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Optimising management of women with HPV (not 16/18): Findings from a national HPV screening program

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HIGHLIGHTS

- For HPV (not 16/18) with low-grade cytology (≤ LSIL), deferring colposcopy for 12 months does not increase CIN3+/CIN2+ risk.
- Deferring colposcopy 12 months raises CIN3+ risk in Aboriginal and Torres Strait Islander women with HPV (not 16/18), ≤ LSIL.
- CIN3+ risk was very low in women aged ≥50 years with HPV (not 16/18) and ≤ LSIL when colposcopy is deferred for 12 months.
- CIN3+ risk persisted in women with primary screen in 2019 when colposcopy was deferred 12 months for HPV (not 16/18), ≤ LSIL.
- No cancers were identified in women with HPV (not 16/18), ≤ LSIL when colposcopy is deferred for 12 months.

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ABSTRACT

Background. Australian guidelines updated in 2021 recommend a second 12-month follow-up HPV test, instead of immediate colposcopy, for participants with HPV (not 16/18) and negative/low-grade cytology at both primary screening and 12-month follow-up (excepting Aboriginal and/Torres Strait Islander women, those aged ≥50 years or ≥2 years overdue for primary screening). We examined the safety of this change using naturally-occurring variation in colposcopy timing after a 12-month follow-up test.

Methods. Using National Cancer Screening Register data (December 2017–April 2022), we employed Kaplan-Meier analyses to estimate the cumulative incidence of serious cervical abnormalities in those with colposcopy within six months (immediate) versus 12–18 months (deferred) after 12-month follow-up. Analyses were restricted to women who, at their primary screening test, were aged 25–69 years and not ≥2 years overdue, and stratified by age group, Indigenous status, socio-economic status, state/territory, and year of primary screening.

Results. Among 31,499 women with immediate colposcopy and 2562 with deferred colposcopy, the cumulative incidence of cervical intraepithelial neoplasia grade 3 or worse was slightly higher at 24 months in the deferred group (8.3 %; 95 % CI: 6.9–9.9 %) compared to the immediate group (5.7 %; 95 % CI: 5.3–6.0 %). By 36 months, the difference was small and not significant (deferred: 11.3 %; 95 % CI: 8.6–14.7 % vs immediate: 9.9 %; 95 % CI: 8.8–11.2 %). Similar patterns were observed in stratified analyses, except for Aboriginal and Torres Strait Islander women, where a difference persisted to 36 months (deferred: 28.1 %; 95 % CI: 13.4–52.9 % vs immediate: 7.0 %; 95 % CI: 4.4–11.0 %).

Conclusions. Our findings support the safety of updated guidelines for deferring colposcopy and the different recommendation for Aboriginal and Torres Strait Islander women. Although these data do not directly support the different recommendation for those aged ≥50 years, longer follow-up studies are required, given the potential for delayed detection of covert canal lesions in this age group.

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1. Background

Primary high-risk human papillomavirus (HPV) DNA screening is now well-established in cervical screening programs across many high-income countries and is being introduced in a range of low- and middle-income countries through pilot programs and phased national roll-outs [1,2]. The optimal management of HPV-positive individuals is a key issue due to the varying risks of cervical cancer associated with different oncogenic HPV genotypes, the need to balance colposcopy referrals and risk, and capacity for follow-up in different settings [3]. Previous research has shown that HPV16/18 types account for 40 % – 58 % of precancers and ~ 70 % of cancers while other high-risk HPV genotypes (i.e., HPV not 16/18) account for 31 % of cervical precancers and ~ 30 % of cervical cancers [4–6], supporting the need for differential management strategies for HPV16/18 vs HPV (not 16/18) types.

Several prior studies have investigated the effectiveness, safety, and cost-effectiveness of different risk-based triage strategies for women with specific intermediate-risk criteria such as those with HPV (not 16/18) types detected and negative or low-grade liquid-based cytology (LBC) results (i.e., low-grade squamous intraepithelial lesion (LSIL), atypical squamous cells of undetermined significance (ASC-US) (≤LSIL)) [4,7–11]. Direct referral to colposcopy for individuals with HPV (not 16/18) and ≤ LSIL, without further risk-based triage, presents a major challenge to the healthcare systems with limited colposcopy capacity and may lead to associated harms (e.g., physical distress, anxiety), increased costs and colposcopy service capacity problems [7,9,12]. Evaluations from Australia, Norway and the Netherlands suggest that instead of direct referral for colposcopy, 12-month surveillance for women with HPV (not 16/18) and ≤ LSIL can substantially reduce unnecessary colposcopy referrals while maintaining a balance of benefits, harms, cost-effectiveness, resource optimisation and patient outcomes [4,7,8].

National guidelines from several countries, including Australia [13], the USA [14], Canada [15] and several European countries [16,17] incorporate a risk-based management approach for women with HPV detected, with variation between colposcopy referral and follow-up testing, depending on other test results (generally cytology, and in some cases HPV16/18 genotyping). However, there remains variation across countries in criteria for colposcopy referral at both the initial screen and during follow-up, based on individual risk assessment. In particular, to date, there is no universally established optimal management strategy in place for screening participants who test positive for HPV (not 16/18) with low-grade cytological abnormalities at initial and follow-up tests [10].

Australia has a well-established National Cervical Screening Program (NCSP) that, since December 2017, has recommended primary HPV testing with partial genotyping for HPV16/18 every five years. For those classified as higher risk, colposcopy is recommended as a follow-up procedure, while those classified as intermediate risk (including participants with HPV (not 16/18) and ≤ LSIL results at their primary screening test) are recommended to have a follow-up HPV test at 12 months [18]. Prior to February 2021, if any HPV was detected at their 12-month follow-up test, they were then considered higher risk and referred for colposcopy regardless of HPV type. A review of National Cancer Screening Register (NCSR) data from the first two years (i.e., December 2017–December 2019) of the renewed NCSP in Australia reported that women with HPV (not 16/18) and ≤ LSIL results at both initial screen and 12-month follow-up had a low risk of harbouring serious abnormalities, but constituted approximately 62 % of colposcopy referrals in women aged 25–69 years, suggesting they could be managed safely with a second 12-month follow-up test (i.e., 24 months after initial screen) [19]. Guidelines were updated accordingly from February 2021: specifically, non-Indigenous women aged less than 50 years, with HPV (not 16/18) detected and ≤ LSIL results at both their routine screen and 12-month follow-up test were no longer considered higher risk at their 12-month follow-up test (referred for colposcopy). Instead, they were classified as intermediate risk (12-month follow-up test recommended), unless they were ≥2 years overdue at the time of their original screening visit [20]. Following the precautionary principle, management for all other women at their 12-month repeat test was unchanged (Box 1).

