How MyProstateScore 2.0 (MPS2) Helps Predict the Presence of Clinically Significant Prostate Cancer Transcript

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Introduction to MPS 2.0

Hello, everyone. Welcome to the Prostate Cancer Summit 2.0. It's my pleasure to introduce to you Doctor Spencer Heaton, the Chief medical officer at LYNX DX, the producers of My Prostate Score 2.0.

We got the Prostate Summit 2.0 and we have 2.0. Wow, I love that. I just realized that. Hey. So, doctor, Heaton. And thanks for joining me. How are you today?

Yeah, I'm doing great. My pleasure. Thank you for having me on. So, as you can imagine, I'm a little bit excited over the fact that, my two tests just recently got approved to be used in New York state, and I already had one of your reps come over to set me up.

This is like, you know, fresh, hot off the press here. So that was, I guess that was it, right? That was the last date that you guys had to, get approval for and you're in.

That's right. Or as excited as you are, two is available in all 50 states now to be ordered and collected in office or at home across the board. You know, I love it. So all right, so our listeners, these are, mostly we, we were talking about before recording who's the listen, mostly patients, but even physicians who really are laypeople as well, because they're not very integrative.

And they don't just do prostate cancer and urology like a urologist. So like what I do. So in my mind, the significance of MPS 2 is the following. The common doctor Geo line that people say is like, no one wakes up in the morning and say, God, I can't wait to get a prostate biopsy today.

I never heard that from anyone. Sometimes urology is, I feel, just general urologist. I it's just a biopsy is the way we do things. What's the big deal?

I think it's a serious big deal. Right? Because you're poking. And anytime you poke healthy tissue, I'm always interested. What? What is it that we don't know when we're focusing and there's inflammation in the prostate.

Sometimes inflammation is chronic, and it sticks for a while.

How the Urine Test Works

That discomfort, then they call it prostatitis. Is it due to the, biopsy? I don't know, but I want to avoid a biopsy if I can. That's the bottom line.

And two, seems like it can give us some direction, in that process. So why don't you explain to us what my prostate score 2.0 is and what are we looking at? And we'll start there.

Yeah. You bet. I think you've, framed the problem very well. And it's that, you know, a prostate biopsy is a great. And very useful procedure. The challenge is understanding who should be getting a prostate biopsy.

You know, getting, your PSA level check to your prostate specific antigen level checked as part of, prostate cancer screening is recommended for men starting as young as 40 or 40 5 or 50, depending on kind of, some of your risk factors.

And if your PSA is elevated, you know, historically, those men have been taken to prostate biopsy to see if they're elevated because they have cancer.

But there's a lot of reasons that can elevate your PSA besides prostate cancer. So if you if you take all those patients to biopsy, only 20% of those biopsies are going to come back for what's known as clinically significant prostate cancer or, you know, treatable prostate cancer, the type you would then take forward to treatment.

So, MPS two is a noninvasive urine test designed for men with an elevated PSA. To answer the question, should you go to biopsy? So you provide a, simple urine sample?

This can either be done in your health care providers office. It can even be done at home. We shipped kits to your house. You provide a urine sample. We analyze that sample looking at 18 biomarkers in your urine that gives you a risk, a personalized risk profile for clinically significant prostate cancer and actually generates a percent score for you.

That's the percent likelihood that if you go to biopsy, you will find clinically significant prostate cancer. So when this comes back low risk, then you're one of those patients, one of those many patients who has an elevated PSA that doesn't need a biopsy.

So it's a great way to understand whether you should or should not go forward with a biopsy. So what's the cutoff percentage number that we're looking at.

PSA Thresholds and Test Ordering

So if it's above what you you know maybe it's clinically significant if they do a biopsy or if it's below unlikely. What's that number. Yeah that number is 11.5%.

And if you look at the report, what you get is it looks like a speedometer, just like, you know, what you see on your car and the little needle will kind of move up and down the dial, for the test that you can collect at home or in the office without getting a digital rectal exam.

The threshold is right there at 11.5%. So anything below that we, we recommend you don't need a biopsy. Anything above that, your risk is high enough to discuss with your provider, whether you should proceed or not.

What? If so, is there a PSA number that, So once it's above, X is when you order the MPs to, for example, when I use a urine test, I use it on everyone.

