# Cervical screening update

**Prof Deborah Bateson:** Welcome everyone. Welcome to this evening's webinar on Australia's National Cervical Screening Program. My name is Deborah Bateson. Oh, I have to remember the 'professor' bit, actually. I'm Professor Deborah Bateson and I'll be your host for this evening. So first, of course, I'd like to provide an Acknowledgement of Country. I'd like to acknowledge the traditional owners of the lands from where each of us are joining this webinar today. And I wish to pay my respects to their Elders past, present and emerging. And in fact, I'm on the land of the Gadigal people of the Eora nation.

So just a bit of housekeeping to start, with just around, 'Where is my control panel?' So basically just to run through a bit of housekeeping notes, the webinar's being recorded and it'll be made available for you in the coming week. Just to remind us all that we've all done a lot of these now, but your settings for this webinar are in the black control panel at the bottom of your screen. And if you can't see the panel, like the image on the slide, just hover your cursor over the bottom section of the shared presentation screen and the panel will appear. So thank you. I'm sure you're all over it.

Again, just around 'listen only' mode, as this is a webinar, we've put everyone on mute so we're not disrupted by background noise. Please interact with us using the Q&A box. So I'm sure you can all see that at the bottom, at the bottom of the screen. Please don't enter any personal information other than your name and the question, as other attendees will be able to see this. If someone else has asked a question that you really would like answered, please do give it the 'thumbs up'. This is really great because it means then that questions with more 'likes' are going to move up to the top of the list, and they're definitely going to be asked. But we'll have lots of time for questions actually. So we want you all to put as many questions in as you can. So we've got a dedicated Q&A session at the end of the webinar.

You can ask questions throughout, but we're going to answer all the questions at the end. So thank you for that. We look forward to those. So Jean Hailes has partnered with RACGP tonight to deliver this webinar, and I'd like to thank them for supporting general practice and providing this educational opportunity for us all. We've got three presenters tonight, Associate Professor Megan Smith, Professor Marion Saville, and myself, Deborah Bateson. Now first to introduce Megan Smith. So Associate Professor Megan Smith co-leads the Cervical Cancer and HPV stream at the Daffodil Centre, a joint venture between the University of Sydney and the Cancer Council in New South Wales. She's an epidemiologist and a simulation modeller, very exciting, with extensive experience in policy evaluations for cervical cancer prevention that have directly informed screening and policy decisions in Australia, in New Zealand and in England. Associate Professor Smith is currently co-leading an NHMRC project looking at how to scale-up self-collection in primary care, and she's authored over 130 publications. And I'd like now to hand over to Associate Professor Megan Smith to commence the presentations. Thank you, Megan.

**A/Prof Megan Smith:** Thank you very much, Deborah. And I will just take a minute to share my screen, right, which I hope is now slideshow mode for you all. So thank you again very much for the opportunity to join this evening. I've been invited to speak to you about the impact of COVID-19 on cervical screening. So as an important piece of background, I'd like to start with the implications of transitioning to a longer screening interval. When the NCSP transitioned from two-yearly PAP tests to five-yearly HPV tests in December 2017, people were recommended to have their first HPV test two years after their last PAP test. So this means that during the transition, most of the screen-eligible population would attend for their first HPV test within the first two years of the transition. Based on participation over a two-year period leading up to then, you would expect about 58% of the screen-eligible population to have attended in the first two years. And a much smaller proportion would attend their first HPV test over the last three years, it's a five year cycle. So those last three year's been, 2020, 2021 and 2022. And again based on typical participation, we thought in the lead up to the program change, you would expect an extra 25% of the screen-eligible population to attend in those three years that haven't attended already. There'll be some people attending in any year for follow-up or surveillance. But from 2020 until late 2022, the only routine screeners who are eligible to attend were either overdue or had never been screened before.

And entirely by coincidence, COVID-19 arrived in the second phase of the five-year cycle, and the advantage of this was actually that by 2020 most women were completely unaffected by disruption because they weren't due for screening anyway for several years. But the issue was the remaining people were already overdue the screening at that point. So to get insight into the differences in the number and the type of people attending year by year, how this would play out in practice, when it's disrupted by covid, sorry, before covid, how this would affect workforce and resourcing needs. We actually took modelling before the program changed back in 2015 to estimate, year by year, the expected number of women we would see who were screened in each year, the HPV and LBC test volumes that would happen each year, and colposcopy demand to inform workforce and other resourcing measures. We use the well-established simulation model that has previously been used to inform multiple assessments for the Medical Services Advisory Committee, including a modelled evaluation that underpins the program transitioning to HPV screenings. It models dynamically HPV transmission in the community, taking into account sexual behaviour and changing vaccination. And it explicitly models detailed screening pathways, including imperfect screening behaviour and test accuracy. It's informed by local data and has been adapted and crosschecked across a range of other settings.

So these show the predicted number of women screened, on the left, and HPV tests year-by-year. As you can see, both of these were expected to fluctuate and be highly variable in the five-year cycle. There was expected to be a substantial drop in the number of tests and the people tested in the third year of the program, roughly equating to 2020, because as mentioned before, most people would've already attended in 2018 or 2019. And we would expect an even bigger drop in years four and five. So even before covid, it was always expected there would be a big drop in screening activity in 2020 compared to 2019. So how does this compare to what happened in practice? Well, here are some comparisons between the expected volume of tests and the drop in tests year-by-year. And this has shown the expected in red and the actual drop is shown in blue.

These are percentages compared to year one of the new programs, so 2018, the first full calendar year. And so the most comparable figures for the observed set is the darker blue. This is based on MBS data, the claims for cervical screening tests, HPV tests. And here we can see that the drop in the total number of tests in 2020 doesn't appear to be a great deal larger than, sorry, it's somewhat larger than expected, but it's not very much larger. And actually the drops in years four and five being a little bit less than anticipated. Potentially this could be, some people were catching up in those years, having missed out in 2020.

