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Men's health: Interesting new research into prostate 14 March 2011 disease and prostate cancer

Researchers suggest that there may be a link between the state of men's bones and prostate cancer. Plus: Australian research into gene therapy for prostate cancer, how recent guidelines on the PSA test may be wrong, the importance of PSA velocity, and a look at various prostate cancer treatments, including brachytherapy. There's a suggestion that surgery may be second best in more men than specialists might think at the moment.

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Transcript

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Norman Swan: Good morning -- today some of the latest information for men on their prostates and not just prostate cancer, new evidence on treatments, testing and more. We're just going to drip, drip, drip away at the evidence because men are confronted with many dilemmas often from quite a young age. Take Mark for instance whose problems started in his 30s.

Mark: The first symptom was suddenly I was having to go to the toilet more often than normal. You don't think about it as a young person but it was starting to impact on my sleep, I was getting up five times a night and I said something's not right so I went to the GP and that really was the beginning of a long relationship with my urologist.

Norman Swan: Mark had what's called prostatitis, inflammation of the prostate which was painful and hard to treat.

Mark: But suddenly my PSA jumped and it jumped noticeably so it was suggested that, all right, we'd better have another look at the PSA to see if it's just a variation or is it a real jump, and it was measured twice more over the year and I had a biopsy as well.

Norman Swan: We'll come back to Mark's story later but where he was at in his

prostate journey was where many men find themselves due to this jump in their PSA level. Let me back up a little to explain.

The PSA test is widely used to detect men who might be at risk of prostate cancer. It's not a test for cancer and can lead men to unnecessary biopsies and even treatment for cancers that might never amount to much.

To give you an idea of how inaccurate the PSA can be, 15% of men with a normal PSA actually have cancer. That's why urologists and others have suggested focussing, rather, on whether the PSA is rising at too fast a speed. The idea is that it might indicate there's a cancer that's growing quickly.

They call it PSA velocity and Australian guidelines, like those overseas, include PSA velocity as a criterion for a prostate biopsy to see what might be lurking in the gland. Research published in the last couple of weeks though, suggests that relying on PSA velocity adds nothing and in fact increases the unnecessary biopsy rate.

Dr Andrew Vickers from the prestigious Memorial Sloan-Kettering Cancer Center in New York was the lead author.

Andrew Vickers: There were some studies that actually were quite promising. The whole series of studies showed that there was a statistical relationship between changes in PSA, PSA velocity and a whole host of prostate cancer outcomes including whether you had prostate cancer, how aggressive that prostate cancer was and how likely it was to return after surgery.

The problem was that a statistical association isn't necessarily a very good grounds for practice.

Norman Swan: And what we're talking about here is how tight is the link between a rise in your PSA and the fact that you've got cancer.

Andrew Vickers: The problem is this, if you take for example the ability to play basket ball, you know tall kids are better at basket ball and tall kids also tend to have bigger feet. So you could show that there was a statistical association between shoe size and basket ball ability but no one would say to the basket ball coach hey, don't just look at how tall the kids are, go measure their shoe size. So what you have to demonstrate is that it tells you more information than what you have in front of you.

The real question is does PSA velocity give you more information than PSA alone and that's what we started to investigate a few years ago.

Norman Swan: And you did this by looking at a large group of men who had been

followed in a prostate cancer prevention trial?

Andrew Vickers: When we looked very specifically at the guidelines produced in the United States by major national cancer guideline groups all of them said go get a biopsy if you have a spike in your PSA, if your PSA velocity is high, go get a biopsy even if there's no other reason to get a biopsy. So if your PSA is in the normal range and you have a normal clinical exam still get a biopsy. So when we realised that there was this study called the Prostate Cancer Prevention Trial in which men had got a biopsy at the end of the study even if you didn't have any of these medical implications for it such as an abnormal digital rectal exam.

We thought well hang on, this is perfect test this guideline that if you have a normal PSA you should go and get a biopsy if your PSA velocity is elevated.

Norman Swan: And?

