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Focus groups examining the information needed for acceptance of de-intensified screening programs: cervical screening in Australia

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ABSTRACT

Objectives: Given the changing understanding of overdiagnosis of screen detected cancers and advances in technology to detect and prevent cancer, updating and scaling back cancer screening programs is becoming increasingly necessary. The National Cervical Screening Program (NCSP) in Australia was recently de-intensified, with changes implemented in December 2017. This study examines women's understanding and acceptance of the reduced screening protocol and how such changes can be communicated more effectively.

Design: Focus groups structured around a presentation of information about the reduced NCSP, with discussions of the information facilitated throughout. Qualitative data analysis was conducted.

Setting: Australia

Participants: Six focus groups were conducted in November 2017 with a community sample of 49 women aged 18-74.

Results

Women demonstrated little or no awareness of the upcoming screening changes in the period just before they occurred. Women expressed most concern and fear that the increased screening interval (from 2 to 5 years) and later age of first screening (from age 18 to 25 years) could lead to missing cancers. Concerns about exit testing were less common. Understanding the natural history and the prevalence of both HPV and cervical cancer, and the nature of the new test (catching it 'earlier') was key to alleviate concerns about the increased screening interval.

Conclusions

De-intensifying screening programs should be accompanied by clear and coherent communication of the changes, including the rationale behind them, to limit concerns from the public and facilitate acceptance of reduced programs. In this case, understanding the biology of cervical cancer was crucial.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- These findings make an important and timely contribution to the potential communication strategies for countries internationally updating cervical screening programs.
- The qualitative design of the study allowed us to explore in depth the views and understanding of women of eligible screening age, as well as observing how women communicated the reasons behind the changes to each other.
- As this was a qualitative study, we cannot express the findings as generalisable across the whole population.
- Additional information may have helped reassure women further that there are processes in place for dealing with exceptional circumstances and it is not a one size fits all approach.

INTRODUCTION

Understanding of the benefits and harms of cancer screening programs has changed radically over the past 10 years with growing evidence of overdiagnosis and overtreatment of screening detected cancers.[1,2] As health technology advances to offer new screening tests, treatments and methods of cancer prevention (eg vaccination), the need to review and update screening programs to ensure the benefits outweigh the harms has never been more pressing. Wilson and Jungner provided a set of principles to guide the practice of screening for disease, based around early detection and treatment,[3] and already four decades ago, recognised that we must avoid causing harm to those who do not need treatment. There is now an increased focus on ethical principles and acceptability when developing or refining existing screening programs,[4] and awareness that screening programs may need to be de-intensified to ensure health benefits outweigh potential harms such as overdiagnosis and overtreatment as evidence changes.[5]

A recent example of de-intensification of cancer screening comes from Australia, where the National Cervical Screening Program (NCSP) was revised in 2017. The changes encompassed new recommendations based on evidence of potential harms attributed to the previous screening regimen,[6] as well as the changing landscape due to the uptake of the human papillomavirus (HPV) vaccination and the development of new screening technology (Table 1).

>>Table 1 here<<

Research has shown internationally that public responses to reducing cancer screening programs has been very negative;[7] most notably in the US, where proposed changes to breast screening in 2009 were ultimately retracted due to the public backlash.[8] Our own research to the proposed changes to the Australian NCSP identified strong concerns about the increased interval between cervical screens [9] principally due to the perception that this would miss cancers and put women's lives at risk.

When implementing any major revisions to a screening program it is important to understand how best to communicate the changes so that people understand and accept the reasons behind it, and to ensure their confidence in the program is not undermined. If the changes involve de-intensification of screening this is particularly important. The changes to the Australian NCSP provided a timely opportunity to explore women's reactions to de-intensifying a cancer screening program and to examine how the reasons for these changes could be effectively communicated. The study aimed to explore women's understanding of the reduced program and its acceptability, with the view of generating insights to guide communication about de-intensification of future screening program changes internationally.

METHODS

Participants

The focus groups were conducted with a community sample of Australian women aged 18-74; those in the age range for which the NCSP (prior and renewed program) is the most relevant.

Participants were contacted via telephone by a fully independent market and social research company (Taverner Research), who used random landline and location known mobile samples from Sydney. To gain a diverse range of perspectives, we used purposive sampling to ensure inclusion of women with varying levels of education and prior participation in screening (including women up-to-date and overdue for screening in all age groups). We excluded women not fluent in English and women who had ever personally been diagnosed with cervical cancer. Taverner interviewers briefly introduced the study, assessed eligibility and availability, and asked respondents whether they would be willing to receive more information about the study. Eligible women who had verbally agreed to being contacted by the research team were emailed a Participant Information Statement and Consent Form. RD contacted potential participants to confirm their interest and eligibility and confirmed participation in the focus groups.

Design

Six focus groups were conducted at three locations across Sydney, with 5-10 women in each group, to explore the views towards the reduced Australian NCSP among women of screening eligible age. Data collection took place in November 2017. Focus groups were facilitated by RD and included an additional researcher as a moderator (BN, SW, CB, JH). Participants were given a $A100 gift card for reimbursement towards time and travel costs.

The focus groups were structured around a presentation of the changes to the NCSP and the rationale for these changes in order to facilitate discussion about what information is important to communicate to women to enable them to understand about the changes. This format gave participants the opportunity to ask questions and discuss the changes amongst themselves throughout. This enabled us to identify areas which may need to be communicated more clearly and to explore how women themselves understood and then explained the changes which were of particular concern to each other.

The groups were split according to age (18-30 year olds, 31-50 year olds and 51-74 year olds) as it was anticipated that views and preferences for information might vary as the changes to the screening program differed by age group.

Presentation and discussion content

The presentation (Supplementary material) was developed by the research team, which included a consumer representative and was reviewed by an independent expert team of researchers and clinicians. A summary outline of the presentation is included in Box 1. This presented the information available on the Australian Department of Health NCSP website [10] at the time of development (September/October 2017) about the changes to the NCSP. We also presented some information developed by the research team to put some of the information into context; for example, presenting

women with figures of incidence and mortality since the NCSP had been introduced and explaining the accuracy of the HPV test compared to the Pap smear.

Box 1: Outline of the presentation

1. Introduction to the renewed National Cervical Screening Program – information taken from the Department of Health website (accessed September/October 2017)
2. Concerns already raised by women about the changes
3. Answers to frequently asked questions
    a. Why is cervical screening changing?
    b. What should women do between now and 1 December 2017?
    c. How will the new Cervical Screening Test work?
    d. Can I have the new Cervical Screening Test now?
    e. Why will the screening age change to starting at 25 years of age?
    f. Should women less than 25 years of age participate in cervical screening between now and 1 December 2017 when the renewed Program is implemented?
    g. How will women be invited to screen using the new Cervical Screening Test?
    h. When should I stop cervical screening?
    i. Will cervical screening prevent all cervical cancers?
    j. What is human papillomavirus (HPV)?
    k. How did I get human papillomavirus (HPV)?
    l. What is the relationship between the human papillomavirus and cervical cancer?
    m. Do I still need to screen if I have received the HPV vaccine?
    n. Will the new Cervical Screening Test replace the vaccination program?
4. Further information about the changes developed by the research team
    a. Why is cervical screening changing?
    b. National Cervical Screening Register
    c. Change: Test
    d. Change: Timing
    e. Change: Age
    f. Exit test
    g. Old versus new program
    h. What happens if I have a positive HPV test?

Throughout the group discussions, women were encouraged to share their thoughts about the information presented and how easy they found the information to understand. The presentation content and types of questions we used to guide the discussions is summarised in supplementary information. We also encouraged women to ask questions throughout, while making it clear that we would initially be simply noting down the questions and would answer any questions still outstanding (i.e., not answered by the intervening information presented) at the end.

Analysis of qualitative data

All sessions were audio recorded and professionally transcribed verbatim. Transcribed focus groups were managed using NVivo 11.[11] Thematic analysis was conducted to identify main themes that captured the views of women about the changes to the NCSP, and which information presented was found to be reassuring about particular concerns or helped them understand the rationale for the changes. The initial coding framework was developed by RD, with input from KM.

The same framework was used by two researchers (RD and BN) to analyse three transcripts each for themes and codes which focused around women's understanding of the rationale behind the changes to the NCSP. These themes and codes were developed and applied to the data, and through numerous meetings an agreement was made on the overarching concepts that were important for women's understanding and acceptance of the changes and the information they needed to address concerns. The framework with which to interpret the data was discussed with KM, and the broader project team had input into the interpretation of the results. The research team members work in the field of public health, with a special interest in reducing overdiagnosis and overtreatment.

Quantitative measures

Brief written questionnaires were administered before and after each focus group. The first questionnaire included demographic questions, questions about cervical cancer and cervical screening, and intentions to go for cervical screening in the future. The second questionnaire (following the presentation) aimed to assess what knowledge and understanding women had taken from the focus groups using a series of multiple-choice items developed for this study, and again asked their intentions to go for cervical screening in the future. These are reported descriptively in the manuscript (Tables 2 and 4).

RESULTS

Sample characteristics

Forty-nine women participated in six focus groups (Table 2). Forty-one had previously attended for cervical screening, with eight not yet having been invited. Of the 41 who had attended screening, 28 were up-to-date and 13 were overdue. The sample was diverse with regards to education, employment and country of birth. Focus groups lasted between 71 and 103 minutes. A minority of women verbally indicated they had heard something about the changes being made to the NCSP, with the increased interval between tests and later starting age most commonly remembered by those women.

>>Table 2 here<<

What information addresses women's concerns?

Following the education session about the changes to the program, we present the three key concepts that were a) important for women to understand and accept the program changes b) that women found reassuring about their particular concerns: 1) Natural history, 2) Incidence and 3) Transition to the new program (NhIT).

1. Natural history and slow development of cervical cancer

Women were concerned and confused about what it means to have HPV, the increased interval between screening tests, and the new test. They were reassured by information explaining the natural history of cervical cancer, particularly the time it takes for HPV to develop into cervical cancer.

Knowledge of HPV among women was fairly low, even in the focus groups with younger women where many of the women had received the HPV vaccine in school. Women had many questions about HPV, including how it is transmitted and whether it is cleared from the body or lies dormant.

Some of the focus groups likened HPV to cold sores or herpes. Giving women information about HPV helped them realise that HPV was very common and not serious unless it progresses. The information also helped women understand that their immune system can clear HPV by itself, often without

intervention (Q1). However, for a couple of women, this information led them to wonder if it was worth having the test at all if HPV was not that serious and the incidence of cervical cancer was so low (Q2).

Women's concerns about the screening interval focused mostly on the potential of 'missing cancers' due to the time between tests being increased. Understanding that HPV caused most cervical cancers, and that the virus can take around 10 years to develop into cervical cancer, helped to reassure women (Q3).

The new HPV test was referred to in the government-provided program renewal information as the 'cervical screening test' and it took some time during the focus groups for women to realise that the test was going to be different in the new program. Women's concerns about the new test were around whether it was safe, accurate and they wanted more information. Once women understood that the new test was to detect HPV, which causes most cervical cancers, women were reassured that this test was detecting something earlier, 'like a step ahead' (Q4).

Women from most focus groups understood the information about the natural history of cancer and used this to interpret the rationale behind the increased screening interval (Q5). Some focus group participants quickly grasped the process of the new test and explained this in a simple way to each other (Q6).

Older women in the sample expressed concern about the exit test, about what this meant for them and why it was decided women would leave the program between 70 and 74 years of age. Information about the slow progression of cervical cancer helped to reassure women about the reasons for the exit test (Q7).

>>Table 3 here<<

2. Incidence of cervical cancer

Women in the younger age groups were mainly concerned about the later start age, whereas women in the older age groups were concerned about both younger and older women, and also concerned that young women were not as aware of their health as they should be (Q8).

All women considered younger women to be more sexually active from an earlier age 'these days', and were therefore worried about the time between young women commencing sexual activity and their first screening test, as they perceived them to be at greater risk of developing cervical cancer earlier.

When speculating about reasons for the later starting age, one focus group considered the number of cases in women under 25 (Q9). Crucially, presenting women with incidence data of cervical cancer in Australia showing that cervical cancer in young women was very rare (in both HPV vaccinated and unvaccinated women) and that despite screening women younger than 25 years of age for over 20 years there has been no change to the rates of cervical cancer or rates of death from cervical cancer in this age group, was key to help reassure women about the later start age of screening (Q10).

The rationale for the later starting age presented information about overdetection and one group discussed this further with questions about how HPV clears itself without need for treatment sometimes (Q11). This led some women in the group to consider the harms of immediate treatment, but in other focus groups surprise was conveyed about overtreatment and there was confusion about at what age it was better to monitor to see if abnormalities resolve themselves. Once it was explained, women did understand that the cells often got better without intervention but there was confusion about why this varied with age.

The women in the younger (18-50) age groups also expressed a desire for more evidence and more data around the incidence of cervical cancer and liked the additional graphs and tables that were included on the slides developed by the research team (see supplementary information).

The two older age groups spent longer discussing the exit test than the younger age group. One group found it interesting how cervical screening contradicts their understanding of screening for other cancers (e.g. breast and bowel), such that you get more screening as you get older (despite both these screening programs also stopping screening by 74 years of age), not less. Many of the women also tried to process the information about the exit test and what this may have meant about cervical cancer incidence in older women, wondering if the incidence is low and therefore not worth it for older women (Q12).

3. Transition to the new program and the screening pathway

Many women expressed concern and confusion over how they, and other women, transition from the old to the new program. Some women were unsure whether they would have another Pap smear, or whether they would go straight to having a cervical screening test at their next test (if after December 1st 2017).

One woman explained that information may be important for those women who will be most affected by the transition period, namely women under 25 who have already received cervical screening, and also those older women who will no longer be eligible for screening in the old program, but whom might now be invited for an exit test.

Women were reassured by the information that they should still go for their next screening test two years after their last test, but that this will be the new cervical screening test and providing their results were normal they would not be invited back for another five years. It was also important to make it clear to women that although the test would be different, the procedure for collecting the specimen would be exactly the same (Q13).

Many women initially wanted to know what happened after the test, as the information from the Department of Health did not give any information on the screening pathway (Q14).

Quantitative data

Prior to the focus groups, in response to short questions about the NCSP and their intentions to screen, 62% (n=29) of women correctly responded that they were in the age eligible for cervical screening and 81% (n=38) of women correctly responded how often women are invited (Table 4). Almost 90% (n=42) of women intended to go for cervical screening in the future.

>>Table 4 here<<

Following the presentation of information about the changes, all women correctly answered when the changes were taking place, with most (>95%; n=46-48) correctly responding to questions about the age of invitation, screening frequency, that HPV will be tested for, and that the experience will be the same for women after the changes. Fewer women correctly responded that the sample would be tested differently (68%; n=32). Of note, less than 60% (n=25) of women were aware that you should go for screening when you are healthy, with 36% (n=15) believing you should go for cervical screening when you notice abnormal changes. In total, 96% (n=46) of women intended to screen in the future.

DISCUSSION

This study showed women had little awareness of the changes to the NCSP just prior to their implementation in December 2017. Women expressed concern about the increased screening interval and later age of first screening because of fears about missing cancer, consistent with our previous research.[9] Concerns about exit testing were less commonly expressed. However, following the information presented, and given the opportunity to discuss among their peers, many participants understood and accepted the reasons for these changes. The findings suggest that if information and the rationale for change is presented clearly women will likely accept de-intensified screening programs. This has implications internationally and for screening programs broadly as well as for cervical screening in Australia.

Clear communication to the public about changes to cervical screening programs, and what these changes may mean for them, needs to be developed in light of these findings. There also needs to be clear guidance for future changes to cervical screening programs, which address the differences between the two tests, making it clear that the test is now detecting a virus prior to abnormal cells. Women need to be aware of what HPV is and how it is linked to cervical cancer, including the slow progression of HPV to cervical cancer and the high chances of regression. Importantly, women also want to see evidence behind the changes, such as the incidence of cervical cancer, to reassure them about the changes to screening age targets. Women discussed these concerns within the focus group sessions, and how they processed the information about the natural history of cervical cancer helped them to understand the reasons for the changes in screening interval and the screening test itself.

Our analysis showed that women found certain pieces of the information presented to them useful and reassuring to justify the changes (Natural history, Incidence and Transition to the new program). The findings from this study demonstrate the fundamental information women extracted to help them make sense of the changes and provides important insights into the lay language women used to explain the changes to each other, which can be used in developing guidance for communication strategies. Overall, women in all age groups expressed similar concerns, but the older women expressed more concern and confusion about the reasons for the exit test, demonstrating areas where communication could be tailored to different age groups. Both groups of women were concerned about what the changes would mean for the younger age groups. The majority of women still intended to screen following the information, demonstrating their continuing confidence and trust in the program.

Most of the information presented to women was new, with their views towards screening shaped by the many years of messages focused on the importance of attending screening and that early detection is key in reducing deaths from cancer. These reactions are not surprising given that research has shown a high public enthusiasm for screening,[12,13] women have spent much of their lives being told about the

importance of having regular screening and early detection, and believe 'more care is better care'.[14] Awareness of HPV among the general public has been found to be limited in many previous studies,[15,16] with women in this study being similar. Equipping women with the information about HPV and that the new test was now going to detect infection with the virus, which was seen to be a 'step ahead', was reassuring. Practical information for women, so they could evaluate what this would mean for them, was important, specifically knowing that the procedure of the test would be the same, and that the difference lies in how the sample is tested.

The information presented from the Department of Health website [17] did not specifically mention over-detection but mentioned the possibility of investigating and treating common cervical abnormalities that would usually resolve. The public can be confused by concepts such as overdiagnosis and it has the potential to undermine trust in screening programs.[18] Over-detection was briefly mentioned in the information developed by the authors, when talking about the later starting age for screening, with regards to cervical abnormalities regressing and the possibility of overtreatment, which can lead to obstetric complications. This concept was not attended to much by women in the focus groups, with surprise expressed in those who did. It was clear that the concept of regression of cervical abnormalities was not well understood and needs explanation for women.[18]

Screening programs will continue to need reviewing to ensure benefits outweigh harms as stated by Wilson and Junger.[3] Findings from this study can be used to consider processes for de-implementation of screening programs in the future. Evident at all stages of the principles of screening is the importance of maintaining public confidence;[3] strategies for communicating these changes and the reasons behind them in a reassuring way, will help maintain public confidence. Formal invitations for cervical screening through the national register may provide an ideal opportunity for educational information to be distributed alongside the invitations.

