



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1664 – Improvements to the National Cervical Screening Program Self-Collection Policy

Applicant: Department of Health

Date of MSAC consideration: MSAC 81st Meeting, 31 March – 1 April 2021

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting expansion of the eligibility to participate in cervical screening using self-collection was received from the Cancer, Hearing and Program Support Division of the Department of Health on behalf of the National Cervical Screening Program (NCSP).

2. MSAC’s advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC supported the amendment of Medicare Benefits Schedule (MBS) items 73071 and 73073 to expand access to self-collection in the NCSP. MSAC concluded that the diagnostic performance of human papillomavirus (HPV) testing is not materially different between self-collected samples and clinician-collected samples, and advised that the associated increase in costs would be justified by the intended increase in screening uptake. However, MSAC noted that there are currently no self-collection kits listed on the Therapeutic Goods Administration’s Australian Register of Therapeutic Goods (ARTG), which presents a potential implementation issue.

MSAC-recommended changes to the descriptors for MBS items 73071 and 73073

Category 6 - PATHOLOGY SERVICES – Group P6, Cytology	
MBS item 73071	A test, including partial genotyping, for oncogenic human papillomavirus that may be associated with cervical pre-cancer or cancer: (a) performed on a self-collected vaginal specimen; and (b) for an asymptomatic patient who is at least 30 years 24 years and 9 months of age For any particular patient, once only in a 7-year 57 month period.
MBS item 73073	A test, including partial genotyping, for oncogenic human papillomavirus: (a) performed on a self-collected vaginal specimen; and (b) for the follow-up management of a patient with oncogenic human papillomavirus infection or cervical pre-cancer or cancer that was detected by a test to which item 73071 applies. For any particular patient, once only in a 24 month period.

Consumer summary

The Cancer, Hearing and Program Support Division of the Australian Government Department of Health applied, on behalf of the National Cervical Screening Program, to expand the funding of self-collection for cervical screening to include everyone eligible for cervical screening.

The National Cervical Screening Program aims to detect cervical cancer at an early stage in people who do not have symptoms. Detecting cervical cancer early is important for improving people's chance of survival. Cervical cancer is usually caused by infection with a particular virus, called human papillomavirus (HPV). In Australia, cervical screening is recommended every five years for all people with a cervix, aged 25 to 74, who have ever been sexually active. The initial step in cervical screening is to check a sample of cells to see whether they have the HPV that can lead to cervical cancer.

Until now, most people have participated in cervical screening by their healthcare provider taking a swab of their cervix, and testing the swab for HPV. This is called a clinician-collected sample. Self-collected samples are when the person takes a vaginal swab by themselves. Within Australia, self-collecting a sample is currently an option only available to people aged 30 or older who have never participated in cervical screening, or who are in a group that is known to have a low rate of participation in the cervical screening program.

MSAC advised that expanding self-collection is an important option to increase access to screening, particularly for people who may feel uncomfortable with a clinician collecting their sample. People who choose to use self-collection would still access cervical screening through their healthcare provider, to allow for education and engagement. However, the healthcare provider would not collect the sample. A further important difference with the process for self-collected samples is that if a person's self-collected sample detects HPV, the next step is for them to return to their healthcare provider or specialist to collect another type of sample for the next step in cervical screening.

MSAC reviewed the evidence and concluded that HPV testing using self-collected samples is just as accurate as using clinician-collected samples. MSAC expected that making self-collection available to more people would encourage more people to participate in cervical screening. This would both increase costs to the government, and better achieve the aim of cervical screening.

MSAC advised that doctors and consumers would need education and support about the changes. Also a kit for self-collection would ideally need to be commercially available (i.e. listed on the Australian Register of Therapeutic Goods) to support broad roll-out of self-collection.

MSAC's advice to the Commonwealth Minister for Health

MSAC supported expanding access to self-collection to include everyone eligible for cervical screening. MSAC considered self-collection to be safe and effective, and that it would likely increase participation in cervical screening.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that the purpose of this application was to examine the evidence to support the change to the MBS to expand access to self-collected samples under the NCSP. The expansion would allow self-collection (through primary care) to all eligible people with a cervix aged between 25 and 74 years (about 6.80–7.23 million people) who have ever been sexually active. Self-collection is currently restricted to people 30 years and over who are overdue for a cervical screening test (CST) by 2 years or more, in a population known to be under-screened, or who have never been screened.

MSAC noted the Department-contracted assessment report (DCAR). Entities involved in framing the application were the Standing Committee on Screening and the Self-Collection Expert Advisory Group (SCEAG). The DCAR focused on the comparative analytical performance of HPV testing based on self-collected versus clinician-collected samples, and on providing a financial impact analysis. MSAC noted the complementary feedback via the public consultation arrangements was extensive and largely positive, indicating in particular that increased self-collection may lead to increased participation in cervical screening in hard-to-reach communities.