To monitor the safety of this management change and also inform the global evidence in relation to management strategies for those with HPV (not 16/18) detected, we undertook an analysis of existing program data from the NCSR to make longitudinal comparisons of the risk of serious cervical abnormalities, utilising the natural variation in the timing between the 12-month follow-up HPV test and subsequent colposcopy.

2. Methods

2.1. Data source

We used data from the NCSR, a comprehensive centralised database of routinely collected test data on individuals participating in the NCSP in Australia [21].

2.2. Study population

The study population included women aged 25–69 years who had an initial HPV screening test between 1 December 2017 and 9 April 2022, with HPV (not 16/18) types detected and ≤ LSIL at both their initial screening and a follow-up test 9–15 months later (our operational definition for the 12-month follow-up test). Women aged 70–74 years were not included, as a routine screen at this age is considered an exit test and colposcopy is recommended for those with any oncogenic type detected. We excluded women from our analysis if they had a total hysterectomy or amputated cervix prior to their index screen or follow-up test, or if they were overdue for screening by ≥2 years at the

Box 1
Overview of the changes to the NCSP recommendation that applies at the 12-month follow-up test in participants classified as intermediate risk on their initial screening test, effective from February 2021* [20].

Original management protocol:
Women with a 12-month follow-up test result of HPV detected (any type) should be referred for a colposcopy (including those with HPV (not 16/18) and LBC prediction of negative, ASC-US or LSIL).

Updated management protocol:
Women with a 12-month follow-up test result of HPV (not 16/18) result and LBC prediction negative, ASC-US or LSIL should have a second HPV follow-up test in 12 months' time (intermediate risk result) instead of referral to colposcopy. This change is not applicable for:

- Women ≥2 years overdue for screening at the time of the initial screen
- Women who identify as Aboriginal and/or Torres Strait Islander
- Women aged ≥50 years

LSIL refers to low-grade squamous intraepithelial lesion, and ASC-US refers to atypical squamous cells of undetermined significance. Detailed guidelines are presented in Figs. S1 and S2 in the supplementary materials.

* Some groups of women fall outside these recommendations as there are separate guidelines specifically for them, including: Immune deficient women; women exposed to diethylstilboestrol (DES) in utero; women currently undergoing Test of Cure following treatment of histological HSIL; and women aged ≥70 years (attending for an exit test).

time of their initial screen (i.e., had no satisfactory cytology test result recorded in the four years preceding their HPV (not 16/18) result on a routine screening test). Although not affected by the change in recommendations, we have included women aged ≥50 years and women identifying as Aboriginal and/or Torres Strait Islander in our analysis for information and comparative purposes.

2.3. Data analysis

Our primary outcome of interest was CIN3+ within a two- and three-year period following their 12-month follow-up test, as the best surrogate of invasive cervical cancer risk, with CIN2+ as a secondary outcome. Among those meeting the inclusion criteria, two groups were defined: those who attended colposcopy 12–18 months after their first 12-month follow-up HPV test ("deferred group"; comparable to those managed according to the updated guidelines), and those who attended colposcopy within six months after their first 12-month follow-up HPV test ("immediate group"; comparable to those managed according to the original guideline). We conducted descriptive analyses of the two groups by various socio-demographic factors including age group, Indigenous status, state/territory, remoteness of residence, area-level index of relative socio-demographic disadvantage (IRSD) quintile (quintile 1 represents the most disadvantaged and quintile 5 represents the least disadvantaged socio-economic group), and year of primary screening test.

We employed Kaplan-Meier analyses to calculate the cumulative incidence of CIN3+ and CIN2+ by time since the first 12-month follow-up visit in the immediate group versus deferred group, further stratified by age group, Indigenous status, state/territory, IRSD quintile and year of primary screening. The log-rank test is often used to compare cumulative incidence distributions between groups in Kaplan-Meier analyses; however, given the time difference in our group definitions, the log-rank test result was not valid since, by design, colposcopy visits in the two groups were clustered around two different time points, and so cumulative incidence curves would a priori differ over the first 18 months. We, therefore, plotted 95 % confidence intervals (CIs) on the Kaplan-Meier curves to visualise the difference; and compared the 95 % CIs between both groups for CIN3+ and CIN2+ cumulative incidences. We suppressed results with cell counts fewer than six (<6) in line with data custodian requirements.

Women without the outcome of interest (CIN3+/CIN2+) were followed until their last test date available in the dataset (extracted on 9 April 2022) or date of death. In the CIN3+ analysis, women with a CIN2 result followed by a CIN3+ result were followed up till their CIN3+ result. Women with a CIN2 result and no subsequent CIN3+ result were censored at their CIN2 result. Women with a total hysterectomy or amputated cervix after their follow-up test at 9–15 months were included in the analysis up until their hysterectomy. If a histology result was available for the hysterectomy sample, it was considered the last test result in the woman's follow-up (as long as there was no CIN3+/CIN2+ result available prior); if no histology result was available, follow-up ended on the date entered for the hysterectomy/amputated cervix. All statistical analyses were performed using the statistical package SAS 9.4.

3. Results

3.1. Cohort description

Overall, 4,145,763 women aged 25–69 years had a primary cervical screening test between 1 December 2017 and 9 April 2022. After excluding women who were overdue for screening by at least two years (n = 908,438), 3,237,325 women remained. Of these, 4.7 % (n = 153,532) were classified as intermediate risk at primary screening. Approximately 61 % of these women attended a follow-up test 9–15 months later (i.e., first 12-month follow-up test), at which 52.3 % again had HPV (not 16/18) detected and ≤ LSIL results. Within this cohort, 30.7 % of women had no record of colposcopy either within six months or 12–18 months after the follow-up test and were therefore ineligible for the current analysis, leaving a total of 34,061 eligible women who were included in our analysis. Overall, 92.5 % of the women in our analysis belonged to the immediate group (i.e., attended colposcopy within six months) while 7.5 % of the women belonged to the deferred group (i.e., attended colposcopy at 12–18 months) (Fig. 1).