And when you restrict the observed tests to only routine screening tests, the drops are much larger than were expected in 2020. So this isn't an 'apples and apples' comparison, but what this does suggest is that people were far more likely to miss a routine screening test than a follow-up test, or they remember the people who were expected to come in that year for routine screening were overdue or never screened. We also undertook some modelling in the very early stages of the pandemic to get insight into what the flow-on effects of this tests would be, and into which groups were most vulnerable to disruptions or delays in screening. We did this in collaboration with others internationally. And so actually looked at the hypothetical impact of disruptions in four countries, Australia, the Netherlands, Norway, and the US, to consider how different screening program designs might differ in terms of the impact of disruptions.

And to do this, and also because real world data on disruptions wasn't available, it was so early, we used standardised and simplified scenarios in all settings that incrementally included disruptions to various points on the screening pathway, the screening test, the surveillance test, coloscopy and treatment, to explore which aspects of the screening pathway had the most impact. The main outcome we looked at was additional cancer cases that would be caused by this disruption, but we also considered upstaging cases and cancer death. Instructions were, in the modelling, assumed to be complete, for example, in the lightest red row here, that no woman would attend for a routine primary screen for 12-month period. But we also assumed that people who missed screening would get caught up fairly quickly after the disruption ended.

So briefly, what we found at the high level was that the number of additional and upstaged cancers would be comparatively small in the countries we looked, at which all had established screening programs. And they are actually the tiny bars that are probably not that easy to see on top of the red bars. The red is the sort of undisruptive burden. And notably, the HPV-based screening programs had fewer cancer cases, even in the context of a total 12-month disruption to all aspects of screening diagnosis and pre-cancer treatment. Then a cytology program in the same setting had this without disruptions. And here I've just circled some of the results for Norway, with the box around them.

So then we also looked at which age groups any additional cancers would be most likely to be diagnosed in. These charts show, for each country, the percentage of the additional cancer cases that would occur in each age group. And consistently in all settings, it was women aged 30 to 39 years in 2020, shown in brown, who had the most additional cancers. And younger women more broadly were the most affected, with 64 to 85% of additional cancer cases predicted to occur in women who were aged less than 50 in 2020. The predicted age distribution of upstage cancers was also broadly similar to that here for additional cancers. And this probably reflects a range of things, including higher underlying risk of cancer in women under 50, having a shorter history of screening to protect them, the protective effect of screening wearing off more quickly in younger women, and in some cases differences in screening participation by age. Now note also that in Australia and the US, women aged up to 39 had previously been offered HPV vaccination, although when they were aged 17 or older, so some risk of prior exposure. But this shows that even with some level of vaccine protection, we shouldn't discount the risk in these younger women from missing screening.

So this chart is similar to the last one, except instead of breaking down the additional cancers into age groups, they're broken down on where in the screening pathway people were when the disruption occurred. And so as well as younger women, we found that generally disruptions to surveillance visits, screening, caused more cancer cases than disruptions to primary screening. However, disruptions to routine screening were more of a problem if the primary test was cytology rather than HPV. And this is probably the reason for the relatively large importance of disruptions to primary screening in Australia, larger than in any of the other countries we looked at, because the only women due to attend in 2020 were those who had not yet had their first HPV test, and their most recent screening test was actually a PAP test in 2017 or earlier, or they've had no test at all in the past.

So how does this help? Well, firstly, it suggests that if there's reduced capacity due to disruptions, or capacity doesn't allow for an ideal rapid catch-up of everyone, it would be more important to keep surveillance visits going than routine screening visits. This should also be easier as there are far fewer women who are under surveillance than there are due for routine screening. It also suggests age might be a useful factor to consider, firstly because it's an indicator that's readily available at the point of care usually, whereas screening history may not be so readily available. Secondly, because age is directly relevant to how you might reach women in a mass media recovery campaign or any recovery campaign. And for example, this finding actually informed the design of the national media campaign in Australia towards the end of 2020. There was a campaign across breast, bowel and cervical screening.

And these findings helped to inform the content design, which platforms the campaign went out on, which languages to prioritise for translation. And these were all very different for this younger group who we were interested in for cervical aged under 50, compared to, of course, the older age groups who were eligible for breast and bowel cancer screening. But this also suggests, and we've since explored this with more explicit modelling, but people who are overdue for screening are the key people to catch up on their screening tests. Those who are up-to-date with HPV screening are reasonably resilient to disruptions.

So to wrap up, there was a big drop in screening test in 2020, but a lot of this was due to the longer screening interval. So disruptions to cervical screening were probably relatively small, and appear to have affected routine screeners more than those on follow-up or surveillance. But those who were due to attend the routine screening were already overdue, and that's important because the groups who seem, based on modelling, to be most vulnerable to disruptions are those who were overdue, those in some sort of follow-up and younger women in their thirties and forties. So this provides some insight into the groups we should be focused on when catching up.

And now, it's my pleasure to introduce our second presenter this evening, Professor Deborah Bateson. Deborah Bateson is a Professor of Practice at the Daffodil Centre, a joint venture between the University of Sydney and Cancer Council in New South Wales, and formerly Medical Director at Family Planning New South Wales. Deborah has worked as a clinician, researcher, educator and advocate in sexual and reproductive health for over 20 years with a focus on equitable access to cervical screening services and reproductive healthcare. Deborah is leading an NH&MRC study to increase cervical screening participation among people with an intellectual disability. And is Chair of the National Cervical Screening Program, Self-Collection Implementation Committee, Deputy Chair of the Quality and Safety Monitoring Committee and a member of the Cervical Screening Guidelines Working Party. Over to you, Deb.

