

Welcome to Digital Health Unplugged. I'm Tammy Lovell, Editor at Digital Health and I'm joined today by Valentina Milanova, Founder and CEO of Women's Health Startup Daye, which won the Rewired Pitchfest competition this year.

Welcome to the podcast Valentina, how are you today?

Hi Tammy, great to be here, thank you for having me.

Welcome and so what was it like for you to win Pitchfest this year?

It was super exciting for us to win Pitchfest because women's health rarely gets recognition, it's still a very stigmatized topic, particularly in the United Kingdom.

So anytime we have an opportunity to share more about cervical cancer or period and pelvic pain, and the different conditions women struggle with, I always really treasure these opportunities.

Yeah, I was really excited to see like a FemTech company win as well and you said it's particularly stigmatized in the UK. Why do you think that is?

Well, I'm not from the UK so there's a limited perspective I can share but from what I've seen as an outsider, we do struggle with a bit of a stiff upper lip problem and particularly when it comes to gynaecological health conditions, we're very shy about sharing our experiences and then it's somewhat unusual the way in which women's health is delivered in the UK.

In most countries in Europe, in the United States, there's an OBGYN model where an obstetrics and gynaecology specialist is your women's health doctor but, in the UK, it's your GP who looks after your contraception, your hormonal replacement therapy, your pap smear, your cervical cancer test and I have a lot of respect for GPs but they are general practitioners.

They have to keep up to date with a variety of different clinical developments across a variety of different diseases.

So as a result of this model, which is GP first delivery of women's health care, I think we've further emphasised and further worsened patients' ability to advocate for themselves, feel heard and really understand their own physiology.

Yeah, I think that's so true because it's very hit and miss because if you go to the GP, you might get someone who's really interested in women's health and has studied, you know, got an interest in that or you might get somebody who just isn't as knowledgeable on those topics.

So, you know, it can be very kind of potluck who you get really because they don't necessarily have that specialist knowledge.

And it's very challenging when you only have eight minutes to talk about complex gynaecological health conditions for which there's already a data gap, right?

We didn't allow women to take part in clinical trials up until 1993, so we understand very little about how to treat and how to diagnose the female physiology, not just in gynaecological health, in general health conditions as well.

So women are diagnosed later than men, significantly later than men in across 700 different diseases, including heart attacks.

So research from the British Heart Association demonstrated that 50% of women who show up in an emergency room with an active heart attack get turned away because doctors are only really trained to recognise the heart attack symptoms that show up in the male physiology, not in the female physiology.

Gosh, that's really scary. And I'm just really shocked by what you just said, that women couldn't take part in clinical trials until 1993. I didn't know that. What was the reason for that?

This patriarchal view of women as the best source of life, which had to be protected from everything, including clinical research.

So it was assumed that a female patient could be pregnant at any point in time, even if they first had a negative pregnancy test, which is why women were excluded from clinical trials.

And then separately, medical misogyny, which shows up not just in human clinical trials, but in animal clinical studies as well.

So because of our menstrual cycle, researchers consider women harder subjects to study compared to men, which is why we're still to this day excluded from clinical trials.

And this bias starts at the animal study level before a new compound or a new medical device can even make its way into a human clinical trial. It's often tested on animals such as rats or rabbits or sheep.

And in those studies, researchers often prefer to use male mice over female mice. So the gender bias and the gender gap starts really early in medical research.

1993, that's so recent. I'm just really shocked to hear that. So obviously, you're really passionate about women's health. Can you tell me a bit about your journey to being a founder in this space?

Well, I'm part of the generation of women who suffered from a number of different gynaecological health conditions and never really felt like we have tangible answers to them. I'm hoping that this will not be the case for future generations.

And I genuinely believe that solving for women's health is the single most important challenge we have within our lifetime.

Before we turn to space exploration and flying cars and artificial intelligence, we really have to figure out some of our issues closer down to earth.

And we can't have healthy societies or healthy economies if we have unhealthy women. And this is very much the case in the UK.

You may have seen this week, the statistics came out on healthy life years and healthy life expectancy.

They have declined across the UK population, but particularly for women in the UK, there's stronger decline in the healthy life expectancy and particularly for underserved and economically disadvantaged women in the UK.

So I feel very, very strongly that this is the central challenge we have to focus on within our lifetime.

What do you think is driving that decline in life expectancy and in health?

There's an overwhelming lack of funding for women's health. There's a lack of research funding. There's a lack of private investments. There's a lack of government funding.

Even though we've seen the new women's health strategy, the amounts that are being invested in women's health are pitiful. They are disproportionate compared to the size of the challenge, how far behind we are in women's health.

