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Norman Swan: Hello and welcome to the Health Report with me, Norman Swan. Today: Endometriosis, the bane of many women's lives with not enough known about what causes it and certainly not enough about treatments. But are women in Australia being denied a treatment that's available overseas, or is it marketing hype from the pharmaceutical industry?

A tool to help women who are suspected of having ovarian cancer to make the best decision about where to be investigated.

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And whether bowel cancer screening really does work to prevent what's called colorectal cancer. A large Australian study has just reported its findings, and one of the researchers was Professor Emily Banks, an epidemiologist at the Australian National University in Canberra. Thanks for coming on to the Health Report.

Emily Banks: You're welcome, Norman.

Norman Swan: What were you trying to answer here?

Emily Banks: Well, what we really wanted to do was to look at the real-world scenario for people going for colorectal cancer screening. We already know from randomised control trial evidence that colorectal cancer or bowel cancer screening is effective in reducing death rates from colorectal cancer, and we also have evidence that people diagnosed with colorectal cancer at screening have an earlier stage of disease than those diagnosed outside of screening. But what we wanted to see was what the real-world experience for consumers would be if they actually went through the bowel cancer screening test.

And what we found, by following 200,000 people participating in the Sax Institute's 45 and Up Study was that over a four-year period following having had a screening test there was around a halving or a 44% reduction in the risk of being diagnosed with a new cancer in those people who attended screening and had the all-clear, and those people who hadn't been for screening at all.

Norman Swan: Which is really good news. We should just explain this study. In fact we had it on the program I think last week as well, another study from it. This is where people aged 45 and over in New South Wales, a very large number of them, their health and well-being is being followed for many years.

Emily Banks: That's right. So we have over 250,000 people in New South Wales aged 45 and over who have filled in a questionnaire for the 45 and Up Study and given us permission to follow their health over time, and that's actually over 10% of the New South Wales population in that age group are in the study.

So what we did was we got from the questionnaire whether or not people had actually been through bowel cancer screening and we divided people into those who had and had not. And what we found was that those who said they had had around a 44% reduction in the risk of developing a new colorectal cancer in the four years following that baseline questionnaire.

Norman Swan: I could have said I had it and hadn't. How do you check that they are telling the truth?

Emily Banks: Well, we don't really know exactly, but what we know is that the vast majority of people who say they've been for some form of bowel cancer testing will have been for some form of bowel cancer testing. And those who say they have not will generally not have been. And what that imperfection will tend to do is actually dilute the estimates. So that 44% reduction in risk may actually be an underestimate.

We also adjusted for a number of things. So we know that people who attend screening are different from people who don't attend screening, for a number of different reasons. So we also adjusted for age, sex, body mass index, people's income, their education, whether they lived remotely or in an urban area, their family history of bowel cancer, whether they were using aspirin, whether they smoked, whether they had diabetes, whether they drank alcohol, and their physical activity, and some other dietary factors. So we ended up with a fairly robust comparison of people who reported they had and had not been for screening.

And another piece of information that tells us that probably these estimates are valid is that we found that the reduction in risk was greater for those bowel cancers lower in the bowel, so rectal cancers and cancer of the lower colon compared to cancers of the colon higher up. And that's also been shown before.

We did find that people who are living remotely were slightly less likely to ever have been screened, and previous studies from the 45 and Up Study have also shown that people from particular migrant backgrounds, particularly East Asian migrant backgrounds, are less likely to take up the offer of having bowel cancer screening.

Norman Swan: How much of a difference was there between whether or not you had the faecal occult blood screening, which is the national bowel screening campaign where you test whether or not there is blood in your poo, versus having had a colonoscopy?

Emily Banks: Well, we actually found that there was around a 50% reduction in risk with endoscopy, which is some form of tube being put in the bowel. We had around a 40% reduction for those reporting faecal occult blood testing, so it was actually quite similar between those two groups.

