____ (mm dd yyyy Initiated) _____/_____/_____ (mm dd yyyy Completed)

88. Intent of radiation: Cure Palliative Other:_____

89. Area(s) radiated: _____

90. Total RADS: _____

91. Results of radiation therapy: _____

_____

92. Adverse effects? Y / N No Data If yes, explain: _____

: _____

93. Discontinue radiation early? Y / N / No Data If Yes, reason: _____

94. **Additional Radiation?** Y / N / No Data

95. Dates of radiation: _____/_____/_____ (mm dd yyyy Initiated) _____/_____/_____ (mm dd yyyy Completed)

96. Intent of radiation: Cure Palliative Other:_____

97. Area(s) radiated: _____

98. Total RADS: _____

99. Results of radiation therapy: _____

_____

100. Adverse effects? Y / N No Data If yes, explain: _____

: _____

101. Discontinue radiation early? Y / N / No Data If Yes, reason: _____

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

F. PRIOR CONVENTIONAL TREATMENT (cont'd)

102. **Other conventional therapies?** Y / N / No Data *(if no or no data, go to #114)*

103. Bone marrow transplant? Y / N / No Data _____/_____/_____ (mm dd yyyy)

104. Result: _____

_____

105. Hormonal cancer agents? Y / N / No Data _____/_____/_____ (mm dd yyyy Initiated) _____/_____/_____ (mm dd yyyy Completed)

106. Type: _____

107. Regimen: _____

108. Other: _____ _____/_____/_____ (mm dd yyyy Initiated) _____/_____/_____ (mm dd yyyy Completed)

109. Regime /outcome: _____

110. Other: _____ _____/_____/_____ (mm dd yyyy Initiated) _____/_____/_____ (mm dd yyyy Completed)

111. Regime /outcome: _____

112. Other: _____ _____/_____/_____ (mm dd yyyy Initiated) _____/_____/_____ (mm dd yyyy Completed)

113. Regime /outcome: _____

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

G. Tracking of Cancer Progression

114. **Imaging procedures:**				
	Procedure	Date mm/dd/yyyy	Area	Result
A				
B				
C				
D				
E				
F				
G				
H				
I				
J				

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

G. Tracking of Cancer Progression (cont'd)

115. **Tumor markers**? Y / N / No Data
List type (CEA, CA-125, PSA, e.g.)

	Type	Date	Results		Type	Date	Results
A				N			
B				O			
C				P			
D				Q			
E				R			
F				S			
G				T			
H				U			
I				V			
J				W			
K				X			
L				Y			
M				Z			

Patient's ID Code: _____

H. COMPLEMENTARY / ALTERNATIVE THERAPIES

116. **Reason(s) for pursuing CAM cancer therapy**

Side-effects of conventional therapy

Failure of conventional therapy

Other: _____

No Data

117. Patient in Hospice care when beginning CAM? Y / N / No Data

CAM Therapy

118.	**Start Date** mm dd yyyy	**End Date** mm dd yyyy	**Therapy Type/ Protocol**
A	___/___/____	___/___/____	
B	___/___/____	___/___/____	
C	___/___/____	___/___/____	
D	___/___/____	___/___/____	
E	___/___/____	___/___/____	
F	___/___/____	___/___/____	
G	___/___/____	___/___/____	
H	___/___/____	___/___/____	
I	___/___/____	___/___/____	
J	___/___/____	___/___/____	

Patient's ID Code: _____

H. COMPLEMENTARY / ALTERNATIVE THERAPIES (cont'd)

119. **Other CAM therapies administered concurrently?** Y / N / No Data *(if yes, list)*

	Start Date mm / dd / yyyy	End Date mm / dd / yyyy	
A	___/___/____	___/___/____	
B	___/___/____	___/___/____	
C	___/___/____	___/___/____	
D	___/___/____	___/___/____	
E	___/___/____	___/___/____	
F	___/___/____	___/___/____	
G	___/___/____	___/___/____	
H	___/___/____	___/___/____	

Patient's ID Code: _____

H. COMPLEMENTARY / ALTERNATIVE THERAPIES (cont'd)

120.	**Documented toxicity, side-effects from CAM therapies/ interventions?**	Y / N / No Data *(if no or no data, go to #134)*

mm / dd / yyyy

121.	Lungs	Date first documented: ___/___/____	
122.	Cardiac	Date first documented: ___/___/____	
123.	Liver	Date first documented: ___/___/____	
124.	Renal	Date first documented: ___/___/____	
125.	Gastrointestinal	Date first documented: ___/___/____	
126.	Dermatological	Date first documented: ___/___/____	
127.	Endocrine	Date first documented: ___/___/____	
128.	Gynecological	Date first documented: ___/___/____	
129.	Bladder	Date first documented: ___/___/____	
130.	Neurological	Date first documented: ___/___/____	
131.	Other	Date first documented: ___/___/____	
132.	Other	Date first documented: ___/___/____	
133.	Other	Date first documented: ___/___/____	

Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: _____

I. DISPOSITION

134. **Is patient alive?** Y / N / No Data As of ____/____/_____
mm dd yyyy

135. If yes, current condition: _____

136. If no, cause of death: _____

137. Pathology reports from autopsy available? Y / N / No Data

138. Last contact with patient: ___/___/____

139. Quality of life measures available? Y / N / No Data

140. List: _____

Appendix B: Case Report Form

Appendix B: Case Report Form

CAM Therapy:			
Case:			
Condition:			
Abstractor:		**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:			

Criteria for inclusion: (check all that apply)			
	Diagnosis confirmed		
	Documented start date for CAM therapy		
	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevent Information:	
Sex:	
DOB:	
Diagnosis:	
Diagnosis date:	
CAM therapy dates:	
Conventional therapy dates:	
Last contact date:	
If deceased, date of death:	

Appendix B: Case Report Form (continued)

Code	Date	Date Imputed?	Dates verified?	Description of Event I

Appendix B: Case Report Form (continued)

Description of Event II	Event verified?	Retreive report?	Notes

Appendix C

IAT Patient Questionnaire
IAT Next-of-Kin Questionnaire
Naltrexone Patient Questionnaire
Naltrexone Next-of-Kin Questionnaire

PATIENT INTERVIEW FOR IMMUNOAUGMENTED THERAPY (IAT)

RA

1700 MAIN STREET
SANTA MONICA CA 90401

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT

PATIENT INTERVIEW SCHEDULE

TEAR SHEET (to be completed prior to the interview)

1. Patient's ID CODE: 01 _____

   Site: _____ Patient # _____

2. Patient's Name: _____ _____
   LAST NAME FIRST NAME

   Next-of-Kin Name: _____ _____
   LAST NAME FIRST NAME

3. STATE: _____

4. Consent Letter Received: _____ /_____ /_____

5. Doctor's Name and/ or Clinic for CAM: _____

6. Therapy Type: _____

7. Date Interviewed: _____/_____/_____ Interviewer: _____

8. Date Checked: _____/_____/_____ By: _____

9. Date Data Entered: _____/_____/_____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: (_____) _____-_____

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: _____

NOTES

_____

_____

_____

OUTCOME CODES

AM = Answering machine
BZ = Busy signal (phone, fax or modem)
CI = Completed interview
O = Other (describe)
PI = Partial interview
CB = Call back
DS = Disconnected
AP = Made an appointment
NA = No answer
WN = Wrong number
PP = Phone problem
RF = Refused

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

PATIENT INTERVIEW SCHEDULE

STRICTLY CONFIDENTIAL

The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of your physician. Its purpose is to obtain, as accurately as possible, information concerning the care that you received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.

THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.

All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess your therapy. You may stop the interview at any time.

The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?

Yes _____ No _____ If no, *May I ask you your reason for declining?*

_____

_____

Thank you for your assistance.

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

First, I would like to ask some background questions about you.

1. What is your birth date? _____ /_____ /_____
   If refused, enter REFUSED
   If don't know, enter DON'T KNOW

1a. What is your age? _____
   If refused, enter RF
   If don't know, enter DK

2. What is your sex?

	(Check one)
Male	_____ (1)
Female	_____ (2)

3. What is your marital status?

	(Check one)
Single	_____ (1)
Married	_____ (2)
Divorced	_____ (3)
Widowed	_____ (4)
Refused	_____ (7)
Don't know	_____ (9)

4. What is your highest level of education?

	(Check one)
Grade school	_____ (1)
High school	_____ (2)
Some college	_____ (3)
College degree	_____ (4)
Graduate degree	_____ (5)
Refused	_____ (7)
Don't know	_____ (9)

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

5. What is your ethnic origin? (Check all that apply)

Caucasian	_____ (1)
Black/African American	_____ (2)
Hispanic/Latino	_____ (3)
Asian/Pacific islander	_____ (4)
Other	_____ (5) Please could you specify: _____
Refused	_____ (7)
Don't know	_____ (9)

6. What type of health insurance do you have? (Check all that apply)

HMO	_____ (1)
PPO	_____ (2)
Fee for Service	_____ (3)
None	_____ (4)
Other	_____ (5) Please could you specify: _____
Refused	_____ (7)
Don't know	_____ (9)

7. What insurance coverage did you have for Immunoaugmentation Therapy?

HMO	_____ (1)
PPO	_____ (2)
Fee for Service	_____ (3)
None	_____ (4)
Other	_____ (5) Please could you specify: _____
Refused	_____ (7)
Don't know	_____ (9)

8. What is your current or most recent occupation? (ENTER VERBATIM)

_____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

SECTION B. HEALTH STATUS

We would like to begin by asking about your current health.

		No	Yes	RF	DK
9.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	7	9
10.	Do you have any trouble taking a long walk?	1	2	7	9
11.	Do you have any trouble taking a short walk outside of the house?	1	2	7	9
12.	Do you have to stay in a bed or a chair for most of the day?	1	2	7	9
13.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	7	9
14.	Are you limited in any way in doing either your work or doing household jobs?	1	2	7	9
15.	Are you completely unable to work at a job or do household jobs?	1	2	7	9

During the past week, have any of these things happened to you not at all, a little, quite a bit, or very much?

		Not at all	A little	Quite a bit	Very much	RF	DK
16.	Were you short of breath?	1	2	3	4	7	9
17.	Have you had pain?	1	2	3	4	7	9
18.	Did you need to rest?	1	2	3	4	7	9
19.	Have you had trouble sleeping?	1	2	3	4	7	9
20.	Have you felt weak?	1	2	3	4	7	9
21.	Have you lacked appetite?	1	2	3	4	7	9

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

(continued)		Not at all	A little	Quite a bit	Very much	RF	DK
22.	Have you felt nauseated?	1	2	3	4	7	9
23.	Have you vomited?	1	2	3	4	7	9
24.	Have you been constipated?	1	2	3	4	7	9
25.	Have you had diarrhea?	1	2	3	4	7	9
26.	Were you tired?	1	2	3	4	7	9
27.	Did pain interfere with your daily activities?	1	2	3	4	7	9
28.	Have you had difficulty in concentrating on things like reading a newspaper or watching television?	1	2	3	4	7	9
29.	Did you feel tense?	1	2	3	4	7	9
30.	Did you worry?	1	2	3	4	7	9
31.	Did you feel irritable?	1	2	3	4	7	9
32.	Did you feel depressed?	1	2	3	4	7	9
33.	Have you had difficulty remembering things?	1	2	3	4	7	9
34.	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4	7	9
35.	Has you physical condition or medical treatment interfered with your social activities?	1	2	3	4	7	9
36.	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4	7	9

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

For the following questions, on a scale of 1 to 7, where 1 is "Very Poor" and 7 is "Excellent" please tell me the number between 1 and 7 that best applies to you.

37. How would you rate your overall physical condition during the past week?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

38. How would you rate your overall quality of life during the past week?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

SECTION C. Immunoaugmentation Therapy (IAT)

I would now like to ask you some questions about your Immunoaugmentation (IAT) treatment.

39. How did you learn about the Immune Augmentation Therapy center? (Check all that apply)

	(Check)	
Physician	____	(If checked, record the following) Can you tell me that person's name?_____ Is this person your primary care physician or a specialist or both? (CHECK ALL THAT APPLY) Primary Care ____ Specialist ____ What type of specialist are they?_____ Refused ____ Don't know ____ Is this person a Complementary/Alternative Provider? Yes ____ No ____ Refused ____ Don't know ____
CAM provider, not a physician	____	Can you tell me that person's name? _____ Do you know what is their specialty? _____
Another patient of the clinic	____	
Friend / Family Member / Co-Worker who is not a patient of this clinic	____	
Friend or relative of Doctor at the clinic	____	
Local newspaper, radio, or TV	____	
Advertisement	____	Where did you see or hear the advertisement? _____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

Question 39 continued…	*(Check)*	
Other	____	Specify:_____
Refused	____	
Don't recall	____	

40. At the time you started IAT, had your medical doctor for cancer recommended you seek complementary/alternative treatment*?*

Yes ____
No ____
Refused ____
Don't know ____

41. Did you inform any of your medical doctors that you were using IAT?

Yes ____
No ____
Refused ____
Don't know ____

41a. (IF YES) Does that include your oncologist?

Yes ____
No ____
Refused ____
Don't know ____

42. Did the IAT clinic request medical records from your primary doctor?

Yes ____
No ____
Refused ____
Don't know ____

42a. (IF YES) Were the records obtained?

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

Yes ____
No ____
Refused ____
Don't know ____

43. Did you have other forms of complementary or alternative medicine for the treatment of the cancer?

Yes ____ What were they? _____
No ____
Refused ____
Don't know ____

44. Would you take IAT if you had the chance to begin your treatment over again?

Yes ____
No ____
Refused ____
Don't know ____

45. Was there any difference between how you felt with IAT care and your other care?

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did you choose IAT for treatment of your cancer? (Check all that apply)

___ Failure of another form of complementary/alternative medicine
___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Side effects of another form of complementary/alternative medicine
___ Philosophical congruence
___ Other, specify _____
___ None of the above (no reason)
___ Refused
___ Don't know

47. Did you use conventional therapy for your cancer?

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

47a. (IF NO) How come? (Check all that apply)

___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Philosophical reasons
___ Some other reason (specify) _____
___ None of the above (no reason)
___ Refused
___ Don't know

47b. (IF YES) Did you complete conventional therapy?

Yes ____
No ____
Refused ____
Don't know ____

47b. (IF COMPLETED) Was the following statement true:

"I completed conventional therapy, but was not cured"

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

48. What did you expect from your IAT treatment? (RECORD VERBATIM)

49. When you were being treated with IAT, did you tell your friends that an alternative medical practitioner was treating you?