And they're disproportionate compared to the size of the population. A lot of the women's health funding in the UK is also not ring-fenced, NHS women's health funding that is.

So even though we have women's health hubs now, and this is great, it's amazing that we have them and we should keep investing in them, but we also need to recognise that they are overwhelmingly underfunded and they don't have access to ring-fenced funding.

What kind of thing would you like to see be funded more?

Very simple things that women need in order to be actively participating in our societies and economies. So first, we can't keep pretending that period pain is normal and something that we should keep gritting our teeth through.

We need to recognise that period pain has an impact on not just one's quality of life, but one's ability to live life to the fullest.

And there's plenty of data to this. The British Medical Journal in 2012 published a study which demonstrated that the average female in the UK loses 12 productive days each year due to unmanaged period and pelvic pain.

So we need solutions, we need recognition for the societal and economic burden, as well as the individual burden of period and pelvic pain. We also need to invest more in gynaecological cancers.

Too few women in the UK are aware of what the symptoms of gynaecological cancers are, and for those who are aware and are noticing the symptoms, we have to recognise that they exist within a system that has trained these patients to ignore the symptoms of gynaecological cancers, because the symptoms of gynaecological cancers like ovarian, cervical, endometrial cancer are similar to the symptoms of PMS, premenstrual syndrome.

So bloating, heaviness, breakthrough bleeds, these are all symptoms that we have been trained to ignore.

We have been told they're normal, they're nothing to worry about, they're part and parcel of being a woman.

And lastly, within the category of gynaecological cancers, there's a real bright spot in women's health, and that's cervical cancer. We have the tools to eradicate cervical cancer within our lifetime. This isn't a pipe dream.

We have the science, we have the tools available to us, but what we're lacking is a redesign of the system that really fits the needs and expectations of the patient.

And it is scientifically possible for us to eradicate cervical cancer within our lifetime, and this is very important because cervical cancer on a global level is the second deadliest female cancer.

And in the UK, we're seeing a disengagement with cervical cancer screening programmes, which is a huge shame. It's a preventable cancer, which even if it doesn't take a patient's life, it greatly affects their quality of life.

If you develop cervical cancer, even if it's early stage, parts of your cervix may need to be removed, which affects your fertility, it affects your sexual life, it affects your ability to carry a pregnancy to term.

So cervical cancer and its eradication are something that we should really get behind because it's a low-hanging fruit. We have the tools, we need to eradicate cervical cancer.

So from that, I'm just going to move on to your product, which is the diagnostic tampon, which can detect HPV, one of the causes of cervical cancer.

So can you tell me a bit more about that product? Yes, so HPV is the main cause of cervical cancer.

Over 99% of cervical cancers are caused by HPV. HPV stands for human papilloma virus.

It is a sexually transmitted infection, which affects the way in which cervical cells grow and develop. And HPV is preventable through vaccination. We have excellent vaccines available to us.

However, not everyone has been vaccinated. And even for the patients who are vaccinated, they're only vaccinated against a maximum of nine high-risk HPV strains.

Now, we know that there are 14 which are associated with cervical cancer, and there's other ones which are currently being investigated for their relationship with cervical cancer.

So having an HPV vaccine and having an HPV test are the two most important tools we have in the fight against cervical cancer.

So what we've done today is we've designed a new, friendly, accessible way for patients to collect a sample for HPV at home using a tampon, which is a familiar device.

90% of women in the UK use tampons either regularly or have used a tampon in the past. No one needs to be trained on how to use a tampon.

We're perfectly capable of figuring it out. And being able to collect a sample that's highly reliable at home and test for HPV from your couch, from your sofa, produces a lot of benefits for the patient in terms of comfort, in terms of cultural sensitivities, but it also enables the patient to not have to take up resources from what is a very strained national health service.

So it enables the patient to have a more comfortable experience while also saving the time of a nurse or a doctor who would have otherwise had to take the sample.

Is the diagnostic tampon a replacement for a smear test?

So the way in which our cervical cancer programme is structured at the moment is a patient goes and has a pap smear. They go to their NHS clinic and they have a pap smear.

The pap smear is an exam whereby the cervix is aggravated and cells are collected from the cervix and then analysed for HPV first for the presence of the virus.

And then only if the virus is found are those cells later analysed for abnormal cervical cell growth. So we already do HPV screening within the NHS.

What we're proposing is to have the patient look after the first part of the cervical cancer prevention journey to understand whether they have HPV or not by themselves at home.

And then only the patients with a high-risk HPV strain should be referred for the more invasive, more time-consuming, more costly pap smear or cytology exam.

And this is in line with international guidelines by the World Health Organization. It's endorsed by a variety of international bodies for cervical cancer prevention.