Norman Swan: Why should…particularly if you are having a colonoscopy, why should you find tumours on the left side, in other words on the lower part of the bowel near where it comes out, rather than where it begins on the right side of the bowel, why should the detection rate be higher for tumours on the left side of your bowel rather than on the right?

Emily Banks: So the faecal occult blood test actually by its name, it means it's detecting hidden blood in the faecal matter, and the lower down the bowel the tumour is, the more likely that the blood is less altered, and so it makes it easier for the test to pick it up. The other thing is that it's easier also to pick it up by putting a tube into the bowel the lower down in the bowel it is, the easier it is to reach. Having said that…

Norman Swan: But it's a pretty long black snake that goes right around to the proximal colon, so what's wrong with the people who are doing the test that they are not finding the so-called proximal tumours?

Emily Banks: Really most of what we are looking at here is cancers picked up by the faecal occult blood test, not so much by a colonoscopy. I think these are just properties of the test. I don't think it's about operator failure. The other thing is, having said that, we still saw a substantial reduction in risk for cancers of the proximal bowel, so high up in the bowel. So it's not saying that these screening tests are not effective for cancers high up in the bowel, it's just saying that they are actually even better when the cancer is further down the bowel.

Norman Swan: How long does the effect last of screening?

Emily Banks: Well, we followed people for an average of 3.8 years. We actually saw this reduction in risk over that time. We can't really comment beyond that time but it does look as if this reduction in risk is quite a long duration.

Norman Swan: Of course the bowel cancer screening randomised trials showed annual screening was needed for this, and the debate is really if you are having endoscopy how often do you need the endoscopy, but that's a conversation for another time.

Emily Banks: I agree.

Norman Swan: So what's the message for people? Have your screening?

Emily Banks: The message for people here is obviously people need to make an informed decision about whether or not they have bowel cancer screening. But this is a piece of good news, it's part of the puzzle which shows that if you do go for screening and you have the all-clear you can have an expectation that on average you will have around a halving in your risk of colorectal cancer over that subsequent period, and we see that that lasts for up to four years after screening.

Norman Swan: Emily Banks, thanks for joining us on the Health Report.

Emily Banks: Thank you.

Norman Swan: Professor Emily Banks is an epidemiologist at the Australian National University in Canberra.

And you're listening to the Health Report here on RN, with me, Norman Swan.

Ovarian cancer is still a much feared malignancy among women because although treatments have improved, as have survival rates, they could do a lot better.

There aren't any screening tests for ovarian cancer, like they have for bowel or breast which means when an ovarian tumour is suspected, there isn't time to be lost. A key goal is to get the right treatment first time, which is what a newly released study from Europe has tried to help with.

To comment, I spoke to Associate Professor Peter Grant, who's in the Department of Gynaecological Oncology at the Mercy Hospital here in Melbourne.

Peter Grant: They are trying to allow for the appropriate triage or direction of women to where they should have their care based when they are known to have an ovarian mass.

Norman Swan: So tell me the typical story that would **lead** to the dilemma that this is trying to help.

Peter Grant: I guess the typical story we encounter is a phone call from rural Victoria, a woman who has had an ultrasound that shows an ovarian mass, should she have her operation at a centre where she lives, 200 kilometres from Melbourne, or should she be sent to a gynaecological cancer service? And I'**m** sure this happens all around the country.

Norman Swan: And why would she have had the ultrasound in the first instance?

Peter Grant: She probably presented with some symptoms—discomfort, pain—or someone may have found a mass on other investigations, scans done for other reasons, or even just routine examination had identified a lump.

Norman Swan: And it's usually not just an ultrasound through the abdomen, it's often through the vagina that you do this.

Peter Grant: Yes. The vaginal ultrasounds give much, much better definition of pelvic masses than a trans-abdominal ultrasound.