These findings demonstrate key information which could be applied to other screening programs to aid in public understanding about changes to screening programs. Information about the natural history of the cancer, in addition to information about the prevalence and risks of disease and how to transition from the old to the new program (NhIT), presented in a clear format, can help the public to understand the reasons for these changes and alleviate concerns.

Elimination of cervical cancer could be a real possibility in the future,[19,20] particularly in Australia where the successful school-based HPV vaccination program for girls and boys has shown significant reductions of incidence in the vaccine related HPV genotypes which are high risk types for cervical cancer.[21,22] Additionally, the recent approval and implementation of the nonavalent vaccine is likely to reduce the incidence of HPV further.[23] Therefore, there is the possibility within our lifetime that the NCSP may be phased out entirely.[20] However, in the meantime it is necessary to communicate that screening is still important, but that there are potential harms associated with cervical screening, such as overtreatment of abnormalities that may otherwise spontaneously resolve. Information about overdiagnosis has been shown previously to be met with confusion or scepticism.[24] Future studies may be best placed to focus on reducing overtreatment of cervical abnormalities, particularly in those women of child bearing age who are most at risk of obstetric complications.[25] Future research also needs to explore the impact of the reduced screening program on clinical practice, both at the GP level and referral rates.

These findings make an important and timely contribution to the potential communication strategies for countries internationally updating cervical screening programs. The content presented in the focus group sessions represented information available to women at the time and was developed by a multidisciplinary team including a consumer, and reviewed by both clinical independent experts and pilot tested with consumers. The qualitative design of the study allowed us to explore in depth the views and understanding of women of eligible screening age, as well as observing how women communicated

the reasons behind the changes to each other. This gave valuable insight into what information is important for reassuring women about the changes.

Recruitment of women through an independent market and social research company enabled the participants to vary in age, education, prior screening and ethnicity. Almost 40% of the sample were born outside of Australia. As this was a qualitative study, we cannot express the findings as generalisable across the whole population.

There were a few aspects that women asked about which were not addressed during the presentation, such as whether there are different screening recommendations for specific population subgroups including women with a family history of cervical cancer, women who had become sexually active at a young age, and immunosuppressed women. We did not want to overload women with information and our research aim was to find out what women understood about the changes following the presentation. Some of these points were raised throughout the sessions, and therefore were talked about at the end, and it may be that this additional information helped reassure women further that there are processes in place for dealing with exceptional circumstances and it is not a one size fits all approach.

Conclusions

Most of the information presented to women in these focus groups was new to them. Key pieces of information about the natural history, incidence of cancer and how to transition across the programs (NhIT), helped explain the reasons behind the de-intensification of the Australian NCSP and can be applied to other screening programs. This can be provided to women in a concise and accessible format accompanying invitations to cervical screening in the future. These findings can be used on a broader level to develop a framework for developing communication strategies around future changes to screening programs.

Ethics approval and consent to participate: The University of Sydney Human Research Ethics Committee reviewed and approved this study (project number 2017/489). Participants' written consent was collected prior to the start of each focus group.

Availability of data and materials: No additional data available.

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Conflict of Interest: The authors declare no conflict of interest.

Author contributions: RD and KM conceived the study. RD, SW, CB, JH and KM were involved in designing the study and developing the methods. RD coordinated the running of the study and conducted the focus groups, together with BN, SW, CB and JH. RD and BN read transcripts, developed the analytical framework, and contributed to the analysis. RD drafted the manuscript. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

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Table 1: The changes implemented to the Australian National Cervical Screening Program on 1st December 2017 [6]

Change	New program (2017 -)	Old program (1991-2017)
Test technology	The Cervical Screening Test takes cells from the cervix to test for HPV infection	The Pap test took cells from the cervix and examined these cells for physical changes
Interval	The Cervical Screening Test is every 5 years	A Pap test every 2 years
Age	Women will be invited for a Cervical Screening Test from the age of 25 years	Cervical screening began at 18 years of age
Age	Women will have their last Cervical Screening Test ('exit test') between 70 and 74 years of age	Cervical screening ended at 69 years of age

Table 2: Sample characteristics

Sample (n=49)	n (%)
Age	
18-30 year olds	16 (32.7)
31-50 year olds	13 (26.5)
51-74 year olds	20 (40.8)
Marital status	
Married/living with partner	23 (47.9)
Divorced/separated	8 (16.7)
Widowed	1 (2.1)
Single	16 (33.3)
Children	
Yes	24 (50)
No	24 (50)
Family history of cervical cancer	
Yes	1 (2.1)
No	46 (97.9)
Country of birth	
Australia	30 (61.2)
Europe	5 (10.2)
Asia	10 (20.4)
Other	4 (8.2)
Education	
University degree	22 (47.8)
Diploma or trade certificate	10 (21.7)
High school certificate	11 (23.9)
School certificate	3 (6.5)
Employment	
Working full time	20 (41.7)
Working part time	12 (25)
Retired	10 (20.8)
Not in paid work	6 (12.5)
Last Pap smear	
Up-to-date (< 2 years ago)	28 (68.3)
Overdue (2+ years ago)	13 (31.7)

Note: some items had a small amount of missing data

Table 3: Quotes from focus groups to support the themes

Code	Reference	Page
Q1	"But for me it almost kind of dumbed down the reason for the test. You can get it, you have to be sustained, right, persistent exposure to the virus before you get the full cancer, cervical cancer. And also you might clear itself in many cases. So it's actually very reassuring that it's not that serious a condition. That's what I got from that really." (FG6, 31-50 years old)	10
Q2	"The only one thing for me is like they actually, again dumbed down the seriousness of HPV to me. 'Cause 2 women in 100 000, I was like, oh, that's not too bad. So you're going to screen the whole of the nation of women to detect two possibilities in 100 000. That's what I got from that." (FG6, 31-50 years old)	10
Q3	"Well, I guess if it takes a long time, up to 10 years, for the HPV virus to affect the cells then you might detect it in a year and then it's going to be a number of years until it actually affects you." (FG2, 18-30 year olds)	10
Q4	"But now it's going to pick up the… the infected, um, HPV infection before it gets to abnormal cells." (FG1, 51-74 year olds)	10
Q5	"It's looking for different cells which take, is it 10 years to develop into a cancerous cell, which kind of makes sense to have it every 5 years. Um, to test it every 5 years 'cause if it's going to develop it's already half way developed and not even to a cancerous cell." (FG5, 18-30 years old)	10
Q6	"Ok. So everyone will get HPV testing, then if they find specific strains then they'll look for [abnormal] cells." (FG2, 18-30 year olds)	10
Q7	"I understand the 70-74 now because they say it doesn't develop for 10 years anyway. And once they make sure that the 70-74 year olds are safe before they even exit." (FG3, 31-50 year olds)	10
Q8	"…the way we live our life has changed and I think younger people really aren't as, um… aware, I think, of their well-being and how important it is when they are young. And how quickly we grow old." (FG1, 51-74 year olds)	11
Q9	"Maybe they weren't finding as many… cancer diseases under the age of 25?" (FG5, 18-30 year olds)	11
Q10	"I felt the, the thing that made me a bit calmer though was that it said that there's been no change in, um, deaths or, um, I think picking up cancer in women aged 20-25 or something since they've had a screening program. So it made me feel a bit calmer about moving the age to 25. Seems legit." (FG2, 18-30 years old)	11
Q11	"I think because it clears up on its own. So I think there was that point about over-detection, so it does clear up. So if you are tested every two years and you have it then it could, if like… then they might, they might, um, treat it. But it might, would have cleared up on its own potentially." (FG2, 18-30 year olds)	11
Q12	"Can I just ask why it cuts out at 74? Is the incidence low, or it's just too painful, or it's not worth it?" (FG4, 51-74 year olds)	12

Q13	"The actual procedure is exactly the same for the patient, I guess you can say. The person being tested. And it's just what happens after that's changing." (FG2, 18-30 years old)	12
Q14	"But if you go and something is detected, um, do you have to wait 5 years for them… like if they think something's detected will we have to wait for another 5 years for them to say, oh yes, something has been detected now, but it may have been there before but we don't know, sort of thing? How that's going to sort of go?" (FG5, 18-30 year olds)	12

Table 4: Responses to questions about the cervical screening program before and after the focus groups

	n* (%)
Prior to focus groups	
Are women your age eligible for free cervical screening? Yes	29 (61.7)
How often are women invited to attend? Every 2 years	38 (80.9)
Do you intend to go for cervical screening in the future (when you do not have symptoms)? Yes	42 (89.4)
After the focus groups	
When should you go for cervical screening? When healthy	25 (59.5)
When are the recommendations for cervical screening changing? 1st December 2017	49 (100)
What age will women be invited for cervical screening after the changes? 25 years of age	46 (95.8)
How often will women be invited for screening after the changes? Every 5 years	48 (98)
Will the experience of cervical screening be the same for women after the changes? Yes	48 (98)
Will the sample taken from the cervix be tested in the same way after the changes? No	32 (68.1)
The sample from the cervix will be testing for: HPV	40 (97.6)
Do you intend to go for cervical screening in the future (when you do not have symptoms)? Yes	46 (95.8)

*n represents the number of women who chose the correct answer for all items apart from intentions for screening in the future

Supplementary material: Focus group presentation topics and key discussion questions

Introduction to the changes to the cervical screening program

- Had anyone heard anything about this before today?
- Do you feel that you understand the information I have just presented?
- What are your thoughts on what I have just presented?

List of advantages and concerns about the changes generated by women

- What do you want to know to make you feel comfortable with the changes? Is there any more information you would like?

Presentation of concerns expressed in an online petition about the changes to the program

- Has this information prompted any more thoughts?

Presentation of further information about the changes

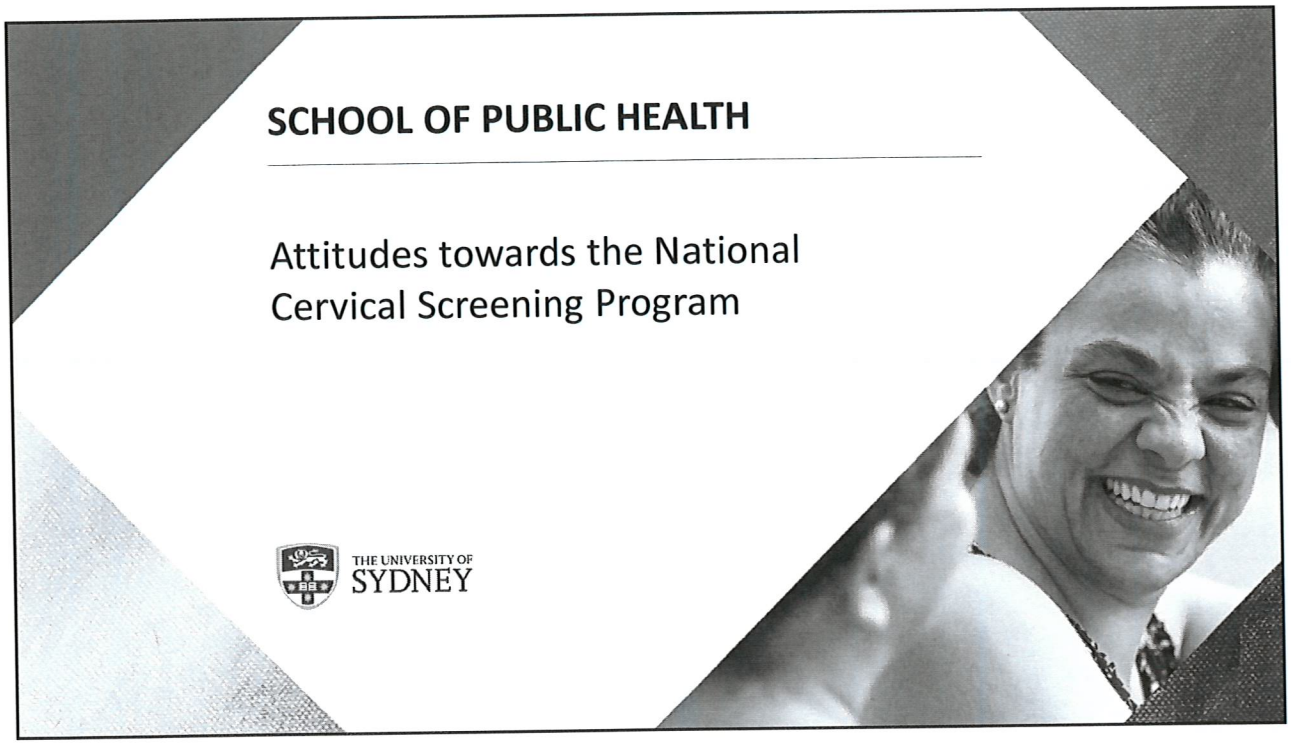
- Did anyone have any thoughts or questions about what I have just presented? (asked at regular points throughout presentation)
- Was the information easy to understand?
- Is there any other information you would have liked?

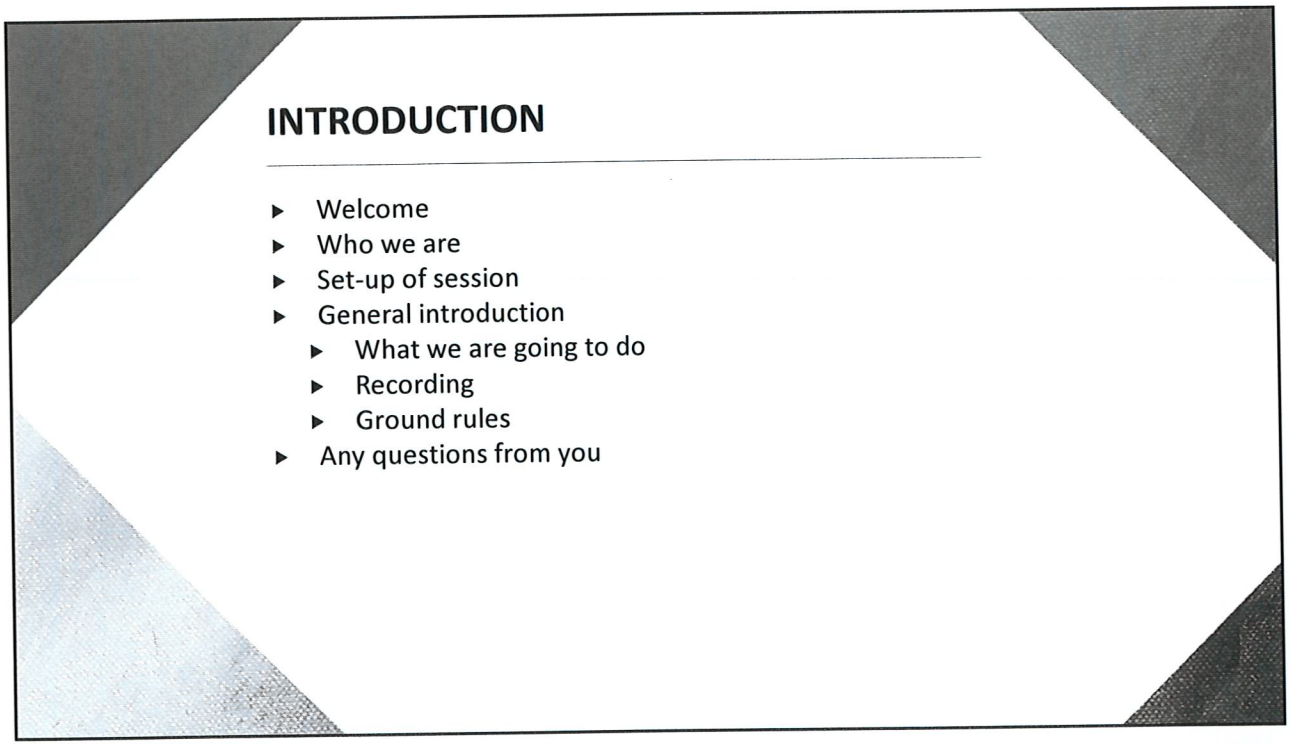
Following all information presented from the Department of Health website

- How easy or hard do you think it is for people to understand the reasons for these changes?
- Do you have any ideas about how best to explain the reasons for these changes to other people?
- What could be added, removed or changed from the information I presented to you?
- How would you suggest the expansion or scaling back of screening programs are handled in the future?
- When should the public be informed of a change in policy?
- How should this information be communicated to people?
- After the information you've heard today, how will you feel when you receive your invitation for cervical screening in future?
- Has your intention to attend cervical screening changed at all because of today's session?

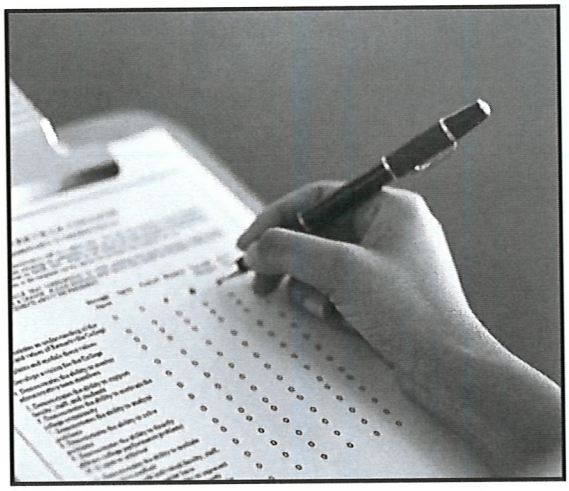
Presentation of alternative slides giving evidence about the changes

- How does this information compare with the information already presented?
- Was the information easy to understand?
- Did you have a preference over how the changes were explained to you?


