Yale CANCER CENTER answers

WNPR Connecticut Public Radio

*Hosts*

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Associate Professor of Surgical Oncology

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## Alternative/Complimentary Medicine in Cancer Care

**Guest Experts:**

**Wendelin Nelson**
*Clinical Specialist for Oncology, Yale School of Medicine*

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**Yale Cancer Center Answers**

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*Welcome to Yale Cancer Center Answers with doctors Francine Foss and Anees Chagpar. Dr. Foss is a Professor of Medical Oncology and Dermatology, specializing in the treatment of lymphomas. Dr. Chagpar is Associate Professor of Surgical Oncology and Director of the Breast Center at Smilow Cancer Hospital at Yale-New Haven. If you would like to join the conversation, you can contact the doctors directly. The address is [canceranswers@yale.edu](mailto:canceranswers@yale.edu) and the phone number is 1-888-234-4YCC. This week, Dr. Chagpar welcomes Scott Soefje and Wendelin Nelson for a conversation about complimentary therapies and investigational drugs in cancer care. Scott is Associate Director of Oncology Pharmacy Services and Wendelin is a Clinical Specialist for Oncology at Yale School of Medicine. Here is Anees Chagpar.*

Chagpar Let's start off, Wendelin, by having you tell us a little bit about your background and what you do and how this ties in with complimentary therapies?

Nelson I am a clinical pharmacist, so I have a doctoral degree with a specialty credential in oncology. I also have had additional training in nutritional support and I have a strong interest in nutrition and how it relates to overall body health and health in cancer patients in particular. Certainly this is an issue that comes up frequently and it is part of what I do on a daily basis. My job really has to do with optimizing pharmacotherapy and that includes making sure that drug dosing is optimal and making sure that we are addressing adequate side effect management and supportive care and also looking at drug interactions. And drug interactions are not only between medications for other problems such as diabetes or hypertension, but it also includes interactions between the chemotherapy and other nutritional supplements or herbal medications. Many of the chemotherapy drugs that we use originally came from botanical sources or marine biology sources. So, although they are natural products they still can have the potential for causing side effects and interacting with other agents, so this is something that I look at with every single patient.

Chagpar We are going to pick up on a lot of that conversation, but first, Scott, tell us a little bit more about your background as well and what you do in terms of investigational drugs?

Soefje I am the Associate Director in charge of the Oncology Pharmacy Services and one of our major roles in oncology is to help with clinical trials and clinical research that is being done at Smilow. We have an investigational drug service within the oncology department that manages the investigational drugs and helps dispense the investigational drugs, helps with the protocols, helps with the patients, and reviews the therapies, those kinds of things. I come from this with a long history in investigational drug research. Prior to coming to Yale, I was in San Antonio at a phase I facility. Phase I meaning that it is the first time these drugs are being used in humans. I have an extensive background with research and investigational drugs and find it a fascinating part of oncology, and partly why I got into oncology is I like all of the new drugs, the new pharmacology that's being developed within the oncology world.

Chagpar Wendelin, I want to start with you to talk a little bit about herbal supplements and nutritional supplements in particular because I think that for a lot of people who are faced with the diagnosis

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of cancer, it is an incredibly scary thing and the last thing people want to think about is chemotherapy, they'd much rather gravitate to, what can I do to eat better, what can I do in terms of herbal supplements? Are there things that people can do in terms of both of those things that may help them through their cancer journey? And the second part of the question is, can any of those things really replace their cancer therapy? Can you talk a little bit about the differences between what has often been referred to as complimentary therapy versus alternative therapy?

Nelson Yes, the first subject I want to touch on is nutrition. Nutritional support is always extremely important, maintaining an adequate diet, a balanced diet, is important and sometimes that becomes difficult. If patients feel episodically that they have nausea, that can be problematic, however, we have excellent medications now for controlling those particular symptoms and the way we support patients now is entirely different than the way we did in terms of supportive care a few years ago.

Chagpar Tell us more about that supportive care and how you provide people nutrition, because that is important as you are going through chemotherapy and your body may feel run down and you are nauseated, how do you help as a pharmacist to get these people the nutrition they need?

Nelson We speak to people about their diet and we also have dietitians who work within both the inpatient setting and the clinic setting who are always available to discuss dietary needs and the optimal way of meeting nutritional support needs both in terms of macronutrients, or calories, and micronutrients for patients who are receiving chemotherapy. Another issue that sometimes comes up when people are getting chemotherapy is their sense of taste will change as a result of the drug therapy, and that is something that needs to be discussed in an upfront way and there are things that patients can do, avoiding extremes of temperature, avoiding foods that are extremely spicy, also texture becomes extremely important for patients who are having alterations in their sense of taste and their ability to tolerate foods. Foods that are richer or creamier tend to be little better tolerated than the foods that have rougher textures.