Norman Swan: And of course the problem here is if a doctor or a GP or even a general gynaecologist thinks that a woman might have ovarian cancer, it's not like breast cancer or even colon cancer where it's easy to biopsy, find out what it is and then decide the definitive treatment, you've actually got to do the full operation to find out what's going on.

Peter Grant: Yes, there are some situations where ovarian cancers are advanced cancers where you can get a diagnosis before surgery by taking a sample of fluid or an obvious area where this cancer has spread. But in many situations where this paper looks at, we are looking at women with an isolated mass in the pelvis, nothing else to find clinically, and you don't know is it a cancer or not. And until it's actually removed, you won't know.

Norman Swan: And the question is once you get in and find if it is cancer, you really want somebody who's doing this kind of cancer surgery all the time to do the definitive operation.

Peter Grant: In general that's true. It appears as though women with ovarian cancer or who are found to have an ovarian cancer, as a group do better, have better outcomes if they are managed in a centre that deals with gynaecologic cancer.

Norman Swan: Because you do a more definitive operation?

Peter Grant: Yes, well, if this is an advanced cancer we are more likely to achieve surgical outcomes that **lead** to a better prognosis in that we are able in general to remove the vast bulk of tumour. If it's an early cancer the most critical thing we need to do is find out is there evidence of spread of this cancer to anywhere else, and that involves surgery that isn't done except by people who are trained in this area.

Norman Swan: Okay, so what are the criteria that they suggest in this paper you take into account to decide whether or not you get your operation done by a general gynaecologist in a country town versus coming in to, say, Melbourne, or in the case of other states major metropolitan areas where there are gynaecological cancer experts?

Peter Grant: They've looked at some patient related characteristics, in particular age of the patient, and the result of a blood test, the CA125 which is a tumour marker. And then they've looked at particular

characteristics of the mass as identified by the ultrasound, and they've got a series of criteria that they can evaluate and assign a score to. And when you put these all together in an algorithm you come up with a risk of malignancy index for that particular woman.

Norman Swan: How reliable is that index?

Peter Grant: The data that this paper has presented said it's very reliable at separating benign from malignant. They've looked at various other categories of malignant tumours that are very early, so-called stage one versus advanced stage cancers, and also looked at cancers that may have occurred in the ovary but got there from somewhere else. But it seems to be a good discriminator of benign from malignant.

Norman Swan: It doesn't avoid the need for an operation but it might avoid the need for a trip to town.

Peter Grant: It does, it's a means of trying to tell this woman, look, your risk of malignancy score on this ultrasound and your blood test and probably other discriminators that aren't included in this, such as a physical examination, say, look…

Norman Swan: That's a bit radical, isn't it?

Peter Grant: It is rather, but it's still an important part of triaging these women and that's not addressed in this paper at all, but it may allow this woman to have her surgery done in a country town rather than come to Melbourne.

Norman Swan: It's not the only risk score around. Do you think it's going to be adopted by gynaecologists?

Peter Grant: There are other risk scores. I think this suggests that maybe it has a better performance in selecting patients that are truly benign from patients who may warrant referral. But one of the things that is really unclear in this is who does the ultrasound and how good are they at doing this ultrasound, interpreting what they are finding?

Norman Swan: So the assumption there being that maybe if it's a small country town the local radiologist doesn't do many of them each year and may or may not be as good as he or she might be.

Peter Grant: That's right. It seems to be the case that volume and experience is really important in performing good ultrasounds, and this paper really doesn't address that. It's done in lots of different centres, 24 centres, but each of those centres the ultrasound was done by people who seem to have experience. It was done in a hospital unit or it was done by a dedicated gynaecology ultrasound unit or a cancer service, but there's no mention of how does this perform in a community-based radiology setting.

Norman Swan: So for a woman having a discussion with her GP, who she gets referred to for her ultrasound is a critical part of the story.

Peter Grant: It really is important I think, but it's not answered in this paper.