Andrew Vickers: Firstly what we found is that knowing a man's PSA velocity did not give you any more information than PSA, particularly for the aggressive cancers, the ones we're really worried about as likely to shorten a man's life. PSA velocity was not at all helpful in finding those particular tumours and if you'd applied the guideline what we found out is that it would lead to a huge number of unnecessary biopsies -- about one in seven men would end up getting biopsies.

Norman Swan: One in seven men?

Andrew Vickers: Who are aged between 50 and 70. And what I should add is that the prostate biopsy is no picnic, you have a probe that's put up your backside and then needles are fired across the rectum into your prostate.

Norman Swan: Yes, I'm shifting uncomfortably as we speak and of course the more biopsies you do the more likely you're to find cancer that may not have any meaning.

Andrew Vickers: Our conclusions were using these criteria would lead to a huge number of unnecessary biopsies with no real benefit to patients.

Norman Swan: So what's the answer? I know that the Memorial Sloan-Kettering has a risk tool to evaluate your risk to suggest whether or not you go ahead and have a biopsy? What are the elements then that should be considered in terms of whether or not you should get on the train to the biopsy?

Andrew Vickers: The big message of our paper is that if your PSA is in the normal range and you have a normal clinical exam you can be reassured that there's really no need to get a biopsy unless your PSA is elevated or you have an abnormal clinical

exam. However if your score is high that doesn't mean go and get a biopsy straight away. In many, many cases if you just wait a few weeks your PSA will go down so one of the first pieces of advice is if you have a high PSA just wait a few weeks, come back you know six weeks, three months later, get a repeat PSA test and see if your PSA is elevated.

Norman Swan: Andrew Vickers is a prostate cancer researcher at Memorial Sloan-Kettering Cancer Center in New York. And you're listening to the *Health Report* here on ABC Radio National with me Norman Swan.

One of the world's leading centres for prostate cancer research and treatment is Johns Hopkins University School of Medicine in Baltimore where urologist Dr Stacey Loeb has been studying the link between a man's bones and his prostate risk.

Stacey Loeb: One of the primary sites of prostate cancer spread is to the bones so there's been a lot of interest in looking at what is the link between prostate cancer and bone. There are actually also some prior studies suggesting that bone density is associated with a risk of breast cancer so we wanted to look at the link between bone density and prostate cancer.

Norman Swan: What did you do?

Stacey Loeb: We used a population known as the Baltimore Longitudinal Study of Ageing that was initiated in 1958.

Norman Swan: This is one of the world's longest studies of ageing covered many years ago in fact on the Health Report looking at a group of people and following them through into old age.

Stacey Loeb: Absolutely, so in this population as part of the study of the effects of ageing on the body many men underwent a bone density measurement back in the 1970s and 1980s from which we were then able to observe the incidence of prostate cancer in these men over time.

Norman Swan: And what did you find?

Stacey Loeb: We found that consistent with what's been shown previously bone density does decline in men with age.

Norman Swan: Just before you go on, one of the myths is that men don't get osteoporosis and in fact men do.

Stacey Loeb: Absolutely, however in the men that later developed prostate cancer they had less of a decline with age.

Norman Swan: For their age they had denser bones?

Stacey Loeb: Yes and they had less decline over time which suggested perhaps that there are some common factors involved with bone growth and maintenance and with prostate carcinogenesis

Norman Swan: So what you're not able to say from this is cause and effect. I mean there has been some relationship between male hormones and enzymes related to male hormones and the incidence of prostate cancer and male hormones do boost bone density. So is this just a sign that you might have high male hormones?

Stacy Loeb: It could be a sign of a common factor like male hormones, there is another very interesting recent study showing that men with higher serum calcium levels had a higher risk of fatal prostate cancer. So there could be some involvement of the calcium parathyroid hormone access. There's also been a lot of recent focus on the micro environment so it could be that there are local growth factors in the micro environment that allow for the growth of prostate cancer as well as the maintenance of bone.

Norman Swan: What are the clinical implications if any?

Stacey Loeb: Well this is not a study designed to look at a predictive tool one being I've been asked is whether you would check bone density as sort of a screening to predict prostate cancer and that really wasn't the implication. The implication of this study is that it's very provocative that we did demonstrate this link between bone density measurements 20 years prior to diagnosis with prostate cancer. And even more interesting high risk prostate cancer had the least decline in bone density with age. This study really sets the stage for more work and to defining the factors that allow for prostate carcinogenesis and allow for these metastases to take shape in the bone.

