

CENTER FOR MIND-BODY MEDICINE
COMPREHENSIVE CANCER CARE 2000

CONCURRENT: NCI/Best Case Series

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MODERATOR: Jeffrey White, MD

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P R O C E E D I N G S

DR. WHITE: Medical oncologist, hematologist for the National Cancer Institute, and the director of the Office of Cancer Complementary and Alternative Medicine at NCI. And certainly, pleased to see you all come out and to learn about the Best Case Series Program.

Was anyone here last year when we went over this? So only a couple of people. So good, this is basically relatively new information for most people.

This is a different format actually than what we did last year at this conference. The goal of this session is, first, to make people aware of the NCI Best Case Series Program, what it is, how it works, what the goals are, but that's my session. That's my section of it, the beginning of it.

But then after that is the more important element, I think, which is how has it worked in the past? And really, for the practitioners that are in the audience, it's an opportunity for you to learn from people that have been through the Best Case Series Program to find out how they dealt with it, how they were able to actually pull together the needed information, present it in an appropriate form, and really show the best of the work that they've been able to do.

I said I really want this to be an opportunity for you to learn and ask your questions. Hopefully, we'll have plenty of time at the end for you to get out all your questions or at least maybe afterwards come up and talk about your -- if you have an interest in putting together one of these Best Case Series presentations, then you will have learned much more about how to do it.

So let's learn what this Best Case Series Program is. All right. Well, just a little background. Actually, before I go to that, I'll just tell you a little history.

From the early time of the Cancer Institute, people have come to NCI with anecdotal information about cancer therapies having effect, unconventional cancer therapies.

But it wasn't really until 1991 that a Best Case Series Program was really put together with some materials and talked to practitioners about what would really be needed, what kind of data is needed for an independent evaluation of responses of unconventional or alternative complementary approaches.

From 1991 until 1998 or thereabouts, or '99, the program was basically I think little known, hardly at all advertised, but still had some activity. And within it actually into the early phases, Dr. Gonzalez got involved in it. But he'll tell you about later his experience in the early years of the Best Case Series and how the information was pulled together.

Then it's gone on with the development of the Office of Cancer Complementary and Alternative Medicine. Now we have an opportunity to formalize and advertise this program and to increase the activity of it and, hopefully, to start looking at many more Best Case Series.

So what are we looking for? Well, basically the Best Case Series is designed to look at therapies that affect a tumor response. So that a mass that's visible on a radiographic study, MRI, CT scan, X-ray, could be followed through a period of time and show a response and shrinkage of the tumor, hopefully a complete remission.

It is this type of documentation and this type of therapy that we're primarily interested in the Best Case Series Program. So we're looking at documentation of response. Certainly, we'd be interested in the context of therapies, looking at therapies and looking at the effect on symptomatology, quality of life, and these kind of issues.

The primary end point of the Best Case Series is to demonstrate effectively, in a well-documented fashion, the treatment approach that has a response of a quantifiable tumor. So we need documentation of tumor shrinkage.

We need, as I pointed out, the quality of life is certainly something that we could look at as a secondary issue.

So we ask for -- this is part of our sort of process of getting out to the community and let people know about it, hopefully, is people contacting us to submit the required documentation for a Best Case Series.

So first, it would be contacting the Office of Cancer Complementary and Alternative Medicine. We have a new flier that will explain a lot of this material. There'll be many copies of these available at the NCI's booth to explain this process more. So contact us and, first, talk to us about what it is that you would like to do. Let us help you understand the program and give you more documentation about or, you know, materials about how to do it.

And the goal is to, and I'll show you at the end, is to get to a presentation, to a panel of alternative medicine practitioners and cancer therapists of all this data. What you're going to need is to have at least four or five completely documented cases of remissions of cancers treated with complementary -- basically an alternative approach.

If these patients had been receiving some concurrent conventional therapy, you know, let us know about it, let us look at that information, as well, but the primary goal of this is to look at patients that have received an alternative approach and that have had a response.

So throw out the case report form for each of these patients. We said a minimum of 4 or 5. If you have 15, 20 patients that you really want all that data to be reviewed, we'd be happy to do it. If you have 100 patients, then we'll stop because we need to make it doable. But a minimum of four or five to get to the presentation at the end.

I don't have a case report form to show you right now because I don't want to spend too much time on my part of the presentation. But basically, what you have is the clinical history, the patient's signs and symptoms, detailed treatment history, what kind of therapy they had before, during, and after your therapy.

Then their history and a physical examination at the time of your treatment, what symptoms they had, and what sites of disease were present. Then you want copies of the reports documenting the state of the disease.

You need copies of the pathology report documenting the tumor type and site and I should have put operative reports, copies of the medical imaging reports, the x-rays, the CT scans, ultrasounds, MRIs, that demonstrate the presence of a tumor that could be followed serially, and throughout the course, it's therapy.

So this is the initial paperwork documentation that's required. All of that would be submitted for each of the patients all at one time, reviewed in my office for completeness, and at that point, if you got the documentation looks complete, then we ask that you would obtain and submit your pathology materials, the actual slides that are demonstrating the biologic diagnosis, and the actual radiographic materials or copies of them that you've already submitted as the paperwork documentation for. And these would be reviewed by NIH pathologists and radiologists.

On the basis of this, if all this documentation is complete and demonstrates a confirmed diagnosis of cancer ——— radiographic emission documented, then you're scheduled for a presentation to the Cancer Advisory Panel. I'm sorry, CAPCAM is Cancer Advisory Panel for Complementary and Alternative Medicine.

This is a panel of 15, approximately 15 people, radiologists, epidemiologists, and the statisticians, oncologists, oncology nurse, there's CAM therapists, there's a patient advocate. It's a chartered panel of the NIH that is constructed to give advice to the director of the National Center for Complementary and Alternative Medicine and, at the same time, I sit on it as an ex-officio on that panel.

The advice that is given is used by NCI, also, in determining some of our priorities in looking at CAM therapies.

The goal then, the type of advice that we would expect, is recommendations that say that this therapy or this Best Case Series demonstrated an effect. We would recommend that some further investigation and may make specific recommendations about what further type of research should be pursued: Prospective clinical trial or outcomes monitoring, which we can talk more about, or something.

It would then be the onus on the NCCAM, the National Center for Complementary and Alternative Medicine, and the NCI to produce the appropriate mechanisms for following this research or pushing forward research in this area.

The CAPCAM meets twice a year, generally, June and December. I know this year, our June meeting was cancelled. There's going to be a meeting in September. And a new addition to the program is that the practitioners, their travel and accommodations will be paid for their presentations. So again, to give a little incentive for this.

But you have to get through the whole process before you get to that point.

I guess, this should have gone before the other one. Cancer Advisory Panel for Complementary and Alternative Medicine, what it's composition is, and that it advises the National Center for Complementary and Alternative Medicine.

Originally, what I thought what we ought to do is just to go through all the presentations. And I think probably still it would be nice to just step through each presentation, let you hold your questions until the end unless there's some pressing, you know, lack of clarity with what I've already presented.

