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Thanks!

Thought of The Day

You can win big battles
by winning small victories

— Manuel Corazzari

Public meetings cancelled until further notice

Covid-19 Update

Covid is still with us. However vaccinations are now progressing at an increasing pace so we are optimistic that in a just a few more months the crisis will end. Because the majority of our support group participants fall into the age category that is most vulnerable to Covid, we will be especially careful to be sure that we sit tight until the health authorities say it's safe to move forward once again.

Watch our newsletter for updates on this changing situation.

In the meantime, stay safeand get vaccinated as soon as possible to hasten the arrival of the end of this scourge.

The Board

A Genetic Biomarker Test for Newly Diagnosed Prostate Cancer

Hormone Therapy for Prostate Cancer? A Genetic Test Could Help Decide

Range of scores for the Decipher test showing low, intermediate, and high risk of prostate cancer metastasis

A large study has confirmed that a genetic test can correctly predict how likely it is for recurrent prostate cancer to spread (metastasize) to other parts of the body. The test could help people with prostate cancer and their doctors choose the most appropriate treatment, the researchers concluded.

If a person's PSA level starts to rise after surgery to remove the entire prostate (radical prostatectomy), that generally means the cancer has come back. The standard treatment for prostate cancer that has come back after prostatectomy is radiation therapy, either alone or with the addition of hormone therapy.

Because hormone therapy can cause distressing side effects—including hot flashes, loss of energy, and loss of sexual desire—the treatment is typically reserved for patients with aggressive cancer that is

more likely to spread, explained the study's lead investigator, Felix Feng, M. D., of the University of California, San Francisco.

Most people with recurrent prostate cancer “don't want hormone therapy unless they absolutely have to receive it,” he added. But it's currently challenging to determine which patients have aggressive cancer that may require the addition of hormone therapy.

The new study found that the genetic biomarker test, called Decipher, may have the

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The Manitoba Prostate Cancer Support Group offers support to prostate cancer patients but does not recommend any particular treatment modalities, medications or physicians ; such decisions should be made in consultation with your doctor.

MPCSG – active since 1992.

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ability to do just that. Using data from an NCI-sponsored clinical trial, researchers found that people with higher Decipher scores were more likely to have cancer that spread years later and to die from the cancer. The results, published February 11 in *JAMA Oncology*, also showed that hormone therapy helped people with higher scores live longer but was far less helpful for those with lower scores.

Although the Decipher test was developed nearly a decade ago, the new findings are important because previously there wasn't enough evidence to recommend its routine use in patient care, explained Sean McGuire, M.D., Ph.D., in an accompanying editorial *Exit Disclaimer*.

The Need for a Better Biomarker

Doctors currently use certain criteria—like the tumor grade and PSA level—to recommend whether patients with recurrent prostate cancer should get hormone therapy in addition to radiation. But studies have shown that these characteristics aren't very good at identifying people who truly need the combination treatment.

"A patient could have a rising PSA [level] and die of something else" rather than prostate cancer down the road, explained Adam Sowalsky, Ph.D., head of NCI's Prostate Cancer Genetics Section, who was not involved in the study.

The Decipher test was developed to address the need for a reliable biomarker, and retrospective studies that looked back in time have shown

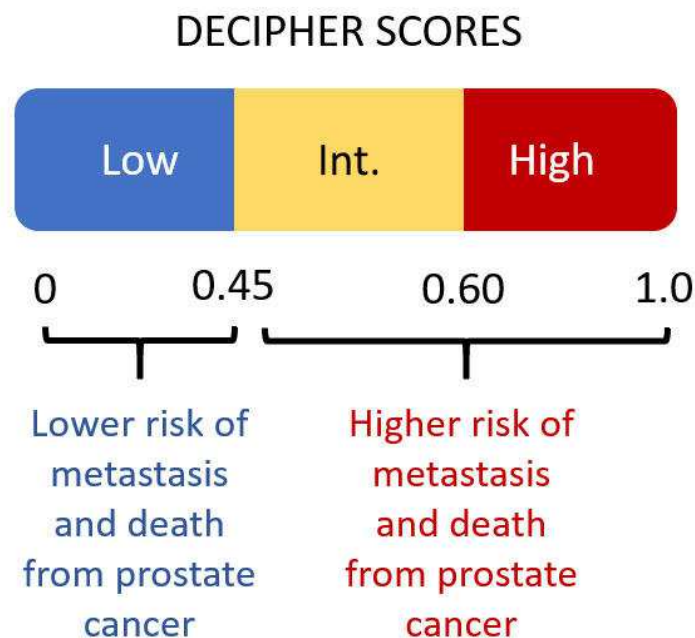
that it does indeed outperform standard markers like PSA level. The test looks at the activity of 22 genes in prostate tumors and calculates a score from 0 to 1.