Norman Swan: I spoke to Stacey Loeb before Memorial Sloan-Kettering published their paper on PSA velocity so I didn't challenge the practice at Johns Hopkins of relying quite heavily on PSA velocity. However Dr Loeb's research has found that having a biopsy isn't a trivial exercise. It has risks and should only be done when the chances of finding cancer are deemed high enough.

Stacey Loeb: For example some men have undergone many repeat biopsies over time. Now each biopsy has risks associated with it, we just finished a large study and the Medicare database...

Norman Swan: That's your aged population?

Stacey Loeb: Yes, Medicare is the insurance group for over the age of 65 in the United States, so we just studied more than 17,000 men from the Medicare database who underwent prostate biopsy to determine the risk of hospitalisation and serious infectious complications within 30 days. In fact there does appear in this country and abroad to be an increasing risk of serious infectious complications after a prostate biopsy which makes this debate all the more relevant. It becomes more important to pick the right people to screen and the right people to biopsy given that the risk of complications from biopsy has been increasing over time.

Norman Swan: Stacey Loeb is a urologist at Johns Hopkins School of Medicine in Baltimore. Well let's go back to Mark who did go on to have more than one biopsy.

Mark: The first biopsy came back negative but in 2009 I had another biopsy just to make sure that you know, I've got a family that I want to be part of that family for as long as possible, so we decided that having a biopsy was a good idea. I had 16 biopsy needles and 2 of them came back with cancer cells. Having had a PSA score that had been higher than normal we'd always discussed the possibility is this just something that's going to happen and it's a matter of when but it's still a shock to be told you've got prostate cancer.

We were given the information that I could have surgery, I could have radiotherapy and there's various options within radiotherapy -- I could have external beam therapy, brachytherapy and the surgery of course. There are two options, there is open surgery or there's robotic surgery.

Norman Swan: And Mark like most men in that situation chose surgery. But one of the other options according to a review of the available evidence seems to offer results that are at least as good as radical prostatectomy, that's the surgery, if not better. It's called brachytherapy -- the insertion of radioactive seeds.

Professor Tom Pickles was part of a review of men with low, medium or high risk prostate cancer who had either surgery, brachytherapy or what's called external beam radiotherapy which is the traditional form where the person is on a table under a huge machine. Dr Pickles is a radiation oncologist at the British Columbia Cancer Agency in Vancouver.

The thing with this study was that they were making the best of a bad lot because there are very few good quality randomised controlled trials in prostate cancer.

Tom Pickles: Exactly, yes.

Norman Swan: And we should just describe brachytherapy.

Tom Pickles: There are two ways of doing brachytherapy: there's low-dose rate and

high-dose rate brachytherapy. Low dose-rate brachytherapy is done as a day case procedure, the patient is usually anaesthetised and through the skin of the perineum which is underneath the scrotum about 25 needles are inserted directly into the prostate gland so it doesn't go through the rectum like a biopsy. And that's good because it means the infection rate is very, very low. The radioactive seeds are preloaded in the needles.

Norman Swan: And high dose?

Tom Pickles: High dose is usually used for high-risk prostate cancer in combination with regular external beam radiation therapy and the difference is that the radioactive seeds are not left there permanently, they are higher activity and typically that treatment is given as one, two or three bouts of treatment.

Norman Swan: And of course the dilemma for men is that either they're not offered alternatives or when they're offered them it's really confusing to make up your mind about which treatment you might have.

Tom Pickles: This is an area of particular interest to me because it's always struck me as being very unreasonable for a patient who firstly is told that he's got cancer and then sometimes, even at the same visit or even in the same sentence, is offered a treatment and the surgeon is obviously wanting to put a good spin on it and sometimes the patient will sign up really without having duly considered his option. Not every patient who is diagnosed with prostate cancer by a long shot gets a consultation with an oncologist. It's taken a long time to get through to people.