The two groups were similar in age at initial screening (mean age: ~ 41 years in each; broadly similar five-year age group distribution, with ~ 30 % aged 25–29 years). In both groups, Indigenous status could not be ascertained for ~ 25 % of women, but where it could be, the vast majority (~ 98 %) of women were non-Indigenous. Compared to those in the immediate group, the deferred group had a higher proportion of women living in the most disadvantaged areas (17.2 % vs 13.1 %), major cities (80.1 % vs 73.8 %), Victoria (36.4 % vs 27.1 %), Western Australia (15.2 % vs 11.4 %) and South Australia (10.2 % vs 7.0 %); whereas those living in New South Wales (30.0 % vs 17.9 %) and in inner regional areas (17.6 % vs 12.0 %) were more likely to be in the immediate than the deferred group. Most women had their initial HPV (not 16/18) screening test result between December 2017 and December 2018 (deferred: 55.7 %, immediate: 50.9 %). The mean follow-up time since their 12-month follow-up test was 19.6 months in the deferred group and 15.8 months in the immediate group. CIN3+ was detected in 5.1 % of women in the deferred group and 4.4 % of women in the immediate group. The detection rate of CIN2+ was similar in both groups (deferred: 9.4 % vs immediate: 9.9 %). Cancer was detected in <6 (<0.02 %) women in the immediate group, and no cancers were identified in the deferred group (Table 1).

3.2. Cumulative incidence of CIN3+ and CIN2+

The 24-month cumulative incidence of CIN3+ was slightly, but significantly, higher in the deferred than in the immediate group (8.3 %; 95 % CI: 6.9 % –9.9 % vs 5.7 %; 95 % CI: 5.3 % –6.0 %), as the corresponding 95 % CIs did not overlap during this period. However, by 36 months, the cumulative incidence was similar in the two groups (11.3 %; 95 % CI: 8.6 % –14.7 % vs 9.9 %; 95 % CI: 8.8 % –11.2 %); and the difference (<1.5 %) was no longer significant as the corresponding 95 % CIs overlapped. Findings were similar for CIN2+, with a slightly higher 24-month cumulative incidence of CIN2+ in the deferred than in the immediate group (14.0 % vs 11.7 %), which thereafter reduced and was no longer significant (~ 0.9 % difference; 95 % CIs overlapping after around 24 months) (Fig. 2, Table S1, Table S2).

3.3. Cumulative incidence of CIN3+ and CIN2+ by socio-demographic factors

Overall, the cumulative incidence of CIN3+ remained slightly higher in the deferred than in the immediate group across most age groups. However, the differences between the two groups were small, ranging from 1.4 % to 3.9 % at 24 months, and 0.6 % to 5.7 % at 36 months; and were not significant at either timepoint for any age group. In both groups, the 24-month cumulative incidence of CIN3+ was highest in younger age groups (25–29 years and 30–39 years) (deferred: ~ 10 %; immediate: ~ 7 %). By 36 months, the cumulative incidence of CIN3+ was highest in those aged 40–49 years (15.8 %) in the deferred group, whereas in the immediate group, it was highest in younger age groups (12.6 % in 25–29 years, 11.4 % in 30–39 years). In both the immediate and deferred groups, older women (50–59 and 60–69 years) had the lowest cumulative incidence of CIN3+, at both 24 months (deferred: 3.0–4.1 %, immediate: 2.7–3.2 %) and 36 months (deferred: 3.0–9.8 %, immediate: 6.1–6.3 %).

Among non-Indigenous women, the cumulative incidence of CIN3+ was quite similar in the deferred and immediate groups at both 24 months (7.9 % vs 6.0 %) and 36 months (11.1 % vs 9.9 %). However,

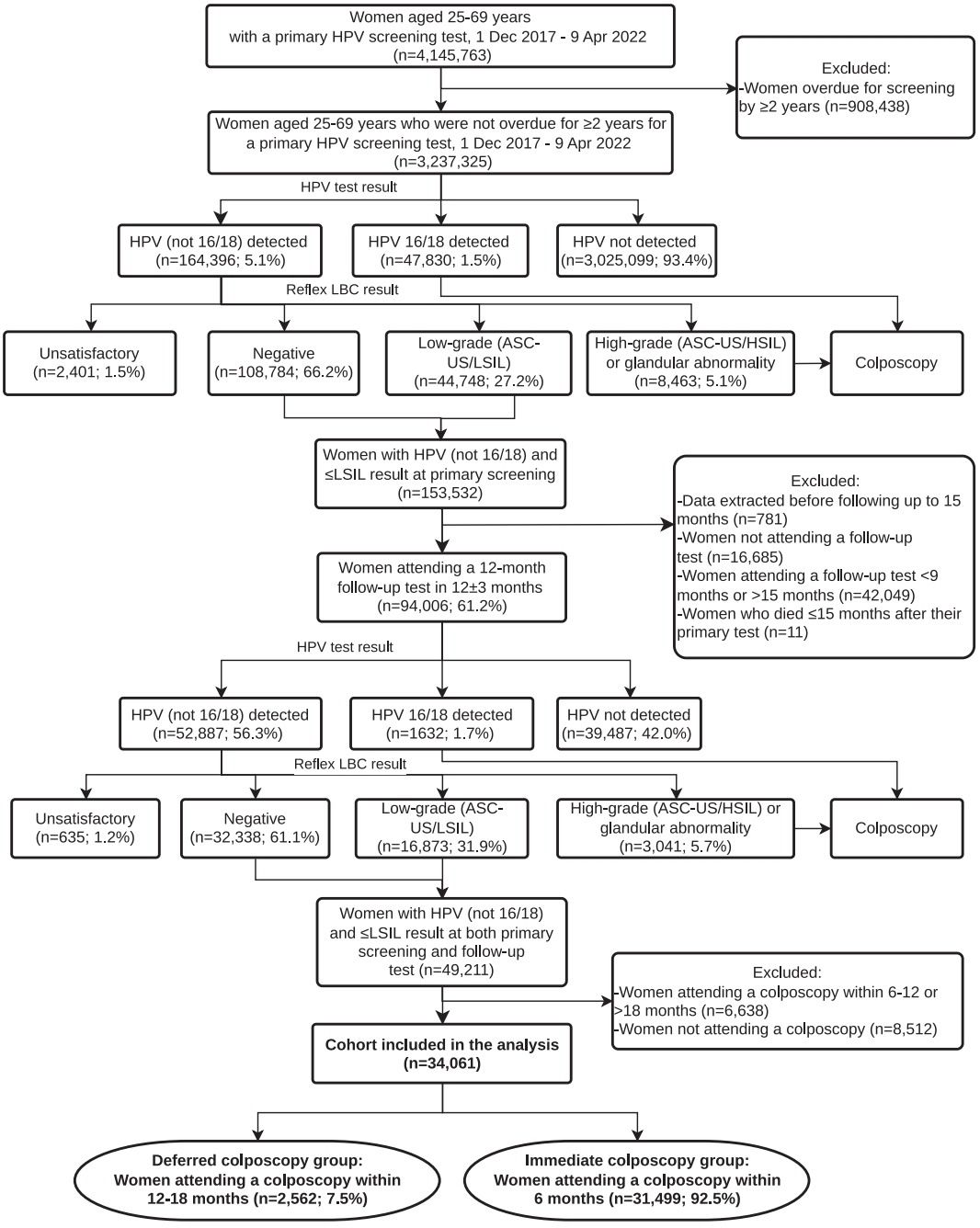


Fig. 1. Flow diagram showing the selection of women with HPV (not 16/18) and ≤ LSIL results from the NCSR data included in the analysis.