Yes ____
No ____
Refused ____
Don't know ____

50. How far did you travel for IAT? (CHECK ONE)

5 miles or less ____
6-10 miles ____
11-20 miles ____
21-30 miles ____
over 30 miles ____
over 100 miles ____
over 500 miles ____
over 1000 miles ____
over 2000 miles ____
Refused ____
Don't know ____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

51. Do you have a family medical doctor?

Yes	____
No	____
Refused	____
Don't know	____

51a. If yes, how often do you see this doctor?

Yearly	____
Monthly	____
Weekly	____
Other	____ (specify) _____
Refused	____
Don't know	____

52. The last time you went to see your family medical doctor, how satisfied were you with the care you received? Were you… (READ RESPONSES AND CHECK ONE)

Extremely satisfied	____
Very satisfied	____
Satisfied	____
Somewhat satisfied	____
Not at all satisfied	____
(DON'T READ) Refused	____
(DON'T READ) Don't know	____

53. Did you rely primarily upon alternative medicine providers for all of your medical care?

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

Yes	____
No	____
Refused	____
Don't know	____

Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: _____

SECTION D: CONFIRMATION OF THE MEDICAL FILE

Now, I would like to confirm the information we obtained from your medical files that we sent to you prior to this conversation.

54. Did you receive the materials we sent?

Yes ____
No ____ Arrange to resend information and/or make appointment for another phone conversation

55. If you have the documents we sent you, can we review them with you now?

Yes ____
No ____

56. (IF NO) Would you like us to schedule another time to do it?

Yes ____
No ____

56a. (IF STILL NO) *May I ask your reason for declining?*

NEXT OF KIN INTERVIEW FOR IMMUNOAUGMENTED THERAPY (IAT)

RA

1700 MAIN STREET
SANTA MONICA CA 90401

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin

PATIENT INTERVIEW SCHEDULE

TEAR SHEET (to be completed prior to the interview)

1. Patient's ID CODE: 01 _____

   Site: _____ Patient # _____

2. Patient's Name: _____ _____
   LAST NAME FIRST NAME

   Next-of-Kin Name: _____ _____
   LAST NAME FIRST NAME

3. STATE: _____

4. Consent Letter Received: _____ /_____ /_____

5. Doctor's Name and/ or Clinic for CAM: _____

6. Therapy Type: _____

7. Date Interviewed: _____/_____/_____ Interviewer: _____

8. Date Checked: _____/_____/_____ By: _____

9. Date Data Entered: _____/_____/_____

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: (_____) _____-_____

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: _____

NOTES

_____

_____

_____

OUTCOME CODES

AM = Answering machine
BZ = Busy signal (phone, fax or modem)
CI = Completed interview
O = Other (describe)
PI = Partial interview
CB = Call back
DS = Disconnected
AP = Made an appointment
NA = No answer
WN = Wrong number
PP = Phone problem
RF = Refused

PATIENT INTERVIEW SCHEDULE

STRICTLY CONFIDENTIAL

The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of the patient's physician. Its purpose is to obtain, as accurately as possible, information concerning the care that (PATIENT) received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.

THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.

All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you or (PATIENT) from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess the therapy. You may stop the interview at any time.

The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?

Yes _____ No _____ If no, *May I ask you your reason for declining?*

_____

_____

Thank you for your assistance.

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

SECTION X: RELATIONSHIP

What was (PATIENT'S) relationship to you? (CHECK ONE)

Spouse ____
Mother ____
Father ____
Son ____
Daughter ____
Brother ____
Sister ____
Other ____ (SPECIFY:_____)

We realize that you may not be able to answer many of the questions we will ask about (PATIENT). We appreciate your help in answering what you can.

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

First, I would like to ask some background questions about (PATIENT).

1. What was their birth date? _____ /_____ /_____
   If refused, enter REFUSED
   If don't know, enter DON'T KNOW

1a. What was their age? _____
   If refused, enter RF
   If don't know, enter DK

2. What was their sex?

	(Check one)
Male	_____ (1)
Female	_____ (2)

3. What was their marital status?

	(Check one)
Single	_____ (1)
Married	_____ (2)
Divorced	_____ (3)
Widowed	_____ (4)
Refused	_____ (7)
Don't know	_____ (9)

4. What was their highest level of education?

	(Check one)
Grade school	_____ (1)
High school	_____ (2)
Some college	_____ (3)
College degree	_____ (4)
Graduate degree	_____ (5)
Refused	_____ (7)
Don't know	_____ (9)

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

5. What was their ethnic origin? (Check all that apply)

Caucasian _____
Black/African American _____
Hispanic/Latino _____
Asian/Pacific islander _____
Other _____ Please could you specify: _____
Refused _____
Don't know _____

6. What type of health insurance did they have? (Check all that apply)

HMO _____
PPO _____
Fee for Service _____
None _____
Other _____ Please could you specify: _____
Refused _____
Don't know _____

7. What insurance coverage did they have for Immunoaugmentation Therapy? (Check all that apply)

HMO _____
PPO _____
Fee for Service _____
None _____
Other _____ Please could you specify: _____
Refused _____
Don't know _____

8. What was their most recent occupation? (ENTER VERBATIM)

_____

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

SECTION B. HEALTH STATUS

During the time (PATIENT) was being treated with IAT, how would you rate their health? For the following two questions, on a scale of 1 to 7, where 1 is "Very Poor" and 7 is "Excellent" please tell me the number between 1 and 7 that best applied them.

37. How would you rate their overall physical condition during that time?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

38. How would you rate their overall quality of life during that time?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

SECTION C. Immunoaugmentation Therapy (IAT)

I would now like to ask you some questions about the Immunoaugmentation (IAT) treatment.

39. How did {PATIENT} learn about the Immune Augmentation Therapy center? (Check all that apply)

	(Check)	
Physician	____	(If checked, record the following) Can you tell me that person's name?_____ Was this person their primary care physician or a specialist or both? Primary Care ____ Specialist ____ What type of specialist are they?_____ Refused ____ Don't know ____ Is this person a Complementary/Alternative Provider? Yes ____ No ____ Refused ____ Don't know ____
CAM provider, not a physician	____	Can you tell me that person's name? _____ Do you know what is their specialty? _____
Another patient of the clinic	____	
Friend / Family Member / Co-Worker who is not a patient of this clinic	____	
Friend or relative of Doctor at the clinic	____	
Local newspaper, radio, or TV	____	
Advertisement	____	Where did they see or hear the advertisement? _____

Question 39 continued	(Check)	
Other	____	Specify:_____
Refused	____	
Don't recall	____	

40. At the time (PATIENT) started IAT, had their medical doctor for cancer recommended they seek complementary /alternative treatment*?*

Yes ____
No ____
Refused ____
Don't know ____

41. Did they inform any of their medical doctors that they were using IAT?

Yes ____
No ____
Refused ____
Don't know ____

41a. (IF YES) Does that include their oncologist?

Yes ____
No ____
Refused ____
Don't know ____

42. Did the IAT clinic request medical records from their primary doctor?

Yes ____
No ____
Refused ____
Don't know ____

42a. (IF YES) Were the records obtained?

Yes ____

No ____
Refused ____
Don't know ____

43. Did they have other forms of complementary or alternative medicine for the treatment of the cancer*?*

Yes ____ What were they? _____
No ____
Refused ____
Don't know ____

44. Would you recommend IAT to someone else?

Yes ____
No ____
Refused ____
Don't know ____

45. Was there any difference between how they felt with IAT care and their other care?

Yes ____
No ____
Refused ____
Don't know ____

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did they choose IAT for treatment of their cancer? (Check all that apply)

___ Failure of another form of complementary/alternative medicine
___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Side effects of another form of complementary/alternative medicine
___ Philosophical congruence
___ Other, specify _____
___ None of the above (no reason)
___ Refused
___ Don't know

47. Did they use conventional therapy for the cancer?

Yes ____
No ____
Refused ____
Don't know ____

47a. (IF NO) How come? (Check all that apply)

___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Philosophical reasons
___ Some other reason (specify) _____
___ None of the above (no reason)
___ Refused
___ Don't know

47b. (IF YES) Did they complete conventional therapy?

Yes ____
No ____
Refused ____
Don't know ____

47b. (IF COMPLETED) Was the following statement true:

"(PATIENT) completed conventional therapy, but was not cured"

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

48. What did they expect from their IAT treatment? (RECORD VERBATIM)

49. When (PATIENT) was being treated with IAT, did they tell their friends that an alternative medical practitioner was treating them?

Yes ____
No ____
Refused ____
Don't know ____

50. How far did they travel for IAT? (CHECK ONE)

5 miles or less ____
6-10 miles ____
11-20 miles ____
21-30 miles ____
over 30 miles ____
over 100 miles ____
over 500 miles ____
over 1000 miles ____
over 2000 miles ____
Refused ____
Don't know ____

51. Did they have a family medical doctor?

Yes ____
No ____
Refused ____
Don't know ____

51a. If yes, how often do they see this doctor?

Yearly ____
Monthly ____
Weekly ____
Other ____ (specify) _____
Refused ____
Don't know ____

52. Were they satisfied with the care they received from the family medical doctor? Were they… (READ RESPONSES AND CHECK ONE)

Extremely satisfied ____
Very satisfied ____
Satisfied ____
Somewhat satisfied ____
Not at all satisfied ____

(DON'T READ) Refused ____
(DON'T READ) Don't know ____

53. Did (PATIENT) rely primarily upon alternative medicine providers for all of their medical care?

Yes	____
No	____
Refused	____
Don't know	____

Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

SECTION D: **CONFIRMATION OF THE MEDICAL FILE**

Now, I would like to confirm the information we obtained from (PATIENT'S) medical files that we sent to you prior to this conversation. Again, we realize you may not be able to confirm much of this, but it would help us if you can.

54. Did you receive the materials we sent?

Yes ____
No ____ Arrange to resend information and/or make appointment for another phone conversation

55. If you have the documents we sent you, can we review them with you now?

Yes ____
No ____

56. (IF NO) Would you like us to schedule another time to do it?

Yes ____
No ____

56a. (IF STILL NO) *May I ask your reason for declining?*

PATIENT INTERVIEW FOR NALTREXONE THERAPY

RA

1700 MAIN STREET
SANTA MONICA CA 90401

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy

PATIENT INTERVIEW SCHEDULE

TEAR SHEET (to be completed prior to the interview)

1. Patient's ID CODE: 01 _____

   Site: _____ Patient # _____

2. Patient's Name: _____ _____
   LAST NAME FIRST NAME

   Next-of-Kin Name: _____ _____
   LAST NAME FIRST NAME

3. STATE: _____

4. Consent Letter Received: _____ /_____ /_____

5. Doctor's Name and/ or Clinic for CAM: _____

6. Therapy Type: _____

7. Date Interviewed: _____/_____/_____ Interviewer: _____

8. Date Checked: _____/_____/_____ By: _____

9. Date Data Entered: _____/_____/_____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: (_____) _____-_____

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: _____

NOTES

_____

_____

_____

OUTCOME CODES

AM = Answering machine
BZ = Busy signal (phone, fax or modem)
CI = Completed interview
O = Other (describe)
PI = Partial interview
CB = Call back
DS = Disconnected
AP = Made an appointment
NA = No answer
WN = Wrong number
PP = Phone problem
RF = Refused

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

PATIENT INTERVIEW SCHEDULE

STRICTLY CONFIDENTIAL

The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of your physician. Its purpose is to obtain, as accurately as possible, information concerning the care that you received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.

THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.

All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess your therapy. You may stop the interview at any time.

The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?

Yes _____ No _____ If no, *May I ask you your reason for declining?*

_____

_____

Thank you for your assistance.

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

First, I would like to ask some background questions about you.

1. What is your birth date? _____ /_____ /_____
   If refused, enter REFUSED
   If don't know, enter DON'T KNOW

1a. What is your age? _____
   If refused, enter RF
   If don't know, enter DK

2. What is your sex?

	(Check one)
Male	_____ (1)
Female	_____ (2)

3. What is your marital status?

	(Check one)
Single	_____ (1)
Married	_____ (2)
Divorced	_____ (3)
Widowed	_____ (4)
Refused	_____ (7)
Don't know	_____ (9)

4. What is your highest level of education?

	(Check one)
Grade school	_____ (1)
High school	_____ (2)
Some college	_____ (3)
College degree	_____ (4)
Graduate degree	_____ (5)
Refused	_____ (7)
Don't know	_____ (9)

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

5. What is your ethnic origin? (Check all that apply)

Caucasian	_____ (1)
Black/African American	_____ (2)
Hispanic/Latino	_____ (3)
Asian/Pacific islander	_____ (4)
Other	_____ (5) Please could you specify: _____
Refused	_____ (7)
Don't know	_____ (9)

6. What type of health insurance do you have? (Check all that apply)

HMO	_____ (1)
PPO	_____ (2)
Fee for Service	_____ (3)
None	_____ (4)
Other	_____ (5) Please could you specify: _____
Refused	_____ (7)
Don't know	_____ (9)

7. What insurance coverage did you have for Naltrexone therapy?

HMO	_____ (1)
PPO	_____ (2)
Fee for Service	_____ (3)
None	_____ (4)
Other	_____ (5) Please could you specify: _____
Refused	_____ (7)
Don't know	_____ (9)

8. What is your current or most recent occupation? (ENTER VERBATIM)

_____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

SECTION B. HEALTH STATUS

We would like to begin by asking about your current health.

		No	Yes	RF	DK
9.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	7	9
10.	Do you have any trouble taking a long walk?	1	2	7	9
11.	Do you have any trouble taking a short walk outside of the house?	1	2	7	9
12.	Do you have to stay in a bed or a chair for most of the day?	1	2	7	9
13.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	7	9
14.	Are you limited in any way in doing either your work or doing household jobs?	1	2	7	9
15.	Are you completely unable to work at a job or do household jobs?	1	2	7	9

During the past week, have any of these things happened to you not at all, a little, quite a bit, or very much?