SCHOOL OF PUBLIC HEALTH
Attitudes towards the National Cervical Screening Program
THE UNIVERSITY OF SYDNEY


INTRODUCTION
Welcome
Who we are
Set-up of session
General introduction
What we are going to do
Recording
Ground rules
Any questions from you

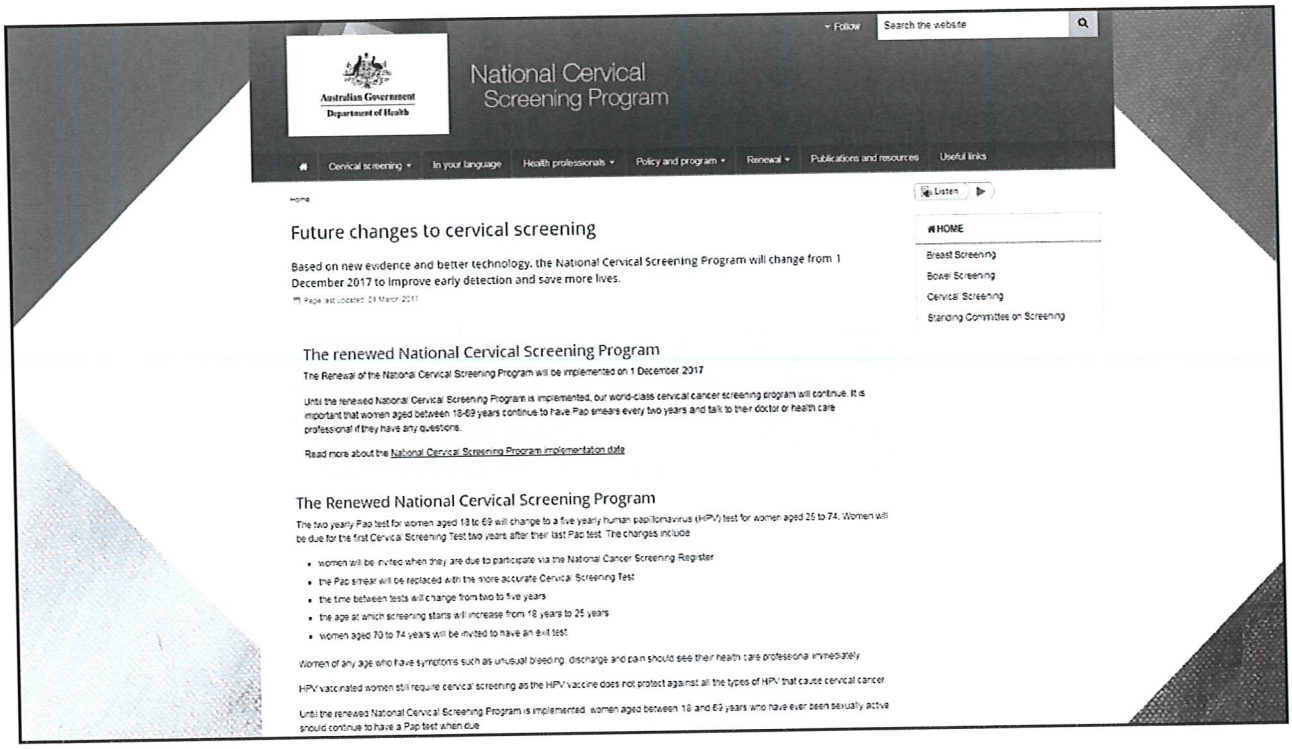
COMPLETE QUESTIONNAIRE 1



WELCOME

Today we want to hear your thoughts about the cervical screening program.

We want to present to you some information which has recently been displayed on the National Cervical Screening Program website and get your thoughts.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Useful links
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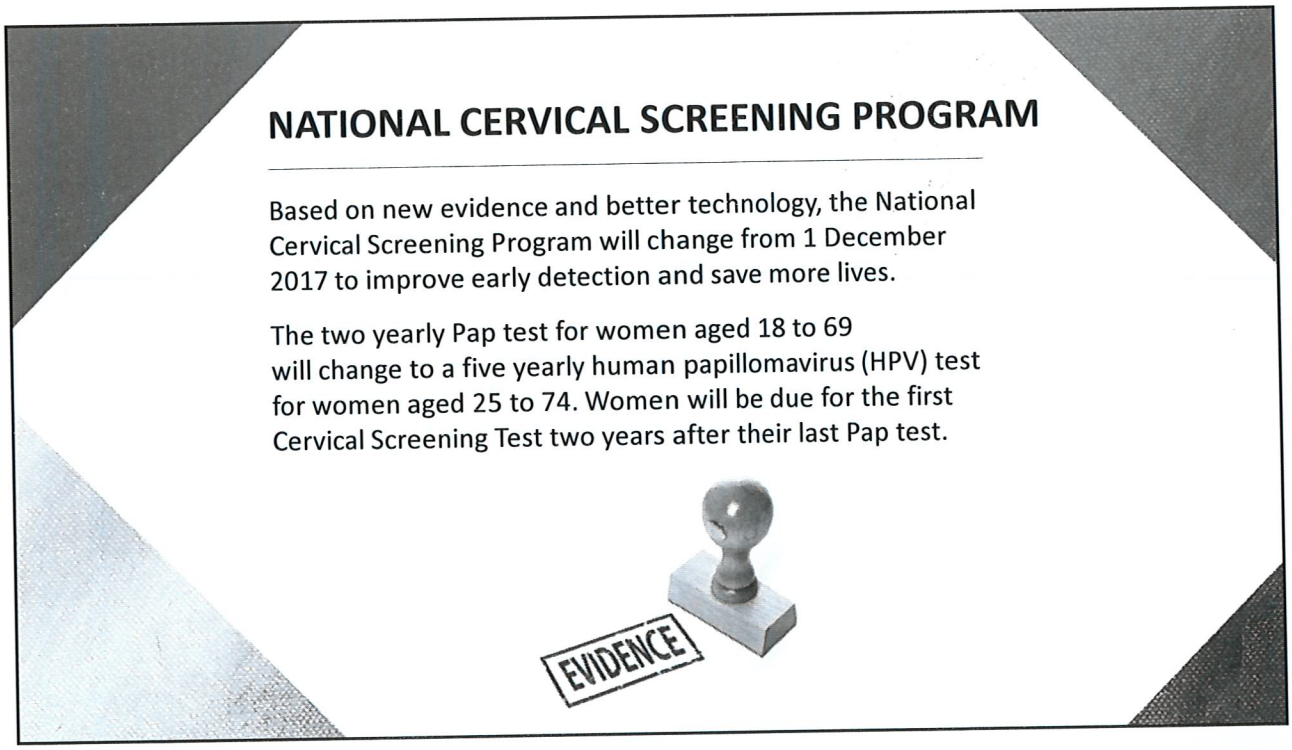
Listen
HOME
Breast Screening
Bowel Screening
Cervical Screening
Standing Committee on Screening
Future changes to cervical screening
Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017 to improve early detection and save more lives.
Page last updated: 21 March 2017
The renewed National Cervical Screening Program
The Renewal of the National Cervical Screening Program will be implemented on 1 December 2017
Until the renewed National Cervical Screening Program is implemented, our world-class cervical cancer screening program will continue. It is important that women aged between 18-69 years continue to have Pap smears every two years and talk to their doctor or health care professional if they have any questions.
Read more about the National Cervical Screening Program implementation date
The Renewed National Cervical Screening Program
The two yearly Pap test for women aged 18 to 69 will change to a five yearly human papillomavirus (HPV) test for women aged 25 to 74. Women will be due for the first Cervical Screening Test two years after their last Pap test. The changes include
women will be invited when they are due to participate via the National Cancer Screening Register
the Pap smear will be replaced with the more accurate Cervical Screening Test
the time between tests will change from two to five years
the age at which screening starts will increase from 18 years to 25 years
women aged 70 to 74 years will be invited to have an exit test
Women of any age who have symptoms such as unusual bleeding, discharge and pain should see their health care professional immediately
HPV vaccinated women still require cervical screening as the HPV vaccine does not protect against all the types of HPV that cause cervical cancer
Until the renewed National Cervical Screening Program is implemented, women aged between 18 and 69 years who have ever been sexually active should continue to have a Pap test when due


NATIONAL CERVICAL SCREENING PROGRAM
Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017 to improve early detection and save more lives.
The two yearly Pap test for women aged 18 to 69 will change to a five yearly human papillomavirus (HPV) test for women aged 25 to 74. Women will be due for the first Cervical Screening Test two years after their last Pap test.
EVIDENCE

NATIONAL CERVICAL SCREENING PROGRAM

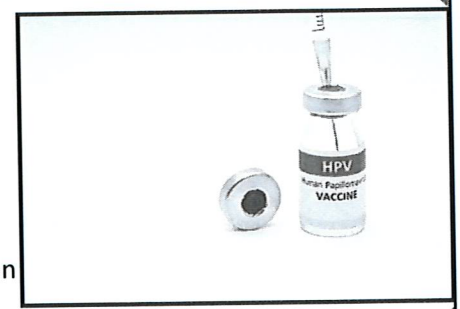
The changes include:

- Women will be invited when they are due to participate via the National Cancer Screening Register
- The Pap smear will be replaced with the more accurate Cervical Screening Test
- The time between tests will change from two to five years
- The age at which screening starts will increase from 18 years to 25 years
- Women aged 70 to 74 years will be invited to have an exit test

NATIONAL CERVICAL SCREENING PROGRAM

Women of any age who have symptoms such as unusual bleeding, discharge and pain should see their health care professional immediately.

HPV vaccinated women still require cervical screening as the HPV vaccine does not protect against all the types of HPV that cause cervical cancer.



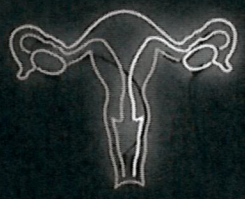
Until the renewed National Cervical Screening Program is implemented, women aged between 18 and 69 years who have ever been sexually active should continue to have a Pap test when due.

DISCUSSION

CONCERNS

Some concerns which arose in a petition which was set up and opposed the changes were:

- valuing women's health and rights;
- political statements
- cost and health care funding;
- specific concerns to screening program (e.g. interval and age of onset of screening)



DISCUSSION

PRESENTATION

The following slides present information available on the National Cervical Screening Program website

Frequently asked questions

Why is cervical screening changing?

What should women do between now and 1 December 2017?

How will the new Cervical Screening Test work?

Can I have the new Cervical Screening Test now?

Why will the screening age change to starting at 25 years of age?

Should women less than 25 years of age participate in cervical screening between now and 1 December 2017 when the renewed Program is implemented?

How will women be invited to screen using the new Cervical Screening Test?

When should I stop cervical screening?

Will cervical screening prevent all cervical cancers?

What is human papillomavirus (HPV)?

How did I get human papillomavirus (HPV)?

What is the relationship between the human papillomavirus and cervical cancer?

Do I still need to screen if I have received the HPV vaccine?

Will the new Cervical Screening Test replace the vaccination program?

WHY IS CERVICAL SCREENING CHANGING?

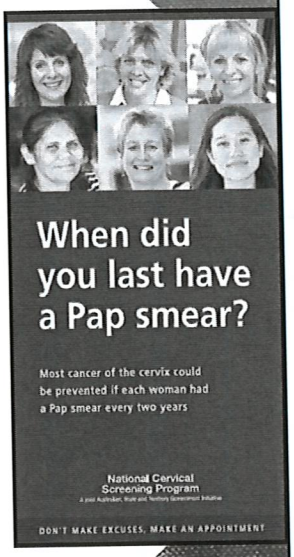
Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017 to improve early detection and save more lives.

WHAT SHOULD WOMEN DO BETWEEN NOW AND DEC 1ST?

It is very important that women continue to participate in the current two yearly Pap test program to ensure they are not at risk of developing cervical cancer.

Pap tests have already halved the incidence and mortality from cervical cancer since the introduction of the National Cervical Screening Program in 1991.

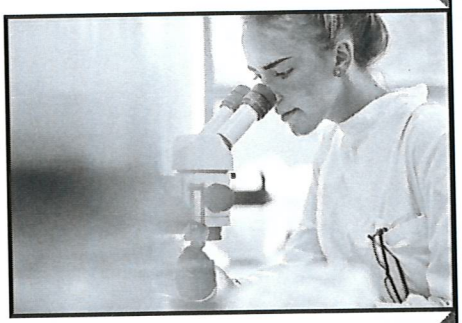
Women will be due for the first Cervical Screening Test two years after their last Pap test.



HOW WILL THE NEW CERVICAL SCREENING TEST WORK?

The new Cervical Screening Test detects human papillomavirus (HPV) infection, which is the first step in developing cervical cancer.

The procedure for collecting the sample for HPV testing is the same as the procedure for having a Pap smear. A Health Care Professional will still take a small sample of cells from the woman's cervix. The sample will be sent to a pathology laboratory for examination.



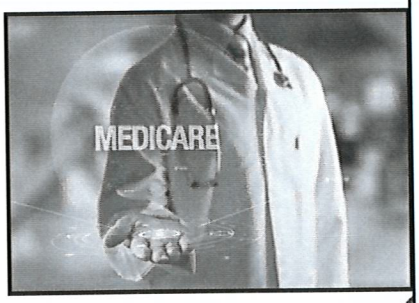
HOW WILL THE NEW CERVICAL SCREENING TEST WORK?

While the current Pap test can detect abnormal cell changes, the new Cervical Screening Test will detect the HPV infection that can cause the abnormal cell changes, prior to the development of cancer.

Persistent HPV infections can cause abnormal cell changes that may lead to cervical cancer. However, this usually takes a long time, often more than 10 years.

CAN I HAVE THE NEW CERVICAL SCREENING TEST NOW?

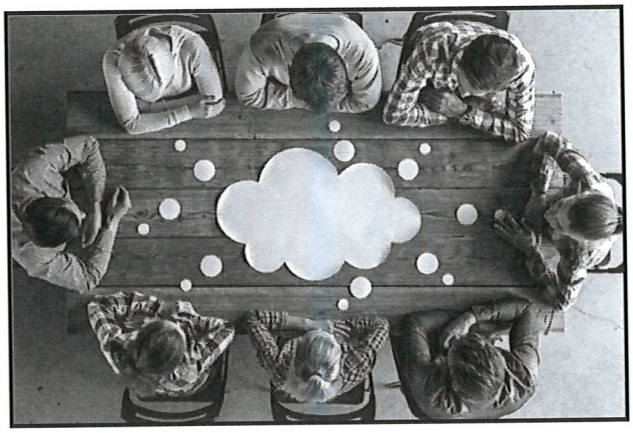
Women aged between 18 and 69 who have ever been sexually active should continue to have their Pap test when due.



The new Cervical Screening Test will be available on the Medicare Benefits Schedule from 1 December 2017. Until then, it is important to undertake two yearly Pap tests to prevent cervical cancer.

Women of any age who have symptoms (including pain or bleeding) should see their Health Care Professional immediately.

DISCUSSION



WHY WILL THE SCREENING AGE CHANGE TO 25?

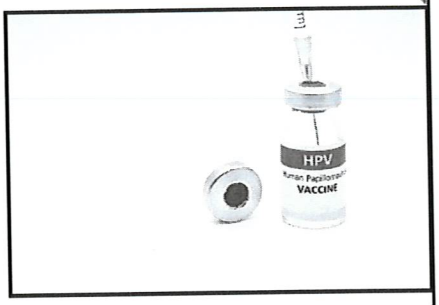
From 1 December 2017, women will be invited to screen from 25 years of age. This change is because evidence shows that:

- cervical cancer in young women is rare (in both HPV vaccinated and unvaccinated women)
- despite screening women younger than 25 years of age for over 20 years there has been no change to the rates of cervical cancer or rates of death from cervical cancer in this age group

WHY WILL THE SCREENING AGE CHANGE TO 25?

From 1 December 2017, women will be invited to screen from 25 years of age. This change is because evidence shows that:

- investigating and treating common cervical abnormalities in young women that would usually resolve by themselves can increase the risk of pregnancy complications later in life
- the HPV vaccination has already been shown to reduce cervical abnormalities among women younger than 25 years of age and, in contrast to screening, is ultimately expected to reduce cervical cancer in this age group.



SHOULD WOMEN UNDER 25 PARTICIPATE IN SCREENING BETWEEN NOW AND 1ST DEC?

The National Screening Program currently recommends that all women who have ever been sexually active should start having Pap smears between the ages of 18 and 20, or one or two years after first becoming sexually active, whichever is later.

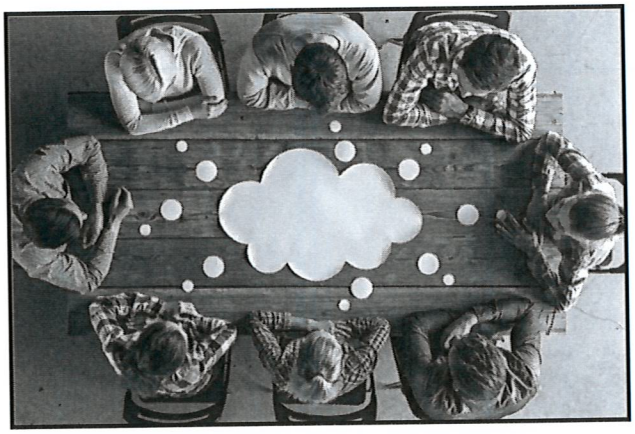
Until 1 December 2017, women are advised to continue screening in accordance with this policy however, if women have any questions about cervical screening and their individual situation they are encouraged to discuss these with their Health Care Professional.

WHEN SHOULD I STOP CERVICAL SCREENING?

Women between 70 and 74 years of age who have had a regular Cervical Screening Test will be recommended to have an exit HPV test before leaving the National Cervical Screening Program.

Women older than 69 years of age who have never been screened or not had regular screening tests should have a Cervical Screening Test if they request screening.

DISCUSSION



HOW WILL WOMEN BE INVITED TO SCREEN USING THE NEW CERVICAL SCREENING TEST?

From 1 December 2017, women aged 25 years or over who have not yet started cervical screening will receive an invitation to have the new cervical screening test.

The National Cervical Screening Register will send an invitation to women to let them know they are due for their test and also remind women if they become overdue for their regular test.

Women already participating in the program will be invited to screen within three months of the date when they would have been due for their two yearly Pap test.

WILL CERVICAL SCREENING PREVENT ALL CERVICAL CANCERS?

No. There is no effective population based screening test for rare neuroendocrine cervical cancers. Given the current state of scientific evidence, neither the current Pap test nor the new Cervical Screening Test (primary HPV test) can effectively detect rare neuroendocrine cervical cancers.

The changes to the National Cervical Screening Program from 1 December 2017 are based on new evidence and better technology and will improve early detection and save more lives.