among Aboriginal and Torres Strait Islander women, the cumulative incidence of CIN3+ was noticeably higher in the deferred than in the immediate group, at both 24 months (20.9 % vs 7.0 %) and 36 months (28.1 % vs 7.0 %). Although confidence intervals were wide, due to the number of Aboriginal and Torres Strait Islander women and detected CIN3+ cases being very small (deferred: $n = 7/41$, immediate: $n = 21/464$), they did not overlap at 36 months.

When stratifying by the year of primary screening test, we could only compare results between the deferred and immediate groups for the years December 2017–2018 and 2019 (up to 24 months). Cumulative incidence of CIN3+ could not be compared between the deferred and immediate groups for 2020 and 2021 due to insufficient follow-up time. The cumulative incidence of CIN3+ did not differ between the immediate and deferred groups for those whose primary screening test was in December 2017–2018. Differences in CIN3+ cumulative incidences were observed, however, for those whose primary screening test was in 2019 (deferred: 21.4 % vs immediate: 6.7 % at 24 months), with a comparatively steeper increase between 12 and 18 months than in most other strata. The 95 % CIs did not overlap for 2019 between 18 and 24 months. The full follow-up data for 36 months were not available for those whose primary test was in 2019 (Fig. 3, Table 2).

In analyses stratified by IRSD quintile or state/territory, differences in cumulative incidence of CIN3+ at 24 months were observed in two groups (IRSD quintile 5: (10.3 %; 95 % CI: 7.3 % –14.4 % vs 4.7 %; 95 % CI: 4.2 % –5.4 %); Victoria (7.8 %; 95 % CI: 5.7 % –10.7 % vs 4.9 %; 95 % CI: 4.4 % –5.6 %)); however, by 36 months, the difference was no longer significant in any state/territory, or IRSD quintile (Table 2, Figs. S3 and S4).

Table 1
Characteristics of deferred and immediate colposcopy groups.

Baseline characteristics of participants	Deferred colposcopy group: Attending a colposcopy within 12–18 months ($N = 2562$)		Immediate colposcopy group: Attending a colposcopy within 6 months ($N = 31,499$)	
	n	%	n	%
Age (years; mean ± SD) at primary screening	40.5 (±13.1)		41.2 (±13.2)	
Age group (years) at primary screening				
25–29[^]	792	30.9	8794	27.9
30–34	393	15.3	5051	16.0
35–39	281	11.0	3411	10.8
40–44	206	8.0	2683	8.5
45–49	230	9.0	2633	8.4
50–54	170	6.6	2376	7.5
55–59	192	7.5	2542	8.1
60–64	171	6.7	2333	7.4
65–69	127	5.0	1676	5.3
Indigenous status[$]				
Aboriginal and Torres Strait Islander	41	2.1	464	2.0
Non-Indigenous	1872	97.9	23,149	98.0
IRSD Quintile[¥]				
1 (Most disadvantaged)	441	17.2	4106	13.1
2	415	16.2	5527	17.6
3	475	18.6	6482	20.6
4	636	24.9	7337	23.3
5 (Least disadvantaged)	592	23.1	7983	25.4
State/territory[α]				
New South Wales	458	17.9	9464	30.0
Victoria	931	36.4	8526	27.1
Queensland	374	14.6	5840	18.5
Western Australia	390	15.2	3598	11.4
South Australia	262	10.2	2196	7.0
Tasmania	62	2.4	853	2.7
Australian Capital Territory	58	2.3	679	2.2
Northern Territory	25	1.0	341	1.1
Remoteness of residence[β]				
Major Cities	2052	80.1	23,236	73.8
Inner Regional	307	12.0	5557	17.6
Outer Regional	161	6.3	2226	7.1
Remote	29	1.1	329	1.0
Very Remote	14	0.5	150	0.5
Language				
English	207	8.1	3152	10.0
Other than English	158	6.2	1178	3.7
Unknown/Missing	2197	85.8	27,169	86.3
Country of birth				
Australia	1036	40.4	10,975	34.8
Outside Australia	173	6.8	1372	4.4
Unknown/Missing	1353	52.8	19,152	60.8
Year of primary screening test				
2017 Dec-2018	1428	55.7	16,025	50.9
2019	1037	40.5	13,772	43.7
2020	97	3.8	1698	5.4
2021	0	0.0	<6*	<0.02*
2022	0	0.0	0	0.0
Year of 12-month follow-up screening test				
2017 Dec-2018	65	2.5	911	2.9
2019	1332	52.0	14,945	47.4
2020	1070	41.8	13,906	44.1
2021	95	3.7	1721	5.5
2022	0	0.0	16	0.1
Length of follow-up[§] **(months; mean ± SD)**	19.6 (±6.9)		15.8 (±9.4)	
Most serious histology result				
CIN2+	241	9.4	3116	9.9
CIN3+	130	5.1	1401	4.4
Cancer	0	0	<6*	<0.02*
None	2321	90.6	28,383	90.1

[^] We have used ten-year intervals to classify the age groups for women aged 30–69 years. However, for the 25–29- year age group, we have used five-year intervals, because our analysis only includes women aged 25-29- year age group.

[$] For Indigenous status, information was missing for 25.3 % ($n = 649$) women in deferred group and 25.0 % ($n = 7886$) women in immediate group (i.e., records indicated "declined to answer"/"not stated"/"inadequately described").

[¥] IRSD quintile information was missing for 0.1 % ($n = 3$) women in deferred group and 0.2 % (n = 64) women in immediate group.

[α] State/territory information was missing for 1 woman in immediate group.

[β] Remoteness information was missing for 1 woman in immediate group.

[§] Measured from the 12-month follow-up test (after HPV (not 16/18) with ≤ LSIL LBC result at the initial screen).

[*] Counts <6 and proportions based on cells <6 are suppressed for confidentiality.

