

# Yale CANCER CENTER *answers*

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## **Targeted Biopsies for Prostate Cancer**

### **Guest Expert: Peter Schulam, MD**

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*Welcome to Yale Cancer Center Answers with your hosts doctors Francine Foss, Anees Chagpar and Dr. Steven Gore. Dr. Foss is a Professor of Medicine in the Section of Medical Oncology at Yale Cancer Center, Dr. Chagpar is Associate Professor of Surgical Oncology and Director of the Breast Center at Smilow Cancer Hospital and Dr. Gore is Director of Hematological Malignancies at Smilow. Yale Cancer Center Answers features weekly conversations about the research, diagnosis and treatment of cancer and if you would like to join the conversation, you can submit questions and comments to [canceranswers@yale.edu](mailto:canceranswers@yale.edu) or you can leave a voicemail message at 888-234-4YCC. This week you will hear a conversation about prostate cancer with Dr. Peter Schulam. Dr. Schulam is Professor of Urology, Chair of the Department of Urology and Chief of the Department of Urology at Yale School of Medicine. Here is Steven Gore.*

Gore Peter, I am a gentleman of a certain age and I think about my prostate a lot. I know not to share too much, but I think many guys, certainly over 50, but even over 40, we hear about prostate cancer all the time. Is this something people are really worried about?

Schulam Yes. I think there is a lot of misunderstanding out there about prostate cancer. As you mentioned, as you get older, we all begin to become a little more cognizant of the prostate and, do I have prostate cancer, should I be looking to see if I have prostate cancer? I think the bottom line and what we have to understand is there were recommendations from the United States Preventive Task Force that recommend against screening.

Gore Against screening?

Schulam Against screening, yes. So, we have to take that and pull back and ask ourselves, why did they say that? And I think the recommendation was based on the fact that in the past, we overtreated prostate cancer.

Gore Let's go back a little bit. So, most men will have some growth in their prostate over a time, right?

Schulam Right, and we have to separate that out. There are 2 types. There is benign growth of the gland, which is called benign prostatic hypertrophy. As we get older, the gland gets larger. As the gland gets larger, it can affect our ability to urinate. So as we get older, you may find that you go to the bathroom more often, you may get up in the middle of the night, or you have what we call, post void dribbling. That is all a normal process and usually is rarely ever linked to cancer.

Gore One of the gifts of aging?

Schulam It is. The other side of this is prostate cancer, which usually does not have any associated symptoms and the only way to detect prostate cancer is by screening, which involves both the digital rectal exam, you are feeling the prostate through the rectum to see if you can palpate a hard nodule, and PSA and in fact, PSA is nonspecific. PSA, which stands for prostate specific antigen, is something that can be detected in your blood, so it is a normal blood test just like you would

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have for a glucose or sodium check and you can get a value that comes from that. That number does not necessarily mean you have cancer and in fact as you already mentioned, as we get older, the prostate gets larger, PSA comes from both the benign part of the gland and can come from cancer. So, it is not a specific marker. All it does is basically reflect either it can be from a growth or from cancer, so it is not specific, we need more data in a diagnosis of prostate cancer.

Gore I think I remember hearing that if you live long enough, many people will have a prostate cancer and never know.

Schulam Never manifested, you would have never known and in fact that is true. There are studies out there that say, if you look at 80%, this is an autopsy study so those that have passed away from other causes, if you look at 80% of 80-year-old men and looked at their prostates, you would find evidence of prostate cancer and that is important, and not all prostate cancer can be lethal, and this is coming all the way back to the beginning, the US Preventive Task Force said we should not be screening for prostate cancer. I do not think that is a good recommendation. I think the better recommendation is, who should be treated, because in the past, if we detect a prostate cancer, we treated everyone the same. The fault in that is that you over treat, and some may say, well that is great, it does not matter if you over treat it. The problem is, the treatment for prostate cancer has longterm quality of life issues, inability to have erections potentially, urinary leakage, and if it were a completely benign procedure and there were no morbidities or complications associated with it, you would say, over treatments are not necessarily bad because we can have such a great affect or impact on quality of life.

Gore Quality of life.