So what I'd like to do next is introduce Dr. Nicholas Gonzalez, who has been through this Best Case Series Program. I think many of you are already familiar with him and he's presented at this conference several times.

He will tell you about his experience of the Best Case Series process, back in '93 was it?

DR. GONZALEZ: Ninety-three.

DR. WHITE: Ninety-three. And it'll give you a perspective, hopefully, then with the next presentation which would be a Best Case Series Program from '98-'99. Then at the end, we can just take questions from the group.

DR. GONZALEZ: I spoke for 6 hours on Wednesday and then there was an hour of questions, and some of you were at that conference on Wednesday. And at that conference, I spoke about how I do what I do and the history of what I do, and I realize this is not the place for that, but I thought a couple minutes of background would be essential just to kind of give you some context for how this all developed.

The program I use to treat patients is a nutritional program and it involves three components. No intensive diet. Now, the interesting thing about our program is we have different diets for different patients; we don't have one diet. Our diets range from pure vegetarian to meat two or three times a day.

We find solid tumor patients, epithelial cancer patients, tumors of the breast, the lung, the pancreas, the colon, the uterus, et cetera, tend to do well on a vegetarian diet. Blood-based tumors, tumors of the bone marrow, leukemia, and lymphoma patients seem to do best on a meat-based diet. We have 10 basic diets.

You use large doses of supplements. Yes, we use vitamins and minerals and trace elements, and the protocols tend to be individualized. We don't think they have a particular anticancer effect. As many of you know, particularly those of you who heard me speak on Wednesday, the main anticancer aspect of our program are large doses of proteolytic pancreatic enzymes derived from the pig pancreas.

We believe pancreatic enzymes not only digest food, which is their main function in orthodox physiology, but also have a very powerful anticancer effect.

I wasn't smart enough to think of that myself. The Scottish embryologist John Beard, about whom I spoke for 2-1/2 hours on Wednesday, first proposed, in 1902, that the proteolytic pancreatic enzymes represent the body's main defense against cancer and could be useful as a cancer therapy.

He wasn't a physician. He wasn't really a cancer researcher. His area of expertise was embryology and his work is still quoted in the embryologic literature 100 years later. He presented his work in Scotland. He was a professor at the University of Edinburgh in 1902. He

was universally derided, although there were a number of physicians who took his work very seriously and actually used injectable pancreatic enzymes to treat cancer.

Up in my room, I have a series of cases from the major medical journals, such as JAMA and the British Medical Journal, documenting tumor regression, and I think you could cautiously say cure, with advanced biopsy-proven cancer treated only with enzymes, and this is 1905, 1910, 1915. And I have a wonderful historical library of anecdotal case reports from the orthodox medical literature at that time.

Beard wrote a book in 1911 called *The Hands-On Treatment of Cancer*, that I think is one of the most important books on oncology; probably 50 people read it at the time. He died in obscurity in 1923, as radiation therapy and the beginnings of chemotherapy began to take over oncology. Chemotherapy more since World War II, but certainly radiation therapy is really being proposed as a very simple, easy, nontoxic way of treating cancer back in the '20s, of course, in the teens of the last century.

It'd take a generation of radiation oncologists to die of leukemia before we realized how toxic radiation could be and the fact that even if you get tumor reduction, it doesn't mean you get a cure, which actually, 80 years later, kind of relates to the NCI's approach to response and discussions about what constitutes a response.

Beard's work was largely forgotten except in certain areas of the alternative world. There were physicians and practitioners who periodically would resurrect his work. The most formidable and most notable and the most controversial of these was my mentor, Dr. William Kelley, the eccentric and controversial dentist who, over a 20-year period, developed a very intensive way of treating cancer using diet, supplements, large doses of pancreatic enzymes, the controversial detoxification routines, such as coffee enemas.

Again, it isn't the purpose of this session to talk about the theorem behind those things. I just want to give you a context of where I'm coming from.

I learned about Dr. Kelley in 1981, after my second year of medical school at Cornell. I was fortunate at the time that I was already kind of being taken under the wing of Robert Good, who, at that time, was president of Sloan-Kettering Cancer Institute.

And I see Chuck Simone in the background. I know that Robert Good wrote the introduction to his book back in the '80s, and Dr. Simone is very familiar with Dr. Good. Dr. Good was a very interesting, very controversial figure. He was, at that time, the most published author in the history of the biomedical sciences.

He was trained as a pediatrician, had a Ph.D. in physiology, had been formerly chairman of pathology at the University of Minnesota, a very eminent man. His area of expertise, if he had an area of expertise that you could specifically say, well, this is what he really does, was immunology.

He was one of the first people to determine what the thymus did. He did one of the first, if not the first, bone marrow transplant in 1969. And he had a habit of taking students at Cornell under his wing and generating kind of a research interest in those students.

I had met Kelley in the summer of 1981. Again, the details of which aren't important for this session. At that time, he was very controversial. He was just coming off of that Steve McQueen fiasco. Steve McQueen, the actor who did Kelley's program.

Kelley was desperate to have his work tested. This is 1981, before the NCI had an Office of Alternative Medicine, before there was a National Center for Alternative Medicine, before any of those things were up and running.

It was a very controversial time to be treating cancer patients with nutrition, particularly if you were a dentist and not a physician, so there were all kinds of legal issues involved.

When I met Kelley, he expressed one interest and one intention. Whatever's said about him or isn't said about him, whatever people may think or not think about him today in 2000, in 1981 he had one intention. He wanted his work properly evaluated by the orthodox medical community.

He believed he was doing something of value. He also said in our first session that if he was doing something of value it needed to be tested properly so it could be mainstreamed into orthodox medicine where any big therapy belongs. I thought that was a very noble and honorable intention, and he maintained that intent through the next 5 years.

Under Dr. Good's direction, initially, as a medical student, but subsequently as an immunology fellow in his research group which, at that point, eventually moved to the University of South Florida, I completed an intensive investigation of Kelley's work.

I mention that not to just take up time, but that really, in my estimation, was my first experience with a Best Case Series. And I think it's kind of interesting to just review how I did that.

We were confronted with an alternative practitioner in 1981, who had treated literally over 10,000 patients using this nutritional program over a 20-year period. It was a mass of information.

One of the first things Kelley did for which I respect him to this day enormously, is he opened all his records to me. There were no secrets. His successes, his failures, the people that loved him, the people that wrote him hate letters, all that stuff was opened to me from the time I first started investigating his work. There were no secrets.

We were confronted with a mass of records. Half of them were in Dallas, where we had an office, half of them were in Washington state; some of them went back 25 years. At one point, he had had a fire in his house, some of his records were destroyed. And I was confronted with this enormous project that Dr. Good was encouraging me to do without the slightest idea how to do it.

And Dr. Good, who was an extraordinarily good research director, immediately gave me some direction. And this, to my estimation, might be the beginnings of my understanding or my competence with the Best Case Series. He said we have to put some order into this and we're going to do it in three ways. He said, first, you have to understand how he's treating patients, and this is just kind of interesting. No matter what you're investigating, you've got to know what the guy's doing, you know. You talk about enzymes, you got to do historical research, you got to look at any studies, any cases that have been treated in the past by other people. Put that all together.