		Not at all	A little	Quite a bit	Very much	RF	DK
16.	Were you short of breath?	1	2	3	4	7	9
17.	Have you had pain?	1	2	3	4	7	9
18.	Did you need to rest?	1	2	3	4	7	9
19.	Have you had trouble sleeping?	1	2	3	4	7	9
20.	Have you felt weak?	1	2	3	4	7	9
21.	Have you lacked appetite?	1	2	3	4	7	9

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

(continued)		Not at all	A little	Quite a bit	Very much	RF	DK
22.	Have you felt nauseated?	1	2	3	4	7	9
23.	Have you vomited?	1	2	3	4	7	9
24.	Have you been constipated?	1	2	3	4	7	9
25.	Have you had diarrhea?	1	2	3	4	7	9
26.	Were you tired?	1	2	3	4	7	9
27.	Did pain interfere with your daily activities?	1	2	3	4	7	9
28.	Have you had difficulty in concentrating on things like reading a newspaper or watching television?	1	2	3	4	7	9
29.	Did you feel tense?	1	2	3	4	7	9
30.	Did you worry?	1	2	3	4	7	9
31.	Did you feel irritable?	1	2	3	4	7	9
32.	Did you feel depressed?	1	2	3	4	7	9
33.	Have you had difficulty remembering things?	1	2	3	4	7	9
34.	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4	7	9
35.	Has you physical condition or medical treatment interfered with your social activities?	1	2	3	4	7	9
36.	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4	7	9

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

For the following questions, on a scale of 1 to 7, where 1 is "Very Poor" and 7 is "Excellent" please tell me the number between 1 and 7 that best applies to you.

37. How would you rate your overall physical condition during the past week?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

38. How would you rate your overall quality of life during the past week?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

SECTION C. Naltrexone Therapy

I would now like to ask you some questions about your Naltrexone Therapy.

39. How did you learn about Naltrexone Therapy and Dr. Bihari's clinic? (Check all that apply)

	(Check)	
Physician	____	(If checked, record the following) Can you tell me that person's name?_____ Is this person your primary care physician or a specialist or both? (CHECK ALL THAT APPLY) Primary Care ____ Specialist ____ What type of specialist are they?_____ Refused ____ Don't know ____ Is this person a Complementary/Alternative Provider? Yes ____ No ____ Refused ____ Don't know ____
CAM provider, not a physician	____	Can you tell me that person's name? _____ Do you know what is their specialty? _____
Another patient of the clinic	____	
Friend / Family Member / Co-Worker who is not a patient of this clinic	____	
Friend or relative of Doctor at the clinic	____	
Local newspaper, radio, or TV	____	

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

Advertisement	____	Where did you see or hear the advertisement? _____
Question 39 continued…	*(Check)*	
Other	____	Specify:_____
Refused	____	
Don't recall	____	

40. At the time you started Naltrexone therapy, had your medical doctor for cancer recommended you seek complementary/alternative treatment*?*

Yes ____
No ____
Refused ____
Don't know ____

41. Did you inform any of your medical doctors that you were using Naltrexone therapy?

Yes ____
No ____
Refused ____
Don't know ____

41a. (IF YES) Does that include your oncologist?

Yes ____
No ____
Refused ____
Don't know ____

42. Did Dr. Bihari's clinic request medical records from your primary doctor?

Yes ____
No ____
Refused ____
Don't know ____

PT ID#: _____

42a. (IF YES) Were the records obtained?

Yes ____
No ____
Refused ____
Don't know ____

43. Did you have other forms of complementary or alternative medicine for the treatment of the cancer?

Yes ____ What were they? _____
No ____
Refused ____
Don't know ____

44. Would you use Naltrexone therapy if you had the chance to begin your treatment over again?

Yes ____
No ____
Refused ____
Don't know ____

45. Was there any difference between how you felt with Naltrexone therapy and your other care?

Yes ____
No ____
Refused ____
Don't know ____

PT ID#: _____

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did you choose Naltrexone therapy for treatment of your cancer? (Check all that apply)

___ Failure of another form of complementary/alternative medicine
___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Side effects of another form of complementary/alternative medicine
___ Philosophical congruence
___ Other, specify _____
___ None of the above (no reason)
___ Refused
___ Don't know

47. Did you use conventional therapy for your cancer?

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

47a. (IF NO) How come? (Check all that apply)

___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Philosophical reasons
___ Some other reason (specify) _____
___ None of the above (no reason)
___ Refused
___ Don't know

47b. (IF YES) Did you complete conventional therapy?

Yes ____
No ____
Refused ____
Don't know ____

47b. (IF COMPLETED) Was the following statement true:

"I completed conventional therapy, but was not cured"

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

48. What did you expect from your Naltrexone therapy? (RECORD VERBATIM)

49. When you were being treated by Dr. Bihari, did you tell your friends that an alternative medical practitioner was treating you?

Yes ____
No ____
Refused ____
Don't know ____

50. How far did you travel to go to Dr. Bihari's clinic? (CHECK ONE)

5 miles or less ____
6-10 miles ____
11-20 miles ____
21-30 miles ____
over 30 miles ____
over 100 miles ____
over 500 miles ____
over 1000 miles ____
over 2000 miles ____
Refused ____
Don't know ____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

51. Do you have a family medical doctor?

Yes	____
No	____
Refused	____
Don't know	____

51a. If yes, how often do you see this doctor?

Yearly	____
Monthly	____
Weekly	____
Other	____ (specify) _____
Refused	____
Don't know	____

52. The last time you went to see your family medical doctor, how satisfied were you with the care you received? Were you… (READ RESPONSES AND CHECK ONE)

Extremely satisfied	____
Very satisfied	____
Satisfied	____
Somewhat satisfied	____
Not at all satisfied	____
(DON'T READ) Refused	____
(DON'T READ) Don't know	____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

53. Did you rely primarily upon alternative medicine providers for all of your medical care?

Yes	____
No	____
Refused	____
Don't know	____

Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: _____

SECTION D: **CONFIRMATION OF THE MEDICAL FILE**

Now, I would like to confirm the information we obtained from your medical files that we sent to you prior to this conversation.

54. Did you receive the materials we sent?

Yes ____
No ____ Arrange to resend information and/or make appointment for another phone conversation

55. If you have the documents we sent you, can we review them with you now?

Yes ____
No ____

56. (IF NO) Would you like us to schedule another time to do it?

Yes ____
No ____

56a. (IF STILL NO) *May I ask your reason for declining?*

NEXT OF KIN INTERVIEW FOR NALTREXONE THERAPY

RA

1700 MAIN STREET
SANTA MONICA CA 90401

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin – Naltrexone

PATIENT INTERVIEW SCHEDULE

TEAR SHEET (to be completed prior to the interview)

1. Patient's ID CODE: 01 _____

   Site: _____ Patient # _____

2. Patient's Name: _____ _____
   LAST NAME FIRST NAME

   Next-of-Kin Name: _____ _____
   LAST NAME FIRST NAME

3. STATE: _____

4. Consent Letter Received: _____ /_____ /_____

5. Doctor's Name and/ or Clinic for CAM: _____

6. Therapy Type: _____

7. Date Interviewed: _____/_____/_____ Interviewer: _____

8. Date Checked: _____/_____/_____ By: _____

9. Date Data Entered: _____/_____/_____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: (_____) _____-_____

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: _____

NOTES

_____

_____

_____

OUTCOME CODES

AM = Answering machine
BZ = Busy signal (phone, fax or modem)
CI = Completed interview
O = Other (describe)
PI = Partial interview
CB = Call back
DS = Disconnected
AP = Made an appointment
NA = No answer
WN = Wrong number
PP = Phone problem
RF = Refused

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

PATIENT INTERVIEW SCHEDULE

STRICTLY CONFIDENTIAL

The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of the patient's physician. Its purpose is to obtain, as accurately as possible, information concerning the care that (PATIENT) received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.

THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.

All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you or (PATIENT) from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess the therapy. You may stop the interview at any time.

The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?

Yes _____ No _____ If no, *May I ask you your reason for declining?*

_____

_____

Thank you for your assistance.

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

SECTION X: RELATIONSHIP

What was (PATIENT'S) relationship to you? (CHECK ONE)

Spouse ____
Mother ____
Father ____
Son ____
Daughter ____
Brother ____
Sister ____
Other ____ (SPECIFY:_____)

We realize that you may not be able to answer many of the questions we will ask about (PATIENT). We appreciate your help in answering what you can.

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

First, I would like to ask some background questions about (PATIENT).

1. What was their birth date? _____ /_____ /_____
   If refused, enter REFUSED
   If don't know, enter DON'T KNOW

1a. What was their age? _____
   If refused, enter RF
   If don't know, enter DK

2. What was their sex?

	(Check one)
Male	_____ (1)
Female	_____ (2)

3. What was their marital status?

	(Check one)
Single	_____ (1)
Married	_____ (2)
Divorced	_____ (3)
Widowed	_____ (4)
Refused	_____ (7)
Don't know	_____ (9)

4. What was their highest level of education?

	(Check one)
Grade school	_____ (1)
High school	_____ (2)
Some college	_____ (3)
College degree	_____ (4)
Graduate degree	_____ (5)
Refused	_____ (7)
Don't know	_____ (9)

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

5. What was their ethnic origin? (Check all that apply)

Caucasian	_____	
Black/African American	_____	
Hispanic/Latino	_____	
Asian/Pacific islander	_____	
Other	_____	Please could you specify: _____
Refused	_____	
Don't know	_____	

6. What type of health insurance did they have? (Check all that apply)

HMO	_____	
PPO	_____	
Fee for Service	_____	
None	_____	
Other	_____	Please could you specify: _____
Refused	_____	
Don't know	_____	

7. What insurance coverage did they have for Naltrexone therapy? (Check all that apply)

HMO	_____	
PPO	_____	
Fee for Service	_____	
None	_____	
Other	_____	Please could you specify: _____
Refused	_____	
Don't know	_____	

8. What was their most recent occupation? (ENTER VERBATIM)

_____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

SECTION B. HEALTH STATUS

During the time (PATIENT) was being treated with Naltrexone therapy, how would you rate their health? For the following two questions, on a scale of 1 to 7, where 1 is "Very Poor" and 7 is "Excellent" please tell me the number between 1 and 7 that best applied them.

37. How would you rate their overall physical condition during that time?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

38. How would you rate their overall quality of life during that time?

(CIRCLE ONE)	1	2	3	4	5	6	7	RF	DK
	Very Poor						Excellent		

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

SECTION C. Naltrexone Therapy

I would now like to ask you some questions about the Naltrexone therapy.

39. How did (PATIENT) learn about Naltrexone therapy and Dr. Bihari's clinic? (Check all that apply)

	(Check)	
Physician	____	(If checked, record the following) Can you tell me that person's name?_____ Was this person their primary care physician or a specialist or both? Primary Care ____ Specialist ____ What type of specialist are they?_____ Refused ____ Don't know ____ Is this person a Complementary/Alternative Provider? Yes ____ No ____ Refused ____ Don't know ____
CAM provider, not a physician	____	Can you tell me that person's name? _____ Do you know what is their specialty? _____
Another patient of the clinic	____	
Friend / Family Member / Co-Worker who is not a patient of this clinic	____	
Friend or relative of Doctor at the clinic	____	
Local newspaper, radio, or TV	____	
Advertisement	____	Where did they see or hear the advertisement? _____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

Question 39 continued	(Check)	
Other	____	Specify:_____
Refused	____	
Don't recall	____	

40. At the time (PATIENT) started Naltrexone therapy, had their medical doctor for cancer recommended they seek complementary /alternative treatment*?*

Yes ____
No ____
Refused ____
Don't know ____

41. Did they inform any of their medical doctors that they were using Naltrexone therapy?

Yes ____
No ____
Refused ____
Don't know ____

41a. (IF YES) Does that include their oncologist?

Yes ____
No ____
Refused ____
Don't know ____

42. Did Dr. Bihari's clinic request medical records from their primary doctor?

Yes ____
No ____
Refused ____
Don't know ____

PT ID#: _____

42a. (IF YES) Were the records obtained?

Yes ____
No ____
Refused ____
Don't know ____

43. Did they have other forms of complementary or alternative medicine for the treatment of the cancer*?*

Yes ____ What were they? _____
No ____
Refused ____
Don't know ____

44. Would you recommend Naltrexone therapy to someone else?

Yes ____
No ____
Refused ____
Don't know ____

45. Was there any difference between how they felt with Naltrexone therapy and their other care?

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did they choose Naltrexone therapy for treatment of their cancer? (Check all that apply)

___ Failure of another form of complementary/alternative medicine
___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Side effects of another form of complementary/alternative medicine
___ Philosophical congruence
___ Other, specify _____
___ None of the above (no reason)
___ Refused
___ Don't know

47. Did they use conventional therapy for the cancer?

Yes ____
No ____
Refused ____
Don't know ____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

47a. (IF NO) How come? (Check all that apply)

___ Failure of conventional therapy
___ Side effects of conventional therapy
___ Philosophical reasons
___ Some other reason (specify) _____
___ None of the above (no reason)
___ Refused
___ Don't know

47b. (IF YES) Did they complete conventional therapy?

Yes ____
No ____
Refused ____
Don't know ____

47b. (IF COMPLETED) Was the following statement true:

"(PATIENT) completed conventional therapy, but was not cured"

Yes ____
No ____
Refused ____
Don't know ____

48. What did they expect from their Naltrexone therapy? (RECORD VERBATIM)

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

49. When (PATIENT) was being treated by Dr. Bihari, did they tell their friends that an alternative medical practitioner was treating them?

Yes	____
No	____
Refused	____
Don't know	____

50. How far did they travel to get to Dr. Bihari's clinic? (CHECK ONE)

5 miles or less	____
6-10 miles	____
11-20 miles	____
21-30 miles	____
over 30 miles	____
over 100 miles	____
over 500 miles	____
over 1000 miles	____
over 2000 miles	____
Refused	____
Don't know	____

51. Did they have a family medical doctor?

PT ID#: _____

Yes ____
No ____
Refused ____
Don't know ____

51a. If yes, how often do they see this doctor?

Yearly ____
Monthly ____
Weekly ____
Other ____ (specify) _____
Refused ____
Don't know ____

52. Were they satisfied with the care they received from the family medical doctor? Were they… (READ RESPONSES AND CHECK ONE)

Extremely satisfied ____
Very satisfied ____
Satisfied ____
Somewhat satisfied ____
Not at all satisfied ____

(DON'T READ) Refused ____
(DON'T READ) Don't know ____

53. Did (PATIENT) rely primarily upon alternative medicine providers for all of their medical care?

Yes ____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

No	____
Refused	____
Don't know	____

Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: _____

SECTION D: **CONFIRMATION OF THE MEDICAL FILE**

Now, I would like to confirm the information we obtained from (PATIENT'S) medical files that we sent to you prior to this conversation. Again, we realize you may not be able to confirm much of this, but it would help us if you can.

54. Did you receive the materials we sent?

Yes ____
No ____ Arrange to resend information and/or make appointment for another phone conversation

55. If you have the documents we sent you, can we review them with you now?

Yes ____
No ____

56. (IF NO) Would you like us to schedule another time to do it?