MSAC supported the proposed changes to the item descriptors for self-collected vaginal specimens (MBS items 73071 and 73073) to facilitate wider uptake of self-collection for HPV testing.

MSAC noted the large body of evidence presented in the DCAR showed no material difference in the diagnostic accuracy of HPV testing between using self-collected and clinician-collected samples (relative sensitivity = 0.98; 95% CI: 0.96 to 1.01; relative specificity = 0.99; 95% CI: 0.98 to 1.01). MSAC noted that the DCAR had included the studies that were most relevant to the Australian setting, which led to small numerical differences compared with the meta-analysis by Arbyn et al.¹. MSAC accepted that these differences were explained by the differences in the inclusion criteria across the meta-analyses. MSAC also noted that the DCAR had downgraded the overall quality of evidence to be low, however, MSAC considered that more confidence can be given to the pooled estimates of diagnostic accuracy, due to the large sample size and consistency of the overall evidence base.

MSAC noted the participation rate within the National Cervical Screening Program of 46.3%² over the two years 2018-19, and the DCAR's finding that people offered HPV testing using self-collected vaginal samples were more than twice as likely to participate in cervical screening, compared with those offered testing on a clinician-collected sample (overall relative participation rate = 2.07; 95% CI: 1.78 to 2.41), with adherence to subsequent follow-up estimated to be 80.7% (95% CI: 75.5% to 85.1%). MSAC noted that studies using an opt-in approach for inviting individuals to participate in screening were the most similar to the Australian context and had the highest relative participation rate. MSAC noted that continuing to encourage people to interact with a clinician was preferred (and supported by consultation feedback) for other reasons beyond increasing participation rates. However MSAC indicated that the evidence presented in the DCAR suggested that other invitation

¹ Arbyn, M. et al. (2018). Detecting cervical precancer and reaching underscreened women by using HPV testing on self-samples: updated meta-analyses. *BMJ* 363, k4823.

² AIHW (2020) [National Cervical Screening Program monitoring report 2020](#). Cancer series no. 130. Cat. no. CAN 138. Canberra: AIHW.

scenarios, such as a complementary mail-out test kit, could be considered in the future as this would likely further increase participation rates.

MSAC considered that broadening access to self-collection would be expected to increase cervical screening in known under-screened populations in particular, but may also prompt switching among the currently screened population from clinician-collected to self-collected samples. MSAC noted that this would increase costs to the government to a varying extent depending on the underlying assumptions, but advised that the increased costs would be justified because maximising screening participation is the intent of a screening program, and the main benefit is in reducing future cancer rates and their associated treatment costs.

MSAC noted several implementation issues, including supporting changes in clinician behaviour through education, and potentially empowering consumers to initiate a conversation about cervical screening with their clinician. Importantly, there is not currently a commercially available self-collection kit that is registered on the ARTG for this purpose. MSAC noted that the kit would likely be the same as the kit already being used for respiratory sampling (e.g. for COVID-19 tests), but that this currently represents an ‘off-label’ use for that kit. MSAC also expected that should a commercially available test be listed on the ARTG, laboratories should be able to support the use of these kits for self-collected cervical screening tests.

4. Background

The NCSP Renewal was considered by MSAC in 2013 and 2014 ([MSAC application 1276](#)). The multi-tiered application allowed for consideration of a range of aspects of the screening program, including the cost-effectiveness of different screening tests and pathways. At its April 2014 meeting, MSAC supported self-collection for under-screened and never-screened women, that has been facilitated by a medical or nurse practitioner (or on behalf of a medical practitioner) who also offers mainstream cervical screening³. MSAC made this recommendation on the basis that it would enable an acceptable option for cervical screening amongst hard to reach groups.

In December 2017, the NCSP Renewal included implementation of an option for self-collection of the sample to be used for HPV testing ([MBS item 73071](#)) for patients who are over 30 and who have never participated or who are under-screened⁴, including patients overdue by at least two years.

At its October 2019 meeting, the MSAC Executive noted that the Standing Committee on Screening of the Australian Health Ministers’ Advisory Council had endorsed short-term and long-term modifications to the NCSP self-collection policy. The Department convened the SCEAG to review the recommendations from SCoS, consider emerging issues, and contribute to a consultation process and implementation plan.

³ [MSAC application 1276](#) – Public Summary Document (PSD)

⁴ Groups who are under-screened include: Aboriginal and Torres Strait Islander women, Culturally and Linguistically Diverse (CALD) women, women with a disability, women living in remote and very remote areas, women who are homeless or without a permanent residence, women who have experienced female genital mutilation, women who have experienced sexual abuse, women who identify as lesbian, gay, bisexual, or are same-sex attracted, transgender men, women from low socio-economic backgrounds, women going through menopause and older women, and women who have chosen to not screen in the past.