Secondly, we have to start looking for cases. In the second third of the book, he said you should have 50 different cases representing a variety of different cancers, all of them have to be biopsy-proven, diagnosed at appropriate institutions by qualified pathologists so there's no question about the diagnosis. All of them have to have poor prognosis or terminal cancer by anybody's standards in orthodox medicine. And all of them have to have either tumor regression, now that was a big "either" then, either tumor regression or survival. One of the things that Kelley made clear to me early on is sometimes tumors go away and sometimes they don't, and sometimes the patients, when the tumors go away, can live as long as patients where the tumors don't go away.

He didn't really understand the mechanism of that, but did immediately, in his own infinite wisdom, said just don't worry about that. If the tumors go away, great. If they don't go away, that's fine, as long as the patients live far beyond what would be considered the standard median survival.

So he was specifically looking for patients with poor prognosis or terminal disease who were under Kelley's care and only under Kelley's care. We wanted patients where we had clean cases where they weren't getting a lot of other intensive therapy, had lived either -- prolonged survival that by anybody's standards would be exceptional or had obvious evidence —— surgical reports of tumor regression.

It took eventually 5 years to do that. Of course, I began the study while I was a medical student, continued it extensively while I was a fourth-year medical student. I had a 4-month block of time to really get involved with this. Then during my 2-year immunology fellowship this is primarily what I did.

To the day I die, will be grateful to Dr. Good that he allowed me to do this while I was doing my immunology training. I eventually went through 10,000 of Kelley's records, evaluated over 1,000 very intensively. By intensive evaluation, I mean, we got complete medical records. I interview all his patients, over 1,000. Of this group, we were able to select 455 that we felt at least met the initial criteria for the second part of the research study. Terrible prognosis, biopsy-proven, radiographic studies either —— survival or tumor regression. We eventually selected that down to 50 patients that we evaluated -- that I evaluated extensively. Some of these patients I interviewed 6, 8, 10 times. Some of them I actually went to their home. We got complete medical records.

Now again, we were looking retrospectively at the patients treated in the past, sometimes 15 years prior to this investigation. Some of these patients may have been good patients, but may have died. Some of them may have been hit by a truck. In these cases, you had to track down the cause of death, you have to find surviving family members, you have to get death certificates. Doing a Best Case Series is not an easy thing because you're really looking at patients treated in the past.

Now a prospective trial, you start treating patients day one, you put patients on your therapy. You have total -- you know, at least some control over what's going on. You can absorb these patients. You can monitor them for compliance. When you're looking at patients in the past, as I learned and as Dr. Good immediately knew, there are going to be problems. First, you could have patients that did well, but you have to have some proof that they did the program. There could be patients that suddenly died. You want know about their compliance. Did their compliance drop off? If they died, did they die of cancer? Did they die of something else? You

have to get death certificates. This is not a simple undertaking when you're reviewing patients treated in the past as opposed to a prospective trial where you start treating patients day one and watch them over time. You can watch them very closely.

Well, as you can imagine, it took a lot of work. What I thought I'd do is just from that original Best Case Series, which was completed in 1986. This is the report that I completed as far as the research fulfillment for my immunology training under Dr. Good. It's 500 pages long. Now the way he did the 50 cases, and these are technical aspects that later led to the way I do my NCI Best Case Series, is that there would be a very lengthy case report on the patient, which I wrote up, and then we actually got permission from the patients to use their medical records and use their name, publicly.

So if I publish this I could actually have their name. We wanted to do everything we could to minimize criticism that the patients didn't exist or I made them up. We have the actual medical reports in this Best Case Series. We have the biopsy reports, doctors' notes.

We don't have a lot of time, we don't want to take up a lot of time. I just thought I'd very quickly go over the two cases to give you an example of the kind of cases we had.

Betty Anna Evans was a 74-year-old woman in 1986, when I wrote this, from ——— 9 years since her diagnosis with metastatic cervical cancer. She had an initial more complicated history. She had, in 1977 had episodic vaginal bleeding that gradually worsened over a 6-month period. She was kind of in denial, went to her gynecologist, biopsy, did a cervical mask, came back carcinoma of the cervix.

They recommended localized radiation, which she had. They wanted to do surgery, of course, but she refused surgery. At one point, she stopped radiation. In mid-February, the doctor called the family, saying he was very concerned.

I actually have the doctor's letter here: "This patient called in to say that she did want to take her off her treatment. I called her daughter and had a long talk. The daughter is to continue and try and change her mother's mind."

There's a lot of intensive pressure to get this woman to do something. She hadn't started any other alternative therapy at that time. She agreed eventually to have radiation insertion therapy, which she had. It didn't really work very well. The patient decided to quit.

She had a repeat biopsy that was positive for cancer and, at that point, she decided that she was just going to die and stopped any treatment.

Throughout the summer, the cancer grew unchecked. In September, because of enlarging pelvic tumors which the doctors describe in the notes, Mrs. Evans developed a partial urinary tract obstruction. A ——— confirmed declining function of both kidneys that Mrs. Evans refused ——— intervention. After vaginal bleeding worsened, she heard about Dr. Kelley. But before she could even see him and start his program, ended up in the emergency room.

She was found to be severely anemic with a hemoglobin of 7.4 and noted to have a large abdominal mass extending into the bladder.

Quote. This is from the medical record: "The lower abdomen we tender and was felt likely that there was some urinary tension, because of the mass rising out of the pelvis, it was difficult to assess."

I had that actually made here. That's what makes a difference in a Best Case Series, if you can actually have the record. This is the emergency room admission note where the provisional diagnosis is cancer of uterus, terminal.

They describe the mass. ——— writes, "The lower abdomen was tender and was felt likely there was some urinary tension. However, because of the tumor mass rising out of the pelvis, it was difficult to assess."

She was started on Brompton's cocktail, which is an old pain remedy that involved oral morphine, sent home to die. Started the Kelley program; within a year, the tumors were gone. The last time I spoke to her which was about 1990, which was, at that point, about 13 years after she'd been diagnosed, she was alive and well with no evidence of cancer, only treated with Kelley. And we had the medical reports from the orthodox physicians saying this woman is terminal, that she has tumors arising out of the pelvis, that she has a frozen pelvis." So that's the way we put these cases together.

Another case; again, which I'll go over briefly because time is so limited. Arlene Van Stratton (?), at that time, was a 51-year-old woman from Wisconsin who was alive at that time when I wrote this, 5 years since her diagnosis of metastatic adenocarcinoma of the pancreas. 1980, had digestive problems, ended up in a local hospital, St. Elizabeth Hospital in Appleton, Wisconsin.

We, again, had permission to use their names and their medical records. The following day, an ultrasound study showed gallbladder disease, gallstones; went to surgery. The gallbladder was filled with stones, but the pancreas was enlarged throughout its entire length and, lo and behold, there was a tumor in the right lobe of the liver.