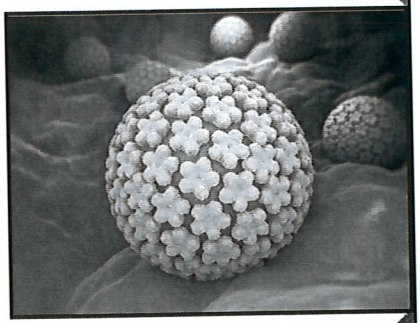
DISCUSSION

WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

The human papillomavirus (HPV) is a common infection in females and males.

Most people will have HPV at some time in their lives and never know it.

There are more than 100 different types of HPV that can affect different parts of the body. HPV types 16 and 18 are most commonly associated with cervical cancer. Genital HPV is spread by genital skin to genital skin contact.



WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

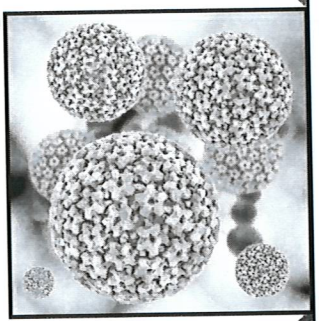
Most HPV infections clear up by themselves without causing any problems. Persistent genital HPV infections can cause cervical abnormalities, which, if they continue over a long period of time (more than 10 years), can lead to cervical cancer.

It is important to remember that most women who have HPV, clear the virus and do not go on to develop cervical abnormalities or cervical cancer.

HOW DID I GET HUMAN PAPILLOMAVIRUS (HPV)?

Genital HPV is spread through genital skin to genital skin contact. Condoms are an important barrier to many sexually transmitted infections, but offer limited protection against HPV as they do not cover all of the genital skin.

Because the virus can be inactive in a person's cells for months or years, for many people it is probably impossible to determine when and from whom HPV was contracted.

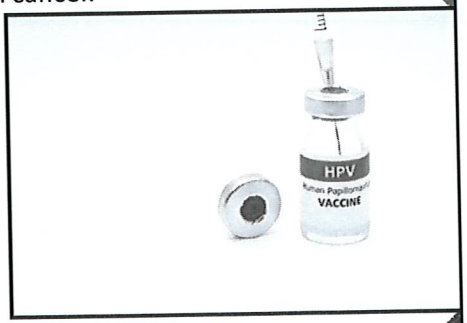


RELATIONSHIP BETWEEN HUMAN PAPILLOMAVIRUS AND CERVICAL CANCER

Persistent infection over many years with one or more cancer-causing types of HPV is the main cause of cervical cancer. In fact, 99.7 per cent of all cervical cancers are caused by HPV infection.

DO I STILL NEED TO SCREEN IF I HAVE RECEIVED THE HPV VACCINE?

Yes. The HPV vaccine does not protect against all types of HPV infection that are known to cause cervical cancer.



WILL THE NEW CERVICAL SCREENING PROGRAM REPLACE THE VACCINATION PROGRAM?

No. Eligible girls (and boys) should still be immunised to reduce transmission of HPV and help to protect the whole community against cervical cancer, as well as other HPV-related cancers such as throat and anal cancers.

DISCUSSION

Frequently asked questions

Why is cervical screening changing?

What should women do between now and 1 December 2017?

How will the new Cervical Screening Test work?

Can I have the new Cervical Screening Test now?

Why will the screening age change to starting at 25 years of age?

Should women less than 25 years of age participate in cervical screening between now and 1 December 2017 when the renewed Program is implemented?

How will women be invited to screen using the new Cervical Screening Test?

When should I stop cervical screening?

Will cervical screening prevent all cervical cancers?

What is human papillomavirus (HPV)?

How did I get human papillomavirus (HPV)?

What is the relationship between the human papillomavirus and cervical cancer?

Do I still need to screen if I have received the HPV vaccine?

Will the new Cervical Screening Test replace the vaccination program?

CHANGES

So just to summarise the changes are:

- Women will be tested using the HPV test rather than the Pap smear
- The time between tests will change from 2 to 5 years
- Screening will now start at 25 years, from 18 years previously
- Women aged 70 to 74 years will be invited to have an exit test

WHY IS CERVICAL SCREENING CHANGING?

- We now know a lot more about cancer than we did in 1991 when the cervical screening program started.
- New tests to pick up abnormal changes have been developed.
- The HPV vaccination has been offered to young girls since 2006 and young boys since 2012.

The decisions have been made based on:

- a thorough review of existing research about cervical screening
- a mathematical model built using information from the Australian population screening program

NATIONAL CERVICAL SCREENING REGISTER

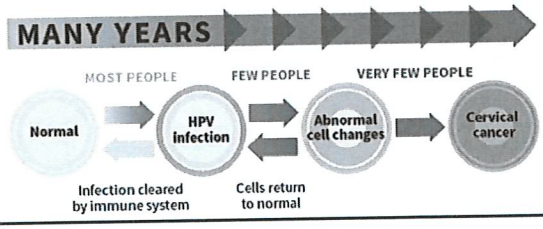
Women will be invited when they are due for their Cervical Screening Test via the National Cancer Screening Register

- The National Cancer Screening Register replaces the current registers in each state and territory
- Women who have ever received a Pap test will automatically be included on the register, but women can 'opt off' the register
- Women who have not had a Pap smear before will be invited through their Medicare enrolment
- Women can choose to be invited to screen by post, email or phone

CHANGE: TEST

The Pap smear, which tests for abnormal cells, will be replaced with the more accurate Cervical Screening Test

- The new test is testing for HPV (human papillomavirus)
- HPV is a virus that causes abnormal cells which can then lead to cervical cancer
- This test aims to pick up HPV before it causes abnormal cells
- This test is more accurate, more sensitive (correctly picking up positive results) and aims to better prevent cervical cancers



CHANGE: TEST

One way of comparing Pap smears and HPV testing is to calculate the negative predictive value of each test. This is the chance that a negative result from the test is truly negative.

Age group	Pap smear (cytology)	HPV test
Overall	99%	99.7%
Under 30 year olds	97.5%	98.7%

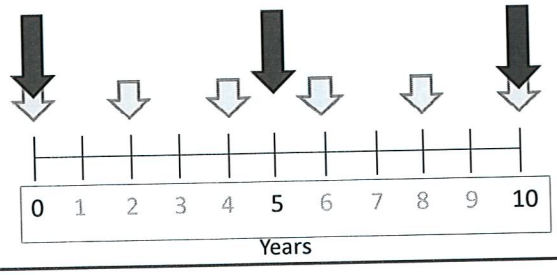
- This means we can be more confident in the results from the HPV test and there is less uncertainty

CHANGE: TIMING

- The time between tests will change from **2** to **5** years

Why is the timing changing?

- This is because the HPV test is more accurate and sensitive and so women do not need to be tested as often
- A woman whose test shows no HPV, is at very low risk of cervical cancer



Current screening program timing between tests

Renewed screening program timing between tests

CHANGE: AGE

18 YEAR OLDS

- The age at which screening starts will increase from 18 years to 25 years

Why change the age?

- The number of women under 25 getting cervical cancer is very low, less than 1 woman per 100,000 women
- The number of women under 25 dying from cervical cancer is even lower

We know the two yearly cervical screening program has shown:

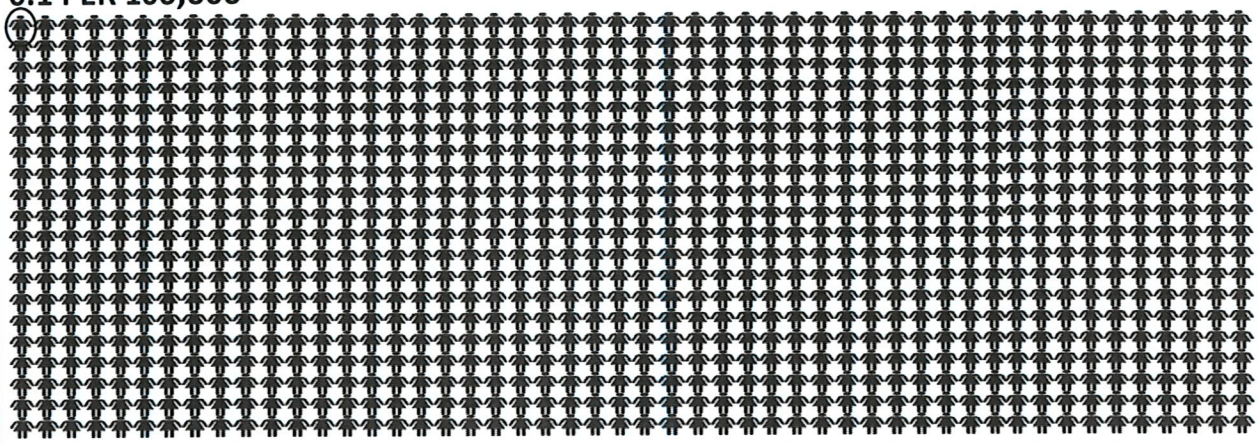
- **no** impact on the number of women under 25 getting cervical cancer
- **no** impact on the number of women under 25 dying from cervical cancer

25 YEAR OLDS

CHANGE: AGE

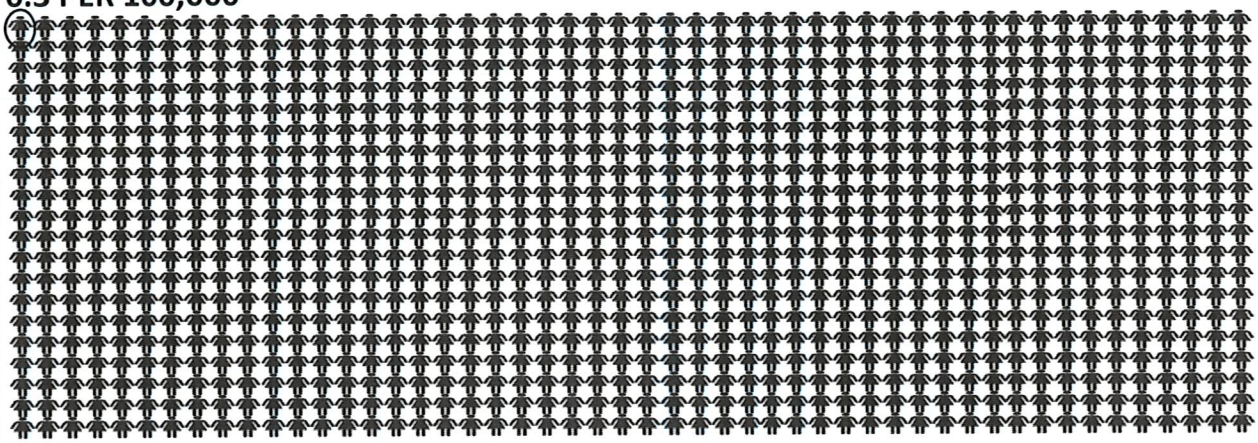
WOMEN AGED 15-19 DIAGNOSED IN 1990 (PRE-SCREENING PROGRAM)

0.1 PER 100,000



CHANGE: AGE

WOMEN AGED 15-19 DIAGNOSED IN 2012 (ORGANISED SCREENING PROGRAM)
0.3 PER 100,000



AGE CHANGE: EVIDENCE

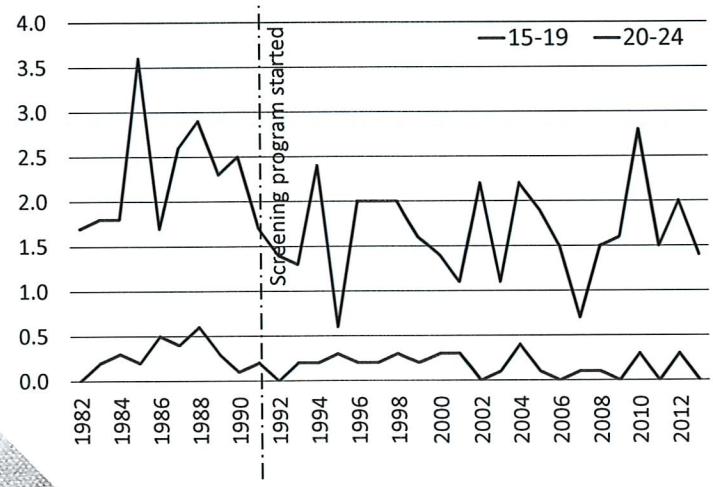
DIAGNOSED (PER 100,000)

Age group	1990 (NO SCREENING PROGRAM)	2012 (SCREENING PROGRAM)
15-19	0.1	0.3
20-24	2.5	2.0
40-44	22.8	13.0

DEATHS (PER 100,000)

Age group	1990 (NO SCREENING PROGRAM)	2012 (SCREENING PROGRAM)
15-19	0	0
20-24	0.1	0
40-44	5.5	1.7

AGE CHANGE: EVIDENCE



CHANGE: AGE

Why change the age?

- HPV is so common in women under 25, and most HPV infections clear by themselves
- This means many women would be sent for further tests that would be unnecessary, this is known as over-detection

Over-detection:

- many cervical abnormalities will regress (resolve by themselves) and others are so slow-growing that they will not become clinically important over a woman's lifetime
- offers no benefit and leads to unnecessary surveillance, diagnostic tests, and treatments with possible harms

EXIT TEST

Women aged 70 to 74 years will be invited to have an exit test

- An 'exit' test, is a test to identify women who are at low risk of cervical cancer
- This will test women for HPV and also look at tests done in the past
- A woman will be low risk and told she no longer needs to be in the screening program if her 'exit' test is negative
- If a women is positive for HPV, she will stay in the program and be monitored as per the screening pathway

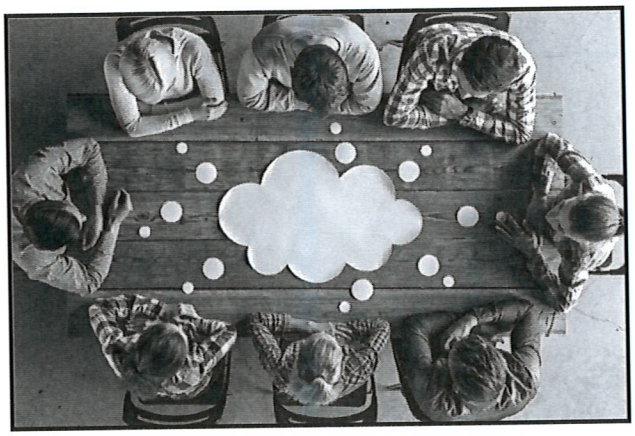
OLD VERSUS NEW PROGRAM

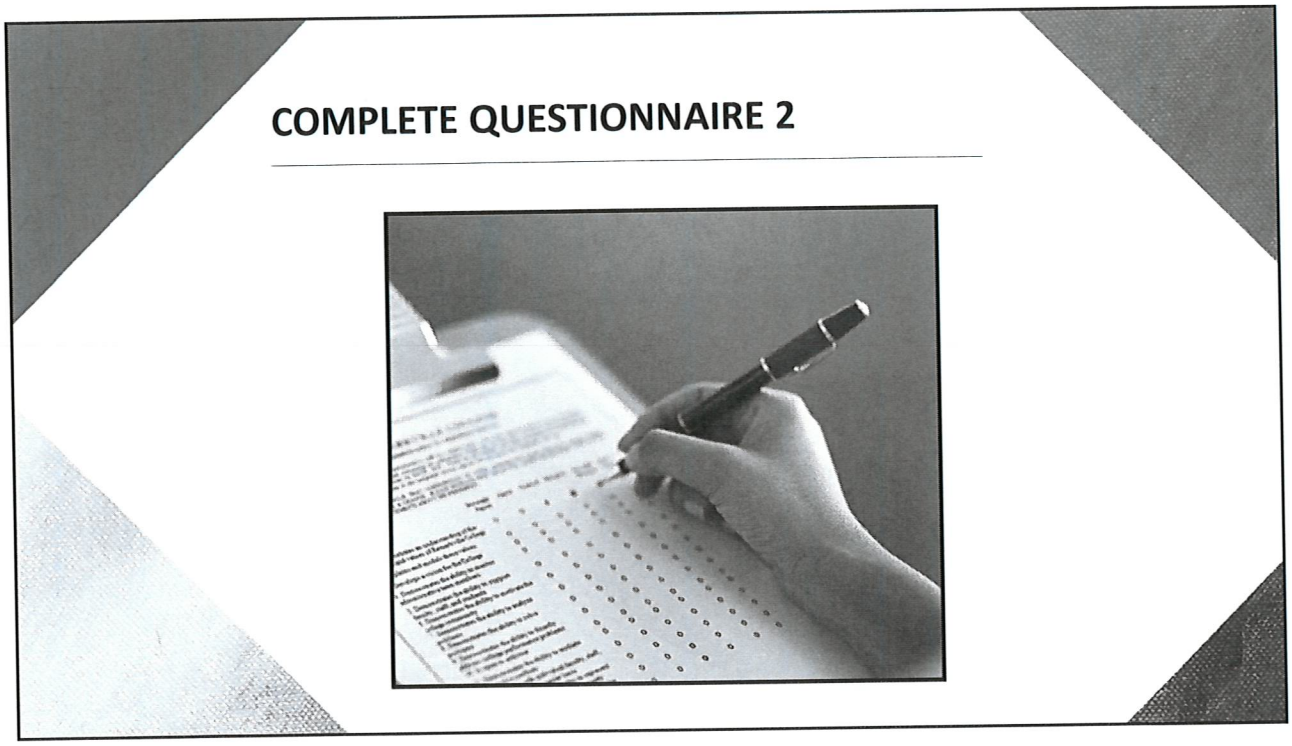
- In Australia, the number of women who are diagnosed with cervical cancer is **7** women in **100,000**, and the number dying from cervical cancer is **2** women in **100,000**
- The new program is expected to show further reductions by:
  - **31–36%** in number of women diagnosed or dying from cervical cancer in unvaccinated women
  - **24–28%** in number of women diagnosed or dying from cervical cancer in cohorts offered vaccination

WHAT HAPPENS IF I HAVE A POSITIVE HPV TEST?