Findings for CIN2+ showed similar patterns in stratified analyses as those for CIN3+, with no major differences and generally overlapping 95 % CIs (Table S3, Figs. S5-S9).

4. Discussion

Our findings suggest that deferring colposcopy for a further 12 months in those with HPV (not 16/18) detected and ≤ LSIL at both primary screening and 12-month follow-up does not result in a higher risk of CIN3+ or CIN2+, with minimal and non-significant differences in cumulative incidence at 36 months (<1.5 % for CIN3+ and ~ 0.9 % for CIN2+) between those who attended colposcopy within six months or in 12–18 months. The number of cancers was extremely small in both groups (deferred, $n = 0$, immediate, $n =$ ≤6 (<0.02 %)). These findings support the safety of the updated guidelines for most participants. A persistent and significant difference in risk was observed, however, for Aboriginal and Torres Strait Islander women (even after excluding those ≥2 years overdue for screening, and in the context of a small sample); therefore, these findings also support guidelines recommending colposcopy referral for this group if HPV is detected at their first 12-month follow-up test. Our analyses do not directly support the earlier referral of those aged ≥50 years, as we found that the risk of disease was similar in the immediate and deferred groups and very low in absolute terms. However, women aged ≥50 years with HPV detected but no visible lesion at colposcopy are at higher risk of harbouring a covert abnormality in the canal compared to younger women with HPV detected [22]. Given the potential for delayed detection of covert canal lesions, studies with longer follow-up periods are required to investigate any differences between deferred and immediate colposcopy in women aged ≥50 years.

Our study adds to the international body of evidence on risk-based management in cervical screening programs, by demonstrating the safety of deferring colposcopy for those with HPV (not 16/18) types detected without high-grade cytological abnormalities, while also highlighting that there can be a need for tailored approaches among specific demographic groups, such as Aboriginal and Torres Strait Islander people. Our estimated 2-year (8.3 %) and 3-year (11.3 %) risks of CIN3+ in the deferred group are in the band of risk set in the Netherlands where follow-up within 6–18 months is recommended (CIN3+ risk 2–20 % within 2–3 years), rather than colposcopy [23]. While several prior studies report risk estimates for CIN3+ among individuals with HPV (not 16/18) detected, including studies from Italy [24], the USA [25] and the UK [26], direct comparisons with these studies are limited by differences in the target population (e.g., whether the group includes cytology findings ≤ LSIL or a different group), follow-up period and statistical measures used. However, our estimated 2-year and 3-year CIN3+ risks are consistent with a risk of 11.7 % within 21 months in a comparable group of 1704 women with HPV (not 16/18) and ≤ LSIL cytology in Norway [4]. Our finding that the risk of cancer within 2–3 years is extremely low among those with HPV (not 16/18) without high-grade cytology is consistent with previous studies reporting immediate risk of cancer conducted in China (no cancer cases found among 106 women aged >16 years with HPV (not 16/18) and negative cytology) [27] and Turkey (1 cancer case (0.1 %) found among 752 women aged 30–65 years with HPV (not 16/18) and negative cytology) [28]. However, these studies did not report cancer risk over 2–3 years.

We observed a significant difference in CIN3+ risks between the deferred and immediate groups for Aboriginal and Torres Strait Islander

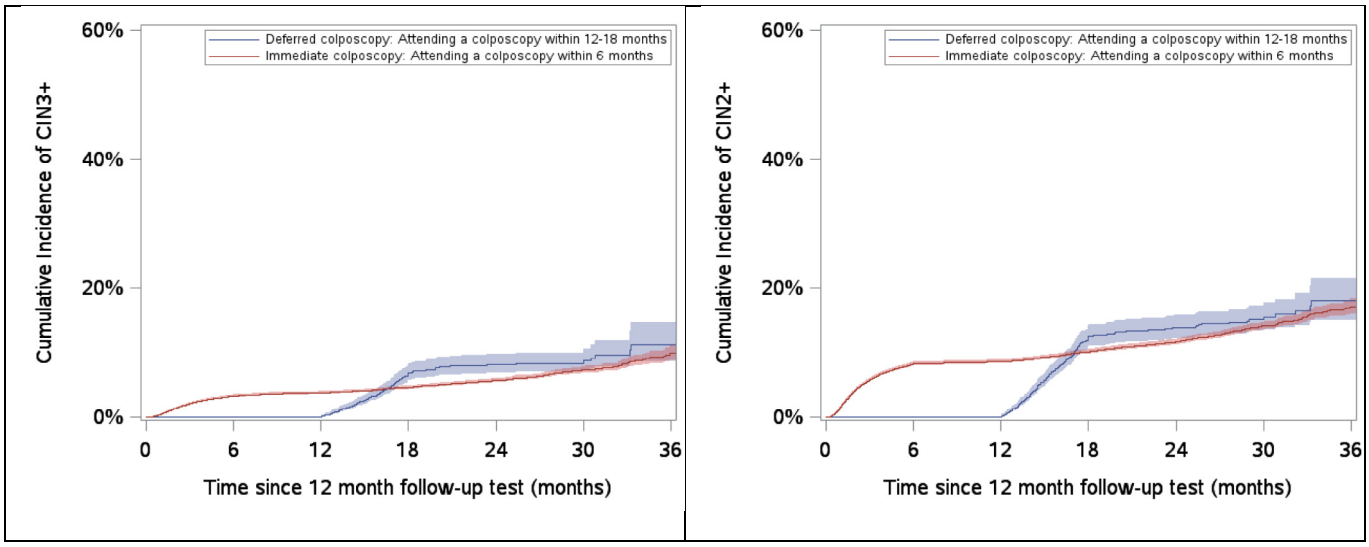


Fig. 2. Cumulative incidence of CIN3+ and CIN2+ by months of follow-up for deferred and immediate colposcopy groups.