The tumor mass was biopsied, you know, the tumor in the liver was biopsied; found consistent with metastatic adenocarcinoma, consistent with pancreatic origin.

She subsequently went to the Mayo Clinic. Now the Mayo Clinic doctors felt she was so advanced that chemotherapy would be a waste of time. In the official records, "the patient's prognosis is judged to be no longer than 15 months at most." They decided that chemotherapy should be reserved for palliation and they said really don't recommend any therapy.

This is from the Mayo Clinic now, and they had a long discussion with her regarding treatment for her cancer. "At the present time, ——— observation since we know of no known treatment that will necessarily prolong her life." She subsequently started the Kelley program and the last time I spoke to her was 1995, 13 years after original diagnosis when she referred a patient to me. I haven't spoken to her since.

Now there's a patient where she never wanted another CAT scan so we have no idea whether she had tumor regression.

In Betty Anna Evans, there was obvious clinical regression of disease. In Arlene Van Stratton, she actually never went back to her orthodox physicians after her original diagnosis, so I can't say that she had tumor regression.

During the 1980s, the NCI standard for a response from chemotherapy, immunotherapy, or whatever, was a 50 percent reduction in tumors at 4 weeks. They use tumor reduction as the gold standard. One of the things we did in our early Best Case Series under Dr. Good's wise direction was to look at tumor regression yes, but also to consider survival because you can have extraordinary survival, that should be a significant finding.

When I finished this, of course, I thought the world would open up, we would get research funding, et cetera. This is 1986-87, before every hospital in New York had a Division of Alternative Medicine. When we tried to publish -- now Robert Good was the most published author in the history of medicine. Believe me, he knew a lot of medical editors from the New England Journal to esoteric research journals. I tried to publish this as an monograph without success.

I tried to publish individual case reports, a series of case reports; tried to publish it as an article; tried to publish it as a review of an alternative therapy; tried to publish it in any way I could with absolutely no success.

I spent 2 years trying to publish this in any way, shape, or form. I couldn't, even with Dr. Good's support and help. We met with just absolute stonewall. People thought either the records couldn't be real, they had to be faked. It's impossible that nutrition could be useful to treat cancer. I have a pile of letters that are just amazing sometimes when you think about it.

There were editors who believed in it and who thought these records looked real, but that it was too controversial and I'm very serious about this. This is the mid-1980s, I don't give up easily.

Dr. Kelley in discouragement closed down his practice. In my attempt to salvage it I went back to -- Dr. Good was in sort of semi-retirement in Florida. He was no longer president of Sloan-Kettering. He didn't have the research base; the resources to kind of support a controversial issue like this.

So I went back to New York with \$200 in my pocket, started seeing patients in 1987 with the intention and the only intention that someday I would have research money to have his work tested properly because I believe that it had value.

The NCI learned of my work. We were in communication throughout 1992. In 1993, they graciously invited me to present cases on July 7, 1993. I'm not sure, I don't remember if whether we used the term Best Case Series at that time. But I think at least toward the time I presented we did because the title of my Best Case Series was "Best Case Series," and _____ presentation, July 7, 1993.

This is my own personal copy which, as you can see, has been through the wars. It was nicely bound at one point. But here, again, I kind of followed the outline I did with my Kelley book in terms of evaluating cases at length and getting the orthodox medical records, and this is what the NCI suggested I do, as well.

You wanted to have biopsy reports. You wanted to have the pathology reports. The NCI also wanted to have the actual radiographic films. Now in a couple of these cases, we had trouble tracking them down.

I eventually put together 25 cases following the format that I had used with my Dr. Good study and we'd have the actual medical records here and the biopsies and a little introduction and a case history and a case report.

One of the things I would advise any physician. When you're going to present to the NCI, you're presenting to the world's leading cancer research organization in the world. You know, approach it accordingly. Have your records organized. Put it together in a book form. Have it so that they can hand it out to all the people at the session.

It just makes it easier. Dr. Friedman, who was then associate director, was very grateful that I went through the -- you know, which isn't really a terrible amount of trouble to put it together in this kind of bound form with all the records easily accessible.

So, you have piles of things from different files, put it together in a book form just the way we did with the first Best Case Series.

Now, I had only been in practice about 5-1/2, 6 years. I wasn't well-known at that time. We didn't have a huge patient base to work from. A lot of the patients who came to see me wanted nutritional therapy for noncancer. It wasn't as if I just treated cancer.

Dr. Parkinson, I believe, was then at the NCI, was one of the people at the meeting. He said, well, you know, how many patients are you treating? You must have treated thousands of cancer patients. Well, the answer is I hadn't at that time, but it's frankly more than 50 percent of the patients I treated then were not cancer patients. They might have had chronic fatigue or just wanted nutritional support although we were really interested in collecting data from advanced cancer patients with the idea of getting formal clinical trials at the money. I really was determined to have this work properly tested.

Again, time is limited. I don't want to take away time from the other presenters. I just want to present a couple cases very quickly; just so you know how I did that.

I'm going to read through it kind of quickly. Reading through it sometimes valuable so you get an idea of how I actually physically did this, since this is a methodology session.

I'm not going to use her name. This patient was a 50-year-old white female psychotherapist with a history of metastatic breast cancer. She had a strong family history of breast cancer. October 1986, routine mammography demonstrated a suspicious mass in the left breast. Biopsy October 30, 1986, detected carcinoma in site ——— thought to be local.

The surgeon suggested a modified radical mastectomy. She only wanted the lumpectomy, which he did. Had no additional therapy; was thought to be limited just to the breast. Did well until July 1989. Physician detected a mass in the right breast; lumpectomy. Documented poorly ——— adenocarcinoma, a very aggressive form of breast cancer. There was a 3-centimeter axillary node, also replaced by metastatic cancer.

Ultrasound, unfortunately, demonstrated the right lobe of the live -- the right liver region consisted of metastatic disease. A needle biopsy of the liver confirmed carcinoma. Bone scan showed increased uptake at C5, but possibly due to degenerative disease.

She began chemotherapy with CAF, which she tolerated poorly. In November 1989, after completing three cycles, refused further treatment. She did nothing March 1990, and went to

Stanford for a second opinion. They suggested chemo right away. She's a very smart lady, read the literature, realized metastatic breast cancer is incurable by the common chemotherapy available at that time.

She learned about me, started with me and I have a very difficult course. She was in such pain from her liver regions when she came to see me, she was on round-the-clock morphine. She had difficulty sticking to the program, but she was tough and really did it and in a year, began to do much better, went off morphine; began to feel so well, without my knowledge, she went off her program. She'd only been on it, I guess, about 15 months when she quit.

In early July 1990, a woman called me distraught, having had a grande mal seizure. MRI showed she had deep brain tumor. Oh, sorry, CAT scan July 11, 1991, revealed a high-density epidural —— of the ——, a small low-density of second term —— right temporal —— lesion, both were consistent with cancer.