Yes ____
No ____

56a. (IF STILL NO) *May I ask your reason for declining?*

Appendix D

Letters to Patients
Including (3) Consent Forms

Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement Patients

June, 2001

Dear

We are currently conducting a national study of patients using alternative and complementary medicine. Dr. John Clement of the Immunology Research Centre in the Bahamas has agreed to participate in this study. As part of the study we wish to obtain the records of patients enrolled in complementary and alternative care to determine the outcomes of these treatments.

You are one of approximately 20 patients from The Centre selected to take part in this Study and your participation is very important to the validity of the results. However, you do not have to participate and your decision whether or not to take part will not affect any services you receive from any health care provider. You were selected by Dr. Clement as a patient who he feels has responded well to Immuno-Augmentive Therapy (IAT).

To complete the study we would like to have access to your files in Dr. Clement's office. In addition, if you are also being treated by any other health provider (s) for the same health problem we would like permission to obtain those records. We would also like to complete a short telephone interview (10-15 minutes) with you regarding the impact these various treatments have had on your health and on the quality of your life.

No provider will be informed by us that you are receiving other care. All the information we obtain from your files is for research purposes only. We will protect the confidentiality of this information, and will not disclose your identity or information that identifies you to anyone except as required by law. We will not identify you in any reports we write. We will destroy all personal information from our files at the end of the study or sooner if no further information is required.

We will not be asking you to take part in any experimental treatments or therapies. We will be simply reviewing your medical records and asking you some questions. There are no direct benefits to you by participating in the Study but it might benefit other patients in general by showing which types of treatment benefit which types of patients.

If you are willing to participate please complete the enclosed authorizations and return them to us. A pre-stamped, addressed envelope is enclosed for this purpose.

You can request additional information about the Study or discuss problems related to the Study by calling the Principal Investigator for the Study, Ian Coulter, Ph.D. at 310-393-0411, ext. 6759.

Yours sincerely,

Ian D. Coulter, Ph.D.
RAND

Mary Hardy, M.D.
RAND

*PLEASE NOTE THAT IF YOU ARE NOT THE PATIENT, YOU HAVE BEEN SENT THIS BECAUSE **IAT** HAS NOTED THAT YOU ARE THE NEXT-OF-KIN AND YOUR INPUT IS VERY IMPORTANT TO THIS NATIONAL STUDY OF ALTERNATIVE TREATMENT.*

Enclosed are the following authorization forms:

Document A: Release for patient records from Dr. Clement (IAT)

Document B: Allowing us (SCEPC) to call you for a short interview

Document C: Release for patient records from any other health providers *(3 forms enclosed – feel free to copy this form if there are more than 3)*

You may consent to A, B or C, or all three.

PATIENT AUTHORIZATION:

To: Dr. John R. Clement
IAT (Bahamas) Ltd.
PO Box F-42689
Freeport, Grand Bahamas, Bahama

I, _____ (*print your name*), authorize the release of a copy of my patient record to the SCEPC study of cancer.

I, _____ (*print your name*), am the legal

next-of-kin to IAT patient _____ (*print his/her name*) and authorize the release of a copy of his/her patient record to the SCEPC study of cancer.

_____ _____
Patient (or legal) signature Date

** You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

Document A

PATIENT AUTHORIZATION:

I, _____ (*print your name*), authorize the Southern California Evidence-Based Practice Center to call me for a short interview

regarding _____ *(print patient's name if you are next-of-kin).*

The best time to call me during the day is: (if possible, please give a 3-hour span)

_____ Phone #: (_____)_____
(time, time zone)

Alternate phone #: (_____)_____

_____ _____
Patient (or legal) signature Date

Document B

Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement Patients (continued)

PATIENT AUTHORIZATION:

To: Dr. Mr. Ms._____ (*insert the name of the provider*)
[circle one]

_____ (*address*)

_____

_____

_____ (*telephone*)

I, _____ (*print your name*), authorize the release of a copy of my medical record to the SCEPC study of cancer.

I, _____ (*print your name*), am the legal

next-of-kin to IAT patient _____ (*print his/her name*) and authorize the release of a copy of his/her patient record to the SCEPC study of cancer.

I request that the copy be sent to:

Ian Coulter Ph.D.
Southern California Evidence Based Practice Center
PO Box 2138
Santa Monica, CA 90407-2138.

_____ _____
Patient (or legal) signature Date

** You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

Document C

Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients

June, 2001

Dear

We are currently conducting a national study of patients using alternative and complementary medicine. Dr. Bernard Bihari and his medical clinic have agreed to participate in this study. As part of the study we wish to obtain the records of patients enrolled in complementary and alternative care to determine the outcomes of these treatments.

You are one of approximately 20 patients from Dr. Bihari's practice selected to take part in this Study and your participation is very important to the validity of the results. However, you do not have to participate and your decision whether or not to take part will not affect any services you receive from any health care provider. You were selected by Dr. Bihari as a patient who he feels has responded well to Naltrexone.

To complete the study we would like to have access to your files in Dr. Bihari's office. In addition, if you are also being treated by any other health provider(s) (both conventional and alternative) for the same health problem, we would like permission to obtain those records. We would also like to complete a short telephone interview (10-15 minutes) with you regarding the impact these various treatments have had on your health and on the quality of your life.

No provider will be informed by us that you are receiving other care. All the information we obtain from your files is for research purposes only. We will protect the confidentiality of this information, and will not disclose your identity or information that identifies you to anyone except as required by law. We will not identify you in any reports we write. We will destroy all personal information from our files at the end of the study or sooner if no further information is required.

We will not be asking you to take part in any experimental treatments or therapies. We will be simply reviewing your medical records and asking you some questions. There are no direct benefits to you by participating in the Study but it might benefit other patients in general by showing which types of treatment benefit which types of patients.

If you are willing to participate please complete the enclosed authorizations and return them to us. A pre-stamped, addressed envelope is enclosed for this purpose.

You can request additional information about the Study or discuss problems related to the Study by calling the Principal Investigator for the Study, Ian Coulter, Ph.D. at 310-393-0411, ext. 6759.

Yours sincerely,

Ian D. Coulter, Ph.D.
RAND

Mary Hardy, M.D.
RAND

Enclosed are the following authorization forms:

Document A: Release for your records from Dr. Bihari

Document B: Allowing us (SCEPC) to call you for a short interview

Document C: Release for your records from any other health providers
(3 forms enclosed – feel free to copy this form if there are more than 3)

You may consent to A, B or C, or all three.

PATIENT AUTHORIZATION:

To: Dr. Bernard Bihari
29th West 15th Street
New York, NY 10011

I, _____ (*print your name*), authorize the release of a copy of my patient record to the SCEPC study of cancer.

_____ _____
Patient signature Date

** You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

Document A

Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients (continued)

PATIENT AUTHORIZATION:

I, _____ (*print your name*), authorize the Southern California Evidence-Based Practice Center to call me for a short interview.

The best time to call me during the day is: (if possible, please give a 3-hour span)

_____ Phone #: (_____)_____
(time, time zone)

Alternate phone #: (_____)_____

_____ _____
Patient signature Date

Document B

Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients (continued)

PATIENT AUTHORIZATION:

To: Dr. Mr. Ms._____ (*insert the name of the provider*)
[circle one]

_____ (*address*)

_____

_____

_____ (*telephone*)

I, _____ (*print your name*), authorize the release of a copy of my medical record to the SCEPC study of cancer.

I request that the copy be sent to:

Ian Coulter Ph.D.
Southern California Evidence Based Practice Center
PO Box 2138
Santa Monica, CA 90407-2138.

_____ _____
Patient signature Date

** You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

Document C

Appendix E: Additional Cases Reviewed—Rejected IAT Cases (E-1)

Appendix E: Additional Cases Reviewed— Rejected IAT Cases (E-1)

Rejected IAT Cases

NAME	DIAGNOSIS	REASON FOR REJECTION
1-R	Adenocarcinoma of the rectum	Definitive surgery
2-R	Carcinoma of the bladder	Care not received in North America (France)
3-R	Breast carcinoma right and left	Multiple recurrences; more than IAT for chemotherapy
4-R	Ductal carcinoma of breast	No records
5-R	Bladder cancer	Incomplete record
6-R	Large-cell lymphoma	Incomplete record
7-R	Squamous cell carcinoma, metastatic-primary unknown; possibly tongue	Poor response to therapy
8-R	Squamous cell carcinoma of chest	Progression of disease on IAT treatment
9-R	Ductal carcinoma of breast, 1 of 12 nodes positive	Probable definitive therapy (surgical excision)
10-R	Carcinoma of the right breast	Definitive surgery 1979; metastases on IAT
11-R	Carcinoma of the bladder	Definitive surgery
12-R	Adenocarcinoma of the prostate	Inadequate documentation - possible
13-R	Ductal carcinoma of breast	Long survival but possible curative surgery

Appendix E: Additional Cases Reviewed— Rejected IAT Cases (E-1) (continued)

NAME	DIAGNOSIS	REASON FOR REJECTION
14-R	Gastroesophageal cancer	Current patient; insufficient followup
15-R	Ductal carcinoma of both breasts '87, recurrence on left 5/00	Definitive therapy (surgical), relapse, other CAM
16-R	Squamous cell carcinoma, floor of mouth	Incomplete record
17-R	Malignant sarcoma	Long survivor; eventually died of the disease
18-R	Squamous cell carcinoma of lung	Progression of disease on IAT treatment
19-R	Astrocytoma	Prolonged survival but poor functional outcome
20-R	Endometrial adenocarcinoma	Recurrence on IAT
21-R	Malignant mesothelioma of the chest	Care not received in North America (Austria)
22-R	Adenocarcinoma of the breast	Definitive surgery—node negative
23-R	Poorly differentiated squamous cell carcinoma of nasopharanyx	Recent start on IAT; insufficient time for followup
24-R	Adenocarcinoma of unknown primary	Lived longer than expected time, but progressed on treatment
25-R	Adenocarcinoma of the prostate	Incomplete record
26-R	Bronchsarcoma protruberans of face	Multiple recurrences; surgery and local excision
27-R	Adenocarcinoma of the pancreas	Progression of disease on IAT treatment

Appendix E: Additional Cases Reviewed— Rejected IAT Cases (E-1) (continued)

NAME	DIAGNOSIS	REASON FOR REJECTION
28-R	Adenocarcinoma of the caecum	Progression of disease on IAT treatment
29-R	Breast carinoma, left	Possible curative resection; no measurable disease to follow
30-R	Carcinoma of the left breast	Confounding conventional therapy
31-R	Lymphocytic lymphoma	Progression of disease on IAT treatment
32-R	Sq. cell carcinoma left vocal cord 5/80, rectal carcinoma 10/90, liver angiosarcoma 9/00	Incomplete record
33-R	Ductal carcinoma of breast	Progression of disease on IAT treatment
34-R	Carcinoma of colon to local nodes	Long survival but possible curative surgery
35-R	Adenocarcinoma of breast	Long survival but extensive conventional therapy
36-R	Squamous cell carcinoma of anum	Definitive surgery
32-R	Small cell carcinoma of the lung	Second primary (adenocarcinoma of breast) on treatment; confounding conventional and unconventional therapy
33-R	Adenocarcinoma of the colon	Long survivor, but questionable documentation of liver metastases; second primary (prostate) developed on treatment
34-R	Metastatic malignant melanoma	Progression of disease on IAT treatment
35-R	Clear cell carcinoma of the kidney	Stabilization of metastatic disease—variable by report. Confounding CAM therapy

Other IAT Cases Reviewed E-2

Patient #1-2

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2

CAM Therapy:	IAT		
Case:	1-2		
Condition:	Adenocarcinoma of the rectum		
Abstractor:	2	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:	Adenocarcinoma of the rectum with incomplete resection (equivocal documentation)		

Criteria for inclusion: (check all that apply)		
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
		Tumor size
	x	Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	7/7/29
Diagnosis:	Adenocarcinoma (infiltrating) of the rectum
Diagnosis date:	Mar-84
CAM therapy dates:	10/8/97-5/11/01
Conventional therapy dates:	Surgery 5/3/89; 8/28/89 Chemotherapy 5/22/89 Radiation 3/90
Last contact date:	5/11/01
If deceased, date of death:	

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
4/19/89	Biopsy rectum (colonoscopy): infiltrating adenocarcinoma
5/3/89	Surgery: transphincter local excision: tumor margin not clear
5/8/89	Biopsy rectum (surgery): in situ and infiltrating adenocarcinoma moderately differentiated - tumor at margin
5/22/89	Chemotherapy: 5-FU, leucovorin
6/5/89	Selenium, bioflavinoid, vitamin C, vitamin A, vitamin E
8/18/89	CT scan abdomen: thickening distal rectal wall: bilateral hydronephrosis: lucent mass 3.8cm x 2cm
8/28/89	Surgery: Abdomino-peritoneal resection with permanent colostomy
8/30/89	Biopsy ano-rectum (surgery): no residual carcinoma; margins clear; negative lymph node
11/12/89	X-ray chest: normal
11/28/89	CT scan abdomen/pelvis: irregular soft tissue mass 4.4cm; resolution of hydronephrosis
12/6/89	Biopsy: needle aspirate: malignant adenocarcinoma
3/22/90	CT scan abdomen/pelvis: mass 4.56cm x 3.35cm in rectal fossa: no change since 11/28/89
3/22/90	CEA 1.1 (normal < 5)
3/28/90	Bone scan: whole body: normal
	Radiation: stopped early due to radiation cystitis (written in report 9/29/89)

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
9/25/90	CT scan abdomen/pelvis: decrease in sacral mass (slight) 4.2 cm x 2.7cm)
11/8/90	AMAS 213mg/ml (normal < 134)
3/6/91	AMAS 219mg/ml (normal < 134)
4/30/91	X-ray chest: normal
4/30/91	CT scan abdomen/pelvis: increase in size of mass from 9/90, tumor vs. inflammation
8/6/91	MRI pelvis: thickening of left levator ani muscle
9/17/91	AMAS 116mg/ml (normal < 134)
12/18/91	MRI pelvis: no recurrence of tumor
12/19/91	MRI abdomen: normal
3/11/92	AMAS 162mg/ml (normal < 134)
3/19/92	X-ray chest: no evidence of metastatic disease
8/18/92	AMAS 130mg/ml (normal < 134)
1/5/93	MRI pelvis: no recurrence or spread of tumor
1/5/93	MRI abdomen: no adenopathy
11/11/93	AMAS normal

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
11/19/93	MRI pelvis: no interval change
11/19/93	MRI abdomen: no change; unremarkable MRI
12/12/94	MRI abdomen: no change
5/24/95	AMAS 137 mg/ml (normal < 134)
6/8/95	MRI abdomen: bilateral renal cysts
6/8/95	MRI pelvis: no interval change; normal study
6/22/95	CEA 0.8 (normal < 5.0)
10/17/95	AMAS 104 mg/ml (normal < 134)
12/26/95	MRI abdomen: no change
12/26/95	MRI pelvis: no change
7/2/96	AMAS normal
9/30/96	X-ray c-spine: spondylotic changes
6/28/96	MRI pelvis: no tumor recurrence
6/28/96	MRI abdomen: no adenopathy
9/17/96	MRI brain lacunar infarcts; periatrial ischemic changes

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
5/13/97	CEA 0.9 (normal < 5.0)
5/30/97	AMAS normal
12/30/97	AMAS 104 mg/ml (normal < 134)
10/8/97-5/11/01	IAT 8 courses

Additional Case Reviewed

Patient #1-5

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-5

CAM Therapy:	IAT		
Case:	1-5		
Condition:	Right renal adenocarcinoma		
Abstractor:	1	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	10/5/01
Comments:	IAT started after right nephrectomy for cure. Metastasis not documented, although retroperitoneal and liver masses were present on CT scan. Retroperitoneal mass not always noted on imaging studies. Endpoint not documented.		