Chagpar Scott, I want to bring you in on this conversation as well in terms of when people are going through cancer therapies and their sense of taste may be changing, maybe their ability to swallow is changing, in terms of how you even deliver medications, are there things that the pharmacy can do to make it easier, an easier pill for people to swallow, no pun intended.

Soefje Sometimes yes, sometimes no, there are times when we can take tablets and make solutions or suspensions out of them, sometimes there are different dosage forms, one of the newer dosage forms to help control nausea is a patch technology, so a patient can put a patch on and that patch can go for three or four days, and we have patches for pain control, so there may be alternate ways to get the drug into patients that would help them and they would not have to swallow it. In the nausea and vomiting world, we now have a IV medication that has a duration of action of four days where as the nausea and vomiting medicines from 10 years ago, their duration of action was

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perhaps 16 hours, and so we can work with the patients to help them get the best side effect control and be able to tolerate the medication, so again, be sure to ask, do not just assume that because we give you these big 'horse pills' that that is the only thing you can take, there may be other alternatives to help.

Chagpar And I guess the other point in terms of talking to your pharmacist, not only about how drugs are delivered, but also in terms of the help that you may need with nutrition. Getting back to you Wendelin, tell us a little bit about why it is so important for people to tell you what herbal supplements they may be taking, what vitamins they may be taking, can you speak a little bit more about that?

Nelson The main issue that we are concerned with is interaction, and interactions can have two potential general consequences, one would be potentially to reduce the efficacy of the chemotherapy, the other would be to worsen side effects, and we want to avoid both of these at all costs and the only way to do this, because the side effect profile is unique, and the way drugs and herbs are metabolized and eliminated in the body is unique, every medication, every herb, has its own unique fingerprint. So, the key is communication, patients need to give us a full list of agents and if they are not sure, put everything in a bag and bring it and many herbal supplementations have multiple ingredients. So we really need to have a complete list to be able to do an exhaustive review of the literature to examine any potential for interactions. If there is any risk for harm at all we want to avoid this. In many situations there is not, but we will not know unless we actually investigate and make that determination.

Chagpar Scott, you know a lot of people are going to be looking at this and they are going to be saying, I am taking natural vitamins, I am taking natural herbs, and I am taking stuff that comes from nature itself, how could this possibly exacerbate any of my side effects?

Soefje Even herbs, even natural agents have to be metabolized by something. The liver is what metabolizes the majority of compounds in our body whether it is drugs, whether it is nutrients, whatever, and as Wendelin said, a lot of our chemotherapy agents actually originated as plant products, so we do have experience with taking a plant product, making it a chemotherapy agent, and using it for the treatment of cancer, and so what we are looking for and what we are always concerned about is that that herbal agent is competing with the metabolism of that chemotherapy agent and we can usually predict whether it is going cause the chemotherapy agent to be around longer, which may increase the side effects, or it may cause the chemotherapy agent to not be around as long and potentially reduce the efficacy of the chemotherapy agent, which we do not want to see either. We are always looking to see what is the interaction going to be. What do we know about the interaction and what can we do to minimize that interaction, or are there added side effects that we can minimize. There are good examples in the literature. One that comes to

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mind is in the Colorado area, for a while people were making something that was called Kombucha tea. It is a tea made out of basically a fungus. It had no drug interaction but the patients who were on chemotherapy, their white blood cell go down, and they were getting fungal infections from this tea because it was being brewed improperly and so again understanding and having education, knowing what the chemotherapy is going to do, knowing what the herb is going to do helps us put the whole picture together and then help people get through this time to the best of their ability.

Chagpar Wendelin, I want to get back to something that both you and Scott have mentioned, which is that if a lot of our drugs today originated as plant based compounds or marine life compounds and natural compounds, could people then look at vitamins and herbs and various fungi and other things and say, maybe this will be better to treat my cancer than routine chemotherapy? Maybe I should do that instead? Can you talk a little bit about that? It seems like it is a trend that is going on for people to start embracing alternative therapies. What are the upsides and downsides of that?

Nelson The most important issue is that it is evidence based. We need to base our decisions on something as critical as the treatment of a diagnosis of cancer, on objective, accurate information and that comes from clinical trials. Those clinical trials may involve medications, and they may involve herbs. The National Institutes of Health has a branch that is devoted to complimentary and alternative medicine and they are now sponsoring a number of trials and a number of different institutions also have trials that are looking at many of these different herbal preparations to see if they are helpful, can they potentially help reduce side effects, are they a reasonable adjuvant to other therapies? But these kinds of questions need to be asked within the appropriate frame work and that is a clinical trial.