She asked what should I do? I said, well, go back on your program and we'll get chemotherapy. She went back on her program, never had chemo, never had tamoxifen, never had any radiation; just went back on my program, all of which is documented and we have the actual scans here.

We have the scan showing the tumor in the liver, the biopsy of the liver. We have the scans showing the two brain tumors. Then we have the final CAT scan. This is the CAT scan they had done April 17, 1992, about 6 months after she'd had the grande mal seizure. Just on my program, there is no mass or mass effect.

The tumors -- there is no evidence of metastatic disease. The tumors were gone. The lesion also was gone. I have the CAT scan of the abdomen. This is from April 17, the same day, 1992, Diane Mapleton (?) Center for Rehabilitation, Boulder, Colorado, Department of Imaging. Normal CAT scan of the abdomen, the liver tumors were gone.

So that was an interesting case because she had a complicated history where she'd had chemo, failed chemo, came to see me, did extremely well clinically. We didn't have any scans done. She didn't want any. Did really well, so well clinically she stopped my program. Went back, developed a seizure, developed metastases, went on the program again till they went away.

It's kind of you have double confirmation of the effect, which was, you know, not a nice way to treat cancer ——.

You don't want recurrences in the brain. It's not a nice thing. But it shows clearly how powerful those enzymes, in my estimation, can be.

Now here's a patient I think is interesting and actually he was interviewed just yesterday by ABC, Morton Schneider. 1991, September of 1991, a routine chest X-ray showed a tumor.

Morton Schneider, 72-year-old white male with a history of metastatic -- initially they thought it was a lung, but then they finally said it was pancreas. I actually had him under lung tumors here. History of cigarette smoking. Routine chest X-ray showed tumor in his right lung. Ultrasound taken September 24, 1991, documented masses in the liver consistent with cancer, the largest measuring 3 to 4 centimeters near the ——, second under 2 centimeters.

Bone scan showed increased uptake. He had ——— September 24, because they figured at his age that would be the easiest place to get tissue. It showed a moderately differentiated adenocarcinoma. They did a CAT scan. It showed a 5-centimeter tumor in the pancreas.

Initially, we thought it was lung and they did the CAT scan, it showed this large pancreatic tumor, so they assumed this was metastatic pancreatic cancer with four tumors in the liver, a large tumor in the lung, and a tumor on the adrenal.

No doctor suggested any therapy because he was thought to be so advanced that therapy would be totally worthless. Almost going to finish; I know time is brief.

Started with me in the fall of 1991. The first thing that happened is he didn't die. Now you're talking about a person, as any doctor in this room knows, has an average survival it can be measured in 2, 3 months.

When you have four tumors in the liver with a moderately differentiated adenocarcinoma, be it from lung or be it from pancreas, you're talking about a very aggressive tumor. I presented him in 1993 at the NCI when he'd been on my program approximately close to 2 years.

Now, we had repeated CAT scans and what was very interesting is the CAT scan from 1993 was virtually interchangeable with the CAT scan in 1991. There were still four tumors in the liver, exactly the same size. There was still a 5-centimeter tumor in the pancreas.

This is really kind of an extraordinary thing. This is not the normal history, the normal natural history of either pancreatic or low, moderately differentiated adenocarcinoma.

With either of those, be it from lung or pancreas, you're gone within 3 or 4 months. Tumors don't just sit there because they're nice and, you know, want to allow Mr. Schneider to have a nice life. He continued on my program after that.

It's kind of an interesting story. When I presented at the NCI in 1993, the gold standard for therapy evaluation was still reduction of tumor, 50 percent reduction in 4 months. When I specifically presented this case, I said, well, here's a guy who had terrible cancer and everyone in the room knew he did.

We have the biopsy proof. We have the repeated CAT scan showing these large tumors that by any radiological evaluation were clearly consistent with metastatic disease and a primary tumor in the pancreas. Yet, the tumors hadn't gone away.

So is this a success or a failure or a case that should be considered or not considered? Well, I thought it should be considered and Dr. Friedman took it seriously in our discussion, which was 3-1/2, 4 hours.

Interestingly enough, Mort didn't want any more CAT scans. His attitude is I'm 74 years old, I'm feeling great. He had a master's in archeology. He was leading art tours at the local art museum. He was, like, a second life having been told he had 6, 8, 10 weeks to live.

In 1998, I finally prevailed upon him, you know, let's get the CAT scans repeated. Now I actually have the CAT scan report in my hotel and I didn't bring it down here, which I wish I did. But I read it on Wednesday and it showed total regression of the pancreas lesion, completely gone;

total regression of the adrenal lesion, completely gone; two of the big liver tumors were completely gone.

The radiologist said, well, if you pushed it, he could see two little nubbins left in the liver, but basically -- and ——— he said, this patient supposedly had metastatic disease, but I just don't see it. He's alive and well 8-1/2 years after being diagnosed with metastatic adenocarcinoma of the liver.

Well, whether the tumors had gone way or not, I would consider that he is, you know, an interesting if not remarkable case.

I know the NCI has gotten more flexible in terms of the definition of a 50 percent tumor reduction in 4 weeks or 8 weeks or whatever it was, and they're considering quality of life and survival.

At that session when I presented in 1993, one of the points I made, knowing that their main interest was tumor reduction, I said you have to think about other things, particularly when evaluating life therapy or perhaps any alternative therapy.

You have to think about quality of life. Even if the tumors don't go away, if the patient lives 8 or 9 years, or at that time 2 years, it's still a remarkable achievement with a terminal and obviously aggressive disease.

I know the NCI has, I'm not saying because of me, but I know they've changed the way they're evaluating cases and are looking into quality of life and are looking into survival.

Again, to bring this to an end, we put these 25 cases together. On the basis of that, the NCI suggested that we do a pilot study with pancreatic adenocarcinoma.

Dr. Friedman suggested pancreatic cancer because it is the worst cancer traditionally. He figured if I showed any effect there, the NCI would take us more seriously.

We ultimately did our pilot study with 10 patients. It was funded by Nestle, the Nestle Corporation. It was started in January of 1994. It was finished in January of 1999. Published in the peer review journal Nutritional Therapy last summer Dr. Friedman initially suggested we use 10 patients.

Now, a pilot study, very briefly, and I have sentences, is a preliminary investigation of a new therapy. It's not a definitive study. It doesn't have two norms. It's not a controlled randomized study and it's not just a study you do with an alternative therapy.

They did a pilot study with chemotherapy and immunotherapy and radiotherapy. It's just an initial investigation with a new idea or new treatment to see whether there's an effect in the terrible cancers for which there is no good orthodox therapy.

Pancreatic cancer is a good cancer to work with because there is no good orthodox therapy. If you could show any effect, as Dr. Friedman, people would take it seriously. He said if you got three patients to live 1 year out of 10, he would consider that significant data.

Well, out of the 11 patients 9 lived 1 year, 5 lived 2 years, 4 lived 3 years, 4 past 3 years, 2 past 4 years, 1 died of a heart attack at 5 years, and we published that last year.