women, but not for non-Indigenous women. Recent program data and previous research in Australia have demonstrated that Indigenous women are more likely than non-Indigenous women to have high-grade cervical abnormalities detected [29,30]. Indigenous women carry a disproportionate burden of cervical cancer in Australia and in several other countries, including Canada, New Zealand, and the USA [31–34]. A major contributor to the disparity in high-grade abnormalities and cervical cancer in Australia is that Aboriginal and Torres Strait Islander women are less likely to have been adequately screened [35,36]. Our analysis excluded individuals who were ≥2 years overdue for screening at the time of their initial test, which would remove some of this difference, although it is possible that Aboriginal and Torres Strait Islander women within the remaining group may still have been more overdue than non-Indigenous women. In our analysis, data on Indigenous status were missing for ~ 25 % of individuals (consistent with contemporaneous national reports using the same dataset [37]), although most of these people are likely non-Indigenous, as ~ 2 % of the cohort with known status identified as Aboriginal and Torres Strait Islander, compared with ~ 2.7 % of women aged 25–69 years in the 2021 Census [38]. Nevertheless, there is likely some under-reporting of Aboriginal and Torres Strait Islander people on the NCSR, and people who identify as such on the NCSR may differ from those who are not correctly identified on the NCSR. It is unknown how this may have affected our findings for Aboriginal and Torres Strait Islander women. Program data indicate that Aboriginal and Torres Strait Islander women are less likely to receive timely colposcopy which potentially provides an additional rationale to refer this group without delay [39]. The lack of accurate national-level cervical screening data for Aboriginal and Torres Strait Islander women is a barrier to fully addressing existing disparities as well as to reaching the WHO cervical cancer elimination targets in Australia [31]. Action is needed to ensure that accurate and complete data for Aboriginal and Torres Strait Islander women are included in the NCSR (and other data collections) including through a coordinated strategy involving Aboriginal and Torres Strait Islander communities, primary healthcare, pathology practices, and other stakeholders. Dedicated studies with larger samples would be needed to more precisely quantify the subsequent risks of serious cervical abnormalities and cervical cancer among Aboriginal and Torres Strait Islander women with HPV (not 16/18) and ≤ LSIL, or among subgroups in this population (for example, Aboriginal and Torres Strait Islander women living in urban vs rural/ remote areas).

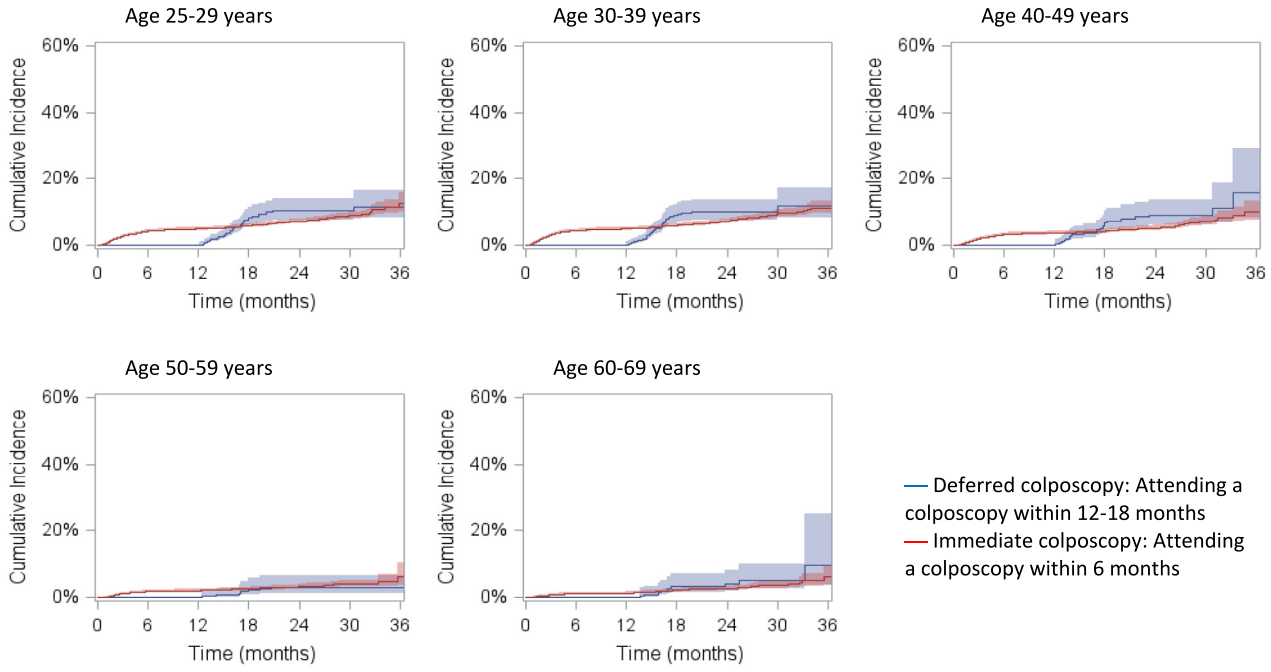
A notable exception to the overall finding was observed among those with a primary screening test in 2019 where the 24-month cumulative incidence of CIN3+ was significantly higher in the deferred than in the immediate group. Comparisons beyond 24 months were not possible for those with a primary test in 2019 as less follow-up time was available for 2019, and therefore, it was not possible to see if the difference was reduced by 36 months (as was generally the case for other stratifications). The difference may have been influenced by the following factors. Those with a primary test in 2019 would have had their 12-month follow-up between October 2019 and March 2021, since in our analysis, these visits were constrained to occurring between 9 and 15 months later. Updated guidelines for managing those at intermediate risk came into effect in February 2021 but were published as active in late 2020 and thus may have been used to guide management prior to February 2021. Therefore, a proportion of women with a primary test in 2019 and colposcopy 12–18 months after their 12-month follow-up test would have been attending colposcopy at 12–18 months because they were being managed under the updated guidelines, and therefore referred because they remained positive for HPV at a second 12-month follow-up test. This would make the deferred group a higher risk subset as, by design, those whose HPV infection had cleared by their second 12-month test were no longer referred. Additionally, there may be some differences in underlying risk of those who attended follow-up at different times during the COVID-19 pandemic over 2020–2021. COVID-19 substantially affected cervical screening and follow-up consultations by exacerbating existing barriers including access barriers and service availability to women's attendance for cervical screening [40,41], which may have led to many women postponing their colposcopy appointment. Those who attended colposcopy within six months during the COVID-19 pandemic were potentially more up-to-date with healthcare broadly than those who attended colposcopy at a later time (i.e., 12–18 months) and thus potentially at a lower risk of CIN3+. However, we may have been able to reduce these effects to some extent by excluding those who were ≥2 years overdue for cervical screening.