For the new study, Dr. Feng and his colleagues set out to see how well the test worked in the context of a clinical trial that had followed participants forward in time. They applied the Decipher test to tumor tissue that was removed during surgery from 352 patients who participated in an earlier clinical trial. Of those patients, 89% were white.

Assessing the Decipher test in the context of this previous trial allowed the researchers to determine whether the test could predict outcomes in patients who hadn't yet been treated and whether it could predict how well that treatment would work, Dr. Sowalsky explained.

Decipher Test Scores

After accounting for differences in participants' ages, races, ethnicities, cancer treatments, and other factors, the researchers found that prostate cancer was more likely to have spread in people with higher Decipher scores than in people with lower scores.



By estimating the future risk of prostate cancer spread and death, the Decipher test could help patients and their doctors make treatment decisions.

Credit: National Cancer Institute

The trial participants—who all had rising PSA levels after surgery—had been randomly assigned to receive radiation alone or in combination with bicalutamide (Casodex), a type of hormone therapy. The participants' medical outcomes had been tracked for about 13 years.

"The remarkable piece is that [testing] these samples predicted the development of metastasis 10 or more years before those metastases developed," Dr. Sowalsky said.

The test scores were also strongly associated with the risk of dying from prostate cancer and dying overall during the study period, the team found.

In addition to looking at the scores on a continuous scale from 0 to 1, the researchers also clustered the scores into three previously defined groups: low (scores below 0.45), intermediate, (scores between 0.45 and 0.6), and high (scores above 0.6). Overall, 42% of the men had a low score, 38% an intermediate score, and 20% a high score.

These score groups were also strongly associated with the risk of metastasis, death from prostate cancer, and survival overall, the researchers found. For example, metastasis occurred in

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15% of people with high scores but just 6% of people with low scores. And while less than 1% of people with low scores died from prostate cancer, 10% of people with high scores died from the disease.

Having cut-off points for low and high scores can help doctors easily determine the most appropriate treatment, Dr. Feng explained.

Although the study wasn't designed to detect a relationship between Decipher scores and how well hormone therapy worked, Dr. McGuire noted, the results did suggest that hormone therapy helped people with high and intermediate scores live longer. Hormone therapy also helped people with low scores live longer, but the improvement was minimal compared with what was seen in people with higher scores.

The Decipher test "may identify a subset of patients with a disease [prognosis] that's so favorable that they don't need the addition of hormone therapy to radiation," explained Dr. Feng. Several of the study investigators received fees from or worked for Decipher Biosciences, the company that makes the Decipher test.

Use in Everyday Medical Care

Current guidelines from leading

medical organizations (such as the American Society for Clinical Oncology) don't recommend routine use of the Decipher test. But the new study results should prompt these organizations to reconsider such guidelines "on the basis of the strength of the evidence," Dr. McGuire wrote. The test's use in everyday medical practice "should become commonplace," he added.

The question of whether hormone therapy should be added to radiation for patients with rising PSA after surgery "is a question I see all the time in my practice," Dr. Feng said. "My patients very much want to know if hormone therapy has a good chance of benefiting them. Tests like this are important because, if we can provide more information to patients and physicians, they can make better choices together."

Decipher is already available to patients and the cost is covered by many insurance payers, including Medicare, Dr. Feng said. Plus, it doesn't require an additional procedure if tumor tissue is readily available from the patient's prostate surgery.

There are still many questions about how to use the Decipher test in different groups of patients with prostate cancer, Dr. McGuire wrote. About 20 ongoing clinical studies are looking to provide some answers.

One area that needs further study is how well the test works in people of color, Dr. Feng noted. Recent evidence has shown that genetic-based tests can be less useful for people of color if there was a lack of diversity among participants in the studies that were done to develop and validate the test.