**Prof Deborah Bateson:** Thank you. So should I share my screen now? Yep. That's great. So I'll do that, and I'll just bring this up here, put it onto the right mode. There we go. Excellent. So hello everyone, again. It's a pleasure to present to you now around the challenge of getting back on top of cervical screening rates, getting them back on track, and what is the role of a GP. So what I'm going to be talking about is looking at which of our patients are more likely to be under-screened in the practice. And I'm going to have a bit of a focus as well on using the National Cancer Screening Register Healthcare Provider Portal. It's such a useful tool, and of course GPs play such a pivotal role. And I'm going to be talking about considering, for instance, a personal or a practice-based audit to identify those who've fallen behind, we've heard about them from Megan, or have never been screened, or are in that sort of follow-up and overdue for follow-up or for referral.

And just to say, absolutely recognise that this is a really busy time for general practice and there's a lot going on. It's been very stressful with covid. And this is just saying, look, there's lots of different contexts. Some practices, you'll have a practice manager, you'll have a practice nurse who can potentially help with these quality improvement activities, but other practices may not. So it's just about reflecting on what can work for you in your practice. And of course we'll continue to do what we always do, which is opportunistic screening for anyone who comes before us who's aged 25 up to 74, finding out whether they're due for screening. And of course, thinking about adding in self-collection as a patient choice. It certainly makes that opportunistic screening a lot easier, and we'll talk about that in some detail, and Marion will talk more. And I just want to highlight the excellent screening program, practitioner Toolkit, as well.

So who is more likely to be under-screened? What are the groups? You might be surprised to know that current participation is around about 62% overall. It is, as Megan sort of highlighted, it will increase because of the longer screening interval, which is good. And we are going to be expecting to see those first people coming in for their second HPV tests from December onwards. And they'll be sent their letters. And of course the young women will be sent their invitation letters already. They get sent three months before they're due. But let's look at who is under-screened. So it includes Aboriginal and Torres Strait Islander women on almost four times greater mortality rate compared to non-indigenous women. CALD communities. And that may include people who've experienced female genital mutilation, for instance, making a speculum examination very challenging. LGBTIQ community, we know lesbian women can be under-screened, some misperceptions sometimes, and of course we're screening anyone with a cervix, including trans men.

Those living with disability, physical or intellectual disability. It is Taryn and Tamsin in the bottom picture from our Family Planning video. And they're wonderful women talking about, actually I think it's Tamsin mentions, the HPV virus, the 'human pavlova virus', which is all always my favourite. People with a history of sexual trauma. You can imagine a speculum examination can be a significant barrier, and that can include also, of course, people with pelvic pain or vaginismus. Previous negative screening experiences, people from low socioeconomic backgrounds, homeless people, rural and remote. And as Megan's pointed out, young people. And we also need to look at that 25 to 29-year-old group who are just coming into the screening program for the first time. And of course, older people. Sometimes misperceptions around 'no need for screening after menopause or if no longer sexually active'. Just to remind us all, almost three quarters of those diagnosed with invasive cancer are under or never screened.

So a polling question for you all. So have you accessed the National Cancer Screening Register Healthcare Provider Portal? We'll bring up the poll and we'll see whether you've actually accessed it or not. And don't worry if you haven't. It always jumps around a bit to start with. And we'll see where it's landing. It's looking like more no's than yes's, although pretty close. So that's great. Thank you. So I'm going to, thank you very much. Excellent. I'm going to move on now to my next slide. And now, how do I move that on? That's a very good point. Do I have to close this, and then I just, there we go. Excellent. So thank you for doing that poll. It really is an incredibly useful tool for us all. It allows you to access your patient's cervical and bowel screening results and histories online in real time.

And to also have a look at what their next screening action is. You can submit program forms. It's not generally for general practice, but you might want to or need to. You can manage your patient's details and preferences. For instance, record their cold status, really important, and you can order bowel screening tests as well for your patients. So how do you access it? Well, there's two ways, in fact. So until relatively recently, it was always through the portal via your PRODA account. So that's, you provide a digital access that authenticates you as being you. And doing it this way, you go onto the website. You can actually have delegates, so your nurses in your practice, your administrator could actually also access it this way if they're given that permission. But possibly the way that's becoming more popular and easier, it certainly is, I realise this, is accessing it through your integrated clinical software.

And at the moment that means MedicalDirector Clinical, Best Practice Premier or Communicare. It's really excellent. What needs to happen is that you need to have a designated responsible officer in your clinic. It may be your practice manager, it could be one of you, it could be you as a doctor, and you are the one that sets that up for the practice. And it then means that everyone in the practice, including the nurses, all the doctors can access it. It's really useful. There's actually over 4,500 providers and delegates now registered with the portal and they have 1,269 practices registered to use the integrated clinical software. And just a quick tip actually, as someone told me to do this, and it's really useful, to actually just navigate the portal, check out your own screening history. So this is not a real person, by the way. So this is just what this looks like with the interface with your medical software.

And this is just, so this person, Lydia, she's new to both bowel and cervical screening. And just, there's lots of online information to help you, but I think one of the most useful things is you can actually book a callback with a digital specialist to walk you through. So this would be the responsible officer who's setting up that practice-based system, to walk through how to get it up and running, because it really is a marvellous thing. And I must say, when I was speaking to the registrar today, they said they've gone down from 8,000 faxes a month, asking for people's screening histories, to round about 200, 250 a month. So really people are finding this incredibly useful. You could also think about clinical audits as well. So again, within the constraints of what you can do personally, and I just thought, obviously we're entering a new triennium, all of these audits are undergoing revision now, so they're ready for the new triennium.