High risk HPV16 or 18 found	• Check for abnormal cells by lab • Further investigation: colposcopy
Intermediate risk – other (not HPV 16/18) HPV found	• Check for abnormal cells by lab • Colposcopy if high-grade abnormalities • Repeat test after 12 months if no abnormal cells or low-grade abnormalities
No HPV found	• Risk of developing cervical cancer in next 5 years very low (lower than for Pap smear) • Screen again in 5 years

DISCUSSION




COMPLETE QUESTIONNAIRE 2

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
#2	Summary of the key elements of the study using the abstract format of the intended publication; typically	2

		includes background, purpose, methods, results and conclusions	
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4-5
Purpose or research question	#4	Purpose of the study and specific objectives or questions	5
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5-6
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research	8

		questions, approach, methods, results and / or transferability	
Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	18
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6-8
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6-7
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	9

Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	8
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	8
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	8
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	9
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	9-13
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	13

Limitations	#19	Trustworthiness and limitations of findings	3/17
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	18
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	18

Author notes

1. Title page page 1

BMJ Open

Examining the information needed for acceptance of de-intensified screening programs: qualitative focus groups about cervical screening in Australia

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Qualitative research
Keywords:	cervical screening, deintensification, information needs, QUALITATIVE RESEARCH

Examining the information needed for acceptance of de-intensified screening programs: qualitative focus groups about cervical screening in Australia

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Running title: Acceptability of de-intensified screening programs

Keywords: cervical screening, deintensification, information needs, qualitative research

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ABSTRACT

Objectives: Given the changing understanding of overdiagnosis of screen detected cancers and advances in technology to detect and prevent cancer, updating and scaling back cancer screening programs is becoming increasingly necessary. The National Cervical Screening Program (NCSP) in Australia was recently de-intensified, with changes implemented in December 2017. This study examines women's understanding and acceptance of the reduced screening protocol and how such changes can be communicated more effectively.

Design: Focus groups structured around a presentation of information about the reduced NCSP, with discussions of the information facilitated throughout. Qualitative data analysis was conducted.

Setting: Australia

Participants: Six focus groups were conducted in November 2017 with a community sample of 49 women aged 18-74.

Results

Women demonstrated little or no awareness of the upcoming screening changes in the period just before they occurred. Women expressed most concern and fear that the increased screening interval (from 2 to 5 years) and later age of first screening (from age 18 to 25 years) could lead to missing cancers. Concerns about exit testing were less common. Understanding of the natural history and the prevalence of both HPV and cervical cancer, and the nature of the new test (catching it 'earlier') was key to alleviate concerns about the increased screening interval.

Conclusions

De-intensifying screening programs should be accompanied by clear and coherent communication of the changes, including the rationale behind them, to limit concerns from the public and facilitate acceptance of reduced programs. In this case, understanding the biology of cervical cancer was crucial.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- These findings make an important and timely contribution to the potential communication strategies for countries updating their national cervical screening programs.
- The qualitative design of the study allowed us to explore in depth the views and understanding of women of eligible screening age, as well as observing how women communicated the reasons behind the changes to each other.
- As this was a qualitative study, we cannot express the findings as generalisable across the whole population and we could only include English-speaking women due to the nature of the methodology.
- Additional information may have helped reassure women further that there are processes in place for dealing with exceptional circumstances and it is not a one size fits all approach.

INTRODUCTION

Understanding of the benefits and harms of cancer screening programs has changed radically over the past 10 years with growing evidence of overdiagnosis and overtreatment of screening detected cancers.[1,2] As health technology advances to offer new screening tests, treatments and methods of cancer prevention (eg vaccination), the need to review and update screening programs to ensure the benefits outweigh the harms has never been more pressing. Wilson and Jungner provided a set of principles to guide the practice of screening for disease, based around early detection and treatment,[3] and already four decades ago, recognised that we must avoid causing harm to those who do not need treatment. There is now an increased focus on ethical principles and acceptability when developing or refining existing screening programs,[4] and awareness that screening programs may need to be de-intensified to ensure health benefits outweigh potential harms such as overdiagnosis and overtreatment as evidence changes.[5]

A recent example of de-intensification of cancer screening comes from Australia, where the National Cervical Screening Program (NCSP) was revised in 2017 to include an older age of invitation for screening, less frequent testing and primary HPV screening (Table 1). A national school-based program for the HPV vaccination was introduced in 2007 for school-aged girls (aged 12-13) plus a 2 year catch up program for girls aged 13-26 and in 2013 for school-aged boys. Current national uptake rates for 3 doses are 80.2% for females and 75.9% for males. [6] The changes encompassed new recommendations based on evidence of potential harms attributed to the previous screening regimen,[7] as well as the changing landscape due to the uptake of the human papillomavirus (HPV) vaccination and the development of new screening technology.

Table 1: The changes implemented to the Australian National Cervical Screening Program on 1st December 2017 [6]

Change	New program (2017 -)	Old program (1991-2017)
Test technology	The Cervical Screening Test takes cells from the cervix to test for HPV infection	The Pap test took cells from the cervix and examined these cells for physical

		changes
Interval	The Cervical Screening Test is every 5 years	A Pap test every 2 years
Age	Women will be invited for a Cervical Screening Test from the age of 25 years	Cervical screening began at 18 years of age
Age	Women will have their last Cervical Screening Test ('exit test') between 70 and 74 years of age	Cervical screening ended at 69 years of age
Screening pathway: HPV negative result	Screen again in 5 years' time	-
Screening pathway: HPV positive (16/18)	Test cells using liquid-based cytology and refer for colposcopy	-
Screening pathway: HPV positive (other type)	Test cells using liquid-based cytology 1) If cells normal or low-grade changes, screen again in 12 months 2) If high grade cell changes, refer for colposcopy	-

Research has shown internationally that public responses to reducing cancer screening programs has been very negative;[8] most notably in the US, where proposed changes to breast screening in 2009 were ultimately retracted due to the public backlash.[9] Our own research to the proposed changes to the Australian NCSP identified strong concerns about the increased interval between cervical screens [10,11] principally due to the perception that this would miss cancers and put women's lives at risk.

When implementing any major revisions to a screening program it is important to understand how best to communicate the changes so that people understand and accept the reasons behind it, and to ensure their confidence in the program is not undermined. If the changes involve de-intensification of screening this is particularly important. The changes to the Australian NCSP provided a timely opportunity to explore women's reactions to de-intensifying a cancer screening program and to examine how the reasons for these changes could be effectively communicated. The study aimed to explore women's understanding of the reduced program and its acceptability, with the view of generating insights to guide communication about de-intensification of future national screening program changes in other countries.

METHODS

Participants

The focus groups were conducted with a community sample of Australian women aged 18-74; those in the age range for which the NCSP (prior and renewed program) is the most relevant.

Participants were contacted via telephone by a fully independent market and social research company (Taverner Research), who used random landline and location known mobile samples from Sydney. To gain a diverse range of perspectives, we used purposive sampling to ensure inclusion of women with varying levels of education and prior participation in screening (including women up-to-date and overdue for screening in all age groups). We excluded women not fluent in English and women who had ever personally been diagnosed with cervical cancer. Taverner interviewers briefly introduced the study, assessed eligibility and availability, and asked respondents whether they would be willing to receive more information about the study. Eligible women who had verbally agreed to being contacted by the research team were emailed a Participant Information Statement and Consent Form. RD contacted potential participants to confirm their interest and eligibility and confirmed participation in the focus groups.

Design

Six focus groups were conducted at three locations across Sydney, with 5-10 women in each group, to explore the views towards the reduced Australian NCSP among women of screening eligible age. Data collection took place in November 2017. Focus groups were facilitated by RD and included an additional researcher as a moderator (BN, SW, CB, JH). Participants were given a $A100 gift card for reimbursement towards time and travel costs.

The focus groups were structured around a presentation of the changes to the NCSP and the rationale for these changes in order to facilitate discussion about what information is important to communicate

to women to enable them to understand about the changes. This format gave participants the opportunity to ask questions and discuss the changes amongst themselves throughout. This enabled us to identify areas which may need to be communicated more clearly and to explore how women themselves understood and then explained the changes which were of particular concern to each other.

The groups were split according to age (18-30 year olds, 31-50 year olds and 51-74 year olds) as it was anticipated that views and preferences for information might vary as the changes to the screening program differed by age group.

Patient and public involvement

We involved a consumer representative (patient advocate) from Health Consumers New South Wales in developing and reviewing study materials, as well as piloting the focus groups. A patient advocate and members of the public were involved in piloting of the materials and study participants were community women recruited from the general Australian public. A lay summary of the results will be sent to all participants who indicated they wanted to receive these.

Presentation and discussion content

The presentation (Supplementary material) was developed by the research team, which included a consumer representative and was reviewed by an independent expert team of researchers and clinicians. A summary outline of the presentation is included in Box 1. This presented the information available on the Australian Department of Health NCSP website [12] at the time of development (September/October 2017) about the changes to the NCSP. We also presented some information developed by the research team to put some of the information into context; for example, presenting women with figures of incidence and mortality since the NCSP had been introduced and explaining the accuracy of the HPV test compared to the Pap test.

Box 1: Outline of the presentation

1. Introduction to the renewed National Cervical Screening Program – information taken from the Department of Health website (accessed September/October 2017)
2. Concerns already raised by women about the changes
3. Answers to frequently asked questions
    a. Why is cervical screening changing?
    b. What should women do between now and 1 December 2017?
    c. How will the new Cervical Screening Test work?
    d. Can I have the new Cervical Screening Test now?
    e. Why will the screening age change to starting at 25 years of age?
    f. Should women less than 25 years of age participate in cervical screening between now and 1 December 2017 when the renewed Program is implemented?
    g. How will women be invited to screen using the new Cervical Screening Test?
    h. When should I stop cervical screening?
    i. Will cervical screening prevent all cervical cancers?
    j. What is human papillomavirus (HPV)?
    k. How did I get human papillomavirus (HPV)?
    l. What is the relationship between the human papillomavirus and cervical cancer?
    m. Do I still need to screen if I have received the HPV vaccine?
    n. Will the new Cervical Screening Test replace the vaccination program?
4. Further information about the changes developed by the research team
    a. Why is cervical screening changing?
    b. National Cervical Screening Register
    c. Change: Test
    d. Change: Timing
    e. Change: Age
    f. Exit test
    g. Old versus new program
    h. What happens if I have a positive HPV test?

Throughout the group discussions, women were encouraged to share their thoughts about the information presented and how easy they found the information to understand. The presentation content and types of questions we used to guide the discussions is summarised in supplementary information. We also encouraged women to ask questions throughout, while making it clear that we would initially be simply noting down the questions and would answer any questions still outstanding (i.e., not answered by the intervening information presented) at the end.

Analysis of qualitative data

All sessions were audio recorded and professionally transcribed verbatim. Transcribed focus groups were managed using NVivo 11.[13] Thematic analysis was conducted to identify main themes that

captured the views of women about the changes to the NCSP, and which information presented was found to be reassuring about particular concerns or helped them understand the rationale for the changes. The initial coding framework was developed by RD, with input from KM.

The same framework was used by two researchers (RD and BN) to analyse three transcripts each for themes and codes which focused around women's understanding of the rationale behind the changes to the NCSP. These themes and codes were developed and applied to the data, and through numerous meetings an agreement was made on the overarching concepts that were important for women's understanding and acceptance of the changes and the information they needed to address concerns. The framework with which to interpret the data was discussed with KM, and the broader project team had input into the interpretation of the results. The research team members work in the field of public health, with a special interest in reducing overdiagnosis and overtreatment.

Quantitative measures

Brief written questionnaires were administered before and after each focus group. The first questionnaire included demographic questions, questions about cervical cancer and cervical screening, and intentions to go for cervical screening in the future. The second questionnaire (following the presentation) aimed to assess what knowledge and understanding women had taken from the focus groups using a series of multiple-choice items developed for this study, and again asked their intentions to go for cervical screening in the future. These are reported descriptively in the manuscript.

RESULTS

Sample characteristics

Forty-nine women participated in six focus groups (Table 2). Forty-one had previously attended for cervical screening, with eight not yet having been invited. Of the 41 who had attended screening, 28 were up-to-date and 13 were overdue. The sample was diverse with regards to education, employment

and country of birth. Focus groups lasted between 71 and 103 minutes. A minority of women verbally indicated they had heard something about the changes being made to the NCSP, with the increased interval between tests and later starting age most commonly remembered by those women.

Table 2: Sample characteristics

Sample (n=49)	n (%)
Age	
18-30 year olds	16 (32.7)
31-50 year olds	13 (26.5)
51-74 year olds	20 (40.8)
Marital status	
Married/living with partner	23 (46.9)
Divorced/separated	8 (16.3)
Widowed	1 (2.0)
Single	16 (32.7)
Missing	1 (2.0)
Children	
Yes	24 (49.0)
No	24 (49.0)
Missing	1 (2.0)
Family history of cervical cancer	
Yes	1 (2.0)
No	46 (93.9)
Missing	2 (4.1)
Country of birth	
Australia	30 (61.2)
Europe	5 (10.2)
Asia	10 (20.4)
Other	4 (8.2)
Education	
University degree	22 (44.9)
Diploma or trade certificate	10 (20.4)
High school certificate	11 (22.4)
School certificate	3 (6.1)
Missing	3 (6.1)
Employment	
Working full time	20 (40.8)
Working part time	12 (24.5)
Retired	10 (20.4)
Not in paid work	6 (12.2)

Missing	1 (2.0)
Last Pap smear	
Up-to-date (< 2 years ago)	28 (57.1)
Overdue (2+ years ago)	13 (26.5)
Missing	8 (16.3)

What information addresses women's concerns?

Following the education session about the changes to the program, we present the three key concepts that were a) important for women to understand and accept the program changes b) that women found reassuring about their particular concerns: 1) Natural history, 2) Incidence and 3) Transition to the new program (NhIT).

1. Natural history and slow development of cervical cancer

Women were concerned and confused about what it means to have HPV, the increased interval between screening tests, and the new test. They were reassured by information explaining the natural history of cervical cancer, particularly the time it takes for HPV to develop into cervical cancer.

Knowledge of HPV among women was fairly low, even in the focus groups with younger women where many of the women had received the HPV vaccine in school. Women had many questions about HPV, including how it is transmitted and whether it is cleared from the body or lies dormant.

Some of the focus groups likened HPV to cold sores or herpes. Giving women information about HPV helped them realise that HPV was very common and not serious unless it progresses. The information also helped women understand that their immune system can clear HPV by itself, often without intervention (Q1; Table 3). However, for a couple of women, this information led them to wonder if it was worth having the test at all if HPV was not that serious and the incidence of cervical cancer was so low (Q2).

Women's concerns about the screening interval focused mostly on the potential of 'missing cancers' due to the time between tests being increased. Understanding that HPV caused most cervical cancers, and that the virus can take around 10 years to develop into cervical cancer, helped to reassure women (Q3).

The new HPV test was referred to in the government-provided program renewal information as the 'cervical screening test' and it took some time during the focus groups for women to realise that the test was going to be different in the new program. Women's concerns about the new test were around whether it was safe, accurate and they wanted more information. Once women understood that the new test was to detect HPV, which causes most cervical cancers, women were reassured that this test was detecting something earlier, 'like a step ahead' (Q4).

Women from most focus groups understood the information about the natural history of cancer and used this to interpret the rationale behind the increased screening interval (Q5). Some focus group participants quickly grasped the process of the new test and explained this in a simple way to each other (Q6).

Older women in the sample expressed concern about the exit test, about what this meant for them and why it was decided women would leave the program between 70 and 74 years of age. Information about the slow progression of cervical cancer helped to reassure women about the reasons for the exit test (Q7).

Table 3: Quotes from focus groups to support the themes

Code	Reference	Page
Q1	"But for me it almost kind of dumbed down the reason for the test. You can get it, you have to be sustained, right, persistent exposure to the virus before you get the full cancer, cervical cancer. And also you might clear itself in many cases. So it's actually very reassuring that it's not that serious a condition. That's what I got from that really." (FG6, 31-50 years old)	11
Q2	"The only one thing for me is like they actually, again dumbed down the seriousness of HPV to me. 'Cause 2 women in 100 000, I was like, oh, that's not too bad. So you're going to screen the whole of the nation of women to detect two possibilities in 100 000. That's what I got from that." (FG6, 31-50 years old)	11
Q3	"Well, I guess if it takes a long time, up to 10 years, for the HPV virus to affect the	12

	cells then you might detect it in a year and then it's going to be a number of years until it actually affects you." (FG2, 18-30 year olds)	
Q4	"But now it's going to pick up the… the infected, um, HPV infection before it gets to abnormal cells." (FG1, 51-74 year olds)	12
Q5	"It's looking for different cells which take, is it 10 years to develop into a cancerous cell, which kind of makes sense to have it every 5 years. Um, to test it every 5 years 'cause if it's going to develop it's already half way developed and not even to a cancerous cell." (FG5, 18-30 years old)	12
Q6	"Ok. So everyone will get HPV testing, then if they find specific strains then they'll look for [abnormal] cells." (FG2, 18-30 year olds)	12
Q7	"I understand the 70-74 now because they say it doesn't develop for 10 years anyway. And once they make sure that the 70-74 year olds are safe before they even exit." (FG3, 31-50 year olds)	12
Q8	"…the way we live our life has changed and I think younger people really aren't as, um… aware, I think, of their well-being and how important it is when they are young. And how quickly we grow old." (FG1, 51-74 year olds)	13
Q9	"Maybe they weren't finding as many… cancer diseases under the age of 25?" (FG5, 18-30 year olds)	14
Q10	"I felt the, the thing that made me a bit calmer though was that it said that there's been no change in, um, deaths or, um, I think picking up cancer in women aged 20-25 or something since they've had a screening program. So it made me feel a bit calmer about moving the age to 25. Seems legit." (FG2, 18-30 years old)	14
Q11	"I think because it clears up on its own. So I think there was that point about over-detection, so it does clear up. So if you are tested every two years and you have it then it could, if like… then they might, they might, um, treat it. But it might, would have cleared up on its own potentially." (FG2, 18-30 year olds)	14
Q12	"Can I just ask why it cuts out at 74? Is the incidence low, or it's just too painful, or it's not worth it?" (FG4, 51-74 year olds)	15
Q13	"The actual procedure is exactly the same for the patient, I guess you can say. The person being tested. And it's just what happens after that's changing." (FG2, 18-30 years old)	15
Q14	"But if you go and something is detected, um, do you have to wait 5 years for them… like if they think something's detected will we have to wait for another 5 years for them to say, oh yes, something has been detected now, but it may have been there before but we don't know, sort of thing? How that's going to sort of go?" (FG5, 18-30 year olds)	15

2. Incidence of cervical cancer

Women in the younger age groups were mainly concerned about the later start age, whereas women in the older age groups were concerned about both younger and older women, and also concerned that young women were not as aware of their health as they should be (Q8).