4.1. Strengths and limitations

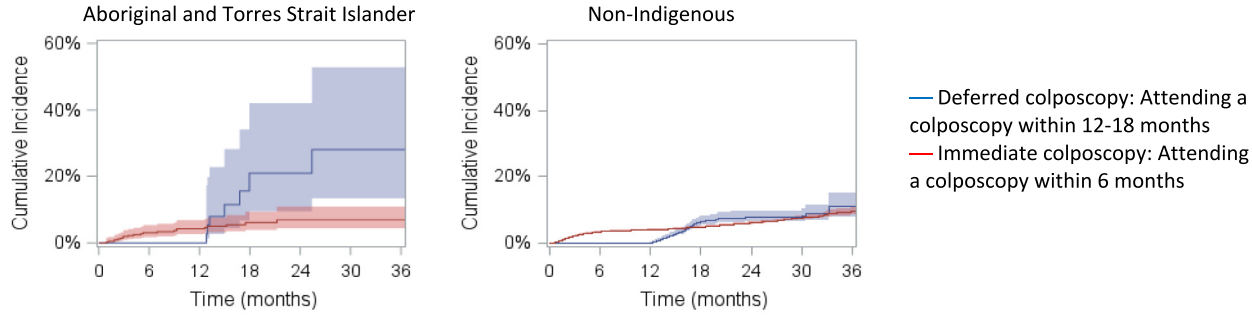
The key strength of this analysis is that it is based on a large comprehensive national set of routinely-collected data, with close-to-complete test information (where tests occurred). Findings from this analysis are likely generalisable to other settings with established population-based cervical screening programs. We were also able to consider risk stratified by age and other socio-demographic factors.

We acknowledge some methodological limitations that should be considered when interpreting the findings. First, we have limited the

A) Cumulative incidence of CIN3+ by age groups



B) Cumulative incidence of CIN3+ by Indigenous status



C) Cumulative incidence of CIN3+ by year of primary screening test

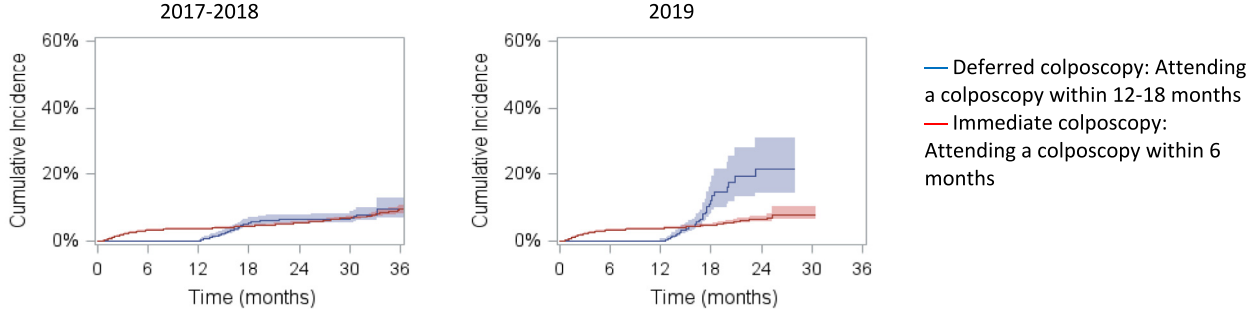


Fig. 3. Cumulative incidence of CIN3+ by months of follow-up for deferred and immediate colposcopy groups stratified by age groups, Indigenous status and year of primary screening test.

Table 2
Cumulative incidence of CIN3+ at 24 and 36 months since 12-month follow-up test by socio-demographic factors and year of primary screening test.

Baseline characteristics of participants	Deferred colposcopy group N	Immediate colposcopy group N	Cumulative Incidence of CIN3+ (95 % CI), by time since 12-month follow-up test (%)			
			24 months		36 months	
			Deferred colposcopy group	Immediate colposcopy group	Deferred colposcopy group	Immediate colposcopy group
Age groups (years) at primary screening						
25-29[α]	792	8794	10.4 (7.7–13.9)	7.2 (6.5–8.0)	11.7 (8.3–16.5)	12.6 (10–15.8)
30–39	674	8462	10.3 (7.6–13.8)	7.3 (6.6–8.1)	12.0 (8.2–17.4)	11.4 (9.6–13.5)
40–49	436	5316	9.1 (6.0–13.6)	5.2 (4.5–6.0)	15.8 (8.2–29.1)	10.1 (7.5–13.4)
50–59	362	4918	3.0 (1.3–6.7)	3.2 (2.6–3.9)	3.0 (1.3–6.7)	6.3 (3.7–10.6)
60–69	298	4009	4.1 (1.9–8.5)	2.7 (2.1–3.4)	9.8 (3.6–25.3)	6.1 (3.8–9.6)
Indigenous status						
Aboriginal and Torres Strait Islander	41	464	20.9 (9.6–42.1)	7.0 (4.4–11.0)	**28.1 (13.4–52.9)**	**7.0 (4.4–11.0)**
Non- Indigenous	1872	23,149	7.9 (6.4–9.8)	6.0 (5.6–6.4)	11.1 (8.0–15.3)	9.9 (8.7–11.2)
IRSD quintile						
1 (most disadvantaged)	441	4106	8.4 (5.3–13.1)	6.4 (5.4–7.5)	9.1 (5.8–14.1)	12.5 (8.7–17.9)
2	415	5527	7.7 (5.0–11.7)	6.4 (5.6–7.3)	7.7 (5.0–11.7)	12.0 (9.3–15.5)
3	475	6482	8.0 (5.4–11.8)	5.8 (5.1–6.5)	16.8 (8.8–31.0)	9.7 (7.3–12.9)
4	636	7337	6.8 (4.5–10.2)	5.7 (5.1–6.5)	6.8 (4.5–10.2)	8.0 (6.5–9.8)
5 (least disadvantaged)	592	7983	**10.3 (7.3–14.4)**	**4.7 (4.2–5.4)**	15.3 (9.0–25.2)	9.1 (7.1–11.7)
State/territory						
New South Wales	458	9464	8.9 (5.9–13.5)	6.1 (5.6–6.8)	15.3 (7.2–31.1)	11.8 (9.7–14.3)
Victoria	931	8526	**7.8 (5.7–10.7)**	**4.9 (4.4–5.6)**	7.8 (5.7–10.7)	8.3 (6.3–11.0)
Queensland	374	5840	6.9 (4.2–11.4)	6.0 (5.3–6.9)	17.5 (9.2–31.6)	10.6 (7.9–14.2)
Western Australia	390	3598	6.9 (4.3–10.9)	5.4 (4.5–6.4)	6.9 (4.3–10.9)	9.2 (6.2–13.7)
South Australia	262	2196	11.2 (7.0–17.6)	6.7 (5.4–8.2)	11.2 (7.0–17.6)	10.4 (7.5–14.3)
Tasmania	62	853	16.9 (8.3–32.7)	6.8 (5.0–9.1)	16.9 (8.3–32.7)	9.8 (5.2–18.0)
Australian Capital Territory	58	679	1.8 (0.2–11.8)	3.2 (1.8–5.6)	1.8 (0.2–11.8)	5.4 (2.8–10.5)
Northern Territory	25	341	12.3 (3.2–41.2)	3.6 (1.8–7.3)	12.3 (3.2–41.2)	3.6 (1.8–7.3)
Year of primary screening						
2017 Dec-2018	1428	16,025	6.5 (5.2–8.2)	5.4 (5.0–5.8)	9.6 (7.0–13.1)	9.6 (8.5–10.9)
2019	1037	13,772	**21.4 (14.5–31.0)**	**6.7 (5.8–7.7)**	.	.
2020	97	1698				
2021	0	<6[*]				