And there'll be a lot available, as you know, on the RACGP website. But just to give you an idea of what these are. So they varied, one on the left, the Douglass Hanly Moir one for instance, it's fairly straightforward. It just sends you information about your screening. Who you've been screening, what the HPV results are, you know, unsatisfactories, it gets you to reflect on your practice and also reflect on possible improvements to your practice as well. The one on the right, that's through Victorian Cytology Service also being updated through GPEx, this is a HPV self-collection clinical audit. And it's a step further. It actually gets you to identify people in your practice who are under-screened. There's a lot of education around HPV self-collection. And then to offer self-collection, and to then audit that against the benchmark.

And it also, again, looks at practice improvements to results management systems, for instance. And so just to set that idea out, I mean, maybe you could actually think of raising it at a practice meeting, thinking about a 'whole of practice' audit and quality improvement activity. What could this look like? Well, it could look at identifying patients who have never screened or are overdue for screening. And you can do this with data extraction tools like Pen CAT or POLAR. You set up a recipe looking at everyone between 25 and 74 who's had no screening or no screening for a certain number of years. So that's something, and then you could potentially set up an SMS, for instance, to all those people. They are just different concepts that you could follow. What about other situations? You could look at who hasn't attended for colposcopy referral and is due.

And you can do this by implementing your recall systems, recall and reminders, who hasn't attended for a Test of Cure, who hasn't returned after an unsatisfactory sample, who hasn't returned for their 12-month or, if they're eligible, a 24-month HPV follow-up test after an intermediate risk cervical screening test. And who hasn't returned for a cytology test after you've taken a self-collected HPV test, and it's a 'not 16/18' result. And we'll talk about it more, but if you remember when you're doing self-collection, this is for cervical screening, it tests for HPV. You can also use it for other places in the pathway where only an HPV test is needed. You can't use it for a co-test where you need an HPV plus a cytology test on the same sample, like for someone with symptoms, for instance.

And this is just the idea of the recall system. We certainly use them at Family Planning. And then we'll do audits on these. And look, I won't go through in detail, this is just, again, examples of what you can look at in terms of just making those improvements to your staff, routinely update preferred contact details. Are the nurses and doctors registered to access the provider portal? Are you identifying under-screened patients? And have you've got recall systems in place. And a welcoming environment, posters and pamphlets. And what about promoting the alternative of self-collection pathways? And this is not to bamboozle you, this is just to highlight that amazing changes have happened to the clinical guidelines. So I'd urge you all to take a look at the updated guidelines. They were updated on the 1st of July, they came live on the 1st of July. And what they've done, as you can see here, these pathways, they've integrated self-collection with clinician collection throughout the pathway wherever that HPV test can occur. So really, really, really useful, I have to say. And just the other thing with the updated guidelines as well as that, all the recommendations, they're all together in one place so you don't have to navigate through the different chapters. So I really would urge you all to do that. So polling question two is, have you offered self-collection as an option in your practice?

Yes or no? Excellent. Oh, that's great. Yeah. So again, just sitting at over half. Yes. And of course that may be with the previous quite restricted eligibility criteria up until July the 1st of course. But equally it may be that you've been very, getting in with it since July the 1st as well. So that's great to see. So thank you for that. I'm just going to close this down and move on to the next slide now. So what I've said before was about opportunistically offering screening. Really important. If you've got Best Practice medical software, in fact, a red alert will actually pop up out of you. I believe that's the only software that does that, to say that this person is due for screening or overdue for screening. It only collects information from your practice. So if they've had a screening test somewhere else, that actually won't show up.

So just to be aware of that. And just to say the register is looking at ways that they can also support you identifying under-screened people. So that would be great. So self-collection, it's a universal choice. And I have to say I found it very easy just to have, in fact, my swabs over there actually, I normally have it in my hand, have a swab on hand at all times, because you can just show people what it is, and it just makes it real, makes it easy. If not today, don't feel like it today, what about next visit? So it's about bringing people into the program who weren't otherwise keen to have a speculum examination, for all the reasons we mentioned before. So this is another alternative. And just to remind us all that while it's preferable in a clinic, self-collection can potentially occur in any setting that you believe is appropriate.

In other words, to bring in someone who would otherwise be under-screened. And you can consider setting up telehealth pathways just to say you do have that responsibility for ensuring that the correct sampling devices are used, and informing patients of their results and any follow up. And you'd work out a way in your practice that you can do that, maybe people could come and collect the swabs, or you could send them to their homes, they could potentially go to a lab, but you'd have to have an arrangement in place for that to happen. And just a reminder too, that, again, we're wanting to ensure that we can bring people into the program. And so, say if someone needs assistance with self-collection, you can provide that. And in fact, if they can't take the vaginal swab themselves, you can actually take that vaginal swab for them if that's their desire, and it's still classified as self-collection.

So I've used this a few times for people with a tremor, for instance. You may use it for someone with low vision, for instance. So it's just opening up these pathways. And I did just want to highlight, do check out the Healthcare Provider Toolkit. There's excellent resources, resources in 11 different languages, and six Aboriginal and Torres Strait Islander languages, which is extraordinary, on the screening program website. So do utilise these resources. It gives tips and information about how to support groups with specific needs. And I just wanted to say, Australia is on track to be the first country in the world to eliminate cervical cancer, but we need to remember that cervical cancer is a disease of inequity, both globally and here in Australia. These are the WHO targets that we need to reach by 2030. And I have to say that you as GPs play an absolute pivotal role in helping us to get there. So thank you for all the work that you do. Thank you.

Now. I'm going to switch hats now, because I'm going to stop sharing, and I'm going to switch hats. I'm going to move to a different zone of my brain because it's my pleasure now to introduce our next speaker. And just remember, do put your questions, I can see there's some questions in the chat. Do keep doing that. We'll come to them all. We've got plenty of time. But I'd now like to welcome our third presenter, Professor Marion Saville. Marion is a cytopathologist and the Executive Director of the Australian Centre for Prevention of Cervical Cancer, a position she's held since the year 2000. And Marion has served on cervical screening advisory committees in Australia, New Zealand and Ontario. She currently chairs a working group to review Australia's guidelines for the management of screen-detected abnormalities in the National Cervical Screening Program. And Marion's worked closely with the Department of Health on various committees, including steering committees, for the renewal of the National Cervical Screening Program in 2017, and implementation of self-collection in 2021–22. So, welcome Marion.