Chagpar Excellent, well on that note we are going to take a break for a medical minute, but please stay tuned to learn more information about complimentary therapies and investigational drugs in the setting of cancer care with my guests Scott Soefje and Wendelin Nelson.

*Medical Minute* *The American Cancer Society estimates that the lifetime risk of developing colorectal cancer is about one in twenty and that risk is slightly lower in women than in men. When detected early, colorectal cancer is easily treated and highly curable. Men and women over the age of 50 should have regular colonoscopies to screen for the disease. Each day more patients are surviving colorectal cancer due to increased access to advanced therapies and specialized care, which is giving colorectal cancer survivors more hope than they have ever had before. Clinical trials are currently underway at federally designated comprehensive cancer centers like the one at Yale to test innovative new treatments for colorectal cancer. New options include a Chinese herbal medicine being used in combination with chemotherapy to reduce side effects of treatment and*

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*help cancer drugs work more effectively. This has been a medical minute and more information is available at yalecancercenter.org. You are listening to the WNPR Health Forum on the Connecticut Public Broadcasting Network.*

Chagpar Welcome back to Yale Cancer Center Answers. This is Dr. Anees Chagpar and I am joined today by my guests Scott Soefje and Wendelin Nelson. We are having such a phenomenal discussion about the role of complimentary therapy and investigational drugs in cancer care and right before the break, Wendelin was telling us about the need for evidence based data to support what we do even when it is in terms of natural therapy. Scott, I want to pick up the conversation there and talk a little bit about clinical trials, which is a concept that Wendelin introduced, what exactly is a clinical trial?

Soefje In a clinical trial we are taking a new product, a different drug, perhaps an herb, perhaps a complimentary medicine, and we are looking to see what it does in a new situation and so there are a couple of different ways, you can have a brand new drug that has never been used before and we're testing to see if it is effective in whatever area we think it may be effective. The other possible type of clinical trial is taking a drug that is currently available and seeing if it may be effective in another indication, another disease state, another tumor type, and so those are the two most common clinical trials we see. Again, it is all about trying to find any controlled scientific manner, whether this drug has the effect that we think it has and at the same time we are also monitoring side effects, toxicities, and what other things we may need to look at as we develop the drug.

Chagpar Wendelin, there are people who are sitting at home listening to our show thinking, that sounds like they are going to give this drug and they are going to see what happens and that is kind of scary. What can you say about that?

Nelson There are years of basic science research that lays the foundation for every clinical trial and every evaluation of every product. So we are not starting from a point of no information. We are starting from a point of having a tremendously refined level of information and what we are trying to do is methodically obtain additional answers so that we can perfect the questions we are asking about either the efficacy of therapy or the control of the disease state.

Chagpar And Scott, that is the only way that new therapies can enter clinical care, right, I mean if the science is going to move forward we need these clinical trials.

Soefje Absolutely, it is one of those things where alternative medicines actually makes a great segue way into this because a lot of the time with alternative medicines, we hear the stories but we do not know all of the patients that it took to get to that story. For instance, if you have one in a million patients that actually have success, most people would not consider that a successful drug, but if we only hear about the one person that has success, you may think it is successful. In the clinical

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trials arena we take everybody. We look at every patient that has been enrolled in a clinical trial and we see what has happened and we compare it to what our current standard of care is to see whether we have advanced that care and whether that advancement of care is worse the risk, the toxicities, the side effects, etc., and make the decision of whether it is the next thing we should be doing to advance cancer care.

Chagpar Wendelin, tell us a little bit more about how this is regulated. I mean it is not like somebody just gets drug X, and we'll see how you do, people worry when they think about clinical trials and investigational drugs that they are not safe, that they are not monitored, how can you tell people who may be thinking about a clinical trial, their doctors are telling them they should really do this clinical trial, most people who participate in clinical trials do better than people who do not, that they are going to be safe?

Nelson The issues that document the safety have to do with the previous studies that have done and it is very important that a patient who is considering enrolling in a clinical trial ask about that information. What do you know about this product so far? What do you know about side effects? What do you know about dosing? What can I expect? And this is all part of the informed consent process, which is an integral part of any patient being enrolled on a clinical trial.

Chagpar Scott, we talked a little bit in a previous show about the role of pharmacy in making sure that drugs are safe in terms of how they get out the door. Does pharmacy have the same role when it comes to investigational drugs?