Schulam Therefore, we have to be a little bit more judicious. I think a better way to look at this is do not ask the question, should or should we not screen? The question really is, if I have prostate cancer, does it need to be treated?

Gore That has got to be a really hard discussion to have with the patients. Not from your perspective necessarily because it is easy for you to say I do not need to be treated, but you are telling me I have prostate cancer and you are not going to treat me? Are you crazy?

Schulam I think that is in part why the US Preventive Task Force said, maybe we should not be screening, and I think that unfortunately they are making a decision that should be based on the patient not a population and I think that is the problem. Interestingly enough, in most of the patients that I meet with, and I predominantly see those patients with prostate cancer, for most men, their spouses, are capable of making that decision once we explain to them what all this means. And that is the most important part, and much of my time is spent educating.

Gore So you are seeing the patients who have the diagnosis of prostate cancer?

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Schulam That is right.

Gore And they are trying to figure out how to take care of it.

Schulam Let's take a step back. Let's say you come in and you are, I am just going to make up an age, this could be bad.

Gore That is okay. Let's see how well you do.

Schulam Let's say you are 55 years old.

Gore Well that is underestimating, but go ahead.

Schulam Okay, so you are 58, which is even easier.

Gore 57 really.

Schulam And you have no family history of prostate cancer.

Gore That is true.

Schulam And the region that is important is that if you do have a family history of prostate cancer, it is a good thing to be evaluated. So we ask ourselves, in men between the ages of 55 and 70 who have at least a 15-year life expectancy, would they like us to screen for prostate cancer? We talk to them, we ask them whether they are interested in having their PSA checked, knowing that this could open up Pandora's Box to a certain extent, but let's take it one step at a time. If they say yes, we draw PSA, and we do a digital rectal exam. More often than not, the digital rectal exam is negative, but the PSA may be elevated. Now, we already talked about the fact that PSA can come from either benign or cancerous cells.

Gore And that got me worried.

Schulam And we have what is called age-related PSAs. As I mentioned, since the prostate gets larger as you get older, the larger your prostate, the more PSA. We have a set cut off that may not be a very good number for someone who is very young because that may underestimate the risk and if you have somebody who is very old, it might overestimate the risk. So, if you are someone in your 50s, we would say, okay you should have a PSA somewhere between 0 and 3.5. If yours comes back at 4 or 5, the question is, what do you do? The first thing we ask ourselves is, how big is your prostate? And we can assess that by ultrasound or if we were to do an MRI. We can actually look at what we call PSA density, but regardless, if you were in my office and you had a PSA of 5, we would say, you are outside the norm, would you like a biopsy and that would be the next step in the diagnosis.

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Gore I'd say, heck no.

Schulam Some men would say that and some men would say, I would like to have a biopsy.

Gore I am teasing. It is just the whole idea of having a prostate biopsy, it sounds horrible.

Schulam Interestingly, it has evolved. It is an in-office based procedure, and there is local anesthesia that is provided to the nerves that surround the prostate prior to the beginning of the procedure. It is actually much more tolerable than it was even just 5-10 years ago.

Gore Okay. I am reconsidering.

Schulam That is why I am here. So, let's say you undergo a biopsy.

Gore Is that done through the rectum?

Schulam Normally there are 2 ways to do it, but 90% of the time it is what we call transrectal. There is a probe that is placed within the rectum. The probe is an ultrasound probe. It helps us identify where the gland is. The gland is about the size of a walnut. Once we can identify the gland, the plan is to actually do 12 biopsies of the prostate.

Gore Are you kidding me?

Schulam I wish I were.

Gore And am I awake during this?

Schulam You are awake.

Gore And I am reasonably comfortable.

Schulam You are reasonably comfortable.

Gore All right, Pete, I am trusting you on this one.

Schulam I told you the ultrasound is used just to identify where the prostate is, but it does not identify any areas to target. So, interestingly enough, the prostate is really the only solid organ in the body currently in which we make a diagnosis based on a random biopsy. Think about that. The reason this is important is that is beginning to change. There is an evolution in how we are diagnosing prostate cancer which we want to get to, but that is the current standard.