**Prof Marion Saville:** Thanks very much, Deb. Appreciate that generous introduction. I will just quickly share my screen. So thank you. My talk is going to be quite brief. I'm going to talk about the accuracy of self-collection and the laboratory requirements, just so that all those technical details are straight so that you can apply all that wisdom that Deb's just articulated. So self-collection for cervical screening, what's the evidence? I'm going to ask you this question. What is the relative accuracy of self-collection for the detection of CIN2+, remembering that that is the target of our screening program. We want to detect those high-grade precancers and treat them to prevent cancer. So somewhat less accurate, but better than no screening at all, much less accurate and should be discouraged, broadly equivalent, or more accurate? And we'll just leave that open for a period.

And so the answers are pretty evenly split between the 'somewhat less accurate, but better than no screening at all' and the 'broadly equivalent'. And that's a very interesting result because of course what's happened is the evidence has evolved with time. So at the time that we set the self-collection policy, prior to going to renewal, the available evidence was very heavily influenced by this meta-analysis by Mark Arbyn and colleagues. And this is looking on what we call 'receiver operator curves'. So sensitivity and 1 minus specificity on the X-axis. And the perfect test is up here in the top left-hand corner. And as you can see, that meta-analysis in 2014 showed that, compared to clinician-collected samples in blue for both CIN2+ and CIN3+, that there was a degradation, particularly in sensitivity, but also specificity, with self-collected samples. So when we struck the policy back there, what we were trying to do was trade off any benefits we might have in reaching under-screened people against the potential loss of sensitivity, or the loss of sensitivity, and therefore potentially of program effectiveness.

And that led to the policy that you will be familiar with, where people had to be at least 30 and two years overdue for screening to be offered self-collection. What happened subsequently is that some of the older screening tests, particularly those based on signal amplification, became replaced by more modern PCR-based assays. And so an updated meta-analysis published by the same author and a highly overlapping group in 2018 separated out the accuracy of self-collection depending on whether it was based on the signal amplification tests. I mean, most labs around Australia have used this old hybrid capture test in years gone by, although not so much now. And separately looked at tests that are PCR-based. And as you see here, the clinician-collected sample in orange, against the self-collected sample in purple, and these very close lines and highly, highly overlapping, 95% confidence intervals.

So we would say now that self-collection is broadly equivalent in its performance to clinically-collected samples for the detection of CIN2+. And that's why, whilst previously it was better than nothing and certainly better than not screening, now we can consider them broadly equivalent. And honestly I've never seen receiver operator curves that looked so overlapping as that. So we know that self-collection is accurate. As I've showed you, the updated meta-analysis talks about CIN2 outcomes. We've done some studies with the Women's Hospital here in Melbourne, the SCoPE study, where we've demonstrated equivalent performance for the detection of HPV on vaginal-collected versus practitioner-collected samples. And those studies were important for regulatory reasons for getting TGA approval in Australia.

So as Deb has mentioned, the National Cervical Screening Program clinical guidelines have been updated so that now all women and people with a cervix age 25 to 74 who've ever had any sexual contact should be screened and can choose to screen either with a clinician-collected sample or a self-collected vaginal sample. And of course there'll be many patients in your practice who are accustomed to the clinician-collected sample, they don't wish to make a change, and that is perfectly fine. Anywhere in the pathway, as Deb has articulated, an HPV test is needed, self-collection should be considered an option. But of course anywhere in the pathway where we need a co-test, we do need that cervical sample so that we're getting cells from the transformation zone so that our liquid-based cytology results are accurate. Cervical screening will continue to be made available through primary care.

So there is no plan to make this a through-the-mail screening test, such as the bowel program. And I think that is really important, because we know that one of the huge successes of the Cervical Screening Program is that in Australia it's embedded in primary care. And we know from a variety of studies and evidence that this change gives us great potential to address and reduce many of the known barriers to screening. And I would say, based on our evidence, over 20 years of trying to encourage unscreened people to come into the program, we can do health promotion, we can write to them, we can remind them, but we're saying in different ways, we want them to do something that for probably somewhere between 10 and 15% of people have just decided they're not going to do. So now we're asking them to do something different.

And this can overcome many of the barriers that Deb articulated earlier. So how does it work from a lab perspective? Just to give you some reassurance about the safety of these tests, they contain controls that look for assay failure. So the polymerase chain reaction can be inhibited by excess blood, other microbiological infections or lubricant, and therefore limit the ability of the assay to detect HPV. But the control ensures that if inhibition has occurred, the assay is marked as invalid and not as negative. There's also a cellularity control that ensures enough cellular material is present in the sample. And so a self-collected swab that has insufficient material, or absent cellular material, which can sometimes happen when an unscreened person decides to open and close the swab and not actually sample, maybe just to stop the discussion about the importance of screening, that will also be reported as invalid or unsatisfactory, rather than negative. One thing to say though is, in most of the assays used in Australia, these controls are combined, and so we're not able to tell you whether this is an assay failure inhibition or whether there weren't any cells or enough cells in the sample, as we used to be able to do with the old cytology samples.

It's important to understand that self-collection devices, the methods and the handling and transport instructions, vary between labs, and that's because we are using potentially different HPV assays with different requirements. Three labs around Australia have had longstanding in-house validation for self-collection. So the important thing in setting yourself up with self-collection is to talk to your local lab, ask if they will process self-collected samples, and ensure that you have the correct consumables, the right swabs, and the instructions for transportation and handling. Confirm that if they don't process self-collected swabs, they'll send those samples on to a lab that does. And if they're not happy to agree to that, then you can just send these samples directly to one of the labs that processes these samples. And the Department of Health is maintaining a list of labs, on the NCSP website, that are accredited to process self-collected swabs, and that list is growing over time.