Norman Swan: So when you did this assessment of these 848 treatment studies and then compared them, trying to control as much as possible, so the best possible evidence is compared, how does it all shape up?

Tom Pickles: Looking by risk group if we look at the low risk prostate cancers the results of brachytherapy show around about a 90% to 95% cure rate out to 9 or 10 years.

Norman Swan: When you say cure rate meaning the cancer hasn't returned within nine or ten years.

Tom Pickles: Yes, and actually if you're free of cancer after that sort of time period it's pretty unlikely that it's going to come back beyond that and we're using PSA as a measure of the success of the treatment. Now PSA screening is very controversial but PSA as a measure of outcomes is actually very sensitive.

Norman Swan: So how does that compare to radical prostatectomy?

Tom Pickles: Well the results across the board of these studies more like 80% to 85% so a good 10% to 15% less than is being achieved with the brachytherapy.

Norman Swan: And that's statistically significant?

Tom Pickles: Well they didn't do any statistics because of the design of the study but I'm sure it would be given the thousands of patients and that's a pretty big difference.

Norman Swan: So that's low risk -- and what about side effects, because radical prostatectomy has a risk of erectile dysfunction and incontinence, whereas brachytherapy can be quite irritable to the bladder and the bowel and you do get some erectile dysfunction. How do the side effects measure up?

Tom Pickles: Well you think on it, so exactly as you say, with surgery incontinence of urine is a much bigger problem than it is with brachytherapy. But on the other hand irritative urinary symptoms like 'I've really got to go right now', or 'when I pee it stings and burns', that's common with brachytherapy but there have been quite a few good quality studies looking at the quality of life of patients two or three years or so after brachytherapy, in fact a good one from Melbourne and they are pretty consistent across the studies. What they show is that the overall impact is slightly less with the brachytherapy, and that applies particularly with erectile function, which is more often preserved with brachytherapy and incontinence. And in addition comparing with external radiation there's less chance of there being any irritation of the rectum.

Norman Swan: Now very few men in Australia would be offered the big machine external beam radiation for low risk prostate cancer surely?

Tom Pickles: Certainly when I see a patient with low risk prostate cancer the typical conversation I have is between surgery and brachytherapy. There are occasional patients who are very elderly or who have some other medical condition which really tells me that they wouldn't be a good candidate for either surgery or brachytherapy but I'd agree with you, they tend to be the minority.

Norman Swan: So what about intermediate risks? So this is when your Gleason score, one of the scores in your prostate cancer that they assess you by is what 6, 7, 8 something like that.

Tom Pickles: It's particularly 7, if it was an 8 it would be defined as high risk so the intermediate risk is for a guy with a PSA between 10 and 20 and a Gleason score of 7 and not in an advanced stage clinically. And there we're seeing about 85% to 90% cure rates with the brachytherapy and around about 70% with the

surgery. So the difference between the two is slightly widening and we see that more with the high risk where the results of surgery fall off more than the results of the brachytherapy do.

Norman Swan: What are the figures for high risk? I mean some people say with high risk you wouldn't even bother doing surgery.

Tom Pickles: That's right it's actually quite controversial, the results are more like 40%. Now when we're talking about brachytherapy we usually use it in combination with either external beam radiation therapy or hormone therapy. So high risk cancer really needs a lot of treatment but with that combination therapy you're still getting 70% to 75% long term cure rates.

Norman Swan: Now there are other treatments around. People are freezing it, there's a new treatment around which is using MRI to guide a high frequency ultrasound probe to fry the tumour or the areas of tumour, there's high powered radiotherapy and there's also the robot which is gaining a lot of interest. Were there enough studies in those areas to make any judgement?

Tom Pickles: Not in this study, in fact there was only a couple of reports of robotic prostatectomy and there the results were just the same as regular prostatectomy.

Norman Swan: And HIFU, this high frequency ultrasound that's just coming in?

Tom Pickles: Well HIFU has been in place in Germany particularly and other parts of Europe for quite a few years. Just last year there was a good quality report published which showed the outcomes were quite disappointing. Around about 70% of patients had long term cancer control and that's much worse than was being achieved with either surgery or brachytherapy. And it wasn't free of side effects -- in fact some of the side effects were significantly worse than you'd get with surgery and others were comparable.