Criteria for inclusion:	**(check all that apply)**		
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	4/6/42
Diagnosis:	Right renal adenocarcinoma, well-differentiated
Diagnosis date:	5/17/79
CAM therapy dates:	10/28/80-12/2/98
Conventional therapy dates:	5/17/79 surgery
Last contact date:	12/2/98
If deceased, date of death:	

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
04/30/79	Renal IVP: duplicate left collecting system, dilated right upper pole collecting system, irregular bladder wall
05/09/79	Renal US: large solid mass in right kidney
05/10/79	Renal arteriogram: mass lesion at lower pole of right kidney
05/11/79	Bone scan of whole body: within normal limits
05/17/79	Right kidney biopsy: well-differentiated adenocarcinoma with focal extension through the renal capsule
05/17/79	Surgery: right nephrectomy
10/01/79	Bone scan of whole body: right kidney absent
12/07/79	CT scan of abdomen: 3.5cm low density area at posterior right lobe of liver
01/18/80	CT scan of abdomen with contrast: no change in low density area in posterior right hepatic lobe
01/18/80	X-ray chest: within normal limits
06/25/80	Bone scan of whole body: right nephrectomy
06/25/80	Renal arteriogram: s/p nephrectomy, no evidence of residual tumor at excision site
06/27/80	CT scan of abdomen: enhancing lesion in right lobe, second area seen
09/29/80	X-ray chest: within normal limits
09/29/80	Liver US: 3 solid lesions in right lobe of liver 3.6cm largest, 2cm other 2 lesions

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
10/13/80	CT scan of abdomen: retroperitoneal mass in area of right pedicle, low density areas in liver
01/08/82	CT scan of abdomen with contrast: mass at posterior of right lobe of liver decreased 3-2.4cm, 4.9cm mass in right renal pedicle decreased to 4cm
03/21/83	CT scan of abdomen with contrast: enhancing hypodense masses in liver, no change
04/09/84	CT scan of abdomen: multiple hypodense areas in right lobe of liver 2-3.5cm, recurrent mass medial and inferior to site of nephrectomy
10/24/84	CT scan of abdomen: absent right kidney
10/25/84	Bone scan of whole body: within normal limits
05/01/89	CT scan of abdomen: double collecting system on left, 3 low density lesions in right lobe of liver, no change since 1984
06/19/92	CT scan of abdomen with contrast: metastatic disease to liver, multiple masses (5-6), largest at right lobe of liver 2cm
07/13/94	CT scan of abdomen and pelvis with contrast: 4 lesions at right lobe of liver, largest 3cm presumed not metastatic
06/19/97	CT scan of abdomen 5-6 low attenuation foci within liver most consistent with metastatic disease
10/28/80-present	IAT 15 courses, then yearly injections

Additional Case Reviewed

Patient #1-12

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-12

CAM Therapy:	IAT		
Case:	1-12		
Condition:	Breast cancer (left breast)		
Abstractor:	IDC	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:	No adjuvant therapy with the surgical excision and node dissection. Patient never achieved remission. Patient deceased from pulmonary embolism.		

Criteria for inclusion:	**(check all that apply)**		
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	3/26/41
Diagnosis:	Left breast Infiltrating ductal cell carcinoma, stage 0, moderately differentiated, node positive, ER/PR positive
Diagnosis date:	12/28/84
CAM therapy dates:	5/14/85-3/3/94
Conventional therapy dates:	12/28/84
Last contact date:	3/3/94
If deceased, date of death:	pulmonary embolism 4/10/94

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-12 (continued)

Date	Description of Events
12/28/84	Biopsy: Left breast pathology: 8 mm well-differentiated ductal cell carcinoma with microcalcification and stromal infiltration with comedo-carcinoma features
12/28/84	Surgery: left partial mastectomy for diagnosis and palliation.
12/28/84	X-ray chest: within normal limits
4/18/85	X-ray chest: within normal limits
4/19/85	Surgery left axilla: moderately differentiated ductal cell carcinoma, 29/30 nodes positive
4/22/85	ERA binding sites: 13.9 fmol/mg, Estradiol receptor cytosol protein 2 mg/ml; PRA binding sites 219.3 fmol/mg; Progesterone receptor cytosol protein 4 mg/ml
4/22/85	Radiation recommended for palliation; patient refused due to personal preference
4/22/85	Liver scan: borderline hepatomegaly
4/23/85	Bone scan: within normal limits
7/8/86	Bone scan: within normal limits
7/8/86	X-ray chest: within normal limits
3/6/87	X-ray chest
12/2/87	Bone scan: within normal limits
12/2/87	X-ray chest: within normal limits
5/14/85	Vitamin C, beta carotene, vitamin E, selenium, multivitamin
5/14/85-3/3/94	IAT 18 courses

Additional Case Reviewed

Patient #1-15A

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-15A

CAM Therapy:	IAT		
Case:	1-15A		
Condition:			
Abstractor:	IDC, JLG	**Date of Abstraction:**	
Interviewer:	IDC	**Date of Interview:**	9/25/01
Comments:	Cancer excised with clean margins 10/87; second primary adenocarcinoma of the cecum excised 2/24/98 with clean margins		

Criteria for inclusion: (check all that apply)		
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
	Documented endpoint:	
		Tumor size
		Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	female
DOB:	7/27/26
Diagnosis:	Squamous cell carcinoma of the larynx, moderately differentiated 10/2/87
Diagnosis date:	10/2/87
CAM therapy dates:	4/26/88-7/3/98
Conventional therapy dates:	10/28/87
Last contact date:	7/3/98
If deceased, date of death:	

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-15A

Date	Description of Events
10/2/87	Biopsy: vocal cord pathology: moderately differentiated squamous cell carcinoma
10/10/87	CT scan of thorax: within normal limits
10/27/87	CT scan of neck: thickening of the right aryepiglottic fold compatible with exophytic mass, extends posteriorly to the pharyngeal wall
10/27/87	X-ray head and neck: single lymph node measuring <1 cm of level of vocal cords on the right
10/28/87	Anterior laryngoscopy, tracheostomy, partial laryngectomy for palliation: cancer involving posterior and superior margins;
10/28/87	Biopsy pathology: surgical excision larynx, posterior and superior margins have infiltrating squamous cell cancer; clean margins
11/5/87	X-ray chest: left pleural effusion
12/30/87	Laryngoscopy for diagnostic: no exophytic lesion inviting biopsy, but biopsy done of glandular appearing tissue near junction of right true cord and epiglottis
12/30/87	Biopsy pathology: direct laryngoscopy of right supraglottic larynx: dysplastic changes focally present
8/23/95	X-ray chest: within normal limits except mild atelectasis
5/28/97	Pelvic US: no pelvic adnexal masses nor fluid collection
2/24/98	Exploratory laparotomy with right hemicolectomy and excision of right lateral abdominal wall for diagnosis and palliation: perforation of cecal carcinoma with abscess. Intention of surgery was appendectomy. Incidentally found cancer
2/24/98	Biopsy cecum: pathology: invasive moderately differentiated adenocarcinoma arising in association with tubulovillous adenoma, invades muscularis with perforation of colonic wall, margins clear: all 12 nodes negative
2/15/99	Colonoscopy: anastomic right side of colon stable
3/2/99	X-ray lumbar spine: mild osteopenia

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-15A

Date	Description of Events
3/3/99	CT scan of abdomen and pelvis: no significant evidence of mass lesion
4/26/88-7/3/98	IAT; 13 courses

Additional Case Reviewed

Patient #1-16

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-16

CAM Therapy:	IAT		
Case:	1-16		
Condition:	Hodgkin's disease		
Abstractor:	IDC, MH	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:	Hodgkin's disease, local excision with no definitive conventional therapy: incomplete documentation; considered disease free in 1/98		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	6/13/62
Diagnosis:	Hodgkin's disease
Diagnosis date:	1/9/81
CAM therapy dates:	1/19/81-11/30/99
Conventional therapy dates:	none
Last contact date:	11/30/99
If deceased, date of death:	

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-16 (continued)

Date	Description of Events
1/9/81	Surgery: tonsillectomy
1/9/81	Biopsy: tonsil : Hodgkin's lymphoma: initially, diffuse histiocytic lymphoma after reviewed at Yale felt to be Hodgkin's disease, lymphocytic and histiocystic predominant type
1/14/81	Biopsy: bone marrow: negative for Hodgkin's disease
1/14/81	Chemotherapy recommended:patient refused due to patient preference; was not followed by oncologist
1/19/81-11/30/99	IAT 19 courses

Additional Case Reviewed

Patient #1-20

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-20

CAM Therapy:	IAT		
Case:	1-20		
Condition:	Adenocarcinoma of the sigmoid colon		
Abstractor:	IDC	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:	no radiation or chemo		

Criteria for inclusion: (check all that apply)		
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
		Tumor size
	x	Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	female
DOB:	10/18/28
Diagnosis:	Adenocarcinoma of the sigmoid colon; Duke stage C
Diagnosis date:	6/9/87
CAM therapy dates:	6/7/88-5/22/01
Conventional therapy dates:	Surgery 6/9/87
Last contact date:	5/22/01
If deceased, date of death:	

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-20 (continued)

Date	Description of Events
	Smoking quit at age 28
6/8/87	Sigmoidoscopy rigid: confirm tumor presence of tumor @20-30cm
6/9/87	Surgery: resection of colon: margins free of tumor
6/9/87	Biopsy colon and nodes: moderately well differentiated adenocarcinoma of sigmoid colon: 3/8 pericolic nodes positive: 1/2 inferior mesenteric nodes positive
6/9/87	No conventional therapy offered by physician; physicians chose to follow serial markers instead
9/18/87	CEA 1.9 ng/ml (normal < 5.0)
6/7/88-5/22/01	IAT: 35 courses
6/9/89	CEA 0.8 ng/ml (normal < 5.0)
10/11/89	CEA 2.0 ng/ml (normal < 5.0)
2/8/90	CEA 3.3 ng/ml (normal < 5.0)
10/1/90	CEA 1.8ng/ml (normal < 5.0)
2/1/91	CEA 1.4 ng/ml (normal < 5.0)
7/9/92	CEA 3.5 ng/ml (normal < 5.0)
11/19/92	CEA 3.6 ng/ml (normal < 5.0)
3/21/93	CEA 4.0 ng/ml (normal < 5.0)

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-20 (continued)

Date	Description of Events
7/21/93	CEA 1.9 ng/ml (normal < 5.0)
11/1/93	CEA 3.0 ng/ml (normal < 5.0)
3/11/94	CEA 5.3 ng/ml (normal < 5.0)
7/27/94	CEA 4.9 ng/ml (normal < 5.0)
3/22/95	CEA 6.3 ng/ml (normal < 5.0)
7/26/95	CEA 4.8 ng/ml (normal < 5.0)
10/1/95	CEA 7.7 ng/ml (normal < 5.0)
4/1/96	CEA 9.5 ng/ml (normal < 5.0)
5/7/97	CEA 8.7ng/ml (normal < 5.0)
7/1/97	CEA 12 ng/ml (normal < 5.0)
5/3/90	Colonscopy: normal
5/23/96	Colonscopy: benign polyp
5/23/96	CT scan abdomen/pelvis normal
11/18/99	Colonscopy: normal

Additional Case Reviewed

Patient #1-21

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-21

CAM Therapy:	IAT		
Case:	1-21		
Condition:	Adenocarcinoma of the lung metastatic to mediastinum		
Abstractor:	IDC	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:			

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
	x	Longevity	
		Quality of Life	
	x	Other:	non-progression of disease

Other Relevant Information:	
Sex:	female
DOB:	7/20/25
Diagnosis:	Adenocarcinoma of the lung, stage III T2 N3 M0. Grade IV (metastatic to mediastinum
Diagnosis date:	6/18/85
CAM therapy dates:	5/13/86-4/23/93
Conventional therapy dates:	Surgery: 6/18/85 Radiation: 6/24/85-7/8/85
Last contact date:	4/23/93
If deceased, date of death:	4/22/99

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-21 (continued)

Date	Description of Event I
1/12/78	Biopsy stomach; normal gastric mucosa
5/16/85	X-ray chest : right upper lobe amorphous area of increased density not well delineated on lateral view
5/28/85	X-ray chest : changes consistent with a mass lesion right upper lobe; mild fibrotic changes
6/11/85	Biopsy pathology: bronchial brushings: no cancer cells
6/11/85	Bone scan full body: normal
6/11/85	CT scan mediastinum: previously noted mass: 4-5cm against mediastinum; 1 cm lymph node and several 15mm lymph nodes present
6/12/85	Surgery: fine needle aspiration right upper lung
6/12/85	Biopsy pathology: lung (fine needle aspiration) large malignant cells present
6/17/85	X-ray chest : compared to 6/12/85 right upper lung mass unchanged
6/18/85	Surgery: right minithoracotomy
6/18/85	Biopsy mediastinal lymph node: 2 parts: part 1-no evidence of malignancy: part 2- metastatic grade IV carcinoma
6/18/85	X-ray chest : no pneumothorax; slight atelectasis
6/24/85-7/8/85	Radiation right lung: 6000 RADS in 30 fractions
7/19/85	X-ray of ankle and wrist : periosteal thickening otherwise normal
12/17/85	X-ray chest : questionable nodule behind the heart on the left
1/5/86	X-ray chest : irregular 3cm mass behind the heart on the right side, only change compared with 4/10/86

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-21 (continued)