Norman Swan: Now, there's this problem with ovarian cancer where it really is…to diagnose it you've actually got to remove the ovaries, so you got to do the definitive operation. It's a very significant step, unlike most other cancers. And people are going around touting blood tests, so there's the CA125, there are other blood tests around, saying they can, just by doing this blood test, tell whether or not you are at risk of having ovarian cancer. What's the state-of-the-art at the moment in terms of all these people trying to get a bit of space in the marketplace to sell their blood tests for ovarian cancer?

Peter Grant: At the moment it is clear we have no screening test for asymptomatic women in the early detection of ovarian cancer. So there is no routine screen that I can tell a woman, 'Go and have this test, it will tell us if you've got an early cancer of the ovary,' whether it's a blood test, whether it's an ultrasound or any other imaging. In someone who presents with symptoms or clinical findings that raise the possibility of cancer, then these tests may be appropriate, but just sending women off for them to be done as a routine has no benefit.

Norman Swan: And just remind us of the symptoms that are indicative that you might need to look for an ovarian tumour.

Peter Grant: The common symptoms are unexplained abdominal or pelvic discomfort, persistent bloating, pain, feeling a lump, changes in bowel function, and particularly…

Norman Swan: Which are new.

Peter Grant: Yes, which are new and persistent, and particularly if you are seen with these symptoms and they are thought to be not important but they still are there, you need to look again and exclude an ovarian mass as a cause.

Norman Swan: And if you are a woman with a strong family history, you may or may not have the genes like the BRCA1 or 2 genes which increase the risk of ovarian cancer, but you've got a strong family history, your mother got ovarian cancer at the age of 50 or something like that, really you cannot rely on any test, the answer is if you are really worried at some point after you've had your children you've really got to have your ovaries out.

Peter Grant: I think before that step you actually should be seen by someone who has some knowledge and expertise in familial cancer to try and sort out what is the true risk. Seeing a genetic person or a gynaecological cancer unit with interest and expertise in this area can actually direct you as to the appropriate course of treatment.

Norman Swan: Are you finding women are having unnecessary oophorectomies, removal of their ovaries?

Peter Grant: I am, yes. You do see that happening. And it may not be unnecessary in the…how can I say, eyes of the woman if she is very worried, but you need to make sure they've got the appropriate information to make those decisions. And just having one family member with an ovarian cancer is often not enough to say, hey look, you should be having your ovaries removed at age 46 or 44 or whatever. I think getting the right advice from people who know what they are talking about can actually sometimes avoid women having an unnecessary procedure.

Norman Swan: And for women or even general practitioners who are listening, is there a place they can go to see a directory of gynaecological cancer services in Australia?

Peter Grant: Yes, there are. If you go to Cancer Australia website there will be a list of all the gynaecologic cancer services in Victoria. There's a website of the Australian gynaecologic cancer…ASGO, Australian Society of Gynaecologic Oncology, lists all the websites. Each state-based cancer service will have a list of specialised centres dealing in this, yes.

Norman Swan: Peter, thank you.

Peter Grant: Thank you.

Norman Swan: Associate Professor Peter Grant, who's in the Department of Gynaecological Oncology at the Mercy Hospital in Melbourne.

We're staying with gynaecology now but to a benign condition, although women who suffer from endometriosis would not say it feels very benign. 74,000 people are clamouring for an endometriosis treatment that the drug **company** doesn't want to sell in Australia, despite having approval to do so.

Katie Silver has the story.

Syl Freedman: At times I can feel like my ovaries are being minced. It can also feel like someone's just got a really strong grip on your insides and they are kind of giving you a **Chinese** burn. You feel as if you kind of have to like claw at the wall to try and get away from the pain.

Katie Silver: 23-year-old Syl Freedman suffers from severe endometriosis, a condition which affects more Australians than asthma or diabetes. It causes fibrous scar tissue to form on the uterus, ovaries, fallopian tubes or bowel. Chronic and incurable, it can result in excruciatingly painful periods and infertility.