Soefje That, and perhaps even a little more. Every investigational drug is part of an extensive clinical trial document, and that clinical trial document has very detailed information on which patients can be enrolled in the clinical trial, and what the criteria is that the patient has to meet to be able to get the drug at that particular time on the clinical trial. So our pharmacy staff is reviewing every order for an investigational drug against the study protocol to make sure that patient meets the criteria within the protocol. As Wendelin said, we usually have access to the basic science data in what is called the pharmacy manual. So we know the stability of the drug. We know what happens when it is used in animal testing. We know what has happened in previous trials that this drug has been used in. So again, our pharmacists are knowledgeable about that and looking at drug interactions, because a lot of times we have an idea what the drug interactions are. We double check doses and we go through the same process with investigational drugs that we go through with chemotherapy. I actually counted them once, and it turns out that there are about ten people who double check the order before the patient actually receives the chemotherapy or the investigational drug.

Chagpar That is tremendous. Wendelin, I want to get back to this whole idea of complimentary versus alternative medicine, and it seems to me that one of the things that you have stressed is that there is a need for evidence. There is a need to really evaluate these natural products in the setting of

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clinical trials. What if there is not a clinical trial looking at an herb and what if I have got a Naturopath and they have been prescribing this stuff to me? Can I still take it when I take chemotherapy?

Nelson We will not know the answer to that unless we have full communication and open disclosure about all products that a patient is taking, and typically I will call the Naturopath and discuss the therapy with them, evaluate the literature and have an open discussion between the oncologist, the Naturopath and the patient in terms of what therapies they are considering. In many situations, the safest way to use these products is to wait until after the patient is off chemotherapy so that then they can safely use some of these particular products, but if we do not have adequate information, if we are not sure that they are absolutely going to be safely combined with some of these medications that we know are extremely powerful, then the best answer is to wait until the patient no longer taking those medications.

Chagpar Scott, what about the people who say, what I heard from my Naturopath or I read in a book, that this herbal preparation or this particular cleansing regimen is beneficial in terms of cancer care. What would you say when they say, I want to do this instead of chemotherapy.

Soefje I would highly recommend against it. Particularly in those tumor types where we know there are curable therapies. We know we can cure a certain number of people and a certain number of tumor types. If you have a disease where you can cure 90% of people, and they differ therapy, and then the disease becomes metastatic where it is no longer curable, that becomes a very sad story. We do not want to see that happen. Again, the complimentary medicines tend to help, our philosophy is, tell us what you are taking, we will look it up, we will give you straight answers about what we know about it. It may be that there is positive data, it may be that there is negative data, and more than likely there is no data, where our recommendation is wait until you chemo is over and then use it. Same thing with the alternatives, I would not differ chemotherapy for an alternative, do the chemotherapy, get through the protocol and then go back to the Naturopath and find out if there is anything that you can take after that point.

Chagpar And it is not that people are always told that they cannot take it. For example, if they are taking a vitamin or if they are taking a tea regimen or some standard herbs, for many of these things they can take it at the same time as their chemotherapy as long as they tell you and there is no interaction. Is that right, or are they told to absolutely stop all of their naturopathic regimens?

Nelson No, many times we can integrate alternative or complimentary therapy and herbal therapy, nutritional supplements with the chemotherapy and radiation that patients are receiving, and as I said before, the key is communication. As long as we know, then we can make informed intelligent rational decisions about the best way to integrate and optimize therapy for the patient, and that is our goal.

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Chagpar One of the things we talked about is the fact that for many of these alternative therapies there is no data. It seems to me that there is so much regulation in terms of the drug industry, the pharmaceutical industry, but we are lacking regulation in terms of many of these herbal products. Can you talk a little bit about how quality and safety is regulated or not regulated in that industry?

Soefje The pharmaceutical industry, when they are developing a drug, there is a very systematic stepwise approach. It generally takes 8 years to 10 years to get a new drug approved in the oncology world and costs billions of dollars to do these clinical trials and so we have a ton of data, and the FDA has very rigid rules to get through the process. The herbal medications and a lot of the alternative medications actually fall under nutrition. They are not regulated as drug products, so therefore they do not have to go through the same rigorous testing process and they do not have to go through the same level of evidence to get on the market. The other thing is, because they are considered food products, they do not have to go through the same manufacturing quality requirements that a drug does. Drugs have a much higher standard to meet than food does as far as what the quality has to be. So one of the concerns we have with herbal products from batch to batch, from manufacturer to manufacturer, the herbal contents may be different and so you may not be taking the same amount. You may not be taking the same drugs from batch to batch or particularly from company to company. So that is why a lot of times we like to see the bottles themselves, because it gives us an idea of what else is in there, what excipients are in there, what other products may be added to the compound and it helps us to make a much better decision overall on the effectiveness of the therapies.

*Scott Soefje is Associate Director of Oncology Pharmacy Services and Wendelin Nelson is a Clinical Specialist for Oncology at Yale School of Medicine. If you have questions or would like to add your comments, visit yalecancercenter.org where you can also get the podcast and find written transcripts of past programs. You are listening to the WNPR Health Forum on the Connecticut Public Broadcasting Network.*