Norman Swan: Based on this evidence albeit it's not the strongest possible evidence that you could have in the absence of randomised trials, what are the questions that a man and his partner should be asking of their doctor presumably that doctor will be either a general practitioner or a surgeon that you're seeing having been diagnosed with prostate cancer?

Tom Pickles: Well I think the first thing is that a man should realise that this is not an urgent situation, prostate cancer typically grows relatively slowly and even the high risk prostate cancers you have the luxury of being able to take weeks, if not months to make an informed decision. So I think the family doctor's role is really to act as the man in the middle or the woman in the middle to help ensure that the patient gets full advice. And by that I mean as well as seeing a urologist maybe make sure that he sees the urologist who also does brachytherapy, because not all of them do, and an oncologist who has a different perspective whether it's to do with brachytherapy or the external radiation, the IMRT as you mentioned is some new incarnation of that. And most of my patients at the end of the day make a decision based upon the perceived side effects; quality of life tends to outweigh quantity. So I think like whether you're going to have surgery or brachytherapy you want to choose somebody who's good at what they do.

Norman Swan: And doing a lot of it.

Tom Pickles: And doing a lot of it. Generally people who do a lot of treatments have better results than less treatment and that's clearly been shown for surgery. I think it's also been shown to a lesser extent with the brachytherapy.

Norman Swan: Professor Tom Pickles is a radiation oncologist at the University of British Columbia in Vancouver.

Mark Mackay, our *Health Report* listener in Adelaide who, as I said, had had a radical prostatectomy in the end reckons men are short-changed when it comes to decision making.

Mark: I don't think the information presented to most people is necessarily helpful when they're under such stress. A, some of it is technical and B, there are so many options in it, the patient's option and I guess this was one of the reasons I contacted the *Health Report* last year when you had the show on prostate cancer. One of the experts was saying patients need to take more control of their disease, but I find that difficult because it implies a level of health literacy that I think is well beyond most people, particularly when you're under stress.

So reading a book isn't necessarily helpful, where do you turn to? And at the end of the day you've got to make a decision. Which one do I go for, and I really need to understand probability because there are all these therapies that are associated with probability and it's not easy. So I guess at the end of the day you have to be either guided by the clinician, or clinicians if you choose to seek a second opinion, and that I think is highly advisable. Reaching a decision is not an easy pathway and I think things could be made a lot easier.

One of the other things that does exist and that is on the web are decision aids, where you can enter your age, your PSA score, Gleason scores -- and it can give you a sort of indicator of outcomes. But I think there's a real problem with them that yes, I can put my numbers in if I know what they are but I don't know necessarily how to interpret the results or how reliable those results are. I think it's really important that people understand the difficulty for the patient in terms of having to choose a therapy and it's also a lot of the information is biased toward the older patient, and that's not helpful either.

Norman Swan: Mark Mackay was talking to Joel Werner.

This week a conference in Sydney celebrates the career and work of one of Australia's leading prostate cancer researchers who, with her colleagues, is close to a very different kind of treatment. Pam Russell is a professor at Queensland University of Technology's Australian Prostate Cancer Research Centre in Brisbane.

Pam Russell: For the last several years I've been working with people from CSIRO and we developed a gene therapy which we hope will be a gene medicine for late stage prostate cancer. An approach called gene directed enzyme pro drug therapy which is a little bit complicated.

Norman Swan: A mouthful.

Pam Russell: Yes but what it means is that we put a gene which expresses an enzyme which can break down a prodrug which is a non-toxic form of a drug into a toxic form which can then kill cancer cells locally.

Norman Swan: So in other words you swallow a drug which is like a sleeper, to use a spy analogy, and then you only wake it up when it gets to the cancer cell with this gene therapy?

Pam Russell: That's a good analogy. We use an enhancer and a promoter from genes that are only expressed in prostate cancer together with...

Norman Swan: These are like control mechanisms for how actively the gene turns out proteins, messages?