Of course, this data was far and above anything people genuinely would see or expect with in operable pancreatic adenocarcinoma. All had biopsy-proven disease despite all my critics saying, oh, they didn't have pancreatic cancer. Well, they did have.

My critics say they had slides we never reviewed, even though it's not necessarily required to have an independent pathologist review slides when a patient has been diagnosed by a board-certified pathologist.

We actually did have an independent pathologist and specialist in pancreatic disease to review the slides and confirm that these were adenocarcinoma, not ——— and other disease.

And 8 out of 11 were Stage 4, 4 had biopsy- proven liver ———, all of them were very sick, all of them, or some of them, were very terminal when they came to see me.

We deliberately took very advanced patients because we didn't want ———, oh, you're just taking baby pancreatic or easy pancreatic cancer patients, as if there were such a thing. We deliberately tried to take as much ——— as we could. Based on those results, the NCI agreed that we needed to do a large-scale controlled clinical trial and ultimately agreed to fund, although the money is coming through the National Center for Alternative Medicine, a \$1.4 million study which we're doing at Columbia University with NCI direct supervision.

Dr. Wright is the supervisor at the NCI. The NIH is involved. The FDA has completely approved everything on the program and it was a wonderful experience to work with all those groups and get everything approved and get the study up and running. The ——— at Columbia have approved everything and the end lesson to all of this is you never know what a good Best Case Series is going to lead to.

Had I not put these together in book form, this first version which I couldn't publish, which led to a lot of bitterness in my own life, helped lead to the NCI Best Case Series presentation.

Both of these tomes got Nestle's involvement. When Nestle's first called me saying they heard about my work and they were looking to invest some money in promising new research, do you have any documents? Well, I had these two things and I shipped them overnight to Switzerland to the chief of research, Pierre Gestry (?), whom Jeff knows and had present last year, the former head of the Pasteur Institute, not just someone out of industry, a very eminent research immunologist had these two books to review.

On the basis of this, without even filling out a grant proposal, Nestle's agreed to fund the pilot study. On the basis of these and the results of the pilot study, we got the big grant at Columbia. So never underestimate what a well-done Best Case Series can do.

I was fortunate, I had Dr. Gugliotti (?) meet with this and the NCI ——— with this. But when you do a Best Case Series really try and pull it together in a formal presentation form, like a book.

It just makes it easier for the NCI and the FDA to go through all the stuff. You can use it for other reasons and you never know where it's going to lead and ——— I'll stop.

DR. WHITE: Thanks, Nick. Nick is one of the only people I know that could cover that kind of material in the period of time. I think he just condensed 6, the 6 hours ———, but, you know, that's just Nick.

DR. GONZALEZ: For better or worse.

DR. WHITE: Yes, okay. So the next presentation is going to be from Dr. Prasanta Banerji, a homeopathic physician from Calcutta, India, who has been involved with the NCI's Best Case Series Program and he'll give you details of that.

I don't want to take any time away from him. Very happy to have him and his father, Dr. Prasanta Banerji, and family here for this conference and for several meetings at the NCI and the NCCAM. Without any further ado, introduce Dr. Banerji.

DR. BANERJI: I'd like to thank Jeffrey for bringing us this opportunity to speak to all of you. Our presentation in this area will be slightly different from Dr. Gonzalez' because what we would like to do for you is try to guide you through the process of what we did to put up a Best Case Series presentation.

See, let me show you when we came to understand that there was an opportunity in alternative medicine, alternative and complementary medicines, for practitioners to put forward their science and get it approved by the NCI or the NCCAM. We went through a process by which this series was put for presentation before the CAPCAM.

Firstly, we had a motivational meeting, motivational meeting which was held in November of 1996, and this meeting was actually the most important part of the whole series because it gave us an idea as to what we actually could gain or what final objective could be obtained from this Best Case Series presentation.

The submission of the case series took place in March 1998. The evaluation and acceptance by the NCI was in March 1999, one whole year during which the evaluation took place by the NCI.

Finally, the presentation before the CAPCAM, that is the Cancer Advisory Panel, on the 8th of July, 1999. So you can see that it took us almost from November 1996 till July 1999, almost 3 years, 3-1/2 years for the whole process to take place.

The motivational meeting; see we think that this meeting was probably the most important component of the Best Case Series phenomenon. The meeting was comprehensive and able to convince us, the participants, about the challenge and necessity of participating in such a program.

This meeting outlined exactly the requirements to be fulfilled in order for acceptance of the cases as a part of the Series. This meeting also gave to us the scope and opportunities that could arise from a successful presentation.

States involved in identifying the patients that would be best to present and obtaining the details necessary to submit a Best Case Series. In our clinic, we had a large volume of minutely recorded cases to choose from.

In recent years, we have been keeping records of cases of different types of surgical and incurable diseases cured by our treatment. These cured cases were reviewed one by one, keeping in mind the requirements of the NCI, and this posed some difficulties for us. As I record a lot on computer.

Those cases which were found to be complete in all respects were singled out and put under scrutiny. When under initial scrutiny the cases were found to be complete in all respects, the pathological and radiological slides were sent to local experts for verification.

After they were verified, the concerned patients were sought to be contacted, a very difficult task taking into consideration the communication problems in India.

When any case met with all these criteria, it was handed over to a team of assistant physicians in our clinic, who were instructed to forward the cases in preformatted tables. So preformatted tables is a little ———, but the preformatted table had a case number, the type of cancer, the type of cancer case that was being put up, the name of the patient, the age of the patient, the duration of illness of the patient, the date of the first visit of the patient, chief complaints ———, if any, initial observations, that is the initial tumor size as verified by scans or MRIs or whatever; attaining ——— of the tumor.

This ——— of that tumor put forth after the initial scrutiny at the NCI, which, and they wanted this to be inserted; a post-treatment observation complications during treatment, if any, treatment given, a summary of the case, visit dates, which were also included on the insistence of the NCI; enclosures that will be sent with the cases for the NCI and notice that the biopsy slide and all original case reports will be produced on request.

Well, it doesn't mention here that the cases presented by us were not actually the best cases. They were the cases available to us whose recording, documentation, and materials plates and slides fulfilled the requirements put forth by the NCI..

DR. BANERJI: To do the obtaining of the materials, we faced several problems, which I think we should also mention here. Problems faced in obtaining the materials necessary to submit a case series. This was done with a great deal of difficulty due to the following reasons.

We are not professional researchers, but clinicians who, through their experience have found something of value to impart.

Our clinic is a doctor's private practice and not a hospital or a research institute, so we lack the manpower and the resources necessary for the Best Case Series. Patients bring their ——— along with them and perform tests suggested by us at another laboratory of their choice and offering this report, were not up to standard or slides were bad or X-ray -- radiological plates of inferior quality.

This is because we do not have our own radiological or laboratory facilities. Next slide, please.

In India, there is a problem. India, being a poor country, patients are often from the lower economic strata of society and unable to perform tests, investigation scans as follow-ups due to financial constraints. From our research foundation, we often finance the scans and investigations of the poor patients, but our efforts are insufficient because there's a daily attendance of 1,000 to 1,200 patients, so it is impossible for us to satisfy these ——— completely.