I'll give you an example. There's a I have a patient who has a PSA of 1.0 62 years old. However, he is. His testosterone is less than, 200. What's the relationship?

The relationship is then when you have really low testosterone men with low testosterone, they're not going to produce PSA because you need testosterone to make PSA.

So it could be a false negative. So I ordered a test that came out actually high and suggested clinically significant prostate cancer. Turns out that yeah his biopsy he has clinically significant prostate cancer.

So is there a number or because it's almost like you don't want to be you don't want to be stuck to a particular range because it could be all over the place.

So you could have a patient that are PSA of 20, no prostate cancer. See that many times or below four for sure. And no prostate cancer. Yeah. You're you're describing well some of the limitations of PSA.

No PSA. It's a great marker. I think it's I would say it's good. Not good. I would say the good is a good prostate biomarker. It is not for prostate cancer.

And if the PSA is 100 that's never good. So we know that it's right. So yeah. Right. It's it's I would say it's it's good or great for its purpose. But you have to understand its purpose and its limitations.

And you've given a good example of, times when PSA could be, falsely low in men with, low testosterone. There's plenty of reasons why it can be falsely high.

Something even like a long bike ride will raise your PSA and then you go get your blood drawn, and it looks like you're in some high risk zone, and you're really not.

So these are some things that people need to be to be aware of. But to answer your question about, you know, using PSA levels as a guideline for when to get NPS two, there's actually two ways to answer that question.

The first is, and I think most importantly is that your, your provider, I guess the, the way that NPS two is validated was going off of provider interpreted risk, meaning the provider would see the patient get a PSA, do a digital rectal exam if their holistic evaluation of the patient warranted, enough risk to go forward with the biopsy.

Those are the patients that we validated. The test is so to answer your question, simply, that's, a fluid decision with you and your provider at what point you would, get, biomarker testing.

Generally you'll see, some hard cutoffs with PSA level, whether it's at, you know, a PSA of two or 3 or 4. There's a lot of controversy around that. I can tell you that.

The second answer to your question is that Medicare, has said that a PSA of three, if you are under 75 is where the risk moves from, you know, a lower to a higher risk.

Interpreting Borderline Scores

That would justify getting a biomarker. So for Medicare, the levels three, but, for just general purposes, it's a more fluid number than that. Okay. So it's not like we it has to be a certain number for, you know, it has to be, you know, a buffer or anything like that.

We can use it to our discretion as, health care practitioners. Correct. Great. You mentioned your cutoff is 11.5. So I have this patient in my office.

He's only 52 years old with a PSA that's not too elevated. Right. It's, probably hovering around four. He seems to have a big prostate. So maybe the PSA of 4.2, whatever it is, is due to the big prostate.

We do an NPS two and his number is 12.5%. As a clinician. And this guy who really doesn't want a biopsy, I would say, well that's still hovering around 11.5.

So maybe, you know, maybe there's still a just it's all about probability like the world works and maybe there's still a little very low percent chance of you having clinically significant prostate cancer as opposed to you being at 50% or 60%.

And maybe we'll do one of the things. Would that approach be a wrong approach? And what if at what point is a significantly higher, above 4.5 to say, hey, you really have to look at this?

What's that real number? Yeah. Again, you've you hit the nail on the head here. And this is why we report the score as a continuum. There are, you know, some other, types of tests out there that tend to that will bucket patients into kind of low risk and high risk.

That's not nearly as helpful as showing your continuous score. So, the cutoff is not meant to create, you know, these binary categories of low risk and high risk, the cutoff exists primarily to provide you some guidance into what would a lump all of the low risk patients together above the the cutoff.

The way that we describe your result is that it's an increasing risk. It's not a high risk. It's increasing. And it'll actually say that on the report, because there's really not much difference between getting a score of 11, which is below the threshold, or 12 which is above the threshold.

They're very similar statistically. And the likelihood, you know, if you go to biopsy with a risk of 12, you're most likely going to have a negative result, right?

That's just what the test would predict. It's hard to say exactly at what point, you should get a biopsy that's going to be shared decision making. It wouldn't be a wrong decision by any means, to go forward, but for biopsy with anybody above the threshold, but we see a lot of providers and patients choose to perhaps just repeat the test in 6 or 12 months.