So at VCS Pathology, we use the Copan FLOQSwab 552C or 552C.80 for collection and transport. And you see those swabs pictured there. And of course, in order to comply with TGA requirements, unfortunately we can't process a swab or a collection device that's not approved for use. The good news is that these swabs have very good stability. They don't need to be refrigerated. They are stable for up to 50 degrees centigrade and a hundred percent humidity. And we have a self-collection claim of stability for 28 days from the date of collection. For this reason, it's really important when you send us a swab, particularly if you're coming from a remote community and it's going through the post, that you label the sample with the date of collection. If you were to use our telehealth supported service, it's really important to ask the patient to record the date of collection on the request form.

And so this just shows you the basis on which we were able to make those claims. So we had the swabs loaded with low amounts of HPV, so that's three times the limit of detection, and we placed them into an oven at 50 degrees and, really, the highest humidity we could practically achieve, for 28 days. And each couple of days, two swabs were removed and tested, and we recorded not only the positivity or negativity, but as you might be aware from the covid days, the CT value. So that's the cycle threshold. How many PCR amplification cycles needed to be done before the HPV was detected. And in this sense, the lower value means a higher viral load. And so you can see that even within 28 days, the red dash line is the threshold of a positive result. And so no swabs, even with a very limited amount of HPV material, gave us a negative result, and that was approved for our 28-day claim at 50 degrees and high humidity.

There are now two commercially available HPV assays for self-collection. These are assays that have got TGA approval for self-collection on label, meaning the lab doesn't have to do in-house validation. One through BD and one through Roche. The Roche protocol requires the swab to be re-suspended into a ThinPrep vial at the time of collection. So make sure you clearly indicate if the sample has been self-collected on the pathology request form. I think one of the things we're all concerned about in the lab is that, if we get a ThinPrep vial, we had typically assumed that that meant we were getting a sample from the cervix that's suitable for liquid-based cytology. But of course, with one of the very big manufacturers being used by some of the very big labs, we know there's going to be a lot of use of the Roche assay and involving this re-suspension into the ThinPrep vial. We don't routinely use this process in VSC pathology, but we have verified it, meaning that if we receive these samples, we can process them. We ask our practitioners to send us the swabs dry.

So thank you very much for all of that this evening. I hope you feel confident about the accuracy of the testing, and in approaching your lab, and making sure that you've got the information you need to offer self-collection to your patients. And back to you, Deb.

**Prof Deborah Bateson:** Thank you, Marion. That's great. Excellent. So thank you to Megan and to Marion. We've got quite a few questions coming through during the presentations, which is fantastic. So I'm going to just start to throw them out now. So thank you so much. So do keep, we want to make sure we can answer them all, of course. So I'm going to start off, and I can see that some people, you've 'up thumbed' them, so that's good. So Marion, maybe I'll ask you this first question, which is that, 'I'm very worried about missing melanoma or lichen sclerosus, et cetera', obviously not doing that genital examination routinely with five-yearly screening and now we self-collect. So what are your thoughts on this?

**Prof Marion Saville:** Well, the guidelines address this point, and this concern was raised in consultation. I mean, I guess the issue is that when we're screening a patient, we've been incidentally examining the external genitalia, but there is no evidence to support the idea that looking at the external genitalia in the absence of any symptoms, or history, or some people are at increased risk of vulva disease. So without a specific indication, there's no evidence that we are doing anything effective by examining patients in the absence of symptoms. This is a screening test.

**Prof Deborah Bateson:** Thank you. Yeah, so you're right, yes, we do what we always do, which is around symptoms, isn't it? So thank you for that. Now there's a next question, which is an important one as well. So this is about patients. Well is a particular patient who's 40, who's only ever kissed people, never had vaginal intercourse, not keen for a speculum, does she need a CST or even self-collected? So maybe if I just add in here that careful thought's being given around this. We know that HPV is very transmissible, of course. We've actually changed the wording from 'people who are sexually active', because we know that's a very confusing term, to actually say 'people who've had sexual contact'. And this sexual contact, I've just looked up, we've actually got the definition of it. It may include sexual intercourse, penetrative sex, oral sex, intimate genital skin contact, for instance, as part of foreplay and anal sex. So I think it's important to just let people be aware that it is that sexual contact that can include that foreplay, fingers, et cetera, and just let people know, obviously if someone hasn't had any sexual contact, then that can be their informed decision. So I think, Marion, anything you'd add to that?

**Prof Marion Saville:** I think that's everything.

**Prof Deborah Bateson:** Excellent. The next question is about swabs, and I think you've covered that very well. Is there an easy explanation of self-collection? Well, before we go into it, just to say there's excellent resources with those flow charts for patients, and in different languages, showing how to do it. Marion, do you want to give a few words on what we would say to our patients?

**Prof Marion Saville:** Look, we've developed a bit of a guide to support GPs' conversation with their patients at VCS pathology. We're happy to share that. And even if you're not referring to us, you're very welcome to use that guide if it helps you. And on the other side, it's got the actual instructions for collection, which are pictorial with very limited texts. So we hope that that will help support your conversations with your patients. But I think the main thing in making a decision is that patients need to understand that there is a chance they may need to come in and have a cervical sample collected. And that's all outlined on the resource, but essentially 2% of patients are going to have HPV 16 or 18 detected. They're going to go directly to colposcopy. The non 16/18 runs somewhere around 6%, but it's highly age dependent and much higher in younger patients than older patients. So we might just send out a link to that resource after the meeting.