Date	Description of Event I
4/30/86	X-ray chest : post-broncosopy - no evidence of pneumothorax
5/13/86-4/23/93	IAT: 14 courses
6/13/86	X-ray chest : post-radiation reduction in size of right hilar mass since 4/30/86. Large right apical mass also smaller
11/4/86	X-ray chest : mass-like density recurrence in right hilum cannot be excluded
3/10/87	X-ray chest : compared to 1/5/87 small density behind left border is no longer seen
4/30/88	Biopsy pathology: bronchial brushings: no cancer cells
1/23/89	X-ray chest : no evidence of associated bone erosion to suggest bone invasion of residual tumor
2/6/89	X-ray chest : no suggestion of mets
7/28/89	X-ray chest : compared with 7/26/88 significant radiation changes in apical pleural thickening
10/23/90	X-ray chest: stable chest; no recurrence
11/25/91	X-ray chest : unchanged from 4/9/91
4/24/92	X-ray chest : stable exam
9/22/92	X-ray chest : no signs of recurrence or metastasis
3/19/93	X-ray chest : unchanged from 9/22/92
4/22/99	Deceased from acute MI

Additional Case Reviewed

Patient #1-24

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-24

CAM Therapy:	IAT		
Case:	1-24		
Condition:	Rhabdomyosarcoma		
Abstractor:	IDC	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:	Multiple local recurrences and distant mets, despite radiation and chemotherapy. No recurrences since 1997		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
	x	Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	2/10/49
Diagnosis:	Rhabdomyosarcoma of chest wall
Diagnosis date:	6/3/93
CAM therapy dates:	3/3/97-2/23/01
Conventional therapy dates:	6/3/93-8/1/96
Last contact date:	2/23/01
If deceased, date of death:	

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-24 (continued)

Date	Description of Events
6/3/93	Surgery wedge biopsy of mass at right scapula for diagnosis and palliation
6/3/93	Biopsy pathology: 18x15x5 cm pleomorphic rhabdomyosarcoma with margins free of tumor
8/93-10/93	Radiation: 6560 cGy to right medial posterior thorax
7/24/95	Surgery wedge biopsy of RUL of lung
7/24/95	Biopsy pathology wedge biopsy of right upper lobe lung: metastatic pleomorphic rhabdomyosarcoma 3 cm, margins clear
2/16/96	Biopsy pathology: rhabdomyosarcoma: 3rd interspace, posterior chest wall; RUL lung with chest wall. Multiple biopsies of chest wall and nodes negative
3/96-8/96	Chemotherapy completed 6 cycles
1/3/97	CT scan of chest, abdomen, pelvis: since 10/8/96, internal resection of duodenal mass, otherwise no significant change, no new disease
1/3/97	CT scan of chest
2/19/97	Surgery duodenectomy of 2nd and 3rd portions for palliation
4/2/97	Surgery pancreaticoduodenectomy (pylorus sparing)--Whipple
4/14/97	CT scan of abdomen: 1 cm simple cyst unchanged, low attenuation areas in left kidney unchanged, 2.5 cm enhancing mass in duodenum
4/14/97	CT scan of chest, abdomen, pelvis: no evidence of local recurrence of tumor in right chest; new 2 cm enhancing intraluminal mass within the duodenum
4/14/97	CT scan of chest: post-surgical changes, irregular soft tissue area (post-surgical) no enlarged lymph node
4/14/97	CT scan of pelvis: unchanged
4/17/97	Biopsy pathology: recurrent pleomorphic rhabdomyosarcoma extending into peripancreatic soft tissue, all 19 nodes negative

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-24 (continued)

Date	Description of Events
4/21/97	X-ray chest: consistent with prior right lung surgery
4/22/97	X-ray chest: post surgical changes
4/22/97	Surgery Whipple procedure for palliation
4/22/97	Biopsy pathology: gall bladder within normal limits
4/22/97	X-ray abdomen: post surgical drains
4/27/97	X-ray chest
4/27/97	X-ray chest: new LLL opacification, right pleural effusion may be bigger
7/7/97	CT scan of chest, abdomen, pelvis: no evidence of metastatic disease or recurrence within the chest abdomen or pelvis
9/21/98	CT scan of chest, abdomen, pelvis: compared to 3/31/98, no new lung nodules, no significant change in abdomen and pelvis
4/19/99	CT scan of chest, abdomen, pelvis: compared to 9/21/98, no abnormally enlarged lymph nodes in abdomen and pelvis, no recurrence or metastasis in chest or pelvis
4/19/99	CT scan: post-operative changes right chest and abdomen, no evidence of recurrence or metastasis
4/19/99	CEA 2.2 (<5)
4/19/99	PSA 0.8 (<4)
3/3/97-2/23/01	IAT
	Quality of life measure: Kavaioncy 95

Additional Case Reviewed

Patient #1-28

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-28

CAM Therapy:	IAT		
Case:	1-28		
Condition:	Chondrosarcoma vs. cellular chondroma of the brain (right middle and posterior fossa)		
Abstractor:	AC	**Date of Abstraction:**	
Interviewer:		**Date of Interview:**	
Comments:	Long survival with good control of disease: eventually died of disease. Next of kin to be interviewed		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
	x	Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	7/9/36
Diagnosis:	chondrosarcome vs. cellular chondroma of the brain
Diagnosis date:	9/24/75
CAM therapy dates:	6/24/80-4/14/89: IAT 14 courses
Conventional therapy dates:	Surgery: 9/24/75
Last contact date:	
If deceased, date of death:	6/12/89 (cause unclear)

Appendix E: Other IAT Cases Reviewed E-2 Patient #1-28 (continued)

Date	Description of Events
	Concurrently has multiple sclerosis
	Family history of cancer: father died of acute leukemia at age 45
9/22/75	Myelogram of posterior fossa: questionable mass in right cerebellum
9/23/75	Scan brain: abnormal lesion in brain stem
9/23/75	X-ray of clavus and sella turcica: no definite abnormality
9/23/75	Arteriogram cerebral: mass in right cerebellum
9/24/75	Surgery: right suboccipital craniotomy: discovered posterior fossa tumor
9/24/75	Biopsy: pathology chondromatous tumor
10/6/75	Pathology (2nd opinion on same tissue sample 9/24/75): cellular chondroma
6/24/80-4/14/89	IAT: 14 courses
6/12/89	Deceased

Other Naltrexone Cases Reviewed E-3

Patient #2-1

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1

Case 2-1

The patient in case 2-1 is a 71-year-old female with a history of chronic lymphocytic leukemia. She was initially diagnosed in 1988, per patient report. She started chemotherapy with chlorambucil and prednisone in August 1988 and stopped early in January 1989, secondary to bone marrow suppression. The following year she was diagnosed with pulmonary histoplasmosis and was treated with five months of amphotericin B. In the fall of 1991, she was diagnosed with a recurrence of CLL and the same chemotherapy was initiated. The chemotherapy was stopped after it was determined to have no effect, and five rounds of fludarabine (a full course) was completed by June 1992. In October 1997, she was diagnosed with a recurrence and fludarabine was started and stopped after it was determined to have no effect. In March 1998, Naltrexone was initiated. In August 1998, a bone marrow biopsy revealed histoplasmosis of the bone marrow and itraconazole was initiated. Since that time she has had intravenous immune globulin and rituxan treatments. In July 2001, her physician told her there has been no improvement in her condition. At last contact (patient interview 10/10/010, the patient reports that her general health is good.

Pathology

1988	**Diagnosed with CLL (per patient report)**

Imaging
None

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

Conventional therapy

8/88-1/89	**Chemotherapy: chlorambucil and prednisone; stopped early due to bone marrow suppression**
Jan-90	**Diagnosed with pulmonary histoplasmosis: amphotericin B (5 month treatment)**
fall/91	**Diagnosed with CLL recurrence**
fall/91	**Chemotherapy: chlorambucil and prednisone; stopped early due to no effect**
fall/91-6/92	**Chemotherapy: fludarabine completed 5 courses**
Oct-97	**Diagnosed with CLL recurrence**
Oct-97	**Chemotherapy: fludarabine; stopped early due to no effect**
Aug-98	**Bone marrow biopsy: positive for CLL and histoplasmosis**
Sep-98	**Started traconazole**
9/1/1998-9/1/00	**Started rituxan weekly for four weeks over 2 years: completed treatment**
2/00-present	**Intravenous immune globulin treatments monthly**
March 1,2001-present	**Rituxan restarted**
2001, July	**No improvement in disease per patient's physician**

Complementary therapy

1998, March	Started Natrexone 3mg qhs

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

Patient # 2-1						
EVENT	**PERIOD 1** **1st qtr 1988 – 4th qtr 1988**	**PERIOD 2** **1st qtr 1991 – 4th qtr 1992**	**PERIOD 3** **1st qtr 1997 – 4th qtr 1997**	**PERIOD 4** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 5** **1st qtr 2000– 4th qtr 2000**	**PERIOD 6** **1st qtr 2001 – 4th qtr 2001**
Diagnosis/biopsy	**1998**					
Surgery						
Radiation						
Chemotherapy	**8/88**	**6/92**	**10/97**			
Rituxan				**1998**		
Ivlg				**1998**		
Naltrexone	**3/98**					

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

CAM Therapy:	Naltrexone		
Case:	2-1		
Condition:	Chronic lymphocytic leukemia		
Abstractor:	IC AC JU	**Date of Abstraction:**	7/12/01
Interviewer:		**Date of Interview:**	10/10/01
Comments:			

Criteria for inclusion: (check all that apply)		
	Diagnosis confirmed	
x	Documented start date for CAM therapy	
	Documented previous anti-cancer therapies	
	No other therapies during the CAM therapy	
	Documented endpoint:	
		Tumor size
		Longevity
		Quality of Life
		Other:

Other Relevent Information:	
Sex:	female
DOB:	2/23/30
Diagnosis:	Lymphocytic leukemia
Diagnosis date:	8/1/88
CAM therapy dates:	3/1/2001-present
Conventional therapy dates:	8/88-2/97
Last contact date:	6/11/01
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

Date	Description of Events
	Comorbitities: hepatitis
1998	Diagnosed with CLL
8/88-1/89	Chemotherapy: chlorambucil and prednisone; stopped early due to bone marrow suppression
Jan-90	Diagnised with pulmonary histoplasmosis: amphotericin B (5 month treatment)
fall/91	Diagnosed with CLL recurrence
fall/91	Chemotherapy: chlorambucil and prednisone; stopped early due to no effect
fall/91-6/92	Chemotherapy: fludarabine completed 5 courses
Oct-97	Diagnosed with CLL recurrence
Oct-97	Chemotherapy: fludarabine; stopped early due to no effect
Aug-98	Bone marrow biopsy: positive for CLL and histoplasmosis
Sep-98	Started traconazole
9/1/98-9/1/00	Started rituxan weekly for four weeks over 2 years: completed treatment
2/00-present	IvIg threatments monthly
Mar-98	Started Natrexone 3mg qhs
Mar 01-present	Rituxan
Jul-98	No improvement in disease per patient's physician

Additional Case Reviewed

Patient #2-6

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6

Case 2-6

The patient in case 2-6 is a 56-year-old female with a history of ovarian carcinoma. She was initially diagnosed in August 1995 after a total abdominal hysterectomy with a bilateral salpingo-oopherectomy. She started chemotherapy with taxol, cysplatin, and asplax in August 1995 and six rounds were completed by December 1995. The cancer persisted and by 1998 or 1999 chemotherapy was started with doxil and topotecan, and a full course was completed. Naltrexone was initiated in September 2000. Since that time, chemotherapy was again started after metastatic disease was found in her liver. Throughout the course of her treatment, she has tried several unconventional therapies to treat her cancer, including full body hyperthermia and mistletoe. At last contact (interview on 10/09/01), the patient reports that her overall condition is very good.

Pathology

Aug-95	**Biopsy: Diagnosis of ovarian cancer in pelvis (patient reports)**

Imaging

8/28/00	**CT scan abdomen compared with 9/11/98: 3.5cm cyst in posterior medial left hepatic lobe anterior to portal vein, unchanged, no sign of metastatic disease**
8/28/00	**CT scan pelvis: no sign of recurrent metastatic disease**
4/19/01	**CT scan chest abdomen pelvis: few tiny nodual densities bilateral axilla, 1cm nodularity right lower lobe lung (new); few tiny cysts in liver; multiple soft tissue densities in liver; pelvic cyst 3.8cm**

Conventional therapy

Aug-95	**Surgery: ovarectomy and hysterectomy**
8/95-12/95	**Chemotherapy: Taxol, cysplatin; and asplax 6 rounds completed**
1998 or 1999	**Chemotherapy: Doxil, topotecan:11 months - completed therapy; followed by doxil 12 months-completed therapy**
10/3/00	**Chemotherapy: erythrotecan and low dose taxol**
2/1/01	**Surgery: laporascopy: reportedly did not reveal anything**
4/19/01	**Chemotherapy: initiated due to lesions on liver presumably metastatic disease: campthzar/cysplatin**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Tumor markers

Aug-95	**CA-125: 65**
Aug-95	**CA-125: <35**
1998	**CA-125: 200**
1998	**CA-125: 110**
Aug-99	**CA-125: 100**
Aug-99	**CA-125: 30**
7/20/01	**CA-125: 765**
8/14/01	**CA-125: 135**

Complementary therapy

10/97-5/98	**Acupuncture**
1998	**Vitamin C and mistletoe, full body hyperthermia**
9/19/00	**Naltrexone 3mg qhs up to 6.5mg qhs**
12/00-4/01	**Went to Mexico had alternative cancer treatment with vaccine**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Patient # 2-6						
EVENT	**PERIOD 1** **1st qtr 1995 – 4th qtr 1995**	**PERIOD 2** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 3** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 4** **1st qtr 2000– 4th qtr 2000**	**PERIOD 5** **1st qtr 2001 – 4th qtr 2001**	
Diagnosis/biopsy	**8/95**					
Surgery	**8/95**				**2/01**	
Radiation						
Chemotherapy	**8/95 12/95**	**1998**		**10/01**	**1/01 4/01**	
Naltrexone				**9/00**		
CT scan				**8/00**	**4/01**	
Tumor markers	**8/95**	**1998**	**8/99**	**2000**	**7/01 8/01**	
CAM other		**1998**		**12/00**	**4/01**	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

CAM Therapy:	Naltrexone		
Case:	2-6		
Condition:	Ovarian cancer		
Abstractor:		**Date of Abstraction:**	7/12/01
Interviewer:	AC JU	**Date of Interview:**	10/9/01
Comments:	Fair case: patient increased pelvic thickening after 7 months of Naltrexone, per patient. Also on chemo		