A Genetic Biomarker Test for Newly Diagnosed Prostate Cancer

Results from a study of a different genetic biomarker test suggest that it could one day help inform treatment decisions for men newly diagnosed with localized prostate cancer.

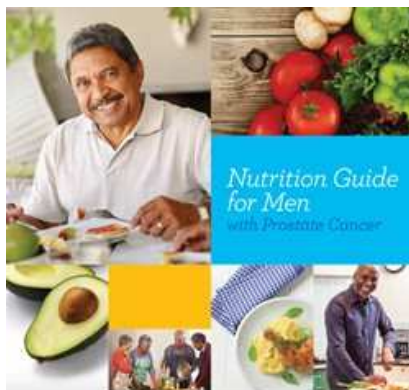
According to findings published February 24 in JCO Precision Oncology, a biomarker test called the Oncotype DX Genomic Prostate Score accurately predicted the long-term risk of metastasis and death.

Disclaimer from prostate cancer in men with localized disease. The test needs to be validated in larger forward-looking studies before it can be used to guide treatment, the study researchers noted.

March 15, 2021, by NCI Staff

Source: <https://www.cancer.gov/news-events/cancer-currents-blog/2021/decipher-test-prostate-cancer-hormone-therapy>

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Nutrition Guide for Men with Prostate Cancer

Prostate Cancer Canada's new nutrition guide resource is now available.

This guide includes helpful information such as

- Eating Well with Canada's Food Guide
- Nutrition Advice for Managing Side Effects of Treatment

- Bone Loss and Osteoporosis
- Muscle Loss and Weight Gain
- Diarrhea
- Hot Flashes
- Frequently Asked Nutrition Questions (FAQs)
- Complementary Therapies
- Natural Health Products (NHPs)
- Choosing Complementary

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Therapies

- How to Find a Registered Dietician
- Additional Resources

"Nutrition Guide for Men with Prostate Cancer" is now available on our website for viewing, downloading.

This guidebook provides men with information about eating well, along

with instruction on how to manage treatment side-effects with food and physical activity. Frequently asked questions related to nutrition and complementary therapies are also presented in this resource.

We hope that this resource helps prostate cancer survivors and their partners, caregivers and family members to better manage their cancer journey.

Access this document at -
<http://manpros.org/pdf/Nutrition.pdf>

Order a copy of this guide at -
[https://www.prostatecancer.ca/Support/Resources-\(1\)/Order-Materials](https://www.prostatecancer.ca/Support/Resources-(1)/Order-Materials)

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Next-Generation Imaging May Lead to Change in Management of Prostate Cancer

The use of next-generation imaging, like PSMA PET, has been shown to be superior compared with conventional imaging and may become a homestay in prostate cancer care in the future.

Next-generation imaging may allow for the detection of metastases that are otherwise undetectable by conventional imaging – highlighting a new technology and agent that may be a homestay in prostate cancer care, according to Phillip J. Koo, MD. At the New York GU 14th Annual Interdisciplinary Prostate Cancer Congress® and Other Genitourinary Malignancies, Koo, Chief of Diagnostic Imaging, Northwest Region Oncology Physician Executive, Banner MD Anderson Cancer Center, Phoenix, Arizona, discussed the advantages of next-generation imaging, like prostate-specific membrane antigen (PSMA), and how it may translate into future use once more agents are FDA approved.

Next-Generation Imaging Advantages

While conventional imaging techniques—such as bone scans, CT, or MRI—date back to the 1970s, their use does have limitations. For example,

Koo noted that although bone scans are widely available and can help to identify bone lesions, they rarely identify asymptomatic disease or positively identify disease with the absence of a high PSA. Similarly, while CT scans can follow treatment response and can detect metastases, they cannot detect recurrent tumors and are dependent on size for nodal evaluation, which can result in poor sensitivity.

Therefore, this is why there has been a shift in focus toward next-generation imaging. In particular, this strategy may allow clinicians to see things that they wouldn't be able to see using conventional imaging.



“It’s almost like the difference between a high-definition TV versus your standard TV,” Koo explained. “And we all recognize [that] with high-def, it’s

just amazing what more you can see and how better appreciated that becomes.”