Her mother Lesley finds it difficult to watch.

Lesley Freedman: As a parent, watching your child or your daughter suffering, that is just excruciating. The normal over-the-counter pain relief doesn't even touch it.

Katie Silver: The reason it's called endometriosis is that it comes from the word 'endometrium', which is the lining of the uterus. And what happens in the condition is cells from the uterus spread to other parts of the body.

Luk Rombauts is a professor of gynaecology at Monash University and board member of the World Endometriosis Society

Luk Rombauts: Why is it so painful? Because each time that a woman goes through a period, those lesions, those little blisters will also start bleeding, just like the lining inside the uterus does, and it causes local inflammation and pain and that leads to scarring and that can eventually **lead** to infertility.

Katie Silver: What causes it?

Luk Rombauts: That's a very good question. We know that in about 90% of the women, when they have their period, that some of the menstrual blood flows back through the tubes inside the pelvis. So we believe

that in women that eventually develop endometriosis there's something wrong with their immune system, that's at least a current belief that we have and there is further research in that area that will hopefully try and prove that. The white blood cells seem to be unable to clean up those endometrial cells that end up in the pelvis behind the uterus.

Katie Silver: He says other than taking a pill to skip her period, a woman with endometriosis has few options.

Luk Rombauts: Surgery remains the key intervention to start off treatment with, in most women.

Katie Silver: The surgery is called laparoscopy. It's invasive keyhole surgery to remove the lesions on the ovaries. For most people with endometriosis, it's the only way to be diagnosed. And then it's the only real treatment option.

Luk Rombauts says it doesn't even really do the job.

Luk Rombauts: Even though you may feel as a surgeon that you've done a very good job in removing all the visible disease, firstly there are probably already microscopic other lesions present that you will most likely miss. Secondly there is probably a 50% recurrence rate over five years.

Katie Silver: Syl Freedman has undergone two such surgeries in the last 20 months.

Syl Freedman: Well, the first surgery I had in 2012 I was told it was just supposed to be a half-hour day surgery and that recovery wouldn't be that bad. The surgery itself took about three hours, and I was told that I had stage four endo, which is the most severe, it's widespread throughout the body. And the recovery took months. And then not long later I found that my symptoms were starting to come back. So I went back to my surgeon and he thought it was probably a good idea to have a second laparoscopy, and that was less than 18 months later. The recovery was not as long, but really, really traumatic.

Katie Silver: Apart from surgery, the only other treatment is the oral contraceptive pill, and the reason that can work is that it inhibits menstruation and so inhibits the tissue from endometriosis bleeding as well. But it doesn't actually work that well, and Lesley found that in her research too.

Lesley Freedman: One of the things that kept coming up was this drug called Dienogest and it seemed to have a really good track record overseas, and I guess I was just interested. If there's something there that has been designed just for endo and all we have is the OC pill, and Syl certainly wasn't getting much joy out of those, she kept having to change brands, I thought I'll just ring and find out why we haven't got it.

Katie Silver: The drug is marketed as Visanne and it's made by Bayer Healthcare Pharmaceuticals. Dr Jan Toomey is the **company**'s medical director.

Jan Toomey: Visanne is a progestogen, which means it's a form of progesterone which is the natural hormone secreted by the body which promotes the appropriate environment for pregnancy. It works principally by lowering the natural production of oestrogen in the body. We know that endometriosis is an oestrogen driven disease, and so if you can keep the body's levels of oestrogen relatively low, then that tends to inhibit endometriosis.

Katie Silver: Luk Rombauts from Monash University agrees it's a valuable drug for treating the condition.

Luk Rombauts: Visanne is another important instrument in the medical armamentarium that gynaecologists have overseas. It's certainly something that has proven in good randomised controlled trials to be a useful drug.

Katie Silver: But while women in most parts of the world can use it, those in Australia can't. This is despite it being approved in 2010 by the Therapeutic Goods Administration for **sale** and marketing here.