[α] We have used ten-year intervals to classify the age groups for women aged 30–69 years. However, for the 25–29- year age group, we have used five-year intervals, because our analysis only includes women aged 25–69 years.
[*] Counts <6 are suppressed for confidentiality.

analysis period to the first 36 months after the 12-month follow-up test, as only 1 % of women had follow-up data beyond this point; however, this likely captures the most clinically important period. Second, we were unable to use the log-rank test to compare outcomes between groups, because by design the two groups of interest differed for at least the first 18 months of follow-up. Instead, we compared the 95 % CIs around the outcomes of interest between groups. We were also unable to use Cox-proportional hazard models (to take additional confounding variables into account), due to violations of the proportional hazards assumption; we instead present stratified results. The following three additional data limitations would have affected both groups non-differentially, thus potentially not altering the main findings. First, histology data may be incomplete in some cases, which would limit the accurate assessment of CIN3+ (and CIN2+) cases. Second, our estimates of age were restricted to using month and year of birth; thus calculated age would be incorrect by a very small margin for some women (although the effects of this have been decreased by using age groups). Third, the classification of remoteness area was based on the 2016 Census data definitions (the most recent available at that time) and the woman's most recent address, both of which may differ slightly to that at the time of the screening test or colposcopy in 2018–2021.

In addition, this observational analysis understandably included many more people in the immediate (92.5 %) than the deferred (7.5 %) colposcopy group, reflecting the clinical guidelines in place at that time. If there were systematic differences such that those who attended colposcopy nearer to the recommended time (immediate group) were at higher risk than those who attended much later than was recommended, the comparable risk we observed between the two groups at 36 months may mask an underlying increase in risk in the deferred group due to the delay. While this cannot be completely ruled out, the differences in risk associated with past screening have largely been minimised as our research question excluded those who were two or more years overdue for screening at their primary screening test. The groups differed somewhat by area-level socio-economic disadvantage and remoteness, but our findings stratified by these variables were consistent with the overarching findings. These differences in the immediate and deferred cohorts by area-level socio-economic disadvantage and remoteness likely reflect differences in timely access to colposcopy services, as routine reports show for referrals in this period, the proportion seen within six months tended to be lower in more disadvantaged areas, and South Australia, Western Australia and Victoria, and higher in inner regional areas and New South Wales. It is also lower among those referred at 12 months than those referred at initial screening, suggesting that in settings where resources are stretched, those referred at 12 months are likely seen with lower priority [29]. If anything, these differences suggest the deferred group may be at higher underlying risk than the immediate group, and is consistent with a slightly higher risk seen at 24 months, and so the minimal difference in risk seen at 36 months is reassuring.

5. Conclusions

Our findings support the safety of updated guidelines that defer colposcopy in women with HPV (not 16/18) and ≤ LSIL until they have consistently had these results over a period of two years, and also the different recommendation for Aboriginal and Torres Strait Islander women by demonstrating a significantly higher risk of CIN3+ in this group when colposcopy was delayed. Our analysis does not directly support excluding women aged ≥50 years from the updated guidelines,

as their risk remained low and did not differ significantly between groups. In future, similar studies with longer follow-up periods could be conducted to investigate the subsequent risks of serious cervical abnormalities and cervical cancer for women aged ≥50 years with HPV (not 16/18) and ≤ LSIL.

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Ethics approval and consent to participate

Ethics approval to access this data was obtained from The University of Sydney Human Research Ethics Committee (2022/HE000120).

CRediT authorship contribution statement

Monjura Nisha: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Ya-Lun Liang:** Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Data curation. **Deborah Bateson:** Writing – review & editing, Validation, Investigation. **Marion Saville:** Writing – review & editing, Validation, Investigation. **C. David Wrede:** Writing – review & editing, Investigation. **David Goldsbury:** Writing – review & editing, Formal analysis. **Marc Arbyn:** Writing – review & editing, Validation. **Karen Canfell:** Writing – review & editing, Validation, Supervision, Resources, Investigation, Funding acquisition, Conceptualization. **Megan A. Smith:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

DB is the chair and MS and CDW are the member of the National Cervical Screening Program Clinical Advisory Group of the Department of Health, Disability and Ageing, Australia. DB and KC are co-PIs on a major implementation program "Elimination Partnership for Cervical Cancer in the Indo-Pacific" which receives support from the Australian government, the Minderoo Foundation and equipment donations from Cepheid Inc. MS is employed by the Australian Centre for the Prevention of Cervical Cancer (ACPCC), which has received equipment or supplies from Abbott, AusDiagnostics, Cepheid, Copan, Hologic, Microbiologics, MicroBix, NRL, Qiagen, Rovers, Roche, Seegene for research and validation studies. She is also a member of the Global Initiative Against HPV and Cervical Cancer Advisory Board, the Pacific Friends of Global Health Advisory Board, University of Melbourne. CDW is the chair of ACPCC. MAS, MN, YL and KC receive contract funding through their work institution from the Department of Health, Disability and Ageing, Australia to monitor the safety of the National Cervical Screening Program. KC and MS are co-PIs of an investigator-initiated trial of HPV screening in Australia ("Compass"), which is conducted by the ACPCC which has previously received equipment and a funding contribution for the Compass trial from the Australian government, Roche Molecular Systems USA and Micobix. KC is a chair or member of a number of government or meetings convened by the World Health Organization (WHO), or philanthropic organizations such as Bill and Melinda Gates Foundation (BMGF). She is also a chair of the Expert Advisory Group to the Elimination Response for Australian Government, and Cancer Screening and Immunization Committee of Cancer Council Australia. MA is involved in Horizon 2020 Framework Programme for Research and Innovation of the European Commission, through the RISCC Network (Grant No. 847845); German Guideline Program in Oncology, WHO Guidelines on Screening and Treatment of Pre-Invasive Cervical Disease; European Commission Initiative on Cervical Cancer (EC-CvC); VALGENT and VALHUDES.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ygyno.2025.11.012.

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