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Gore Is that because we are detecting the cancer or trying to detect the cancer at an early stage before it actually forms a nodule?

Schulam No, there actually was just not the technology up until just recently, I would say within the last 5-10 years, to actually image the prostate. A CAT scan was not specific believe it or not, ultrasound was not specific. However, there is a newer technology that is available. It is a multiparametric MRI. Basically it is an MRI, magnetic resonance imaging, of the prostate in 3 phases and those 3 phases are why it is multiparametric, it allows us to actually detect what we call regions of interest within the prostate that are highly suspicious. So, for the first time ever, we can now do a targeted biopsy.

Gore And you are doing the biopsies in the MRI machine?

Schulam That is an interesting point. You can do that. There are some technologies out there that will allow us to do that, but because the MRI, remember it is not ferromagnetic compatible, so you cannot go into an MRI scanner with anything metallic because of a large magnet. What we actually do is we use image fusion, so we actually obtain an MRI, a multiparametric MRI on a patient and the radiologist sits down and does what is called segmentation, and what that means is he takes the data and he creates a 3D model of the prostate, and then they look within that and they determine what are the regions of interest. All this gets put into a data set that gets transferred to a machine in our clinic and what happens here is, we then do an ultrasound as we normally would do, but this is actually a special ultrasound on a robotic arm and it obtains a 3D ultrasound of the prostate. Then, we take that data set with the MRI data set and fuse it. Now in the clinic under ultrasound guidance, we can target the lesions that were identified by the MRI. It is a complex piece of machinery, but here we have been doing it for the last 2 years, we have done over 270 patients and it is our best means by which to detect prostate cancer. We have added an additional step, not only are we just doing digital rectal exams, PSAs, and a random biopsy, but now we can begin considering targeted biopsies. The reason this is important is if when I saw you, you had a PSA of 5, and I biopsied your prostate and I found high-grade disease, and we will get to that in a minute what we mean by high grade, we would recommend treatment, but let's say we found low-grade disease and not very much of it, and I told you that the likelihood that we think this is lethal is very low, we would both argue together that maybe we should consider something called active surveillance. Yes, you have cancer, but it is low grade. We do not think it is lethal, we should do nothing. This way, you do not subject yourself to the morbidity of the procedure for very little benefit and I think this is where in medicine, art comes in, because this is very difficult to do and the technologies that are required and it is a little bit more complex. So, if you had that diagnosis, the next question you would have for me is, you took 12 cores, you found a little bit of low grade disease, is that all I have?

Gore Yeah, what if you missed it with these random things?

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Schulam Exactly.

Gore I am not feeling good about that.

Schulam Those are the majority of the patients I see, because the first thing we do when we meet those patients is we tell them, you are absolutely right, PSA is not specific and the random biopsy could have missed an area, so what we do at Yale for everyone, anyone who comes in who wants to consider active surveillance, meaning they had a diagnosis on the outside of low grade, low volume disease, we wait about 3-6 months because prostate cancer is slow growing, there is no rush, we obtain a multiparametric MRI and then we repeat the biopsy, but what we do is in addition to doing the 12 core systematic biopsy, any regions of interest identified are then targeted. What is interesting is, had we not done that multiparametric MRI, so just the 12 cores, there is a 30% chance we can miss a cancer, a significant cancer. If we do a multiparametric MRI and the biopsy, the likelihood that we are going to miss a cancer is about 3%. So, it is an order of magnitude better. Now, if we do that and our biopsies match the biopsies that you had done on the outside, we can sit down and tell you that there is a very strong likelihood that this is what you have and we can do active surveillance. It is much more comforting and it is a bit more data.

Gore That is really incredible. We are going to need to take a break just now, but I would like to take this up after our medical minute. At this point, we are going to take a short break for a medical minute. Please stay tuned to learn more information about prostate cancer with Dr. Peter Schulam.