And unfortunately, even though it was UK researchers who worked on the discovery between HPV and cervical cancer and who worked on the HPV vaccine, the UK is falling behind in terms of implementing an HPV self-sampling programme.

We're currently behind Slovakia, Poland, New Zealand, Australia, the United States, countries in the Nordics.

So I feel very strongly about this innovation because it saves the NHS time and money, which it desperately needs right now, and it creates a much more patient-friendly experience.

So this could actually reduce the amount of women that need to go for a smear test by replacing it with being able to do this at home.

And obviously, going for your smear test is very important, but it's not a pleasant experience and it hurts. So this is a way you could do something at home yourself. What gave you the idea of having a tampon that you could use at home? Where did you get that idea from?

Well, I came across research. There's actually research dating back to the 1980s from the University of Westminster where tampons were used to collect samples for HPV and STI screening.

There's other research from the 1990s where tampons were again used for the same purpose. And I was very perplexed as to why this research had never made its way to conventional medical practice.

And they, as a company, was already manufacturing tampons because we started as a menstrual health product manufacturer.

So we decided to run our clinical investigations and we were able to identify that, yes, tampons in fact collect a similar quality sample to a clinician-collected swab, in some cases outperforming the clinician-collected swab.

So because tampons stay in the vaginal canal, they cover the full vaginal canal, they reach the cervix with the help of an applicator, they're a very reliable tool for collecting samples from the vagina.

You mentioned before about the women's health strategy. What's your views on the strategy that was recently released by the government?

Well, first I want to say that we are incredibly lucky to have Dame Lesley Reagan and Dr Sue Mann leading the way on women's health innovation in the UK. They're incredible advocates and incredibly effective in what they do.

I personally feel endlessly inspired by their work, but they're up against a challenging system which doesn't yet fully recognize the NHS costs of poor women's health outcomes, the economic and societal costs of poor women's health outcomes.

So the women's health strategy is an excellent way forward.

I still think it's insufficient given the breadth and scope and size of the challenge that we have ahead of us, and also given the size of the opportunity of having healthy women in the UK.

We have a huge demographic crisis in the UK, and women now graduate from universities with bachelor's and master's degrees more than men do.

Up to the point of our first child, we are also compensated at a higher rate than men professionally.

We are an economic powerhouse which is currently stuck at home with a hot water bottle because of our unmanaged period pain, or we're forced to drop out at the peak of our professional development because of unmanaged menopause or perimenopause symptoms.

So I really wish that the government would appreciate not just the challenge associated with women's health, but also the huge economic opportunities.

And again, there are so many low hanging fruits like enabling HPV self-sampling which would save the NHS costs and would make the experience much, much better for the patient.

Response to the diagnostic tampons, have they been popular with women?

Yeah, we're very happy to have served over 12,000 patients so far with the diagnostic tampon, and we're part of the NHS Innovation Accelerator for the next three years. We started working with the National Health Service.

This is innovation which benefited from public funding. We benefited from Innovate UK and Biomedical Catalyst funding.

And while it is incredibly frustrating for me when I hear from NHS stakeholders, oh, why don't you just go after the US market?

You know, you'll be so successful there. Don't waste your time. The NHS is slow, the NHS is complicated. Just go to the US and make a killing, effectively.

I feel very individually responsible for producing a return on investment for the public funds that we have received to develop this innovation in the UK. A return on investment, not just globally.

Yes, I do greatly care about global health, but I also very much care about the health of women in this country.

It's not just the diagnostic tampons you offer either. I saw that you've got lots of other sort of products and services on your website. Some of the things I saw in there, so I saw you had like CBD tampons as well. And then I saw you had like a scented candle called Your Vagina Smells Fine. What are some of the thinking behind these products?

Yeah, there is a women's health innovator. We believe that women's health should be comprehensive.

In order for women's health to be done right, you need the patient to understand and manage their vaginal, menstrual and hormonal health together.

This is why we have such a comprehensive product portfolio that stems our period and pelvic pain clinic, which speeds up the time to diagnosis for endometriosis and PCOS, which currently takes seven to 12 years to diagnose in the UK.

We have hormonal health testing, which enables the patient to understand their reproductive health, their thyroid health. Hashimoto's, which affects more women than diabetes in the UK, again, takes 10 years on average to diagnose.

And as I mentioned in the beginning, we started as a menstrual health product manufacturer.

We started manufacturing tampons and pads because I realized that tampons and pads are incredibly monopolized in the way in which they're manufactured, and the quality standards are not as high as they should be for a product that's used vaginally or used near the vulva.

So we're very proud to be the only global tampon manufacturer that manufactures two medical device standards.