Moreover, he added, several specialized imaging techniques have emerged that may permit the acquisition of digital images at high resolution, which may have diagnostic potential to introduce new opportunities to more accurately assess disease burden. However, there is a lack of standardization or practical application of next-generation imaging in prostate cancer.

Next-generation imaging works by taking advantage of the unique biological aspects of prostate cancer carcinogens. Molecular imaging probes, of which several are already in clinical use or under evaluation, can be divided into images with increased cell metabolism, those that target prostate cancer-specific membrane proteins and receptor molecules, and those that bind to the bone matrix adjacent to metastases to the bone.

Therefore, increased metabolism and vascular changes in prostate cancer cells can be evaluated with radiolabeled analogs of choline,

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acetate, glucose, amino acids, and nucleotides, Koo explained.

Types of Next-Generation Imaging

One example Koo provided of next-generation imaging was 18F-fluciclovine. Approved by the FDA in 2016, 18F-fluciclovine is a synthetic amino acid PET imaging agent that has demonstrated the ability to recognize amino acid transporters, which have been shown to be upregulated in many cancer cells, he explained.

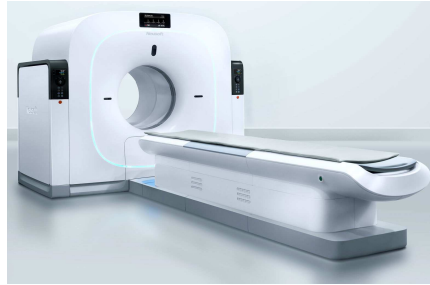
Additionally, because the radiotracer was not metabolized or incorporated into newly synthesized proteins, it may not interfere with normal protein synthesis.

“When the data were first reported in patients with biochemical recurrence with a PSA level of less than or equal to 0.79, it actually had a detection rate of 41% which is pretty remarkable given that lower PSA level. That’s why it created a lot of excitement, that we could image disease better at biochemical recurrence,” Koo said.² Next, clinicians have moved into the evaluation of PSMA PET technology. PSMA is a membrane protein that has been shown to have a significant overexpression in prostatic cancer tissue but low expression in normal tissue. Koo explained that high image quality could be achieved with PSMA PET because of the uptake in ligand bonding PSMA into the prostate cancer tumor cells. PSMA PET agents that are currently under investigation include 68Ga PSMA and 18F-DCFPyL PSMA; however, of note, neither imaging agent is FDA approved yet.

Next-Generation Imaging Versus Conventional Imaging

In a prospective, single-center, open-label, single-arm comparative study, Michael S. Hoffman, MD, and colleagues compared 18F-fluciclovine

and PSMA PET-CT scans for localizing biochemical recurrence of prostate cancer after radical prostatectomy in patients with low PSA concentrations (<2.0 ng/mL).



The investigators found that, among the 50 participants, detection rates were significantly lower with 18F-fluciclovine PET-CT (n = 13 [26%]; 95% CI, 15%-40%) than with PSMA PET-CT (n = 28 [56%]; 95% CI, 41%-70%), with an odds ratio (OR) of 4.8 (95% CI, 1.6-19.2; P = .0026) at the patient level. They concluded that PSMA should be the PET tracer of choice when PET-CT imaging is considered for subsequent treatment management decisions in patients with prostate cancer and biochemical recurrence after radical prostatectomy and low PSA concentrations.³

“The accuracy was much better than conventional imaging, [which was] not surprising, and they had a greater treatment impact,” Koo said. “It also had fewer uncertain results. So that’s something that I think is very important: An imaging test having less equivocal results is more powerful... hopefully this can get rid of that hedge in the future for radiology and nuclear medicine.”

Translating Next-Generation Imaging Into Practice

With all of these data, Koo highlighted that it led to a “monumental day” in December 2020: The FDA approved the first PSMA-targeted PET imaging drug for men with prostate cancer.

“[The approval] actually had 2 indications. Number 1, it had the indications for use in patients with biochemical recurrence, which is something that we were used to. But the biggest difference for this approval was it was actually approved for patients at initial diagnosis,” Koo noted. “So it says that it’s indicated for suspected prostate cancer metastases, which are potentially curable by surgery or radiation therapy. This was pre-definitive treatment, which was something new for these next-generation imaging agents.”

Before concluding, Koo did note that next-generation imaging does not replace pathology: “PET CT can’t detect that microscopic level of detail disease in these patients, so we need to sort of separate the 2, because I often see that being assumed when it comes to pet imaging.”