If they're somewhere in that, you know, maybe 12 to 20, 25% range or so, once you start to get above, you know, 2,025%, I think the risk is probably pretty justifiable to go to a biopsy just to make sure everything's okay.

So people listening to this summit. For the most part, and they don't want biopsies. And I think knowing the audience a little bit, they're saying it has to be a better way.

That's barbaric. Or at least that's how it's looked upon. So I'm thinking, you know, obviously you've got to look at numerous other factors. And at the same time, as a clinician, you have to say, look, this is all about probability, even a view below 11.5.

That doesn't mean it's 100% sure you don't have clinically significant prostate cancer. That's just the way it is. So the way I'm interpreting what you're saying is you start getting a little bit more concerned.

The more the more that that number is higher as it approaches or passes 20.

Using MRI and Other Risk Factors

So 14 okay. Maybe let's see what everything else says. You know, PSA velocity PSA density. Look at the overall picture here. Right. MRI yeah. 1520 above 20 and two above, which is ironically that's the PSA number that the highest PSA that I've seen, with a benign after many biopsies is about a little bit above 20, ironically.

So so in other words, if it's 3040, it's probably a prostate cancer as it relates to PSA. Is that the right way to kind of think about it? Understanding the patient, you know, mentality and what they're looking for?

Yeah, I think that's a very reasonable approach. And way we see this a lot is that, MPs two will be ordered and men with an elevated PSA or an abnormal DRA and or digital rectal exam, and if it's below threshold, they're done.

They can feel confident and you know, that they don't need to proceed with further testing if it's above threshold, even slightly above, what we'll see is, providers ordering an MRI, just to confirm, you know, don't go.

Don't go for the biopsy, get the MRI, see what that shows. And, then now you've got, you know, a few different, data points you can use to make that decision.

Your, you know, your PSA, you have your NPS to score. And at that point, an MRI, you can use all three of those to make the decision of whether to proceed with biopsy.

Right. That sounds great. So here's another scenario. You know, I see a lot of men on active surveillance, right? So they get a biopsy. And so say you have low risk disease, whether it's Gleason six or sometimes Gleason seven, three plus four or low intermediate risk.

I'm interested in, again, preventing unnecessary biopsies for my patients, which in most cases throughout the country, if not the world, they're going to do a confirmatory biopsy a year later.

Right. If you just confirm that yeah, what we got is what we got the first time. I don't want them and I don't want if I'm on active surveillance, that second biopsy can to be used to determine.

So so you have the baseline you have a baseline to. So, I see a lot of men on active surveillance. And so there it's

it's routine to get a second biopsy about a year later after that, first to confirm that.

Yep. That that first biopsy is indeed Gleason six. Or to see if there's any upgrade in their Gleason and their staging. I want to avoid these because I think that many of those are will confirm that.

Yes, indeed there is particularly these by, into in 2025, 2026 where the biopsies are really good, right? For the most part, they're targeted. They use, high, you know, very advanced technology.

So can I use NPS too? And the way I'm thinking about it is this I get a baseline. So when they get diagnosed with prostate cancer, I have their baseline, two.

And let's say that number I'm pulling numbers out of the year is out of the year is 15. A year later they get another two and now it's ten. Right. So it dropped from a year ago.

Can I tell that patient, you know what, if you'd like you don't have to do a confirmatory biopsy. Or do they need to be biopsy. Or should they be biopsy in anyway.

Remember these are the patients. That is not. Yes, doctor. Whatever you want me to do.

Active Surveillance and Repeat Biopsies

These are advocates, self health advocates who want to be proactive and they want to be part of the decision making. It's not like maybe your parent, maybe your father or my father.

Back in the day, they didn't question right. They didn't question their doctors. Whatever you want me to take, I'll take whatever you want me to do. I'll do.

Those days I believe our over. These are proactive people. So I think it. I think it would be reasonable for them to have something else before that second biopsy can mean to be utilized in that fashion.

Yeah. So currently, there are no urine or blood based biomarker tests that are indicated or approved to be used in men on active surveillance, in like, the manner in which you're, that you've described here.

We have a ongoing study in men on active surveillance to do exactly what you've described, which is predict progression grade group progression between initial and confirmatory biopsy, or even between confirmatory and subsequent biopsy.