#### *Medical*

*Minute Smoking can be a very strong habit that involves the potent drug nicotine and there are many obstacles to face when quitting smoking, but smoking cessation is a very important lifestyle change, especially for patients undergoing cancer treatment. Quitting smoking has been shown to positively impact response to treatments and to decrease the likelihood that patients will develop second malignancies. Smoking cessation programs are currently being offered at federally designated comprehensive cancer centers such as Yale Cancer Center and at Smilow Cancer Hospital at Yale-New Haven. The smoking cessation service at Smilow operates on the principles of the US Public Health Service Clinical Practice Guidelines. All treatment components are evidence based and therefore all patients are treated with FDA approved first line medications and smoking cessation counseling. This has been a medical minute brought to you as a public service by Yale Cancer Center and Smilow Cancer Hospital at Yale-New Haven. More information is available at [yalecancercenter.org](http://yalecancercenter.org). You are listening to the WNPR, Connecticut's public media source for news and ideas.*

Gore Welcome back to Yale Cancer Center Answers. This is Dr. Steven Gore and I am joined tonight by my guest, Dr. Peter Schulam and we have been having a very personal kind of discussion about prostate cancer that I hope I do not have, but really an important topic that I think many, probably most of our male listeners, think about. You were telling me about this multiparametric MRI and

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how that has increased your ability to detect, to get accurate prostate biopsies, or more predicted prostate biopsies. If I were to come to you and not had a biopsy, would I automatically get the new test or would you go old fashioned first?

Schulam Interestingly, I would prefer to do the multiparametric MRI first because the biopsy itself can affect the read of the MRI for up to a year out because a little bit of bleeding in the prostate affects the read and the problem is insurance.

Gore I was going to ask you about that.

Schulam Not all insurance companies will approve it, some like to see a negative biopsy or a biopsy with low grade, low volume beforehand. Interestingly, in Great Britain, Dr. Mark Emberton, who is the Chair of Surgery and Urology at University College London has now set a precedent in Great Britain that we are obtaining multiparametric MRIs on all patients before biopsy with the thought that someday maybe we do not even need to do the biopsy, if we have enough, if we understand the data well enough, if we do a multiparametric MRI and we do not see any regions of interest or what we think is high grade disease, do you really need a biopsy, and if we do, do you still need that 12 cores, can we just do a targeted biopsy like we do for every other cancer in the body. Now, this is a little bit premature, but because there are times in which the MRI can be negative and we can miss, we are still on the learning curve, but I think this is the ultimate goal. To get back to your question, there are times in which someone will come to me without having had a biopsy and we will obtain an MRI and then do a targeted biopsy. Other times, in which we go straight to biopsy and depending upon what we find, we may determine to do the MRI after the initial biopsy.

Gore Got it. You keep using this term low volume, low grade. Is that what it was?

Schulam Low volume, low grade.

Gore Can you tell our listeners a little more about that and what that means?

Schulam Sure. So, grade in prostate cancer is read out as Gleason grade and Gleason grading is based on architecture. I tell my patients, imagine you are looking at a cobblestone street. If everything looks well organized, you have no suspicious areas, there is no cancer. As there becomes irregularity in the cobblestone street, you then begin to grade that irregularity, and the Gleason grading goes from 1 to 5; 1 meaning the cells are a little bit out of order, 5 they are way out of order. That would be a higher grade cancer. Prostate cancer grows in islands, so when you look under the microscope and you look at a core of tissue that you have taken, you actually see islands of tissue, and so what the pathologist does is they look and identify the largest island and grades that one first. Usually in needle biopsies, you do not grade from 1 to 5, it is only 3 to 5. So they say, it does not look that bad, it is a Gleason 3. Then they look at the next island and grade that from 1 to 5, but again really just 3 to 5 and they will say that does not look that bad, it is 3. So that is a 3+3 Gleason 6 disease. The patients will hear, I have Gleason 6 disease. It really does not matter for low grade disease because 6 you can only obtain mathematically with 3+3.

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Gore Especially if they are only starting at 3.

Schulam That is our low grade. What is interesting is now you start to say, okay now there is some Gleason 4 disease and the reason why this understanding how we grade makes a difference. So if someone looks under the microscope and the largest island, so the most amount of cancer in this particular core of tissue is Gleason 4, then that gets graded 4 and the next island may be 3, so now that patient has Gleason 4+3.

Gore 7.

Schulam Very good.

Gore I did well in math.