However, Koo added, next generation imaging is here to stay. “For those of you in the audience who are resistant, I recommend that you start getting a bit more and more comfortable each year because it’s not going anywhere.”

Reference:

1. Koo PJ. Next Generation Imaging in Prostate Cancer. Presented at: 14th Annual New York GU Congress; March 12-13, 2021.
2. Bach-Gansmo T, Nanni C, Nieh PT, et al. Multisite Experience of the Safety, Detection Rate and Diagnostic Performance of Fluciclovine (18 F) Positron Emission Tomography/Computerized Tomography Imaging in the Staging of Biochemically Recurrent Prostate Cancer. *J Urol*. 2017;197(3 Pt 1):676-638. doi:10.1016/j.juro.2016.09.117.
3. Calais J, Ceci F, Eiber M, et al. 8F-fluciclovine PET-CT and 68Ga-PSMA-11 PET-CT in patients with early biochemical recurrence after prostatectomy: a prospective, single-center, single-arm, comparative imaging trial. *Lancet Oncol*. 2019;20(9):1286-1294. doi:10.1016/S1470-2045(19)30415-2

March 16, 2021 Kristie L. Kahl
Koo1_NYGU

Conference | New York GU

Source: <https://www.cancernetwork.com/view/next-generation-imaging-may-lead-to-change-in-management-of-prostate-cancer-expert-says>

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Novartis Says Radioligand Therapy Improves Prostate Cancer Survival

Novartis' experimental Lu-PSMA-617 radioligand therapy has improved the survival of prostate cancer patients with a hard-to-treat form of the disease, the Swiss drugmaker said on Tuesday.

The therapy, which Novartis bought with its \$2.1 billion purchase of cancer drugmaker Endocyte in 2018, arms a molecule, or ligand, with a cancer-killing radioactive isotope.

Novartis said the therapy had significantly improved overall survival and radiographic progression-free survival (rPFS) in patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer.

Novartis, which is due to release specific survival data at an upcoming medical conference, bought Endocyte three years ago as it expanded its targeted cancer therapy portfolio of radioligand medicines that includes Lutathera, which has won approval to be used against neuroendocrine tumours.

It hopes Lu-PSMA-617 eventually becomes the targeted treatment for more than 80% of patients with advanced prostate cancer, should it win approval.



"We intend to submit these data to regulatory authorities as soon as possible," John Tsai, the group's Head of Global Drug Development and Chief Medical Officer, said in the statement.

"Patients with metastatic castration-resistant prostate cancer have a less

than 1 in 6 chance of surviving 5 years and need new treatment options," he said.

If discovered early enough, prostate cancer can often be successfully treated via surgery, radiation therapy or hormone therapy that stops tumour-driving testosterone from being produced or reaching prostate cancer cells.

Metastatic castration-resistant prostate cancer is a type of cancer that resists such hormone treatment, and Novartis is hoping that targeted radioligand therapy offers patients a new, effective option.

(Reporting by Brenna Hughes Neghaiwi and John Miller; Editing by Riham Alkousaa and Timothy Heritage)

Reuters Mar 23 ZURICH

Source: <https://www.thechronicleherald.ca/news/world/novartis-radioligand-therapy-improves-prostate-cancer-survival-566974/>

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New Technology that Pinpoints Prostate Cancer Will Transform Care

Medical oncologist Michael Morris calls the new imaging technique the biggest advance in prostate cancer disease detection since the PSA test was developed in the 1980s.

Summary

A new diagnostic tool allows doctors to see whether prostate cancer cells are still in the prostate or have spread elsewhere. This is a major advance in

disease detection that will benefit people across the spectrum of prostate cancer, which affects one in eight men.

Prostate cancer treatment is on the brink of a major advance, thanks to new imaging technology that can pinpoint the location of prostate cancer cells. This new diagnostic tool allows doctors to see whether the cancer cells are still in the prostate or have spread elsewhere — crucial information for determining the best treatment for patients.

Memorial Sloan Kettering medical oncologist Michael Morris explains how the new tool will dramatically change the outlook for men with prostate cancer.

How does this new imaging technology work?