Criteria for inclusion: (check all that apply)			
	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	7/28/45
Diagnosis:	Ovarian cancer
Diagnosis date:	8/1/95
CAM therapy dates:	9/19/00
Conventional therapy dates:	8/95- surgery 8/95-1/96 chemotherapy
Last contact date:	8/14//2001
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Date	Description of Events
	History of migraines, GERD
Aug-95	Surgery: ovarectomy and hysterectomy
Aug-95	Biopsy: Diagnosis of ovarian cancer in pelvis
Aug-95	CA-125: 65
Aug-95	CA-125: <35
8/95-12/95	Chemotherapy: taxol, cysplatin; 6 rounds completed
10/97-5/98	Acupuncture
1998	Vitamin C and mistletoe, full body hyperthermia
1998	CA-125: 200
1998	CA-125: 110
1998 or 1999	Chemotherapy: doxil, topotecan:11month- completed therapy; followed by doxil 12 months-completed therapy
Aug-99	CA-125: 100
Aug-99	CA-125: 30
8/28/00	CT scan abdomen compared with 9/11/98: 3.5cm cyst in posterior medial left hepatic lobe anterior to portal vein, unchanged, no sign of metastatic disease
8/28/00	CT scan pelvis: no sign of recurrent metastatic disease

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Date	Description of Events
9/19/00	Naltrexone 3mg qhs up to 6.5mg qhs
10/3/00	Chemotherapy: erythrotecan and low dose taxol
12/00-4/01	Went to Mexico had alternative cancer treatment with vaccine
2/1/01	Surgery: laporascopy: reportedly did not reveal anything
4/19/01	CT scan chest abdomen pelvis: few tiny nodual densities bilateral axilla, 1cm nodularity right lower lobe lung (new); few tiny cysts in liver; multiple soft tissue densities in liver; pelvic cyst 3.8cm
4/19/01	Chemotherapy: initiated due to lesions on liver presumably metastatic disease : campthzar/cysplatin
7/20/01	CA-125: 765
8/14/01	CA-125: 135

Additional Case Reviewed

Patient #2-14

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14

Case 2-14

The patient in case 2-14 is an 11-year-old female with a history of metastatic neuroblastoma of the right adrenal gland. She was initially diagnosed in February 1996. She had surgery and palliative chemotherapy from March 1996 to December 1996. Response was inadequate and the patient had a stem cell transplant in February 1997. She also received one year of therapy at the Burzinski Clinic starting in August 1997. Recurrent disease was identified in the bone marrow in February 1999. [Naltrexone was initiated in July 1999.] A second course of chemotherapy (topotecan) was initiated in August 1999 but stopped early (February 2000) due to side effects. Currently, she is paralyzed in both lower extremities due to metastatic disease and her prognosis is poor according to the next of kin (interview 10/9/01).

Pathology

11/1/97	**Biopsy: bone marrow- partial replacement of hematopoetic elements with sheets of aggregate malignant cells consistent with recurrent neuroblastoma**
2/22/99	**Biopsy: bone marrow- neuroblastoma**
4/5/99	**Biopsy: bone marrow- neuroblastoma**
8/5/99	**Biopsy: bone marrow- partial replacement by malignant cells**
8/30/99	**Biopsy: bone marrow-neuroblastoma**
8/30/99	**Biopsy: bone marrow- residual, recurrent neuroblastoma**
11/16/99	**Biopsy: bone marrow- residual, recurrent neuroblastoma**
12/16/99	**Biopsy: bone marrow- marked decrease of platelets, trilineage hematopoesis with maturation, clusters of aggregates of malignant cells were not identified, but clot sections showed some irregular areas of fibrosis with aggregates of malignant cells consistent with metastatic neuroblastoma**
2/23/00	**Biopsy: bone marrow- hypercellular for patient's age**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Imaging

7/29/97	**CT scan: abdomen**
3/12/99	**CT scan: chest abdomen pelvis: lesions in L2 suspicious for metastatic disease**
4/5/99	**Bone scan: multiple foci of abnormal accumulation of the tracer in the sternum, thoracic spine, lumbar spine, both sacroiliac joints, and the left superior acetabular region and left anterior 11th rib**
6/21/99	**Bone scan: increased uptake in right humerus, sternum, T/L spine, left SI joint**
6/24/99	**CT scan abdomen/pelvis: new crural lymph node 1cm; 13mc paracaval lymph node minimally change in size with necrosis; 12mm x 11mm soft tissue density in gastric antrum which may represent a lymph node or lesion; new sclerotic lesion at T7**
8/30/99	**Bone scan: whole body- stable osseous lesions**
11/18/99	**Bone scans: no new lesions: T10 lesion improved: resolution of left tibial lesions**
1/12/00	**CT scan: eyes: normal**
1/14/00	**CT scan: abdomen/pelvis: no interval change T7, L2 vertebral lesions**
2/22/00	**Bone scans: no new lesions: improved but persistent bony changes**

Conventional therapy

3/1/96	**Surgery: s/p right adrenalectomy**
3/1/96	**Chemotherapy- topotecan, anti-neoplasmen**
2/97	**Stem cell transplant**
Jun-99	**Platelet infusions-weekly**
8/13/99	**Surgery: central catheter placement**
8/99 – 2/00	**Chemotherapy – topotecan, stopped early due to side effects**

Complementary therapy

8/97 - 98	**Burzinski clinic – anti-neoplastin therapy**
7/21/99	**Naltrexone 1.5mg qhs**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Patient # 2-14						
EVENT	PERIOD 1 1st qtr 1996 – 4th qtr 1996	PERIOD 2 1st qtr 1997 – 4th qtr 1997	PERIOD 3 1st qtr 1998 – 4th qtr 1998	PERIOD 4 1st qtr 1999– 4th qtr 1999	PERIOD 5 1st qtr 2000 – 4th qtr 2000	PERIOD 6 1st qtr 2001 – 4th qtr 2001
Diagnosis/biopsy	3/96	11/97		2/99 4/99 8/99 11/99, 12/99	2/00	
Surgery	3/96					
Radiation						
Chemotherapy	3/96					
CT scan		7/97		3/99 4/99 6/99, 8/99 11/99	1/00, 2/00	
Naltrexone				7/99		

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

CAM Therapy:	Naltrexone		
Case:	2-14		
Condition:	Neuroblastoma of right adrenal		
Abstractor:	AC IC JU	**Date of Abstraction:**	9/15/01
Interviewer:		**Date of Interview:**	10/9/01
Comments:	Good documentation of bone marrow biopsies, blood counts, CT's and bone scans, since starting naltrexone. However, pt has been receiving anti-neoplastin concurrently. Blood counts improved, but biopsies remain full of malignancy.		

Criteria for inclusion: (check all that apply)		
	Diagnosis confirmed	
	Documented start date for CAM therapy	
	Documented previous anti-cancer therapies	
	No other therapies during the CAM therapy	
	Documented endpoint:	
		Tumor size
		Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	female
DOB:	9/27/90
Diagnosis:	Neuroblastoma of right adrenal stage IV
Diagnosis date:	9/1/97
CAM therapy dates:	7/21/99 Naltrexone started
Conventional therapy dates:	chemotherapy (dates unclear)
Last contact date:	6/01
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Date	Description of Events
3/1/96	Surgery: s/p right adrenalectomy
3/1/96	Chemotherapy- topotecan, anti-neoplasmen
7/29/97	CT scan: abdomen
11/1/97	Biopsy: bone marrow- partial replacement of hematopoetic elements with sheets of aggregate malignant cells consistent with recurrent neuroblastoma
2/22/99	Biopsy: bone marrow- (results ?)
3/12/99	CT scan:chest abdome pelvis: lesions in L2 suspicious for metastatic disease
4/5/99	Biopsy: bone marrow- (results ?)
4/5/99	Bone scan: multiple foci of abnormal accumulation of the tracer in the sternum, thoracic spine, lumbar spine, both sacroiliac joints, and the left superior acetabular region and left anterior 11th rib
Jun-99	Platelet infusions-weekly
6/21/99	Bone scan: increased uptake in right humerus, sternum, T/L spine, left SI joint
6/24/99	CT scan abdomen/pelvis: new crural lymph node 1cm ; 13mc paracaval lymph node minimally change in size with necrosis; 12mm x 11mm soft tissue density in gastric antrum which may represent a lymph node or lesion; new sclerotic lesion at T7
7/21/99	Naltrexone 1.5mg qhs
8/5/99	X-ray: chest- no acute cardio-pulmonary process
8/5/99	Biopsy: bone marrow- partial replacement by malignant cells
8/13/99	Surgery: central catheter placement

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Date	Description of Events
8/13/99	X-ray: chest- no complications evident for previously described antral and porta hepatis lymph nodes
8/30/99	Biopsy: bone marrow-neuroblastoma
8/30/99	Bone scan: whole body- stable osseous lesions
8/30/99	Biopsy: bone marrow- residual, recurrent neuroblastoma
11/16/99	Biopsy: bone marrow- residual, recurrent neuroblastoma
11/18/99	Bone scans: no new lesions: T10 lesion improved: resolution of left tibial lesions
12/16/99	Biopsy: bone marrow- marked decrease of platelets, trilineage hematopoesis with maturation, clusters of aggregates of malignant cells were not identified, but clot sections showed some irregular areas of fibrosis with aggregates of malignant cells consistent with metastatic neuroblastoma
1/12/00	CT scan: eyes: normal
1/14/00	CT scan: abdomen/pelvis: no interval change T7, L2 vertebral lesions
2/22/00	Bone scans: no new lesions: improved but persistent bony changes
2/23/00	Biopsy: bone marrow- hypercellular for patient's age
2/17/00-7/11/00	Serial CBC's: improving

Additional Case Reviewed

Patient #2-16

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16

Case 2-16

The patient in case 2-16 is a 62-year-old male with a history of squamous cell carcinoma of the lung with level 4 cervical lymph node involvement. He was diagnosed on 3/00. He declined conventional therapy. In June 2001, he was diagnosed with ascend primary melanoma. Naltrexone was initiated in June 2001. The cancer has continued to spread, and currently the patient has left-sided hemiparesis. His prognosis is poor but the patient reported at his interview (10/16/01) that his physical condition is very good.

Pathology

3/00	**Chest biopsy: fine needle aspiration: squamous cell carcinoma**
5/5/00	**Lymph node biopsy: right neck non-small cell carcinoma**
5/15/00	**Chest biopsy aspiration: pathology: metastatic non-small cell carcinoma**
6/15/00	**Physical exam: 3cm x4cm hard node in right neck**
10/27/00	**Physical exam: 1.75cm x 2.5cm hard node in right neck**
6/14/01	**Biopsy, mid-back: pathology: melanoma in situ, closely approaching the margins**
6/26/01	**Physical exam: 3cm x4cm hard node in right neck**
	Bronchoscopy: pathology: washings and brushing; negative for tumor

Imaging

2/29/00	**CT scan chest: primary tumor in RML of lung; increased hilar/peritracheal nodes**
3/15/00	**CT scan: abdomen/pelvis: enlarged prostate: no evidence of metastatic disease**
4/26/00	**PET scan: whole body: right-sided cervical and right mediastinal malignant adenopathy**
7/28/00	**CT scan chest: extensive mediastinal lymphadenopathy: nodular densities in both lungs**
11/10/00	**CT scan chest: primary tumor in RML of lung (no change); hilar/peritracheal nodes (no change)**

Conventional therapy
none

Complementary therapy

6/1/01	**Naltrexone 4.5 mg QHs**
	Supplements: multiple nutritional supplements, MGN3, shitake mushroom, wheat grass

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

Patient # 2-16						
EVENT				**PERIOD 1** **1st qtr 1999– 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 3** **1st qtr 2001 – 4th qtr 2001**
Diagnosis/biopsy					**3/00 5/00**	**6/01**
Surgery						
Radiation						
Chemotherapy						
CT scan					**2/00, 3/00 4/00 7/00 11/00**	
Naltrexone						**6/01**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

CAM Therapy:	Naltrexone		
Case:	2-16		
Condition:	Lung squamous cell carcinoma with level 4 cervical lymph node		
Abstractor:	AC IC Ju	**Date of Abstraction:**	9/30/01
Interviewer:		**Date of Interview:**	10/16/01
Comments:	Good documentation of improved quality of life, but decrease in neck node only documented on physical exam		

Criteria for inclusion: (check all that apply)			
	Diagnosis confirmed		
	Documented start date for CAM therapy		
	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
	Documented endpoint:		
		Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	7/10/39
Diagnosis:	Lung squamous cell cancer, level 4 cervical lymph node
Diagnosis date:	3/1/00
CAM therapy dates:	6/15/00 Naltrexone
Conventional therapy dates:	none
Last contact date:	6/26/01
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

Date	Description of Events
	Brother died of stomach cancer
2/29/00	CT scan of lungs: reveals tumor and enlarged lymph nodes
	Biopsy done: results unknown
3/15/00	CT scan of abdomen (belly) and pelvis reveals enlarged prostate
4/26/00	PET scan reveals enlarged lymph nodes in chest
5/5/00	Biopsy done: reveals lung cancer
5/15/00	Biopsy done: reveals lung cancer
6/15/00	Physical exam: hard lymph node in right neck
6/15/00	Started Naltrexone
7/28/00	CT scan of lungs: reveals tumor and enlarged lymph nodes
	Started supplements: multiple nutritional supplements, MGN3, shitake mushroom, wheat grass
10/27/00	Physical exam: hard lymph node in right neck smaller compared with prior exam
11/10/00	CT scan of lungs: reveals tumor and enlarged lymph nodes, unchanged
6/1/01	Increased dose of Naltrexone
6/14/01	Biopsy done on mid-back: reveals melanoma

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

Date	Description of Events
6/26/01	Physical exam: hard lymph node in right neck
	Exam whereby a small camera inserted into airway: Cells from exam do not reveal any cancer

Additional Case Reviewed

Patient #2-17

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17

Case 2-17

The patient in case 2-17 is a 68-year-old male with a history of multiple myeloma. He was diagnosed in September 1998. He has completed his first course of chemotherapy from August 1998 to October 1999. He initiated Naltrexone in January 1999. His immune globulin levels were followed closely, and showed an increase in June 2001. At that time he resumed chemotherapy with biaxin, thalidomide, and decadron. Since that time his IgG levels have decreased and at his interview (10/8/01), the patient rated his overall physical condition as good.