Schulam But there are 2 ways to get to 7 right? You can either be 4+3 or 3+4. So, knowing that the first number is the one that you have the most of.

Gore The bigger one.

Schulam Right. 4+3 is actually a little bit more concerning than 3+4. Anyhow this is the grading system for prostate cancer. Now for the volume, because remember we have taken lets say 12 cores, we ask ourselves how many cores are positive, so let's say in your case it came back as 2 cores positive, we would say that is favorable. There are only 2 cores and neither core had anything other than Gleason 6 (3+3). The next question we ask, what percentage of the core was positive? Because if you had a core, and it were let's say an inch long and the whole thing was filled with cancer, that would be 100% of the core. If it were say less than 5%, it may be another. So, historically in the last several years, people have been saying if you want to go on active surveillance, there are many different criteria, but one of the most accepted criteria is that you have no more than 2 cores positive of Gleason 6 and in each core, no more than 50% positive. So that would be conventionally what someone would call low grade Gleason 6, low volume 2 or 4 cores, no core greater than 50% disease.

Gore Got it. That sounds very complicated kind of like, one from column A and one from column B. But I guess this is something you are good at.

Schulam Yeah. Unfortunately, this is a surrogate for actually understanding more about what is going on in the prostate.

Gore It doesn't seem very biological.

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- Schulam And I think at Yale this is where we were trying to look at this a little bit differently.
- Gore How to do that?
- Schulam So, if I told you Gleason 6 disease is not lethal and you had 2 cores positive and you met the initial criteria, you would say great, but let's say you had 4 cores positive and one core was 80% and one core was 70% and the other 2 were less than 50.
- Gore It sounds like a lot.
- Schulam It sounds like a lot, but I would argue if we truly believe that Gleason 6 disease is nonlethal, it should not matter whether you have a lot of it or a little of it. So the real reason why as you had more Gleason 6, the thought that you should not go into active surveillance, is because routinely or conventionally when we take out prostates for Gleason 6 disease, there used to be about a 30% upstaging, so you would say, oh you did not have Gleason 6, you had actually Gleason 7 in there, that is because the biopsy missed it. So now let's overlay the ability to image the prostate on this whole process. If I can actually image the prostate, not identify any areas of concern where I think there is high grade and even if there were a target, the target also was consistent with Gleason 6 disease, maybe we have a different way of evaluating who those patients are who should be on active surveillance, so what we are doing at Yale is, we are not sticking to that conventional criteria of 2 cores, we just look at Gleason 6 disease. We do not put anybody on active surveillance until they have actually had an MRI, so we can confirm, we believe that what they have is actually what they have, based on imaging not just random biopsies. In addition, if you have more than 2 cores positive, we are beginning to incorporate other diagnostic markers, one of them is called Oncotype DX. There is another company, Polaris and these are genomic tests. We actually send your biopsy sample to them and on the specimen from your biopsy, they do a genetic test looking at 17 genes that determine aggressiveness of cancer and they give us a probability of having aggressive disease within that cancer based on the genetic makeup of your cancer. So, if we have 4 or 5 cores positive, someone might say, oh you should not go on active surveillance, but if your genetic test shows that you have a very low probability of having aggressive disease, you may be someone who does not have to worry about it. So, it is becoming a much more complex evaluation, but it is based on more data. In the old days you would say, you made your diagnosis just on a biopsy. Now, we are making the diagnosis on a biopsy, multiparametric imaging, and genetic markers, quite different than what was happening maybe 10-15 years ago.
- Gore I think many of our listeners, when they hear the word genetic, they are thinking about traits, which are inherited from their parents. Is that what you are taking about?
- Schulam No. These are not. These are just looking at mechanisms and looking at tumor suppressor genes, so you are looking for mutations in these genes that may make you more susceptible to an aggressive disease.