At its January 2020 meeting, SCEAG recommended that:

- the policy be modified to allow **all** eligible people a **choice** between a self-collected or a clinician-collected sample, both accessed through a healthcare provider; and
- the policy change be implemented universally and **without staging** (i.e. not via the two-phase process previously endorsed by Standing Committee on Screening).

The MSAC Executive advised in March 2020 that it remained appropriate that an assessment of clinical evidence on the analytical performance of HPV testing in the context of self-collected swabs compared to clinician-collected samples should be provided to ESC and MSAC. A focussed DCAR was commissioned. A report⁵ containing additional modelling by the CCNSW was also commissioned, providing an alternative analysis of potential utilisation and net financial implications.

5. Prerequisites to implementation of any funding advice

The laboratory requirements for cervical screening testing, including self-collected and clinician-collected samples, remain as described by the National Pathology Accreditation Advisory Council (NPAAC)⁶.

6. Proposal for public funding

The proposal is that the eligibility criteria for self-collected samples for cervical screening be expanded to include all people eligible for cervical screening (i.e. people with a cervix aged 25-74 years who have ever been sexually active).

Proposed changes to the existing MBS item descriptors for HPV testing of self-collected samples for cervical screening (MBS item 73071, Table 1) and for follow-up management (MBS item 73073, Table 2) are shown below. Changes to the explanatory notes accompanying the cervical screening test MBS items were also proposed.

Table 1 Proposed changes to descriptor for MBS item 73071

Category 6 - PATHOLOGY SERVICES – Group P6, Cytology
A test, including partial genotyping, for oncogenic human papillomavirus that may be associated with cervical pre-cancer or cancer: (a) performed on a self-collected vaginal specimen; and (b) for an asymptomatic patient who is at least 30 years 24 years and 9 months of age For any particular patient, once only in a 7-year 57 month period.
Fee: \$35.00 Benefit: 75% = \$26.25 85% = \$29.75

Source: Department policy paper, attachment A

⁵ Smith M, Hall M, O'Farrell X, Canfell K. (2021). Predicted utilisation and budget impact of broadening access to self-collection in the National Cervical Screening Program. Report to the Department of Health.

⁶ NPAAC (2019) Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019). Source: [Department of Health](#).

Table 2 Proposed changes to descriptor for MBS item 73073

Category 6 - PATHOLOGY SERVICES – Group P6, Cytology
A test, including partial genotyping, for oncogenic human papillomavirus: (a) performed on a self-collected vaginal specimen; and (b) for the follow-up management of a patient with oncogenic human papillomavirus infection or cervical pre-cancer or cancer that was detected by a test to which item 73071 applies For any particular patient, once only in a 24-month period.
Fee: \$35.00 Benefit: 75% = \$26.25 85% = \$29.75

Source: Department policy paper, attachment A

7. Summary of public consultation feedback/consumer Issues

The Department conducted a formal online targeted consultation process via the consultation hub to seek feedback on the proposed policy changes and requirements for implementation. The Department received 76 responses from a range of stakeholders: healthcare providers (28), the pathology sector (11), sexual health organisations (7), Aboriginal and Torres Strait Islander organisations (6), women’s health organisations (6), Cancer foundations (5), LGBTIQ organisations (4), Primary Health Networks (4), HPV test manufacturers (3), and obstetrics and gynaecology specialists (2).

Consultation feedback was mostly supportive, indicating that if funded, this proposal should lead to increased participation in cervical screening. The concerns raised included clinician education and workflows, and the need for a commercially available self-collected sample kit.

8. Proposed intervention’s place in clinical management

Description of proposed intervention

The proposed intervention is the expansion of self-collection of vaginal samples for cervical screening, to include all people eligible for cervical screening (i.e. people with a cervix aged 25-74 years who have ever been sexually active). MBS funding for HPV testing on self-collected vaginal samples is currently only available for people with a cervix aged 30 years or more, who have never participated in cervical screening, or are overdue for cervical screening by more than 2 years (MBS item 73071).

Self-collected sample testing would continue to be accessed through healthcare providers, who will provide the option to participate in cervical screening via self-collection of vaginal sample or clinician-collection of cervical samples, to all eligible people during a consultation. The practitioner will facilitate access to screening, and arrange delivery of completed samples to a pathology laboratory for a primary HPV cervical screening test.