This form of imaging uses a radiotracer, a radioactive targeting molecule that selectively seeks out and attaches to a protein on the

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surface of cancer cells. That protein, called prostate-specific membrane antigen (PSMA), is not found on most normal cells. When the radiotracer binds to the prostate cancer cells, they can be detected using a PET scanner. On the PET scan, the cancer cells appear as bright spots.

PSMA was discovered several decades ago, and the gene for it was first cloned at MSK in 1993. MSK's involvement with this target has been extensive. Researchers here have been very active in developing agents using PSMA as a target for both imaging and therapy. In recent years, we have collaborated with Johns Hopkins and the pharmaceutical company Lantheus to design and conduct two clinical trials testing one such imaging agent, called 18F-DCFPyL, in men with prostate cancer.

A new drug application has been submitted to the US Food and Drug Administration for this agent based on results from two clinical trials that we published in February 2021, and we anticipate that the FDA will approve the tracer this year.

What did the clinical trials show?

One trial, called CONDOR, evaluated 18F-DCFPyL in men who had undergone radiation or surgery, but who subsequently had a detectable prostate specific antigen (PSA) in their blood. PSA can suggest there are still prostate cancer cells in the body. The key question for these men is where is the residual disease that is generating the PSA? If we can find the site of disease, we can treat them with the appropriate therapy.

Imaging has been the Achilles heel of prostate cancer because the disease is hard to detect after it has spread.

Standard imaging techniques are unfortunately very poor at identifying those sites that occur early, at low PSA levels, when there may be a very small

amount of cancer cells. The new imaging technology works very well in this situation. The CONDOR trial involved 208 men who had a rising PSA after surgery or radiation but whose standard imaging scans detected nothing. The purpose of the study was to correctly identify and pinpoint the location of the prostate cancer. The median PSA of these patients was 0.85, which is low, but the radiotracer correctly identified the location of the cancer in 85% of patients. We reported these results in Clinical Cancer Research.

The other trial, called OSPREY, looked at the use of this agent in 385 men in two different groups. One group included newly diagnosed men who were preparing to undergo surgical removal of the prostate for high-risk disease, meaning these men were at high risk of having cancer that had already spread outside of the prostate. The other group were men who had already had their cancer relapse, meaning it came back after treatment. The point of the study was to define how well the PSMA PET scan identified disease outside of the prostate itself. In more than 80% of cases, a detection on the PET scan outside of the prostate turned out to be prostate cancer. These data were published in the Journal of Urology.

How will this new technology change the care of prostate cancer patients? This is a major advance in diagnostics for prostate cancer, which is a very common disease. It is the biggest advance in disease detection since the PSA test was developed in the 1980s, and it will benefit people across the spectrum of the disease. In fact, PSMA-based imaging has already been approved in other countries, and they have already migrated to this new approach.

Imaging has been the Achilles heel of prostate cancer because the disease is hard to detect after it has spread. For

example, the disease often spreads first to the lymph nodes in the pelvis, but the only way to tell is when the node increases in size, after the cancer has been there a while. Prostate cancer also commonly spreads to bones, but you cannot see the actual cancer cells with conventional imaging methods. Before, the only way to tell it was there was indirectly — by seeing the bone react to damage from the cancer cells by growing new layers of bone. With PSMA PET, we can now detect the cancer cells directly, and much earlier than we could with standard imaging.

Given the previous limitations of standard imaging, doctors have had to make treatment decisions based largely on assumptions and guesswork. For a man with high-risk disease preparing to undergo surgery or radiation, we had to wonder whether there was disease outside of the prostate that we couldn't identify. Our treatments have been designed around incomplete information. For men whose prostate cancer relapsed, we often did not know where the cancer was and had to decide on a treatment plan without this knowledge. With PSMA PET, we have more accurate information to make treatment decisions. In the CONDOR study, for example, findings from the imaging led to a change in the treatment plan in 64% of the men.

There is an entire generation of clinical trials designed around this new type of imaging, including at MSK. The benefit this will bring to patients cannot be overstated, and we are very excited about the possibilities for the field.

Friday, March 26, 2021

source:<https://www.mskcc.org/news/new-technology-pinpoints-prostate-cancer-will-transform-care>

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FUTURE MEETINGS 2021

Our public meetings will not resume until the covid-19 restrictions are lifted.

Watch this space for information on the latest status.

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