We're producing clean rooms. We have gamma irradiation of our products in their final packaging.

We run continuous lab tests to confirm that our tampons and pads don't contain ferver chemicals or toxic heavy metals.

With CBD, is there evidence to support that this can help with period pain?

Yes, we have published RCTs, randomized controlled clinical trials, in journals, including the Journal of Endometriosis and Uterine Disorders.

And again, we're very happy to have supported over 100,000 patients in the UK with this product.

Yeah, that's interesting. So it's something I hadn't heard about before. And I know you're also a sustainable company. So do you want to talk me through a bit about what you're doing there?

Yeah, we wanted to introduce sustainability into our work from the very beginning because it's very hard to retroactively become a sustainable company.

And I don't think that gynaecological health innovation should cost the earth. So we invested heavily in material science innovation, which enabled us to utilize novel fibres and novel materials within our tampons and pads, whether that be the diagnostic tampon or the menstrual health tampon.

So, we use organic materials such as industrial hem fibres, organic cotton fibres, bamboo fibres, which reduce the reliance on petroleum-derived plastics, which are currently used in 90% of the period care products out there.

Just as you wouldn't chew on a piece of plastic for five days each month, right? Nobody would do that.

Why do we think it's acceptable to have a piece of plastic pressing against the vaginal mucosa, which is one of the most absorbent mucosa's in the human body.

And we also designed our packaging for our products so that it is all compostable or recyclable, made with organic dyes.

Again, so that we don't contribute to plastic waste, plastic pollution, and we instead contribute to the health of humans and the health of the planet.

And you also have a period and pelvic pain clinic, don't you? So what led you to offer that service? And what's the difference between what you're offering there and what women could get maybe through the NHS?

Well, at the moment, period and pelvic pain is very underserved on the NHS, unfortunately. As I mentioned previously, most patients have to wait 7-12 years before they receive a diagnosis for the root cause of their period and pelvic pain.

And we don't really have reliable ways to diagnose conditions like endometriosis, for example. We mostly rely on laparoscopic surgery, which is quite invasive.

And in some patient cases, it can result in the patient having more pain than they did before the surgery.

So the latest clinical guidelines are actually focused on diagnosing the patient and starting to treat them on the basis of their symptoms, not on the basis of laparoscopic surgery, which, as I mentioned, is costly, expensive, time-consuming, and could have worsening outcomes.

So the period and pelvic pain clinic utilizes the latest clinical protocols, the latest clinical guidelines from a body of international research in order to map the patient's symptoms to a root cause of their period and pelvic pain and to immediately build them a personalized period and pelvic pain management plan, which is customized to what stage they are in of their menstrual cycle, to their medical history, to their lifestyle, to their preferences.

We use a combination of pharmaceutical and holistic lifestyle interventions in order to really arm the patient with a very rich arsenal of tools which they can deploy to manage their period and pelvic pain.

Another thing that you're involved in as well is medical research. So what kind of research are you doing and what's your goal there?

We're very focused at the moment on identifying novel biomarkers for other invasive and hard-to-diagnose and hard-to-treat gynaecological cancers such as ovarian and endometrial cancer.

So we're very proud to be working with Hampton University on a clinical trial called the VIOLET study, where we're utilizing the diagnostic tampon to identify new biomarkers so as to speed up the time to diagnosis for ovarian cancers, which at the moment in the UK tend

to get diagnosed at stage three or stage four, which is too late in some cases for the patient to have a successful treatment and intervention.

You mentioned earlier about menopause as well. Are you looking at any products around that or any services around that in the future?

There's other innovators which are active in the menopause space who specialize in this. Dr Louise Newsome, for example, is really leading the way in menopause care, in holistic menopause care.

We tend to focus on innovating in areas that there aren't existing good solutions in. So menopause at the moment is not the focus for us, but we do refer our patients to Dr Louise Newsome.

What are you looking at for the future and what's next for Daye?

We're hoping that we can continue our partnership with the National Health Service and continue improving cost-effectiveness, continue improving improvements in quality of life, and we hope that the UK can be the first country to eradicate cervical cancer, again, within our lifetime and preferably sooner rather than later.

Amanda Pritchard committed to eradicating cervical cancer by 2040. This is doable. We're falling behind at the moment in terms of HPV screening, HPV vaccination, cervical cancer screening uptake, so the time for action is now.

It's been really interesting speaking to you, Valentina, and you're obviously so passionate about this topic.

Thank you so much for joining us today and I really wish you all the best for the future. Stay in touch and we'd love to keep up with what you're doing.

Thank you, Tammy. I really appreciate all of these thoughtful questions.

And thank you everybody for listening today and see you next time.

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