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- Gore These are features of the cancer that have developed over time that people are not born with.
- Schulam Yeah, exactly. There is a subgroup of patients who have hereditary-based prostate cancer and this is on the paternal side, so it is not what your mother's family had, but what your father's family had. If you have a father or your father had brothers or your uncles had prostate cancer or you have a brother with a prostate cancer, then we are a little bit more concerned and you should be definitely screened and maybe even start screening at an earlier age.
- Gore You talked about active surveillance. What does that actually entail?
- Schulam That is also evolving because we are now having more people on active surveillance. What we do at Yale is if we determine that you are going to go onto active surveillance, remember it is not based on what has happened on the outside, we want to confirm here by imaging and repeat biopsy. If everything matches what you came in with, then we put you on active surveillance, which means we will follow your PSA every 3 months and then 1 year from your initial MRI biopsy at Yale, we would repeat the MRI and then rebiopsy. I think in the future, it is going to evolve to where we just do the MRI and not the biopsy. We are not quite there yet and it is going to be based on the patients that we have taken care of in the past, the data as we analyze it and as we look forward, but currently active surveillance means following the PSA closely, so if the PSA shoots up, that may initiate a second round of investigation, meaning MRI imaging and repeat biopsy, and if that does not and the PSA stays stable, right now, at the end of the first year, we would do an MRI and a repeat biopsy and then based on what we see then, we will determine the next interval for imaging and biopsy. The idea here is we would probably increase the interval each time so that we decrease the exposure to the biopsy and to the MRI, but I think in the future we are going to begin looking at this with University College London maybe based just on imaging, which is much more tolerable than imaging plus the biopsy.
- Gore Let me just understand this, the longer you show stability.
- Schulam The longer the interval.
- Gore You will increase the interval, so there will be less biopsies.
- Schulam And fewer MRIs as well.
- Gore Got it.
- Schulam And all the while still checking your PSA, perhaps at 6 months or yearly intervals.

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- Gore Let's take the other unfortunate side that I do not have low volume, low grade disease.
- Schulam You have high volume, high grade disease.
- Gore I do not pass your 6 and 2 test, now I am worried. Does this mean I am going to die of prostate cancer?
- Schulam No. Even though they are diagnosed with high grade, high volume disease, the bottom line is that with treatment, and I am not biased, I actually believe this, that radiation is a really good means of treatment as is surgery and as I tell my patients their potential complications are associated morbidities. Morbidities are long-lasting effects of the treatment with both surgery and radiation, so it is best for you to meet with a surgeon, meet with a radiation oncologist and select the bucket of morbidities that you feel more comfortable with. An example is, it is very unlikely to have incontinence with radiation. So for someone who is very concerned about incontinence, they may want radiation over surgery. These are just things that have to be discussed and kind of vetted between the patient and the patient's family and understanding what they are getting into, but the bottom line is, both are very good treatments for prostate cancer. In addition, there are a lot of new drugs and therapies that are coming down the pipe to treat recurrent disease and the patients are doing extremely well, so by no means does the diagnosis of aggressive cancer mean that you are going to decrease your life expectancy. There is a good chance with what we have available to us and close work with our medical oncologists like Dr. Dan Petrylak, that even if you have recurrence after your primary treatment, you are going to do well.
- Gore That is great. What does the surgery consist of these days if I were to choose surgery?
- Schulam About 15 years ago, surgery I would say was minimally invasive either laparoscopic or robotic and interestingly the robot was introduced around 2000, almost everything was done open. Over the course of the last 14 years, I would say greater than 90% of all prostate surgeries are done with the robot. It is an enabling procedure. It is a minimally invasive procedure. I think it does a very good job. I do not think open surgery is better than robotic and vice versa. I think it is really dependent upon the surgeon. If you have a great open surgeon, you can do just as well as if you have a great robotic surgeon. The bottom line is, I think either way is fine, radiation or surgery, surgery is predominantly robotic.

*Dr. Peter Schulam, Professor of Urology, Chair of the Department of Urology and Chief of the Department of Urology at Yale School of Medicine. We invite you to share your questions and comments, you can send them to [canceranswers@yale.edu](mailto:canceranswers@yale.edu) or you can leave a voicemail message at 888-234-4YCC. As an additional resource, archived programs are available in both audio and written format at [yalecancercenter.org](http://yalecancercenter.org). I am Bruce Barber hoping you will join us again next Sunday evening at 6:00 for another addition of Yale Cancer Center Answers here on WNPR, Connecticut's Public Media Source for news and ideas*