All women considered younger women to be more sexually active from an earlier age 'these days', and were therefore worried about the time between young women commencing sexual activity and their first screening test, as they perceived them to be at greater risk of developing cervical cancer earlier.

When speculating about reasons for the later starting age, one focus group considered the number of cases in women under 25 (Q9). Crucially, presenting women with incidence data of cervical cancer in Australia showing that cervical cancer in young women was very rare (in both HPV vaccinated and unvaccinated women) and that despite screening women younger than 25 years of age for over 20 years there has been no change to the rates of cervical cancer or rates of death from cervical cancer in this age group, was key to help reassure women about the later start age of screening (Q10).

The rationale for the later starting age presented information about overdetection and one group discussed this further with questions about how HPV clears itself without need for treatment sometimes (Q11). This led some women in the group to consider the harms of immediate treatment, but in other focus groups surprise was conveyed about overtreatment and there was confusion about at what age it was better to monitor to see if abnormalities resolve themselves. Once it was explained, women did understand that the cells often got better without intervention but there was confusion about why this varied with age.

The women in the younger (18-50) age groups also expressed a desire for more evidence and more data around the incidence of cervical cancer and liked the additional graphs and tables that were included on the slides developed by the research team (see supplementary information).

The two older age groups spent longer discussing the exit test than the younger age group. One group found it interesting how cervical screening contradicts their understanding of screening for other cancers (e.g. breast and bowel), such that you get more screening as you get older (despite both these screening programs also stopping screening by 74 years of age), not less. Many of the women also tried

to process the information about the exit test and what this may have meant about cervical cancer incidence in older women, wondering if the incidence is low and therefore not worth it for older women (Q12).

3. Transition to the new program and the screening pathway

Many women expressed concern and confusion over how they, and other women, transition from the old to the new program. Some women were unsure whether they would have another Pap test, or whether they would go straight to having a cervical screening test at their next test (if after December 1st 2017).

One woman explained that information may be important for those women who will be most affected by the transition period, namely women under 25 who have already received cervical screening, and also those older women who will no longer be eligible for screening in the old program, but whom might now be invited for an exit test.

Women were reassured by the information that they should still go for their next screening test two years after their last test, but that this will be the new cervical screening test and providing their results were normal they would not be invited back for another five years. It was also important to make it clear to women that although the test would be different, the procedure for collecting the specimen would be exactly the same (Q13).

Many women initially wanted to know what happened after the test, as the information from the Department of Health did not give any information on the screening pathway (Q14).

How to communicate these changes?

In terms of how to communicate these changes, verbal explanations from your general practitioner (GP) and through schools were suggested across all groups. Additionally, younger age groups suggested

focusing communication more through social media (e.g. Facebook, Instagram), websites and email, and the older age groups through posters, TV adverts and public awareness campaigns.

Quantitative data

Prior to the focus groups, in response to short questions about the NCSP and their intentions to screen, 62% (n=29) of women correctly responded that they were in the age eligible for cervical screening and 81% (n=38) of women correctly responded how often women are invited (Table 4). Almost 90% (n=42) of women intended to go for cervical screening in the future.

Table 4: Responses to questions about the cervical screening program before and after the focus groups

	n* (%)
Prior to focus groups (old screening program)	
Are women your age eligible for free cervical screening? (Yes, no I'm too young or no I'm too old) Yes	30 (63.8)
How often are women invited to attend? (Every 1, 2 or 3 years) Every 2 years	38 (80.9)
Do you intend to go for cervical screening in the future (when you do not have symptoms)? Yes	42 (89.4)
After the focus groups	
When should you go for cervical screening? (healthy or when noticed symptoms) When healthy	25 (59.5)
When are the recommendations for cervical screening changing? (1st Oct or 1st Dec) 1st December 2017	49 (100)
What age will women be invited for cervical screening after the changes? (18, 20, 25 or 30 years of age) 25 years of age	46 (95.8)
How often will women be invited for screening after the changes? (Every 1,2,3,5 or 7 years) Every 5 years	48 (98)
Will the experience of cervical screening be the same for women after the changes? (Y/N) Yes	48 (98)
Will the sample taken from the cervix be tested in the same way after the changes? (Y/N) No	32 (68.1)
The sample from the cervix will be testing for: (abnormal cells or HPV) HPV	40 (97.6)
Do you intend to go for cervical screening in the future (when you do not have symptoms)? (Y/N)	

Yes	46 (95.8)

*n represents the number of women who chose the correct answer for all items apart from intentions for screening in the future

Following the presentation of information about the changes, all women correctly answered when the changes were taking place, with most (>95%; n=46-48) correctly responding to questions about the age of invitation, screening frequency, that HPV will be tested for, and that the experience will be the same for women after the changes. Fewer women correctly responded that the sample would be tested differently (68%; n=32). Of note, less than 60% (n=25) of women were aware that you should go for screening when you are healthy, with 36% (n=15) believing you should go for cervical screening when you notice abnormal changes. In total, 96% (n=46) of women intended to screen in the future.

DISCUSSION

This study showed women had little awareness of the changes to the NCSP just prior to their implementation in December 2017. Women expressed concern about the increased screening interval and later age of first screening because of fears about missing cancer, consistent with our previous research.[10,11] Concerns about exit testing were less commonly expressed. However, following the information presented, and given the opportunity to discuss among their peers, many participants understood and accepted the reasons for these changes. The findings suggest that if information and the rationale for change is presented clearly women will likely accept de-intensified screening programs. This has implications for national programs worldwide and for screening programs broadly as well as for cervical screening in Australia.

Clear communication to the public about changes to cervical screening programs, and what these changes may mean for them, needs to be developed in light of these findings. There also needs to be clear guidance for future changes to cervical screening programs, which address the differences between the two tests, making it clear that the test is now detecting a virus prior to abnormal cells. Women need to be aware of what HPV is and how it is linked to cervical cancer, including the slow

progression of HPV to cervical cancer and the high chances of regression. Importantly, women also want to see evidence behind the changes, such as the incidence of cervical cancer, to reassure them about the changes to screening age targets. Women discussed these concerns within the focus group sessions, and how they processed the information about the natural history of cervical cancer helped them to understand the reasons for the changes in screening interval and the screening test itself.

Our analysis showed that women found certain pieces of the information presented to them useful and reassuring to justify the changes (Natural history, Incidence and Transition to the new program). The findings from this study demonstrate the fundamental information women extracted to help them make sense of the changes and provides important insights into the lay language women used to explain the changes to each other, which can be used in developing guidance for communication strategies. Overall, women in all age groups expressed similar concerns, but the older women expressed more concern and confusion about the reasons for the exit test, demonstrating areas where communication could be tailored to different age groups. Both groups of women were concerned about what the changes would mean for the younger age groups. The majority of women still intended to screen following the information, demonstrating their continuing confidence and trust in the program.

Most of the information presented to women was new, with their views towards screening shaped by the many years of messages focused on the importance of attending screening and that early detection is key in reducing deaths from cancer. These reactions are not surprising given that research has shown a high public enthusiasm for screening,[14,15] with 56% cervical screening uptake in women aged 20-69,[16] women have spent much of their lives being told about the importance of having regular screening and early detection, and believe 'more care is better care'.[17] Awareness of HPV among the general public has been found to be limited in many previous studies,[18,19] with women in this study being similar. Equipping women with the information about HPV and that the new test was now going to detect infection with the virus, which was seen to be a 'step ahead', was reassuring. Practical information for women, so they

could evaluate what this would mean for them, was important, specifically knowing that the procedure of the test would be the same, and that the difference lies in how the sample is tested.

The information presented from the Department of Health website [20] did not specifically mention over-detection but mentioned the possibility of investigating and treating common cervical abnormalities that would usually resolve. The public can be confused by concepts such as overdiagnosis and it has the potential to undermine trust in screening programs.[21] Over-detection was briefly mentioned in the information developed by the authors, when talking about the later starting age for screening, with regards to cervical abnormalities regressing and the possibility of overtreatment, which can lead to obstetric complications. This concept was not attended to much by women in the focus groups, with surprise expressed in those who did. It was clear that the concept of regression of cervical abnormalities was not well understood and needs explanation for women.[21]

Screening programs will continue to need reviewing to ensure benefits outweigh harms and are deemed acceptable to the population, as stated by Wilson and Junger.[3] Findings from this study can be used to consider processes for de-intensification of screening programs in the future and how to develop communication strategies so that changes to screening programs are deemed acceptable to the population. Evident at all stages of the principles of screening is the importance of maintaining public confidence;[3] strategies for communicating these changes and the reasons behind them in a reassuring way, will help maintain public confidence. Formal invitations for cervical screening through the national register may provide an ideal opportunity for educational information to be distributed alongside the invitations.

These findings demonstrate key information which could be applied to other screening programs to aid in public understanding about changes to screening programs. Information about the natural history of the cancer, in addition to information about the prevalence and risks of disease and how to transition

from the old to the new program (NhIT), presented in a clear format, can help the public to understand the reasons for these changes and alleviate concerns. Other countries needing to design communication strategies for deintensified screening should consider involving members of the public in their development to ensure the information presented is meeting information needs and ensuring confidence in the screening program is maintained. Further quantitative research is needed to test optimum formats for presenting this information.

Elimination of cervical cancer could be a real possibility in the future,[22,23] particularly in Australia where the successful school-based HPV vaccination program for girls and boys has shown significant reductions of incidence in the vaccine related HPV genotypes which are high risk types for cervical cancer.[24,25] Additionally, the recent approval and implementation of the nonavalent vaccine is likely to reduce the incidence of HPV further.[26] Therefore, there is the possibility within our lifetime that the NCSP may be phased out entirely.[23] However, in the meantime it is necessary to communicate that screening is still important, but that there are potential harms associated with cervical screening, such as overtreatment of abnormalities that may otherwise spontaneously resolve. Information about overdiagnosis has been shown previously to be met with confusion or scepticism.[27] Future studies may be best placed to focus on reducing overtreatment of cervical abnormalities, particularly in those women of child bearing age who are most at risk of obstetric complications.[28] Future research also needs to explore the impact of the reduced screening program on clinical practice, both at the GP level and referral rates.

These findings make an important and timely contribution to the potential communication strategies for other countries updating their national cervical screening programs. The content presented in the focus group sessions represented information available to women at the time and was developed by a multidisciplinary team including a consumer, and reviewed by both clinical independent experts and pilot tested with consumers. The qualitative design of the study allowed us to explore in depth the views and understanding of women of eligible screening age, as well as observing how women communicated

the reasons behind the changes to each other. This gave valuable insight into what information is important for reassuring women about the changes.

Recruitment of women through an independent market and social research company enabled the participants to vary in age, education, prior screening and ethnicity. Almost 40% of the sample were born outside of Australia. As this was a qualitative study, we cannot express the findings as generalisable across the whole population.

There were a few aspects that women asked about which were not addressed during the presentation, such as whether there are different screening recommendations for specific population subgroups including women with a family history of cervical cancer, women who had become sexually active at a young age, and immunosuppressed women. We did not want to overload women with information and our research aim was to find out what women understood about the changes following the presentation. Some of these points were raised throughout the sessions, and therefore were talked about at the end, and it may be that this additional information helped reassure women further that there are processes in place for dealing with exceptional circumstances and it is not a one size fits all approach.

Conclusions

Most of the information presented to women in these focus groups was new to them. Key pieces of information about the natural history, incidence of cancer and how to transition across the programs (NhIT), helped explain the reasons behind the de-intensification of the Australian NCSP and can be applied to other screening programs. This can be provided to women in a concise and accessible format accompanying invitations to cervical screening in the future. These findings can be used on a broader level to develop a framework for developing communication strategies around future changes to screening programs.

Ethics approval and consent to participate: The University of Sydney Human Research Ethics Committee reviewed and approved this study (project number 2017/489). Participants' written consent was collected prior to the start of each focus group.

Availability of data and materials: No additional data available.

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Conflict of Interest: The authors declare no conflict of interest.

Author contributions: RD and KM conceived the study. RD, SW, CB, JH and KM were involved in designing the study and developing the methods. RD coordinated the running of the study and conducted the focus groups, together with BN, SW, CB and JH. RD and BN read transcripts, developed the analytical framework, and contributed to the analysis. RD drafted the manuscript. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

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Supplementary material: Focus group presentation topics and key discussion questions

Introduction to the changes to the cervical screening program

- Had anyone heard anything about this before today?
- Do you feel that you understand the information I have just presented?
- What are your thoughts on what I have just presented?

List of advantages and concerns about the changes generated by women

- What do you want to know to make you feel comfortable with the changes? Is there any more information you would like?

Presentation of concerns expressed in an online petition about the changes to the program

- Has this information prompted any more thoughts?

Presentation of further information about the changes

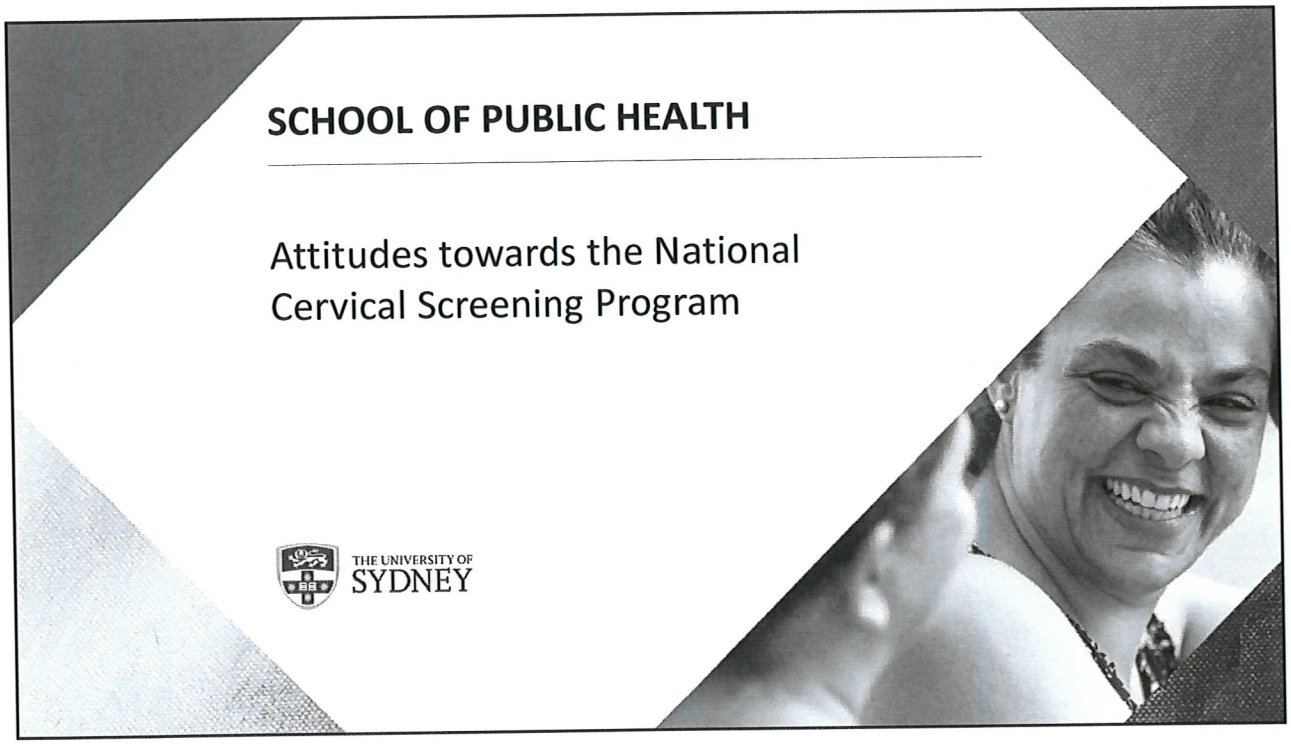
- Did anyone have any thoughts or questions about what I have just presented? (asked at regular points throughout presentation)
- Was the information easy to understand?
- Is there any other information you would have liked?

Following all information presented from the Department of Health website

- How easy or hard do you think it is for people to understand the reasons for these changes?
- Do you have any ideas about how best to explain the reasons for these changes to other people?
- What could be added, removed or changed from the information I presented to you?
- How would you suggest the expansion or scaling back of screening programs are handled in the future?
- When should the public be informed of a change in policy?
- How should this information be communicated to people?
- After the information you've heard today, how will you feel when you receive your invitation for cervical screening in future?
- Has your intention to attend cervical screening changed at all because of today's session?

Presentation of alternative slides giving evidence about the changes

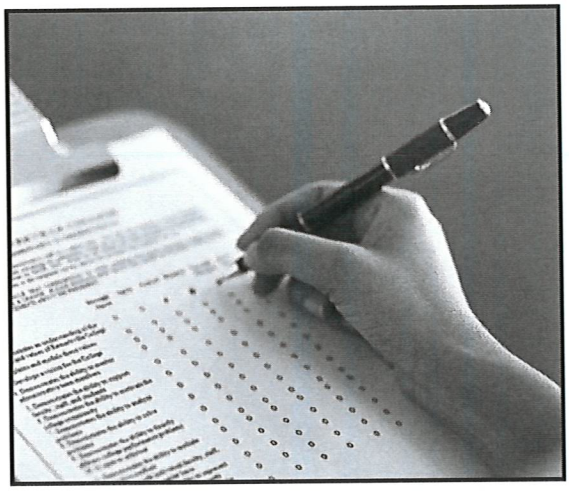
- How does this information compare with the information already presented?
- Was the information easy to understand?
- Did you have a preference over how the changes were explained to you?