Patients who have spent their own money or resources to do the investigations have often not wanted to hand over the original plates and documents to us.

Most of the time, the patients, once diagnosed with cancer, usually visit the government and other hospitals for an opinion. A lot of these hospitals take in all original reports and slides of the patient and, in spite of our best efforts, have refused or ignored our requests to return them.

India is a vast country that does not have a good communication infrastructure in rural places. About 99 percent of India is rural. Due to this, it is sometimes very impossible to follow up cases that have not responded to our communications or letters.

Sometimes we get cases where the patient has been keeping well for years without our knowledge that we discover accidentally when some other relation or friend of the patient comes to us for treatment.

Often we fail to get valuable medical reports because someone, or indigent patient who tend to lose them.

What information was already available to us at the time when we actually started the process of the Best Case Series? The information reported at our clinic usually consists of the following: General condition at the time of first visit to clinic, that is the prescription content which has the name, the age, the sex of the patient; the duration of illness; past history of the patient; the date of the first visit; and clinical features and the signs and symptoms of the patient.

Just the pathological and radiological and other reports and the medicines prescribed. Now during follow-ups, when the patient comes for the second time, we put an update on the clinical features, symptoms and signs, updated recent pathological or radiological reports and other reports are entered into the records; further medicines are prescribed.

What is needed by us for the Best Case Series? Procurement of all original plates and slides that is used to —— slides; an update of the reports in all of the cases; a re-scan for verification of the continuing well-being of the patient wherever possible; video interviews of some cases to add value and interest to the presentation.

How we went about obtaining it. There is no foolproof method of tracking all cancer case follow-ups in our clinic. Immediate update —— the time of these follow-ups. Sending complex letters to a whole spectrum of cases with the hope that some would respond and the range of selection could be improved. Sending assistant physicians to the patients' homes with a view to motivate them to participate in the series. Educating patients about the necessity of participating in such a project so that others could benefit in the same way that they had. Paying for the expense from the —— foundation so that patients would not be taxed for the purpose of research.

Methods used for information exchange at various levels. The information exchange between the concerned parties can be divided into five parts. Motivate them to participate: This would probably mean that —— sent us by Dr. Wayne Jonas and by Dr. Jeffrey White —— and not allowing us to ——.

Participant to patients: This was done mostly by snail mail and took ages to bear fruit. Patient to participant: Mostly by either the patient or a member of their family visiting us at the clinic. It wasn't mentioned here, but usually the patients who have benefited from our treatment, all their relations once understanding the purpose of our request for materials, were cooperative and ready to help with the project.

On the flip side, a case that we mentioned here where, after agreeing to submit all the necessary data, one of the patients, after they were accepted as a presentable case by the NCI, just 1 week before D-Day, suddenly decided not to deliver.

This really caused a lot of inconvenience as NCI had to be notified and that we were withdrawing the case and ———.

Participant to NCI: The information exchange was done by e-mail except for the initial submission of cases in 1998, which was sent as a booklet containing the particulars of each case in the same way that Dr. Gonzalez has shown us. This booklet contained all the particulars of each case with copies of all relevant documents, and and photographs of the radiological plates.

Finally, the presentation: While preparing for the final presentation, we came to realize the immensity of it. Twelve cases would require at least 75 slides and if we were to give an introduction about homeopathy and about our clinic it would run to more than 100.

Taking this into consideration, we hit upon the idea of videotaping the whole presentation, including the slides, and just bring the tape for the CAPCAM. In this way, we could apply our minds to answering the questions of the panel without being diverted by the presentation itself.

Not knowing what further video sort of would be acceptable in the U.S., we even produced a ——— presentation. So unfortunately for you, the whole effort has been put to rest because we have brought our tape with us.

The last thing that happened, we got in the PAL format. There was no problem with showing it in the Marriott but this ——— the PAL format, unfortunately, that player will not take that format, so we would have liked to have shown you a videotape of one of the pieces that we presented before the CAPCAM. But the videotape is here, the record player is here, but they're not compatible, so I'm so sorry.

Conclusion. At the end of the day, we would be entirely ungrateful if we did not mention the contributions of various people without whom this and the CAPCAM presentation would not have seen the light of day. There, Dr. Wayne Jonas, our motivator, he spent 4 hours on a Friday evening convincing us as to the importance and necessity of the Best Case Series Program. Then after that, he followed it up with weekly reminders.

Dr. Jeffrey White of the NCI, who took over motivating us after the end of Dr. Jonas' tenure as director of OAM. Dr. White had the unenviable task of sifting through a pile of information supplied by us and judging which case was presenting and which was not.

The assistant physicians at our clinic, who did the mammoth task of laboriously going through all reports at the clinic, sorting, updating, shaping them into presentable cases. Their invaluable contribution during the actual treatment of the cases also deserves mention here.

The members of the CAPCAM for being patient and receptive to the 2-hour presentation and the subsequent 4-hour question-and-answer session that resulted from it.

Lastly, we'd be failing our duty if we did not thank the patients and their families for being so cooperative and working with us in the germination period of the presentation. Thank you so much.

DR. WHITE: Thank you, Pratip, for that fantastic overview of what the process was like for you. I'd like to just open it up to questions and I'll go right here first.

SPEAKER: Dr. Banerji would you could share the -- briefly share the treatment program that you're using, as well as perhaps a brief synopsis of one or two of the cases.

DR. BANERJI: See, actually, we run a private clinic. I think, you know, if you read the handout that we have put into that book that is given by the conference, it has a fairly comprehensive history of our clinic and the sort of treatment that we give.

But actually, what we do with it for the last three generations, four generations, in fact, we are homeopathic physicians.

We do not practice any type of orthodox or conventional medical treatment. Our patients coming to our clinic are treated solely by the use of homeopathic medicines. Our clinics have been in existence for almost 120 years now, and ——— is only 200 years old. So that's a very long time.

SPEAKER: Yes. My question is more directed towards Dr. White. What would be the next step, assuming that it's proven effectively that these treatments are effective in the sense of regression of tumors, survival rate, et cetera, how are we going to separate the crucial placebo or belief factor in these treatments?

The fact that the enthusiasm and the extreme belief of the doctor and his treatment could be playing a key role in getting the patient to believe that they're going to be healed. What would be the proper control group there?

My own feeling is that you'd have to have a control group where the doctor was separate from the other doctor who is focusing on a treatment that provided primarily belief-building techniques. What do you think of that?

DR. WHITE: Well, let me take it in two parts. I mean, the first is what would be the follow-up to this kind of information? A Best Case Series is a retrospective analysis, and as Dr. Banerji pointed out, in his situation it was not the only cases of efficacy that he felt were present in the history of his clinic. They were the ones with which he had the best documentation. It turned out to be a variety of different tumors.

The other part of it was that, this is a very different environment from the United States that they're functioning in. The patients are receiving probably only this approach. However, what was the next step we felt that needed to be done was to actually go follow prospectively new patients being seen in their clinic with a specific diagnosis.