Pathology

9/2/98	**Biopsy bone marrow: marrow infiltrated by plasma cell c/w plasma cell myeloma**

Imaging

2/15/99	**MRI: lumbar spine: nodule within cauda equina at L2; presumed to be small neuroma; chronic compression fractures in L1 and L5**
6/1/99	**X-ray: pathological fracture in 4 vertebrae in 2 ribs**
1/3/00	**MRI: lumbar spine: nodule at L2 unchanged: numerous punctate focal bony lesions throughout lumbar spine; presumed to represent tiny multiple myeloma deposits**
6/22/00	**Bone scan: whole body: increase uptake in regions T6, T8-T10**

IgG levels

12/2/98	**IgG 9290**
4/14/99	**IgG 5310**
5/6/99	**IgG 4130**
6/3/99	**IgG 4130**
6/4/99	**IgG 4180**
7/14/99	**IgG 2780**
8/4/99	**IgG 3100**
8/30/99	**IgG 2290**
10/22/99	**IgG 1260**
12/5/99	**IgG 1260**
1/20/00	**IgG 1400**
2/17/00	**IgG 1380**
3/16/00	**IgG 1500**
4/11/00	**IgG 1320**
5/9/00	**IgG 1280**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

6/8/00	**IgG 1230**
7/5/00	**IgG 1240**
8/2/00	**IgG 1030**
9/27/00	**IgG 1550**
10/26/00	**IgG 1840**
11/30/00	**IgG 2030**
1/2/01	**IgG 2290**
1/30/01	**IgG 3110**
2/21/01	**IgG 3200**
3/29/01	**IgG 4520**
8/1/01	**IgG 649**

Conventional therapy

9/98-10/99	**Chemotherapy: AB/CM**
2/99-10/99	**Chemotherapy: cytoxan, melphalan, decadron, zofran q 3weeks**
6/1/01	**Chemotherapy: thalodimide, biaxin, decradron**

Complementary therapy

1/29/99	**Naltrexone 4.5 mg QHs**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Patient # 2-17						
EVENT	**PERIOD 1** **1st qtr 1995 – 4th qtr 1995**	**PERIOD 2** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 3** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 4** **1st qtr 2000– 4th qtr 2000**	**PERIOD 5** **1st qtr 2001 – 4th qtr 2001**	
Diagnosis/biopsy						
Surgery						
Radiation						
Chemotherapy		**9/98**	**10/99**		**6/01**	
Naltrexone			**1/99**			
Imaging			**2/99 6/99**	**1/00 6/00**		
CAM other						

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

CAM Therapy:	Naltrexone		
Case:	2-17		
Condition:	Multiple-myeloma stage 3B		
Abstractor:		**Date of Abstraction:**	7/13/01
Interviewer:	AC IC JU	**Date of Interview:**	10/8/01
Comments:	Well-documented decrease in IgG with subsequent rise in IgG to pretreatment levels		

Criteria for inclusion: (check all that apply)		
	Diagnosis confirmed	
	Documented start date for CAM therapy	
	Documented previous anti-cancer therapies	
	No other therapies during the CAM therapy	
	Documented endpoint:	
		Tumor size
		Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	4/30/32
Diagnosis:	Multiple myeloma stage 3b
Diagnosis date:	9/2/98
CAM therapy dates:	1/29/99 Naltrexone
Conventional therapy dates:	
Last contact date:	
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Date	Description of Events
9/2/98	Biopsy bone marrow: marrow infiltrated by plasma cell c/w plasma cell myeloma
9/98-10/99	Chemotherapy: AB/CM
12/2/98	IgG 9290
2/15/99	MRI: lumbar spine: nodule within cauda equina at L2; presumed to be small neuroma; chronic compression fractures in L1 and L5
2/99-10/99	Chemotherapy: cytoxan, melphalan, decadron, zofran q 3weeks
4/14/99	IgG 5310
5/6/99	IgG 4130
6/1/99	X-ray: pathological fracture in 4 vertebrae in 2 ribs
6/3/99	IgG 4130
6/4/99	IgG 4180
7/14/99	IgG 2780
8/4/99	IgG 3100
8/30/99	IgG 2290
10/22/99	IgG 1260
12/5/99	IgG 1260
1/3/00	MRI: lumbar spine: nodule at L2 unchanged: numerous punctate focal bony lesions throughout lumbar spine; presumed to represent tiny multiple myeloma deposits

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Date	Description of Events
1/20/00	IgG 1400
2/17/00	IgG 1380
3/16/00	IgG 1500
4/11/00	IgG 1320
5/9/00	IgG 1280
6/8/00	IgG 1230
6/22/00	Bone scan: whole body: increase uptake in regions T6, T8-T10
7/5/00	IgG 1240
8/2/00	IgG 1030
9/27/00	IgG 1550
10/26/00	IgG 1840
11/30/00	IgG 2030
1/2/01	IgG 2290
1/30/01	IgG 3110
2/21/01	IgG 3200
3/29/01	IgG 4520

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Date	Description of Events
6/1/01	Chemotherapy: thalodimide, biaxin, decradron
8/1/01	IgG 649

Additional Case Reviewed

Patient #2-18

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18

Case 2-18

The patient in case 2-18 is a 43-year-old woman with a history of breast cancer in her mother, who was diagnosed with breast cancer in November 1997. Axillary lymph nodes at the time of diagnosis were negative. She subsequently underwent a lumpectomy and radiation. In March 2000, an MRI of the right hip revealed bone metastases. Radiation to the affected hip was completed. She was started on tamoxifen and aridia in March 2000. Naltrexone was initiated in May 2000. During her interview (10/10/01), she rated her overall condition as very good, although results of a followup scan are mixed.

Pathology

11/1/97	**Biopsy: breast cancer estrogen sensitive, nodes negative**

Imaging

12/1/99	**X-ray right hip: normal**
3/1/00	**MRI: brain: questionable abnormality-repeated in 8 weeks**
3/1/00	**MRI hip—right femoral neck and mid-femur; right acetabulum; scattered throughout osseous of pelvis**
May-00	**CT chest: normal**
5/1/00	**MRI: brain: normal**
9/1/00	**CT chest: negative**
9/6/00	**MRI: hip - extensive metastatic involvement of right femur; patchy metastatic involvement of left femur head and neck**
6/1/01	**CT scan liver had small lesions**
6/1/2001-8/01	**Chemotherapy: AC completed**
8/1/01	**Liver lesions remain: oncologist monitoring**
10/22/01	**CT scan of chest abdomen and pelvis. Decrease nodularity at anterior mediastinum. Probable improvement in hepatic lesions, probable healing and improvement in some bony metastases with exacerbation of others**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Tumor markers

Mar-00	**CA 2729: 650**
5/11/00	**CEA 3.6 (0-5)**
12/1/00	**CA 2729: 79**

Conventional therapy

11/1/97	**Surgery: lumpectomy breast**
6/1/98	**Radiation: right breast and right axilla: adverse effects—radiation edema**
Mar-00	**Radiation: pelvis: adverse effects—on crutches since 4/1/00**
3/15/00	**Started tamoxifen 10mg bid and aridia**

Complementary therapy

5/13/2000-present	**Naltrexone**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Patient # 2-18						
EVENT	PERIOD 1 1st qtr 1997 – 4th qtr 1997	PERIOD 2 1st qtr 1998 – 4th qtr 1998	PERIOD 3 1st qtr 1999 – 4th qtr 1999	PERIOD 4 1st qtr 2000– 4th qtr 2000	PERIOD 5 1st qtr 2001 – 4th qtr 2001	
Biopsy/diagnosis	11/97					
Surgery	11/97					
Radiation		6/98		4/00		
Chemotherapy						
Tamoxifen				3/00		
Naltrexone				5/00		
CAM other						
X-ray			12/99			
Imaging-MRI				3/00 5/00 9/00		
Imaging-CT scan				5/00 9/00	6/01 8/01	
Tumor markers				3/00 5/00		

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

CAM Therapy:	Naltrexone		
Case:	2-18		
Condition:	Breast carcinoma metastatic to femur and pelvis		
Abstractor:	AC IC JU	**Date of Abstraction:**	7/13/01
Interviewer:		**Date of Interview:**	10/10/01
Comments:			

Criteria for inclusion: (check all that apply)		
	Diagnosis confirmed	
	Documented start date for CAM therapy	
	Documented previous anti-cancer therapies	
	No other therapies during the CAM therapy	
	Documented endpoint:	
		Tumor size
		Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	female
DOB:	3/3/58
Diagnosis:	Breast cancer; metastatic to femur and pelvis
Diagnosis date:	11/1/97
CAM therapy dates:	5/13/00 Started Naltrexone
Conventional therapy dates:	9/98-10/00 - radiation
Last contact date:	5/1/01
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Date	Description of Events
	History of breast cancer in mother-currently in remission
11/1/97	Surgery: lumpectomy breast
11/1/97	Biopsy: breast cancer estrogen sensitive, nodes negative
6/1/98	Radiation: right breast and right axilla: adverse effects- radiation edema
12/1/99	X-ray right hip: no tumor present
3/1/00	X-ray right pelvis: positive for mets to pelvis/spine
3/1/00	MRI: brain: questionable abnormality-repeated in 8 weeks
3/1/00	MRI hip--right femoral neck and mid-femur; right acetabulum; scattered throughout osseous of pelvis
Mar-00	Radiation: pelvis: adverse effects- on crutches since 4/1/00
3/15/00	Started tamoxifen 10mg bid and aridia
Mar-00	CA 2729: 650
May-00	CT chest: normal
5/1/00	MRI: brain: normal
5/11/00	CEA 3.6 (0-5)
5/13/00-present	Naltrexone
9/1/00	CT chest: negative

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Date	Description of Events
9/6/00	MRI: hip - extensive metastatic involvement of right femur; patchy metastatic involvement of left femur head and neck
12/1/00	CA 2729: 79
6/1/01	CT scan liver had small lesions
6/1/2001-8/01	Chemotherapy: AC completed
8/1/01	Liver lesions remain: oncologist monitoring

Additional Case Reviewed

Patient #2-19

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19

Case 2-19

The patient in case 2-19 is a 51-year-old male diagnosed with non-Hodgkin's lymphoma, small-cleaved cell type on 9/13/99. He declined conventional therapy and has pursued various unconventional therapies for cancer treatment, including Naltrexone (11/99). He has not been followed by any allopathic physician for over a year. While no recent imaging scans have been performed, he reports a submandibular lymph node that has grown to greater than 3cm over the past year. At his interview (10/18/01), the patient reported that his overall physical condition was good to very good.

Pathology

9/13/99	**Biopsy: lymph node (iliac): Malignant lymphoma non-Hodgkin's, small cleaved cell type predominately follicular and focally infiltrative: working formulation low grade**

Imaging/labs

5/14/99	**CT scan abdomen: significant mesenteric adenopathy with multiple enlarged nodes 6cm. Multiple retroperitoneal prominent lymph nodes 2cm**
1/5/00	**CT scan abdomen: nodes are generally smaller, less dense c/w 5/14/99. Largest retro-peritoneal node 1.5cm instead of 2cm. No additional adenopathy**
7/10/00	**CT scan abdomen: mesenteric adenopathy, smaller nodes and less dense/w prior exam. Scattered, small retroperitoneal also appear smaller measuring 1cm or less. No additional adenopathy. Improved mesenteric and retropertoneal nodes.**
1/19/01	**NK cell function 79 (43-100)**
1/19/01	**Heavy metal screen: Mercury: 8.2 Nickel:11 Aluminum:12 Arsenic:53**

Conventional therapy
None

Complementary therapy

11/22/99	**Naltrexone 3mg Qhs**
10/00-3/01	**Removed mercury amalgam fillings; chelation therapy to remove mercury in blood, high dose vitamin C IV therapy**
10/00-3/01	**CoQ10; pancreatic enzymes, essential fatty acids; vitamin E; milk thistle; turmeric; DHEA; selenium; N-acetyl cysteine, pro biotics**
4/01-8/01	**PolyMVA**
8/01-present	**thymic protein; cereal grass (wheat, barley), digestive enzymes**

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19 (continued)

Patient # 2-19						
EVENT			**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000– 4th qtr 2000**	**PERIOD 3** **1st qtr 2001 – 4th qtr 2001**	
Diagnosis/biopsy			**9/99**			
Surgery						
Radiation						
Chemotherapy						
Naltrexone			**11/99**			
Imaging			**5/99**	**1/00** **7/00**		
CAM other			**8/99**			

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19 (continued)

CAM Therapy:	Naltrexone		
Case:	2-19		
Condition:	Non-Hodgkin's lymphoma		
Abstractor:	AC IC JU	**Date of Abstraction:**	7/11/01
Interviewer:		**Date of Interview:**	10/18/01
Comments:	Excellent care of NHL with Naltrexone + acyclovir. CT documented regression		

Criteria for inclusion: (check all that apply)		
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
	x	Tumor size
		Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	12/28/50
Diagnosis:	Non-Hodgkin's lymphoma: well-differentiated follicular lymphocyte lymphoma; monoclonal B-cell
Diagnosis date:	9/13/99
CAM therapy dates:	10/22/99 Naltrexone
Conventional therapy dates:	none
Last contact date:	6/1/01
If deceased, date of death:	

Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19 (continued)

Date	Description of Events
5/14/99	CT scan abdomen: significant mesenteric adenopathy with multiple enlarged nodes 6cm. Multiple retroperitoneal prominent lymph nodes 2cm
9/13/99	Biopsy: lymph node (iliac): Malignant lymphoma non-Hodgkin's, small cleaved cell type predominately follicular and focally infiltrative: working formulation low grade
9/13/99	Radation recommended: patient refused due to pateint preference
11/22/99	Naltrexone 3mg Qhs
1/5/00	CT scan abdomen: nodes are generally smaller, less dense c/w 5/14/99. Largest retro-peritoneal node 1.5cm instead of 2cm. No additional adenopathy
7/10/00	CT scan abdomen: mesenteric adenopathy, smaller nodes and less dense/w prior exam. Scattered, small retroperitoneal also appear smaller measuring 1cm or less. No additional adenopathy. Improved mesenteric and retropertoneal nodes
1/19/01	NK cell function 79 (43-100)
1/19/01	Heavy metal screen: Mercury: 8.2 Nickel:11 Aluminum:12 Arsenic:53
10/00-3/01	Removed mercury amalgam fillings; chelation therapy to remove mercury in blood, high dose vitamin C IV therapy
10/00-3/01	CoQ10; pancreatic enzymes, essential fatty acids; vitamin E; milk thistle; turmeric; DHEA; selenium; N-acetyl cysteine, probiotics
4/01-8/01	PolyMVA
8/01-present	Thymic protein; cereal grass (wheat, barley), digestive enzymes
10/1/00-present	Submandibular node>3cm on physical exam (progressive); patient not followed by physician >1year