Syl Freedman: It just didn't make any sense and was just infuriating really.

Lesley Freedman: I rang Bayer and they had one of those awful switchboards that you would go round and round in circles, you know, put you on to this number, put you on to…nobody answered the phone for ages, about five weeks, by which time I was really furious.

Katie Silver: What reason did Bayer give you for not releasing the drug in Australia?

Lesley Freedman: They said that they didn't think there'd be much demand for it. We're too far away, there's too few of us, and New Zealand is in an even worse situation than that. And I thought, well, what if I got a few signatures on a few emails. So I was sending emails out to my friends, and Syl came past and said, 'What are you doing that for? I've got 900 friends on Facebook, they'll sign a petition for me.' And so we moved it on to Change.org, and it was just phenomenal. I mean, obviously it had a little bit of publicity,

but even so, the majority of people who signed the petition were people who suffered from endo or their family.

Katie Silver: Lesley and Syl Freedman's campaign saw their petition reach 73,000 signatures in only a couple of weeks. Once they reached 74,500 signatures, Bayer phoned to say they would release the drug in February.

Jan Toomey from Bayer says the drug was released sooner because GPs had indicated they wouldn't prescribe it without seeing the results of long-term clinical trials.

Jan Toomey: When we initially registered it in 2010 and we looked then at how treaters would use it, and so we talked to a lot of potential prescribers, and at that time the message we got from them was that they weren't terribly interested in it as a product. There was only fairly short-term data back in 2010, and they said if we are going to use it at all, longer term it's not something we'd give for a short term. And so the impression we got very strongly was that there wasn't really any particular interest in prescribers for it at the time. And the trigger that initially started us looking again was that at this year's European Society of Contraception there was a symposium on Visanne, and some of the newer data was presented there, and we came away thinking this is actually worth another look now. Very soon after that I met with the Freedmans for the first time.

Katie Silver: Has the petition by the Freedmans had any impact on the decision by Bayer to start to sell Visanne in the Australian market?

Jan Toomey: I think what it did was to expedite the decision-making process. So we went back and consulted physicians again, which we were always going to do. We got a different message. Certainly the Freedmans' petition was excellent in giving us impetus to move ahead quickly with this.

Katie Silver: Jan Toomey says the **company** was justified in choosing not to bring the drug to Australia.

Jan Toomey: We need to make decisions based on whether there appears to be a market for a product.

Katie Silver: There is an unfortunate history of consumer campaigns being covertly driven and funded by the drug companies in order to get the drug to market and push the hand of government. The question is, is this the case for the Freedmans, and are they connected to Bayer?

Lesley Freedman: Gee, I wish I was! I wouldn't be scratching around for money to pay for pamphlets and badges to raise awareness, that's for sure. No, of course not.

Katie Silver: Luk Rombauts from Monash University says Bayer has an obligation to bring the drug to the Australian market.

Luk Rombauts: It is a sad state of affairs that the patients have to bring about a public awareness campaign, put a **company** under pressure to actually bring a very useful drug I think…I mean, it's not the be all or end all, but it's certainly one other important tool for gynaecologists to treat endometriosis, and it's important to know that there's only three approved drugs so far in Australia for the treatment of endometriosis. So it's not like we've got a wealth of different medical treatments that we can rely on.

Katie Silver: Bayer says they are considering applying for Visanne to be on the Pharmaceutical Benefits Scheme, but when it's first released it should be about $80 a month. Either way, the Freedmans say they are happy the drug will soon arrive on our shores.

Syl Freedman: By trying Visanne I would be hoping that it would prolong the need for surgeries and reduce my symptoms inbetween.

Lesley Freedman: The girls are so desperate, and women, with endo, that they are praying that there'll be a cure, that this might be it. It is not a cure, it's a treatment.

Norman Swan: And that special report on endometriosis came from Katie Silver.

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