We would look at all the new cases of lung cancer that came in as an opportunity to do two things. One is to sort of see what is the response rate? How often do these changes happen? How often is this there this kind of efficacy?

The second thing is to give us an opportunity, actually give the Banerjis an opportunity to focus on producing a protocol for how they actually function. I mean, this is not a research environment. This is a clinical setting in which many different things may happen to the patients, as you're sort of pointing out, and they try to formalize or at least take to document what actually happens to each of these patients and to try to produce a protocol.

Our ultimate goal of the protocol would be to move it out of that setting into some other setting and to see if we were able to capture exactly if there's an effective therapy. Can it be reproduced in a different environment?

At that point, I think it's not a question about what you were saying about how do you control. I think it's going to be different in different situations but I think we certainly understand the beginning part of the process a little better than we understand that once we get to the protocol.

Certainly I think control; we do need to have control studies, but to get there there's a couple of steps before that. I think this outcomes monitoring is what we've selected as the next step.

SPEAKER: I assume you're using constitutional approach, right, a different remedy for each person. So that makes it difficult down the road to do --

DR. BANERJI: Actually no.

SPEAKER: Really?

DR. BANERJI: No. We are not using classical homeopathy, as you call it. See? Classical homeopathy involves individualization of each case and —— arriving at one —— and one remedy, which actually is supposed to be the constitutional remedy of that patient, an application of the same resulting in cure. But we are not doing that.

What we are doing is we have devised a specific set of medicines for specific types of cancers - - not cancers actually. See, we are not specialists on cancer. We are general practitioners. In our clinic, on an average day, we have a patient turnout of 1,000 to 1,200 patients. If you give everyone 5 hours -- so we can just imagine. So what we do basically is that we have -- for every type of disease, we have devised a set of specific medicines, and we have done the same for lung cancers or other types of cancers. —— and this could be happening because of her lung —— if this is for a longer period of time.

So we can fix up medicines for almost all types of diseases. —— to see all these cases —— and that —— if you —— the last part of the appendix I must —— recommended and specific medicines should be given. But in this lifetime, it was not possible, but we have done it and really —— in this line. And what —— biggest opportunity in India and where lots of -- all types of diseases, including cancer.

When we started documenting cases, some cases, and then often for the cancer, then we started very aggressively from the cancer cases of different types.

SPEAKER: You mentioned that some of your write-ups that some doses are molecular and some ultramolecular. Where are your cancers? Do they all include some components at molecular doses or some of your cases administrations you use only ultramolecular doses.

DR. BANERJI: Well, we use simple homeopathic medicines. Homeopathic medicines are and their potential is from ultramolecular. So we see there's a definite pharmacopeia way of preparing homeopathic medicines, which actually is really -- it would require another session to go into the molecular state. —— it is a —— of molecular state. After that, it would be nonmolecular state.

So what we have done basically is just use simple homeopathic pharmacopeia from _____ available pharmacies anywhere in the world, mostly from America actually, but we can _____.

SPEAKER: Dr. Gonzalez, I wonder if you could give us a brief idea of where your clinical trials for pancreatic cancer stand at the moment and when you might have some results that we could look at?

DR. GONZALEZ: Interesting question. I didn't have time to go into the details of how it was going. Initially, it was set up as a randomized trial about a year ago, and Jeff and I kind of struggled with that and I always knew there would be problems.

And _____ going back to this gentleman's question, I'm the first person on Earth to say that the belief system of the patient is really important in how they do. Randomized trial patients have no choice and the study was set up when my therapy was being compared to the best available chemotherapy for inoperable pancreatic adenocarcinoma.

Well, patients know in this day and age chemotherapy is a death sentence for inoperable pancreatic adenocarcinoma and our first study had already been published.

Over a period of several months, Columbia got 200 phone calls. A hundred and ninety-seven patients, who would have been perhaps appropriate for the study, refused to enter unless they could be guaranteed my arm of the study.

Now a randomized study is considered the gold standard and I felt we had to at least try. Dr. Klausner thought we had to try. Dr. White thought we had to try. After a year of trying that we all realized it wasn't going to work that way, so we set it up as a case control where patients have choice. If they want chemo, they get chemo; if they want me, they get me.

Hopefully, their belief in chemo will be as strong as the patients' belief in my therapy. We're going to try and match them evenly.

Now in terms of technical methodology it's maybe a little less rigorous than a randomized study, but it's raised all kinds of issues about how you test an alternative therapy where belief is important and a patient who doesn't care whether they get chemo or my therapy for pancreatic cancer is going to be a very unusual patient.

Patients who come to me usually believe in this. They would seek alternatives. By definition, they're seeking something different.

So it's now set up as a nonrandomized trial. It took about 5 months, I guess, Jeff would probably know more accurately than I, to get the protocol rewritten through the NCI, the FDA, the NIH, and Columbia. Columbia has two review boards: One general review board for all the medical protocols and a specific one for oncology.

It took 5 months. As of about 2 weeks ago, we had final approval from the last committee to get up and running. So we are now up and running as of about 10 days ago, so no patients on it yet.

Actually I should say in the original _____ nonrandomized, there were three patients that agreed, one quit, two were assigned I understand to chemotherapy, but I don't know whether that was continued or not because of the change in protocol design.

So there was a 5-month hiatus when the protocol had to be redesigned. And we are up and running again as of about 2 weeks ago.

SPEAKER: Just quickly, is your end point longer survival or is it tumor shrinkage ——— describing those tumors?

DR. GONZALEZ: It's set up as a survival study. We're looking at survival.

SPEAKER: Do you have an idea of what you're looking for?

DR. GONZALEZ: Well, Jeff and I were just talking a couple weeks ago. You know, to get any kind of data that would be beyond criticism is ——— always be criticism, but at least three times.

You would want in the successful group to be three times -- the median to be three times out from the lesser successful groups.

So, for example, if the average survival with chemo, which we suspect will be 5 months, you would want my therapy to be at least -- the median survival to be at least 15, 16, 17 months, as it was in the pilot study.

We're looking for a median survival three times out from the chemo group to be significant.

SPEAKER: How many patients do you intend to --

DR. GONZALEZ: Did you want -- about 45 in each group.

DR. WHITE: Yes, let's take about two questions, if we can, and then you people can come up and talk with the presenters.

SPEAKER: ———?

DR. GONZALEZ: It's actually being done through Columbia. Columbia has a committee on quality of life. It's being an independent -- a lot of the compliance and quality control are correctly being set up independently of myself, although I will also be checking compliance.

Columbia has a quality of life team that will be checking quality of life on a regular basis. They have a compliance team that will be checking patient compliance on our therapy, as well as chemo, of course. So these things are being done. Quality of life is being looked into and being considered as a major end point.

DR. WHITE: I realize there are a lot of other questions, but I think you have to come up and speak with the presenters just because of the time that's left us. But thank you.

(Whereupon, the PROCEEDINGS were adjourned.)

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