**Prof Deborah Bateson:** And they're very simple as well, taking the top off the swab and inserting it into the vagina and rotating it. Well, it actually says 10 to 30 times, doesn't it? And then recapping it. It's a very simple procedure, which is excellent. There's a question about, can we support this, is it reasonable for self-collection to be done at home? And the answer will be, yes, it is reasonable, but as long as you, as the requesting clinician, is taking responsibility for all the steps. Obviously if you've got someone in your clinic and you give them the self-collection swab, you know you're going to get it back again. So there's a chance you're not going to get it back again. You must make sure they've got the correct swabs, they need the dry FLOQSwab to do at home, and to ensure that you do receive it back again, it does get to the lab, and that you convey the results. So there's a lot of processes along the way. Anything you'd add? Yep.

**Prof Marion Saville:** I think it's worth talking to your lab about. I mean, certainly if someone's in the, it's absolutely ideal to get it during the visit so that it gets done and doesn't go away. In studies that we've done, we've had about 85% of people who say they wouldn't have a pap smear in the old days return a sample. So that's a breakthrough in acceptability really. During the pandemic, we offered a self-collection service in Melbourne, of course, the most highly locked down city in the world as everyone knows. So that if a GP had identified someone who was eligible and no-one wanted to go into the practice, they could just send us the request form and we would send that information to the patient, we'd send the kit to the patient with a return envelope, everything was paid for, it came back to us. And then we, of course, issue the results to you, the clinician, to manage those results. But I would say that, even with a follow-up call to the practice at a month, we got about two thirds of those swabs back. So when the patient isn't with you, the likelihood you're going to get the swab declines. But if the patient's refusing to do it in the clinic or it can't happen, well then the likelihood is zero. So it's worth a try.

**Prof Deborah Bateson:** Yeah, thank you.

**Prof Marion Saville:** And talk to your lab about what they're prepared to do for you.

**Prof Deborah Bateson:** Excellent. Very good messages. Thank you, Marion. Megan, one for you. Until which age should we offer the Gardasil vaccination if a patient's never had it before, and how many doses should we offer? And second bit of the question, if someone presented with HPV positive, was HPV positive, in their screening tests, should we still offer the vaccination?

**A/Prof Megan Smith:** Sure. Great question. Well, I suppose the most important thing to think about is—

**Prof Deborah Bateson:** Oh, we've just lost you there. Marion, would you like to take over while we wait for Megan to come back?

**Prof Marion Saville:** So presently, people can access the Gardasil vaccination on the NIP until the age of 19, and that is—

**A/Prof Megan Smith:** ...infections...

**Prof Deborah Bateson:** Go ahead, Megan. We lost you. You froze for a moment.

**A/Prof Megan Smith:** Oh no, sorry.

**Prof Marion Saville:** Start again, Megan.

**A/Prof Megan Smith:** Sorry. Yes. I think key message is probably that once you're 25, what you can do to prevent cervical cancer is to be screened regularly according to the guidelines. Certainly the vaccine is effective at preventing new infections in older women, but as people get older, the time they have for that infection to progress to—

**Prof Deborah Bateson:** We've got some connectivity problems. I'm afraid. We might come back to that one. I'm just going to throw up this interesting question, which is, why would you not recommend self-collection for all? And that's a very good point. So maybe I'll just add a few thoughts, and Marion, I'm sure you've got many. Yeah, sorry Megan, we lost you again. If you'd like to just finish a little succinct sentence, that would be great.

**A/Prof Megan Smith:** I think my succinct question was, once you're 25, focus on screening.

**Prof Deborah Bateson:** Fabulous. So this is a very interesting question of, why would you not recommend self-collection for all? I think my take on it is you obviously, well, we are going to offer it to all. That's the first thing. And I think it comes down to that patient choice. And certainly over time, I suspect more people will take it up. But certainly some of, maybe the older patients, maybe not, they're still keen to, they've been regular screeners often, and they're keen to carry on having that clinician-collected sample. So we wouldn't want to take that away. But I think as time moves on, you'll find more and more people taking it up, particularly young people who are used to self-collecting, STI tests, for instance. So Marion, anything from you?

**Prof Marion Saville:** Only to say, that's how I screen, and I think it's a great question and we definitely offer it to all. But there's something empowering we've found in the research and having some choice about how you screen. So I think it's going to be, I think we would've had a lot of pushback if we made a policy that said only self-collection was available. I think we would've bought an argument we didn't really need to have. And adding choice is always good.

**Prof Deborah Bateson:** Excellent. Now a quick one again for you, Marion. Is it better not to use lubricant for HPV detection?

**Prof Marion Saville:** Look, you would typically only use lubricant for a speculum exam. And at that point, of course, we're wanting to ensure we can do cytology if we need to. And as long as it's a non-carbomer-containing lubricant and sparingly, sparingly applied to the edges of the speculum, then that's fine. And obviously patient comfort is pretty critical here. We don't want patients to have an uncomfortable experience. But for many people, the warm water works just as well. I don't know what you think, Deb?

**Prof Deborah Bateson:** I think, yeah, so I think the warm water works well, actually, I have to say, but it's always an interesting one. Now, I'm conscious that we've only got a few minutes left. We have got quite a few more questions. If everyone's happy to go for another five minutes, but then we'll call it a stop at five minutes. How does that sound, Marion? Or do you think we should call it? Yeah, we'll just make our way through them, but then we'll call a stop after that. So the guidelines don't mention people with hysterectomies if we don't have histology from the uterus or the cervix. Oh, I can't, do you have a memory of the hysterectomy guidelines?

**Prof Marion Saville:** I thought we did, but if we could take a question and come back to you, Vanessa, that would be amazing.