INTRODUCTION

- Welcome
- Who we are
- Set-up of session
- General introduction
  - What we are going to do
  - Recording
  - Ground rules
- Any questions from you

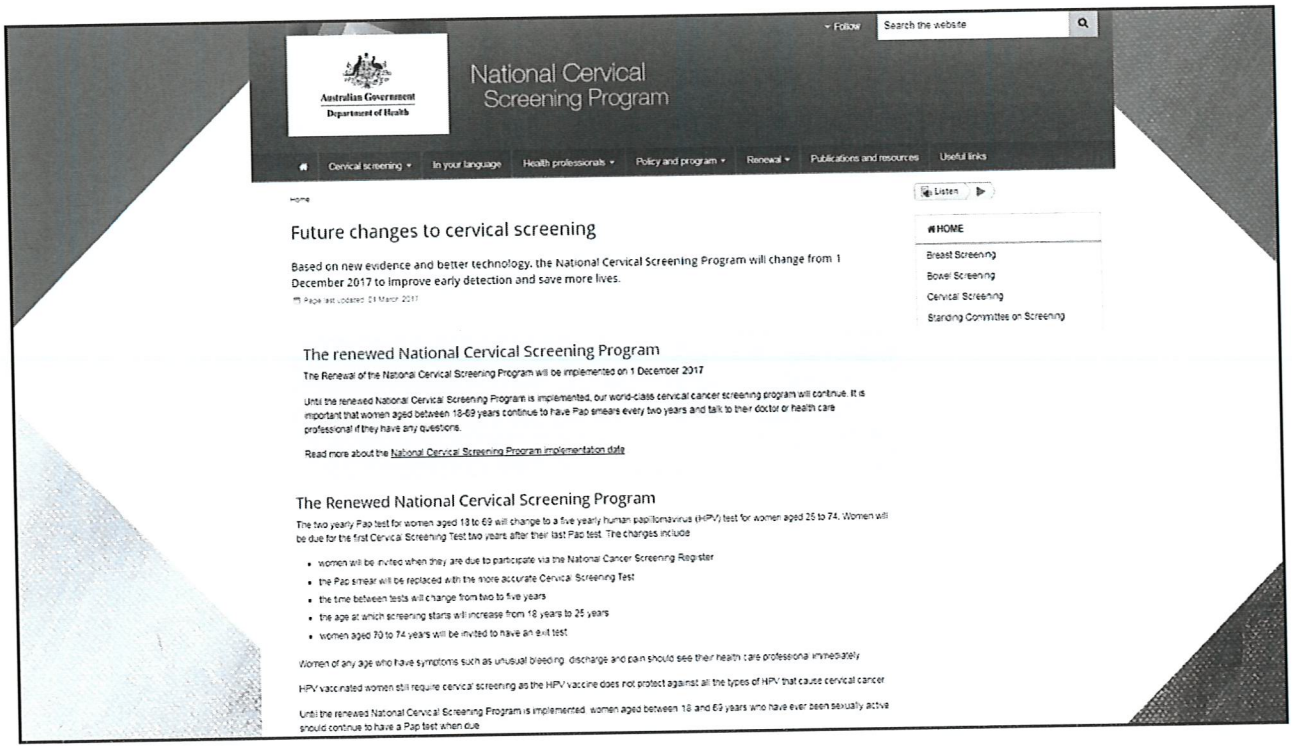
COMPLETE QUESTIONNAIRE 1



WELCOME

Today we want to hear your thoughts about the cervical screening program.

We want to present to you some information which has recently been displayed on the National Cervical Screening Program website and get your thoughts.


Follow
Search the website
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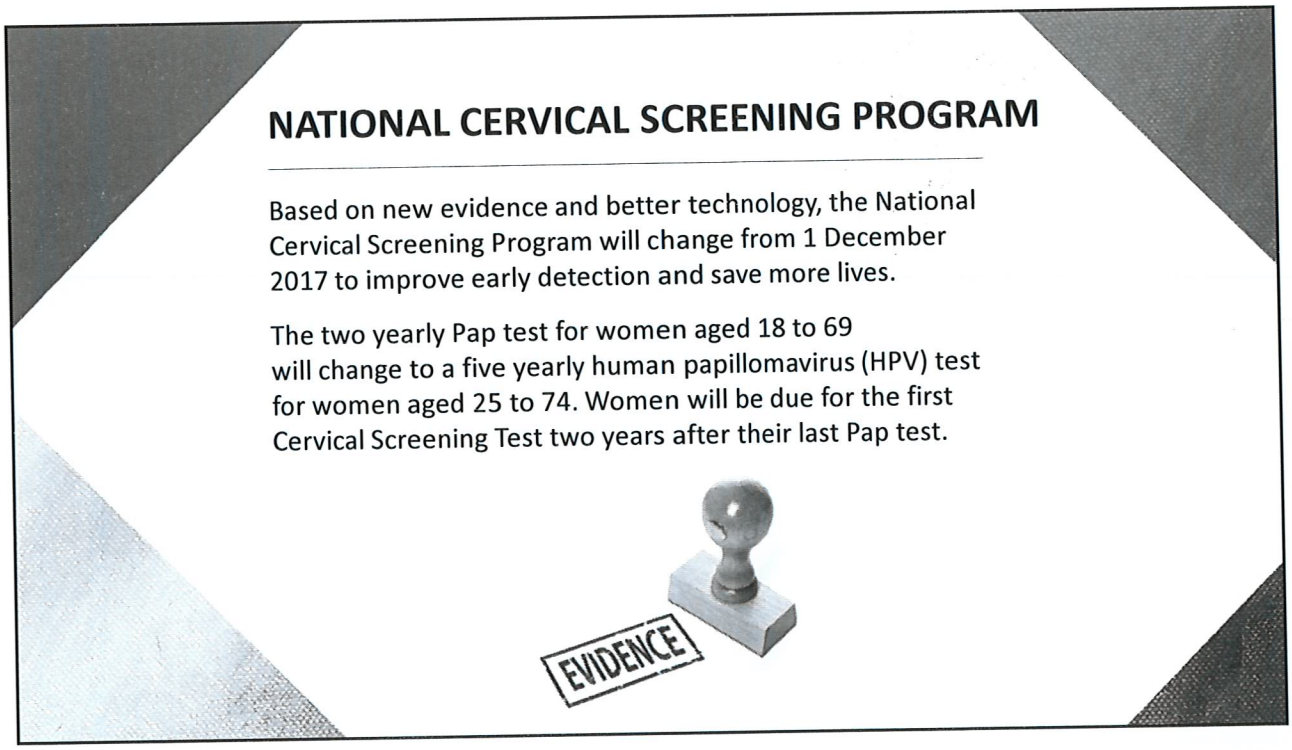
Department of Health
National Cervical Screening Program
Cervical screening
In your language
Health professionals
Policy and program
Renewal
Publications and resources
Useful links
Home
Listen
Future changes to cervical screening
Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017 to improve early detection and save more lives.
Page last updated: 21 March 2017
HOME
Breast Screening
Bowel Screening
Cervical Screening
Standing Committee on Screening
The renewed National Cervical Screening Program
The Renewal of the National Cervical Screening Program will be implemented on 1 December 2017
Until the renewed National Cervical Screening Program is implemented, our world-class cervical cancer screening program will continue. It is important that women aged between 18-69 years continue to have Pap smears every two years and talk to their doctor or health care professional if they have any questions.
Read more about the National Cervical Screening Program implementation date
The Renewed National Cervical Screening Program
The two yearly Pap test for women aged 18 to 69 will change to a five yearly human papillomavirus (HPV) test for women aged 25 to 74. Women will be due for the first Cervical Screening Test two years after their last Pap test. The changes include
women will be invited when they are due to participate via the National Cancer Screening Register
the Pap smear will be replaced with the more accurate Cervical Screening Test
the time between tests will change from two to five years
the age at which screening starts will increase from 18 years to 25 years
women aged 70 to 74 years will be invited to have an exit test
Women of any age who have symptoms such as unusual bleeding, discharge and pain should see their health care professional immediately
HPV vaccinated women still require cervical screening as the HPV vaccine does not protect against all the types of HPV that cause cervical cancer
Until the renewed National Cervical Screening Program is implemented, women aged between 18 and 69 years who have ever been sexually active should continue to have a Pap test when due


NATIONAL CERVICAL SCREENING PROGRAM
Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017 to improve early detection and save more lives.
The two yearly Pap test for women aged 18 to 69 will change to a five yearly human papillomavirus (HPV) test for women aged 25 to 74. Women will be due for the first Cervical Screening Test two years after their last Pap test.
EVIDENCE

NATIONAL CERVICAL SCREENING PROGRAM

The changes include:

- Women will be invited when they are due to participate via the National Cancer Screening Register
- The Pap smear will be replaced with the more accurate Cervical Screening Test
- The time between tests will change from two to five years
- The age at which screening starts will increase from 18 years to 25 years
- Women aged 70 to 74 years will be invited to have an exit test

NATIONAL CERVICAL SCREENING PROGRAM

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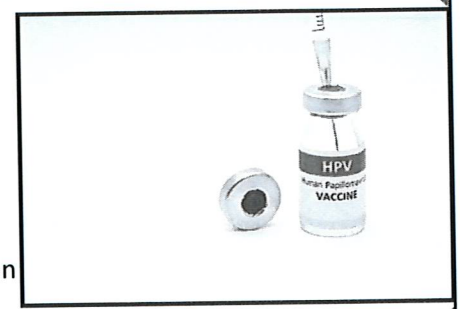


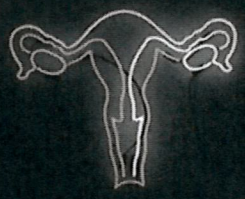
Until the renewed National Cervical Screening Program is implemented, women aged between 18 and 69 years who have ever been sexually active should continue to have a Pap test when due.

DISCUSSION

CONCERNS

Some concerns which arose in a petition which was set up and opposed the changes were:

- valuing women's health and rights;
- political statements
- cost and health care funding;
- specific concerns to screening program (e.g. interval and age of onset of screening)



DISCUSSION

PRESENTATION

The following slides present information available on the National Cervical Screening Program website

Frequently asked questions

Why is cervical screening changing?

What should women do between now and 1 December 2017?

How will the new Cervical Screening Test work?

Can I have the new Cervical Screening Test now?

Why will the screening age change to starting at 25 years of age?

Should women less than 25 years of age participate in cervical screening between now and 1 December 2017 when the renewed Program is implemented?

How will women be invited to screen using the new Cervical Screening Test?

When should I stop cervical screening?

Will cervical screening prevent all cervical cancers?

What is human papillomavirus (HPV)?

How did I get human papillomavirus (HPV)?

What is the relationship between the human papillomavirus and cervical cancer?

Do I still need to screen if I have received the HPV vaccine?

Will the new Cervical Screening Test replace the vaccination program?

WHY IS CERVICAL SCREENING CHANGING?

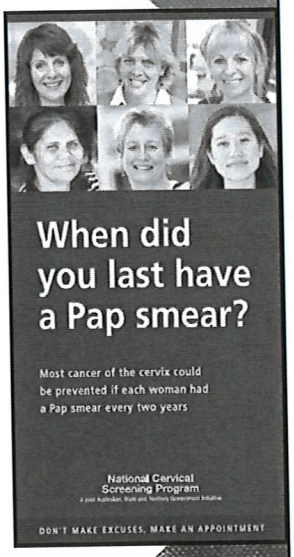
Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017 to improve early detection and save more lives.

WHAT SHOULD WOMEN DO BETWEEN NOW AND DEC 1ST?

It is very important that women continue to participate in the current two yearly Pap test program to ensure they are not at risk of developing cervical cancer.

Pap tests have already halved the incidence and mortality from cervical cancer since the introduction of the National Cervical Screening Program in 1991.

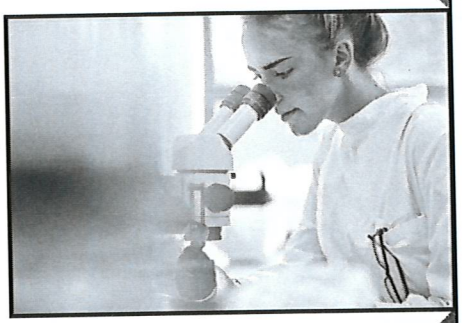
Women will be due for the first Cervical Screening Test two years after their last Pap test.



HOW WILL THE NEW CERVICAL SCREENING TEST WORK?

The new Cervical Screening Test detects human papillomavirus (HPV) infection, which is the first step in developing cervical cancer.

The procedure for collecting the sample for HPV testing is the same as the procedure for having a Pap smear. A Health Care Professional will still take a small sample of cells from the woman's cervix. The sample will be sent to a pathology laboratory for examination.



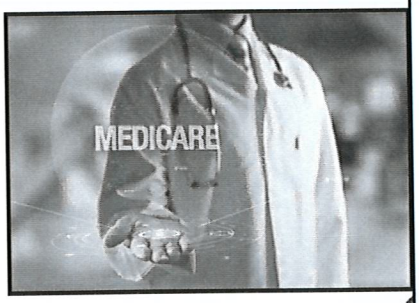
HOW WILL THE NEW CERVICAL SCREENING TEST WORK?

While the current Pap test can detect abnormal cell changes, the new Cervical Screening Test will detect the HPV infection that can cause the abnormal cell changes, prior to the development of cancer.

Persistent HPV infections can cause abnormal cell changes that may lead to cervical cancer. However, this usually takes a long time, often more than 10 years.

CAN I HAVE THE NEW CERVICAL SCREENING TEST NOW?

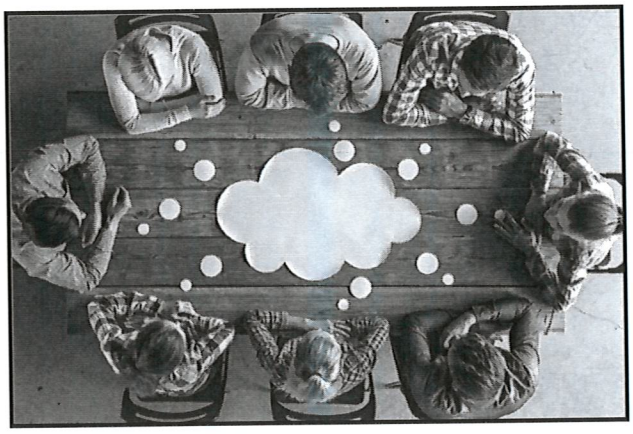
Women aged between 18 and 69 who have ever been sexually active should continue to have their Pap test when due.



The new Cervical Screening Test will be available on the Medicare Benefits Schedule from 1 December 2017. Until then, it is important to undertake two yearly Pap tests to prevent cervical cancer.

Women of any age who have symptoms (including pain or bleeding) should see their Health Care Professional immediately.

DISCUSSION



WHY WILL THE SCREENING AGE CHANGE TO 25?

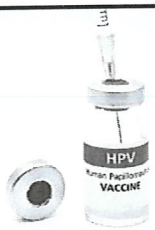
From 1 December 2017, women will be invited to screen from 25 years of age. This change is because evidence shows that:

- cervical cancer in young women is rare (in both HPV vaccinated and unvaccinated women)
- despite screening women younger than 25 years of age for over 20 years there has been no change to the rates of cervical cancer or rates of death from cervical cancer in this age group

WHY WILL THE SCREENING AGE CHANGE TO 25?

From 1 December 2017, women will be invited to screen from 25 years of age. This change is because evidence shows that:

- investigating and treating common cervical abnormalities in young women that would usually resolve by themselves can increase the risk of pregnancy complications later in life
- the HPV vaccination has already been shown to reduce cervical abnormalities among women younger than 25 years of age and, in contrast to screening, is ultimately expected to reduce cervical cancer in this age group.



SHOULD WOMEN UNDER 25 PARTICIPATE IN SCREENING BETWEEN NOW AND 1ST DEC?

The National Screening Program currently recommends that all women who have ever been sexually active should start having Pap smears between the ages of 18 and 20, or one or two years after first becoming sexually active, whichever is later.

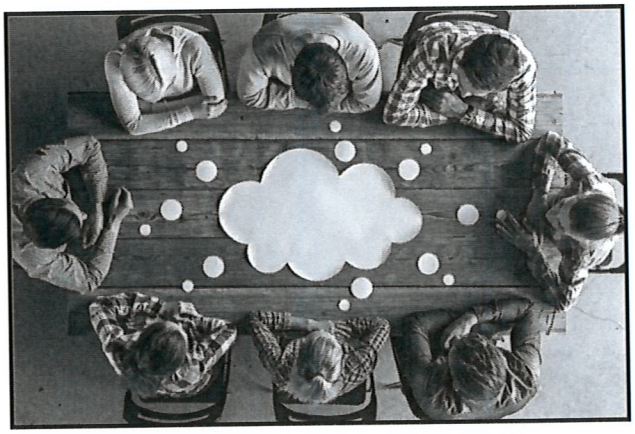
Until 1 December 2017, women are advised to continue screening in accordance with this policy however, if women have any questions about cervical screening and their individual situation they are encouraged to discuss these with their Health Care Professional.

WHEN SHOULD I STOP CERVICAL SCREENING?

Women between 70 and 74 years of age who have had a regular Cervical Screening Test will be recommended to have an exit HPV test before leaving the National Cervical Screening Program.

Women older than 69 years of age who have never been screened or not had regular screening tests should have a Cervical Screening Test if they request screening.

DISCUSSION



HOW WILL WOMEN BE INVITED TO SCREEN USING THE NEW CERVICAL SCREENING TEST?

From 1 December 2017, women aged 25 years or over who have not yet started cervical screening will receive an invitation to have the new cervical screening test.

The National Cervical Screening Register will send an invitation to women to let them know they are due for their test and also remind women if they become overdue for their regular test.

Women already participating in the program will be invited to screen within three months of the date when they would have been due for their two yearly Pap test.

WILL CERVICAL SCREENING PREVENT ALL CERVICAL CANCERS?

No. There is no effective population based screening test for rare neuroendocrine cervical cancers. Given the current state of scientific evidence, neither the current Pap test nor the new Cervical Screening Test (primary HPV test) can effectively detect rare neuroendocrine cervical cancers.

The changes to the National Cervical Screening Program from 1 December 2017 are based on new evidence and better technology and will improve early detection and save more lives.

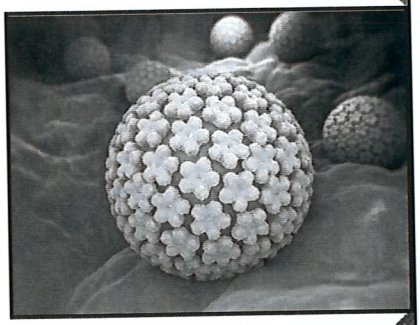
DISCUSSION

WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

The human papillomavirus (HPV) is a common infection in females and males.

Most people will have HPV at some time in their lives and never know it.

There are more than 100 different types of HPV that can affect different parts of the body. HPV types 16 and 18 are most commonly associated with cervical cancer. Genital HPV is spread by genital skin to genital skin contact.



WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

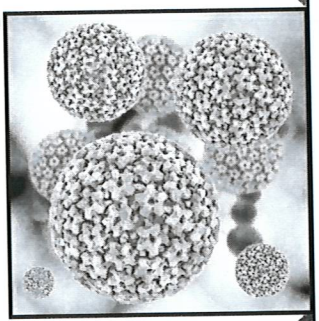
Most HPV infections clear up by themselves without causing any problems. Persistent genital HPV infections can cause cervical abnormalities, which, if they continue over a long period of time (more than 10 years), can lead to cervical cancer.

It is important to remember that most women who have HPV, clear the virus and do not go on to develop cervical abnormalities or cervical cancer.

HOW DID I GET HUMAN PAPILLOMAVIRUS (HPV)?

Genital HPV is spread through genital skin to genital skin contact. Condoms are an important barrier to many sexually transmitted infections, but offer limited protection against HPV as they do not cover all of the genital skin.

Because the virus can be inactive in a person's cells for months or years, for many people it is probably impossible to determine when and from whom HPV was contracted.

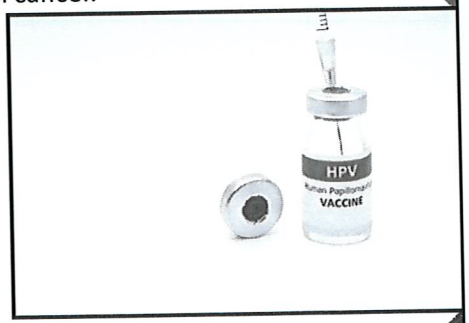


RELATIONSHIP BETWEEN HUMAN PAPILLOMAVIRUS AND CERVICAL CANCER

Persistent infection over many years with one or more cancer-causing types of HPV is the main cause of cervical cancer. In fact, 99.7 per cent of all cervical cancers are caused by HPV infection.

DO I STILL NEED TO SCREEN IF I HAVE RECEIVED THE HPV VACCINE?

Yes. The HPV vaccine does not protect against all types of HPV infection that are known to cause cervical cancer.



WILL THE NEW CERVICAL SCREENING PROGRAM REPLACE THE VACCINATION PROGRAM?

No. Eligible girls (and boys) should still be immunised to reduce transmission of HPV and help to protect the whole community against cervical cancer, as well as other HPV-related cancers such as throat and anal cancers.

DISCUSSION

Frequently asked questions

Why is cervical screening changing?

What should women do between now and 1 December 2017?

How will the new Cervical Screening Test work?

Can I have the new Cervical Screening Test now?

Why will the screening age change to starting at 25 years of age?

Should women less than 25 years of age participate in cervical screening between now and 1 December 2017 when the renewed Program is implemented?

How will women be invited to screen using the new Cervical Screening Test?

When should I stop cervical screening?

Will cervical screening prevent all cervical cancers?

What is human papillomavirus (HPV)?

How did I get human papillomavirus (HPV)?

What is the relationship between the human papillomavirus and cervical cancer?

Do I still need to screen if I have received the HPV vaccine?

Will the new Cervical Screening Test replace the vaccination program?

CHANGES

So just to summarise the changes are:

- Women will be tested using the HPV test rather than the Pap smear
- The time between tests will change from 2 to 5 years
- Screening will now start at 25 years, from 18 years previously
- Women aged 70 to 74 years will be invited to have an exit test

WHY IS CERVICAL SCREENING CHANGING?

- We now know a lot more about cancer than we did in 1991 when the cervical screening program started.
- New tests to pick up abnormal changes have been developed.
- The HPV vaccination has been offered to young girls since 2006 and young boys since 2012.

The decisions have been made based on:

- a thorough review of existing research about cervical screening
- a mathematical model built using information from the Australian population screening program

NATIONAL CERVICAL SCREENING REGISTER

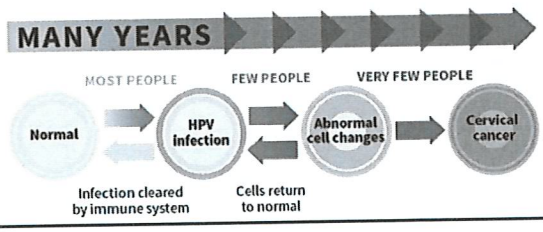
Women will be invited when they are due for their Cervical Screening Test via the National Cancer Screening Register

- The National Cancer Screening Register replaces the current registers in each state and territory
- Women who have ever received a Pap test will automatically be included on the register, but women can 'opt off' the register
- Women who have not had a Pap smear before will be invited through their Medicare enrolment
- Women can choose to be invited to screen by post, email or phone

CHANGE: TEST

The Pap smear, which tests for abnormal cells, will be replaced with the more accurate Cervical Screening Test

- The new test is testing for HPV (human papillomavirus)
- HPV is a virus that causes abnormal cells which can then lead to cervical cancer
- This test aims to pick up HPV before it causes abnormal cells
- This test is more accurate, more sensitive (correctly picking up positive results) and aims to better prevent cervical cancers



CHANGE: TEST

One way of comparing Pap smears and HPV testing is to calculate the negative predictive value of each test. This is the chance that a negative result from the test is truly negative.

Age group	Pap smear (cytology)	HPV test
Overall	99%	99.7%
Under 30 year olds	97.5%	98.7%

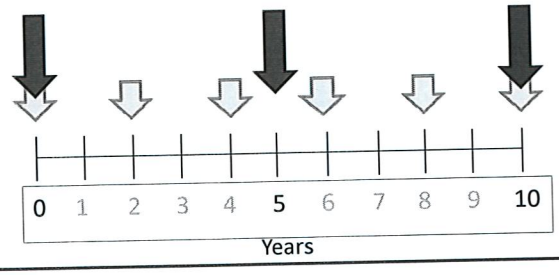
- This means we can be more confident in the results from the HPV test and there is less uncertainty

CHANGE: TIMING

- The time between tests will change from **2** to **5** years

Why is the timing changing?

- This is because the HPV test is more accurate and sensitive and so women do not need to be tested as often
- A woman whose test shows no HPV, is at very low risk of cervical cancer



Current screening program timing between tests

Renewed screening program timing between tests

CHANGE: AGE

18 YEAR OLDS

- The age at which screening starts will increase from 18 years to 25 years

Why change the age?

- The number of women under 25 getting cervical cancer is very low, less than 1 woman per 100,000 women
- The number of women under 25 dying from cervical cancer is even lower

We know the two yearly cervical screening program has shown:

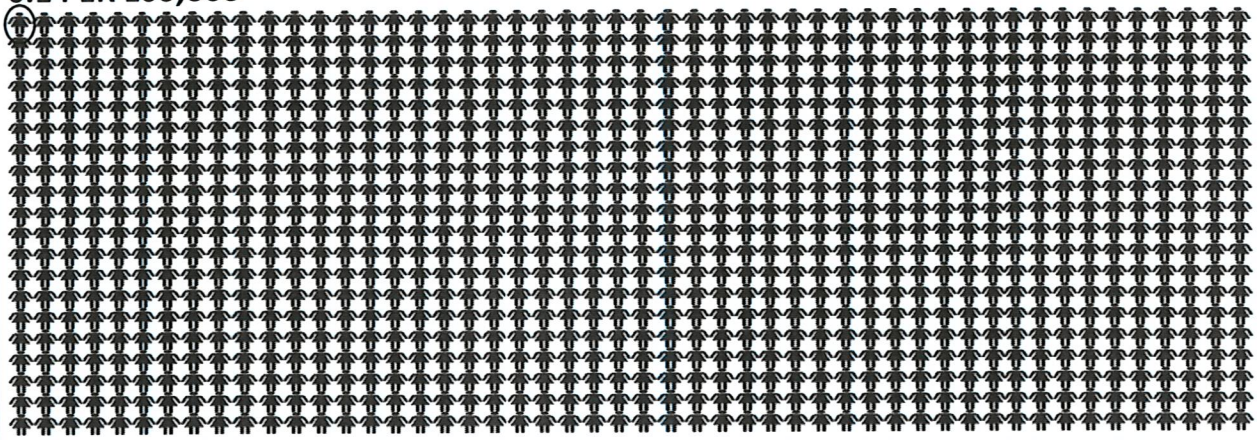
- **no** impact on the number of women under 25 getting cervical cancer
- **no** impact on the number of women under 25 dying from cervical cancer

25 YEAR OLDS

CHANGE: AGE

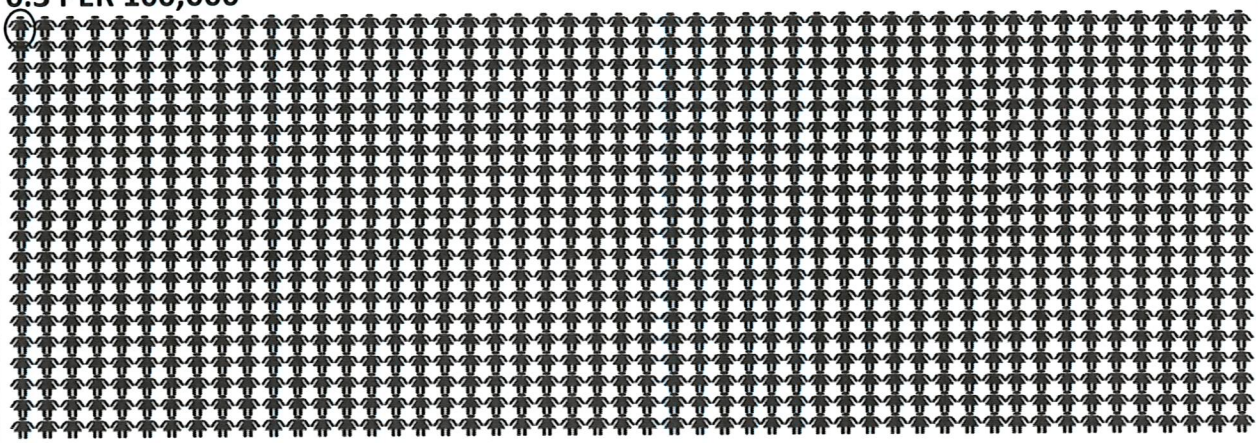
WOMEN AGED 15-19 DIAGNOSED IN 1990 (PRE-SCREENING PROGRAM)

0.1 PER 100,000



CHANGE: AGE

WOMEN AGED 15-19 DIAGNOSED IN 2012 (ORGANISED SCREENING PROGRAM)
0.3 PER 100,000



AGE CHANGE: EVIDENCE

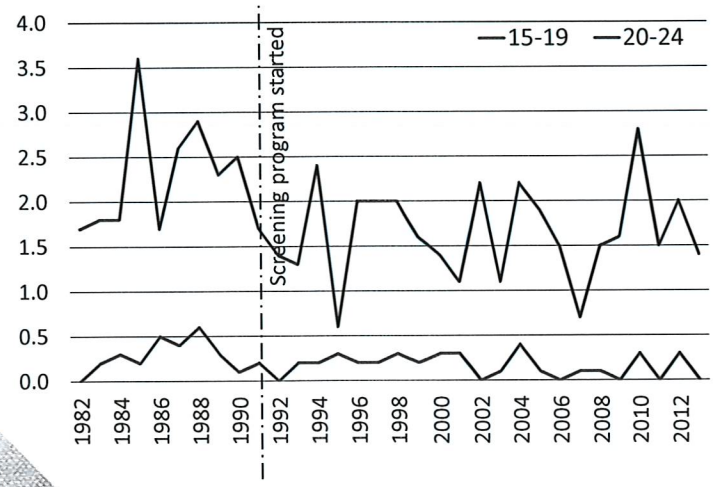
DIAGNOSED (PER 100,000)

Age group	1990 (NO SCREENING PROGRAM)	2012 (SCREENING PROGRAM)
15-19	0.1	0.3
20-24	2.5	2.0
40-44	22.8	13.0

DEATHS (PER 100,000)

Age group	1990 (NO SCREENING PROGRAM)	2012 (SCREENING PROGRAM)
15-19	0	0
20-24	0.1	0
40-44	5.5	1.7

AGE CHANGE: EVIDENCE



CHANGE: AGE

Why change the age?

- HPV is so common in women under 25, and most HPV infections clear by themselves
- This means many women would be sent for further tests that would be unnecessary, this is known as over-detection

Over-detection:

- many cervical abnormalities will regress (resolve by themselves) and others are so slow-growing that they will not become clinically important over a woman's lifetime
- offers no benefit and leads to unnecessary surveillance, diagnostic tests, and treatments with possible harms

EXIT TEST

Women aged 70 to 74 years will be invited to have an exit test

- An 'exit' test, is a test to identify women who are at low risk of cervical cancer
- This will test women for HPV and also look at tests done in the past
- A woman will be low risk and told she no longer needs to be in the screening program if her 'exit' test is negative
- If a women is positive for HPV, she will stay in the program and be monitored as per the screening pathway

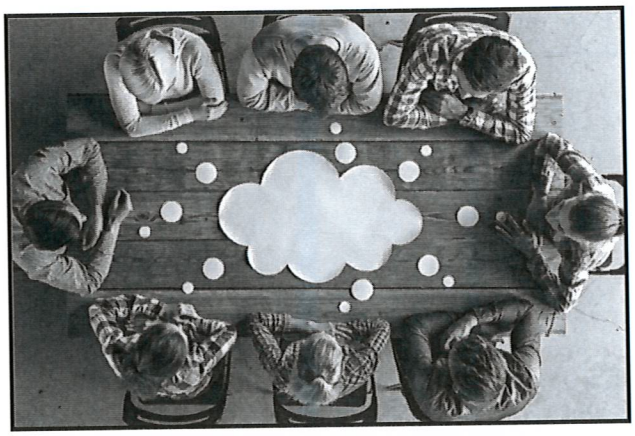
OLD VERSUS NEW PROGRAM

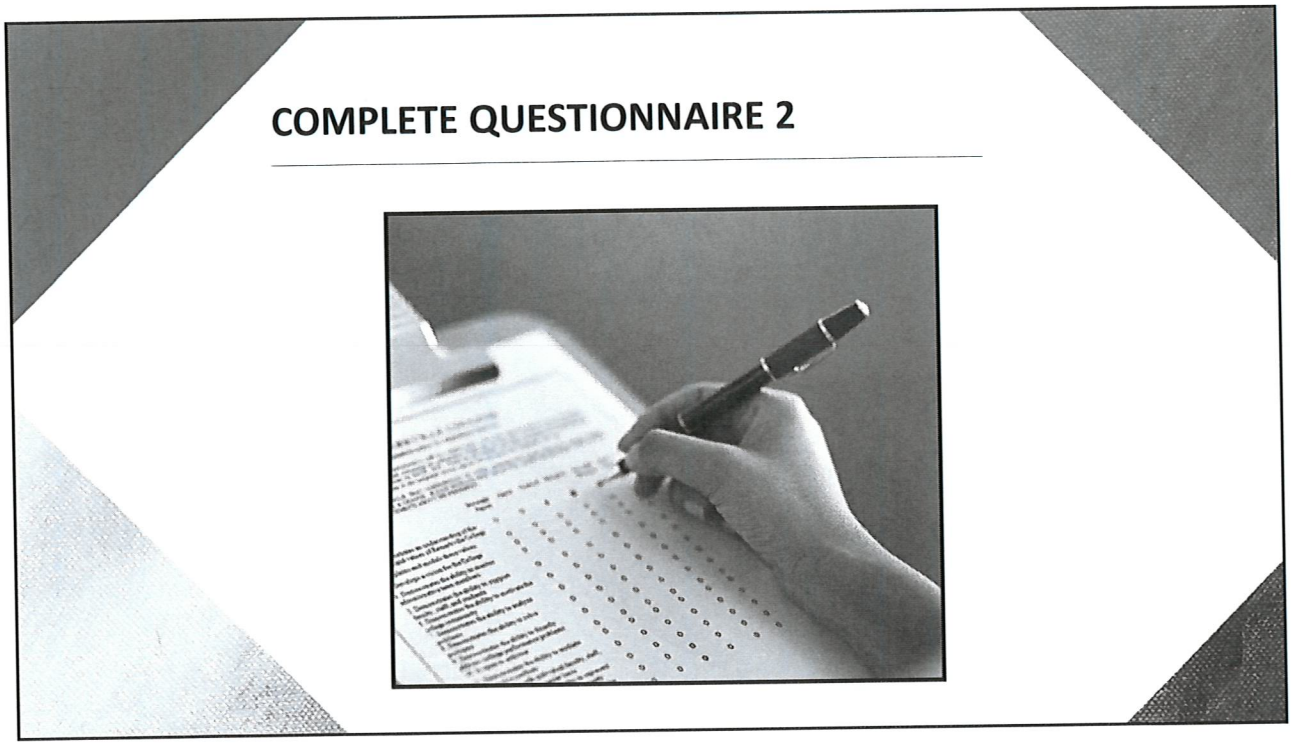
- In Australia, the number of women who are diagnosed with cervical cancer is **7** women in **100,000**, and the number dying from cervical cancer is **2** women in **100,000**
- The new program is expected to show further reductions by:
  - **31–36%** in number of women diagnosed or dying from cervical cancer in unvaccinated women
  - **24–28%** in number of women diagnosed or dying from cervical cancer in cohorts offered vaccination

WHAT HAPPENS IF I HAVE A POSITIVE HPV TEST?

High risk HPV16 or 18 found	• Check for abnormal cells by lab • Further investigation: colposcopy
Intermediate risk – other (not HPV 16/18) HPV found	• Check for abnormal cells by lab • Colposcopy if high-grade abnormalities • Repeat test after 12 months if no abnormal cells or low-grade abnormalities
No HPV found	• Risk of developing cervical cancer in next 5 years very low (lower than for Pap smear) • Screen again in 5 years

DISCUSSION




COMPLETE QUESTIONNAIRE 2

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
#2	Summary of the key elements of the study using the abstract format of the intended publication; typically	2

		includes background, purpose, methods, results and conclusions	
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4-5
Purpose or research question	#4	Purpose of the study and specific objectives or questions	5
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5-6
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research	8

		questions, approach, methods, results and / or transferability	
Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	18
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6-8
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6-7
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	9

Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	8
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	8
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	8
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	9
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	9-13
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	13

Limitations	#19	Trustworthiness and limitations of findings	3/17
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	18
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	18

Author notes

1. Title page page 1