We anticipate publishing the results of that study in early 2026. So what I can say for the short, I believe, means that you have some idea of what that outcome and conclusion is that you're unable to share with us.

They're there. I can tell you that, there, will be options in the near future for urine biomarker testing for men on active surveillance. Yeah, great. Okay.

But as of today, there are unfortunately, there are no noninvasive options anywhere for active surveillance. That's that's one of the largest unmet needs in men's health, right now is if you're on active surveillance, the only way to know if your cancer is progressing is to get a biopsy.

And a lot of men drop out of active surveillance. They get lost to follow up, because the last thing they want is their third or fourth or fifth biopsy.

It's it's very unpleasant, to say the least. And put it kindly. Yeah. Spencer, what is the. So, for example, now I'm all set to use NPS to. I will be using men on active surveillance before the studies come out, because I think there's value there.

And then I'll tell them, look, there's no studies to support this yet, but, you know, this is how I use it. And if it goes

down, this is part of the overall picture as to whether or not you should do a confirmatory biopsy.

But what am I really looking at? What am I looking for there? And it's okay that you kind of help me guide me without the absolute evidence that will be out in 2026, if that's okay with you.

Am I looking for a drop in two or the same score or less? What am I looking for? Yeah. So when it actually, comes, so that you can follow the NPS to your score over time, same way you could follow PSA.

So yeah, it's looking at like a stable score or increasing score. It can give you a lot of useful, useful information when it comes to active surveillance.

What I can tell you is that NPS, too, is a comprehensive biomarker panel. We look at 18 markers in the urine, some of which predict prostate cancer generally and others that predict the higher grades of prostate cancer.

And when you look at the variable expression of these different markers, that's how we're able to predict high grade versus low grade cancer. And, the, the test that is under development for active surveillance, will more heavily, weigh the higher grade markers in ways that will slightly modify NPS to so that, it will be able to more accurately, accurately predict, grade group two versus grade Group three.

You know, as you move up, another way to think of it, you know, it's always hard to talk about grade group with, with patients and providers because you either talk about Gleason score or grade group, which is a great group is fine, actually.

Yeah. Okay. Perfect. So as you progress, you know, the test will be looking at, progression from grade one to 2 to 3. So, currently to answer your question, NPS two, if you follow it over time and it's increasing, will give you an indication that your risk is increasing.

Absolutely. But as we refine the test for use, in men with active surveillance, we will actually be able to provide you a score and a unique threshold that will give you that exact answer, yes or no, whether you should move forward with a confirmatory biopsy or a subsequent biopsy.

So it'll be very it'll be much more informative when the active surveillance test itself is out. So is the prostate cancer screening NPS two as we know it today.

Will that be different than the two as let's say call it? So it's a little bit different things that we're looking at.

Future Active Surveillance Testing

There are even even branded differently literally to a yes or something like that. It'll be it'll be slightly different. Yes. The all of the biomarker there, there will be significant overlap in biomarkers.

But it will be, for all intents and purposes, enough of a different test that it would have, like you said, a different, a different name, same collection, you know, same process generally for the patient, but for our lab, we'll handle it differently.

Wonderful. Well, I think that's plenty for our audience to at least, you know, have an intelligent conversation with their urologist about who and what.

What what is it? Utilization Dr. Heaton. And thank you so much for being on any final words. And how can people learn more about MPS 2.0, yeah. So, MPS two is offered by, lynx DX.

That's l y n x dx. So go to lynxdx.com. You can read all about the test. If your provider is not currently ordering MPS two, it's very easy for them to get set up.

To do so, you can direct them to our our website where they can enroll and order the test for you.

Where to Learn More About MPS 2.0

You can then collect the urine sample in their office, or your provider can have a kit shipped just to your home and collect in the comfort of your own home.

And we'll, Fedex will come pick up the sample and take it away. Couldn't it couldn't be easier. Easy is, easy. Easy. And simplicity is the way to go. Yeah, exactly. Everybody wins.

Thank you so much for being on and, really educating me as well with some of the finer details that I was not aware of. So thanks again for that. And, all the best.

And thank you, everyone for watching prostate Cancer Summit 2.0. We got more to come. Stay tuned. Thank you.