**Prof Deborah Bateson:** Yes, we certainly have the part where we don't know what that histology is, and if the hysterectomy was for a benign cause. So there are comprehensive guidelines around the hysterectomy piece. And yes, we can take that on notice. So thank you for that. I think this one you've already answered as well. Do we send ThinPrep only to the lab, or the swab as well, as we will put the swab in the ThinPrep and then send the ThinPrep.

**Prof Marion Saville:** Yeah, I think it's important that for the Roche assay, what's required is re-suspension from the swab into ThinPrep, and then you discard the swab. But I think most labs offering this as a routine will also be providing you with stickers and easy ways to make sure you can indicate that this is indeed a self-collection sample, so it's not confused with a cervical sample taken by a clinician.

**Prof Deborah Bateson:** Thank you. Vanessa's come back with an interesting thought around the melanoma issue. And we look for skin cancers with skin checks and bowel cancers, bowel et cetera, without symptoms. So I've found a vaginal melanoma while performing a CST without symptoms. Any thoughts on this? I mean, it's a difficult one, isn't it? We don't have a vulval screening program. I mean, it's tricky. Marion, any thoughts?

**Prof Marion Saville:** Look, I think as we're hearing here, an individual experience like that can really weigh on a practitioner's mind, and it's very difficult, and nothing is perfect in screening.

**Prof Deborah Bateson:** Yes, it's screening.

**Prof Marion Saville:** I agree that, I'm no expert in melanoma, but skin checks I think have got good evidence behind them. And perhaps that needs to include the genitalia. I don't know. But I think a cervical screening program around that with the available evidence.

**Prof Deborah Bateson:** Yeah, it's a good point, actually. It does make me remember back to the time when we stopped doing routine bi-manual examinations with pap smears. And I must say the practitioners did find it very hard, because they worried about missing things that maybe they'd picked up before. So it was just that matter of change, and having those thoughts around it. But I do agree with you Marion, it would be perhaps useful to have a think about those conditions on the vulva in terms of skin checks. But thank you for the thoughtful question, Vanessa. Transgender people, are easily done in general practice, so in other words, screening? Yes, certainly we've been offering screening for transgender men. I mean, sometimes they've been using testosterone, sometimes not, of course. If people have been using testosterone for quite a while, then there can be considerable vaginal atrophy and certainly it can be quite painful to insert a speculum. So a self-collection would probably, I mean, people can choose, you would give people that choice. They could choose to use some topical oestrogen prior. I imagine with self-collection it wouldn't necessarily be needed, but that would be an individual choice. So I think, yes, it certainly can be done in general practice. And if failed self-collection, will they be charged, and how much? That's a very practical question.

**Prof Marion Saville:** I mean, certainly Medicare will support a repeat sample following an unsatisfactory. So depending on if the lab is bulk billing pathology, they may or may not be charged. But the fact that it's a repeat after unsatisfactory shouldn't influence that. At VCS pathology we bulk bill everything, as long as it's Medicare-eligible test in a Medicare-eligible person. If that makes sense. So you'd need to ask your lab about that.

**Prof Deborah Bateson:** Fantastic, thank you. And there's just another question around transgender and it being perhaps a little confusing. I mean it is just getting used to thinking about the anatomy, of course. And so, transgender men who have a vagina basically, and a cervix, anyone with a cervix, so it's anybody with a cervix is eligible and should have cervical screening. So that's important. And there's a question around, do women with a partial hysterectomy need an HPV test? So if they've got a cervix still there, usually these days it's removed, but not always, then they certainly need to continue having cervical screening tests. So that's fine. And I think we're almost at the bottom, and there's a useful question about, can self-collective samples we order be tested for chlamydia and gonorrhoea. And Marion, I know this is one you can answer.

**Prof Marion Saville:** Well certainly in our laboratory, talk to your lab. But yes, we think it's useful to use that sample for STI testing where that's indicated.

**Prof Deborah Bateson:** Yes, I think that's important. And last question around information in the national registry, similar to immunisation, so, can GPS look up the patient's last cervical screening test? Absolutely. So in fact, you can look up the patient's whole history, their entire history. So I would urge you all to work out how to access the registry online through your medical practice software or through the portal, so, directly. So I think it's great. And just the last one is, what do you think about a collaboration with other services where women access, are provided with instructions and swabs for self-collection on site, thinking of breast screen? Yes, that's great. We need you on our team, Megan.

**Prof Marion Saville:** Fantastic idea. The guidelines are deliberately allowing that flexibility in the setting of self-collection, so that all sorts of different models of care might be considered by communities, practitioners and labs. And certainly state governments, together with BreastScreen, particularly when the BreastScreen bus is going off to a regional or rural community. I think the main thing is that it is important to have access to screening histories when we do these outreach types of activities. And it's an important point to understand that as we come up to our second round of screening in the National Cervical Screening Program, for the first time ever Medicare has said 'only one test every five years with a three month grace period'. Which means if you early rescreen your patients, sooner than 57 months, so the 60 months less three months, then Medicare is not going to support that, and the lab is likely to send you a bill. So that will be a very live issue in the coming months and you should check your patient screening history before you screen them. But by all means, screen them.

**Prof Deborah Bateson:** Thank you. Well that's a very apt place to end, Marion. And I think that's all we've got time for this evening. So really, on behalf of our webinar partner, Jean Hailes, thank you so much to everyone for attending. I hope you enjoyed the webinar. Thank you for all your fantastic questions and your wonderful engagement. It's really great to get these questions and to be able to answer them. And also a huge thank you, of course, to our presenters tonight. So Megan Smith, thank you so much for all your insights. Marion Saville, thank you so much for all your insights. It's wonderful to have such expert presenters sharing your knowledge and time this evening. So thank you all, and all have a good evening. Thank you. Bye.

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Information about the podcast

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Hosted by Dr Sarah White, CEO at Jean Hailes

Produced by May Jasper

Sound engineering by Derek Myers

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