Pam Russell: Yes, that's right. DNA throughout the body is the same in every cell but the liver cells and the hair cells and you know the eye cells seem to do very different things and look very different. And the way that happens is that we have switches on those cells, which can turn them on and off. and that's the promoter. and we also have switches which can raise or lower the volume. and those are enhancers and other elements. So what we've done is to trap that bit of technology to put it in front of the gene which we want to turn on only in the prostate cancer cells -- well, only in prostate, actually, and not elsewhere in the body.

Norman Swan: And you give it an extra function which is to turn on the drug itself where it matters.

Pam Russell: That's exactly right, yes.

Norman Swan: So after the gene therapy which uses a virus to carry the gene into the person they inject a harmless chemical which is then activated where it's needed -- in the prostate itself. You might have noticed that Pam Russell emphasised the genetic manipulation is to the prostate itself -- not the cancer. That's because prostate cancer isn't just one disease and therefore it's hard to target genes in the tumour itself.

Pam Russell: We know that most prostate cancers are in fact multi-focal. There might be even five different prostate cancers within the one prostate.

Norman Swan: Really, so a man with prostate cancer just in the one man may have five different types of cancer?

Pam Russell: That's right; they've actually probably started from different cancer stem cells in each of those foci which are in the tumour.

Norman Swan: So how do you know what gene to target then if there isn't a cancer gene in prostate cancer?

Pam Russell: First of all we inject it into the prostate so it's not going somewhere else.

Norman Swan: Ah, so you just don't inject it in the arm and hope it gets to the prostate, you're actually right there?

Pam Russell: Yes. But in order to make it safe and only make it turn on in prostate cells we use these gene switches from genes that are only expressed in the prostate.

Norman Swan: So you're bathing the whole prostate gland and catching the cancers at the same time?

Pam Russell: That's right, and when the prodrug is bathing the prostate and getting turned into the toxic drug which can kill the cancer cells, when it turns into the drug -- because it's a very small drug that we've chosen -- it can easily transfer between different cells, so we don't have to get the gene into every cell in the prostate in order for it to work.

Norman Swan: How much testing has been done and where is this at?

Pam Russell: We've done a lot of testing actually, we've done testing in tissue culture and then we've used different animal models to test. And the first lot of testing we did was to use human prostate cancer cells that were injected into nude mice where they formed tumours. Then we treated those with one single dose of the

gene therapy and found that we were able to virtually ablate the tumours.

Norman Swan: You're destroying the whole prostate gland in the end aren't you?

Pam Russell: Yes we are, in the long term it would be nice just to destroy prostate cancer cells and not normal prostate cells. Not only did we test in nude mice but we tested in animals that are called transgenic which developed prostate cancer, they are mice. We've injected those with the gene therapy and shown that we can inhibit the prostate cancer with a single dose at a time when they've already started to develop prostate cancer and that also gives prolongation to their survival. And that local injection of the gene therapy is able to knock out metastases or lumps of tumour that grow in the lung. So the therapy has the added advantage that not only is it targeted and safe but we get this what's called a bystander effect where we get a local bystander effect which was the sort of amplification that I mentioned before through the drug being able to penetrate into the nearby cells and we get this distant bystander effect. So what we believe is that this localised therapy which is going to be given directly into the prostate will have an effect at least on micro clusters or clusters of tumour cells which are circulating in the body and perhaps growing somewhere else.

Norman Swan: So how near is this to the clinic?

Pam Russell: It's very near, all of the necessary pre-clinical testing has been done and it was to go to clinical trial in about 2008 and unfortunately about 2 days before the first patient was coming in to be treated the global financial crises hit. The therapy is owned by a company called Broadvector and everything has been approved and if they can get enough money it will still go ahead.

Norman Swan: Let's hope they can, Professor Pam Russell is at Queensland University of Technology's Australian Prostate Cancer Research Centre in Brisbane. All of the studies involved collaborators from the Prince of Wales Hospital in Sydney, the University of NSW and the CSIRO and the papers are on our website.

You've been listening to the *Health Report* with me Norman Swan and you can follow me on twitter at normanswan and don't forget our ABC News Radio broadcast at 11am on Saturday mornings.

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Guests

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Dr Stacey Loeb

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Professor Tom Pickles

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