Cervical screening involves testing vaginal or cervical samples for the presence of oncogenic human papillomavirus (HPV), a virus that is known to cause cervical cancer. The test, also referred to as the primary screening test, tests for the 13 HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68, and separately identifies the higher risk HPV types 16

and 18⁷. The assay used for testing is a polymerase chain reaction (PCR) test⁸. Clinician-collected screening testing comprises partial genotyping of HPV followed by liquid-based cytology (LBC) to test for cervical cell abnormalities in people with a positive HPV result. Self-collected vaginal samples can be used for HPV testing, but not for follow-up LBC testing.

The Netherlands is the only other country with a cervical screening programme that provides an option for self-collection of vaginal samples for primary HPV testing⁹.

The current participation rate in cervical screening is 46.3%^{10,11}. There is some evidence that self-collection of samples might increase the participation rate in cervical cancer screening¹². Knowing that screening can help reduce cervical cancer incidence and mortality, providing wider options to eligible people for self-collection of samples can decrease the overall incidence of new cervical cancer cases and deaths.

Description of medical condition(s)

Cervical cancer occurs in the cells of the cervix and is one of the most preventable cancers. Cervical cancer develops when abnormal cells in the lining of the cervix begin to multiply and form precancerous abnormalities. If undetected, this precancerous stage can develop into cervical cancer that can spread into surrounding tissue. Because the pre-cancerous stage can last for many years prior to the development of invasive disease, there is the opportunity for early monitoring, detection and treatment, which can help reduce cervical cancer incidence and mortality, and improve survival rates by detecting these cancers early¹³. The effectiveness of cervical cancer screening is demonstrated by the fact that 70% of all cervical cancers in Australia occurred in people who had never screened or were lapsed screeners¹⁴. Further, the rate of death from cervical cancer dropped to 2.1 in 100,000 people in 2017, half the rate since the inception of the screening program¹⁵.

⁷ NPAAC (2019) Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019). Source: [Department of Health](#).

⁸ Anderson, L., *et al.* (2018) National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Sydney: Cancer Council Australia. Source: [Cancer Council Australia](#).

⁹ Aitken, C.A., *et al.* (2019) Introduction of primary screening using high-risk HPV DNA detection in the Dutch cervical cancer screening programme: a population-based cohort study. *BMC Medicine*, 17(1), 228.

¹⁰ Proportion of the target population who had a screening HPV test in the two year period 2018-19. This data collection period is within the transition period from two-yearly pap smears to five-yearly HPV tests under the Renewed NCSP.

¹¹ AIHW (2020) [National Cervical Screening Program monitoring report 2020](#). Cancer series no. 130. Cat. no. CAN 138. Canberra: AIHW.

¹² Arbyn, M., *et al.* (2018) Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. *BMJ*, 363, k4823.

¹³ WHO (2014) Comprehensive cervical cancer control: a guide to essential practice Second Edition. [Source](#).

¹⁴ AIHW (2019) [National Cervical Screening Program monitoring report 2019](#). Cancer series no. 125. Cat. no. 132. Canberra: AIHW.

¹⁵ AIHW (2019) [National Cervical Screening Program monitoring report 2019](#). Cancer series no. 125. Cat. no. 132. Canberra: AIHW.

The most common risk factor for cervical cancer is infection with HPV, responsible for about 93% of all cervical cancers in Australia¹⁶. Of these, the high-risk oncogenic HPVs are types 16 and 18, which are found in 70 to 80% of all cervical cancer cases¹⁷. Most HPV infections resolve themselves, but sometimes HPV can cause cervical cells to become abnormal, that eventually could develop into cancer. Not all these pre-cancerous abnormalities will progress to cervical cancer. However, it is not possible to know which precancerous abnormalities will regress without treatment, and so the detection of these abnormal cells is important to identify cases that would progress to the cervical cancer stage. This potential for progression to cervical cancer can be detected earlier using HPV screening.

Clinical management algorithm

The current (Figure 1) and proposed (Figure 2) clinical management algorithms for cervical cancer screening are illustrated and described below. The DCAR's proposed algorithm differs only in the population eligible for self-collected samples. Note, these algorithms do not include the February 2021 update to the clinical management pathway for people at intermediate risk¹⁸.

¹⁶ Brotherton, J.M.L., *et al.* (2017) Looking beyond human papillomavirus (HPV) genotype 16 and 18: Defining HPV genotype distribution in cervical cancers in Australia prior to vaccination. *Int J Cancer*, 141(8), 1576-1584.

¹⁷ Brotherton, J.M. (2008) How much cervical cancer in Australia is vaccine preventable? A meta-analysis. *Vaccine*, 26(2), 250-256.

¹⁸ Canfell, K, *et al.*, Cancer Council Australia Cervical Cancer Screening Guidelines Working Party. [Oncogenic HPV types not 16/18](#)

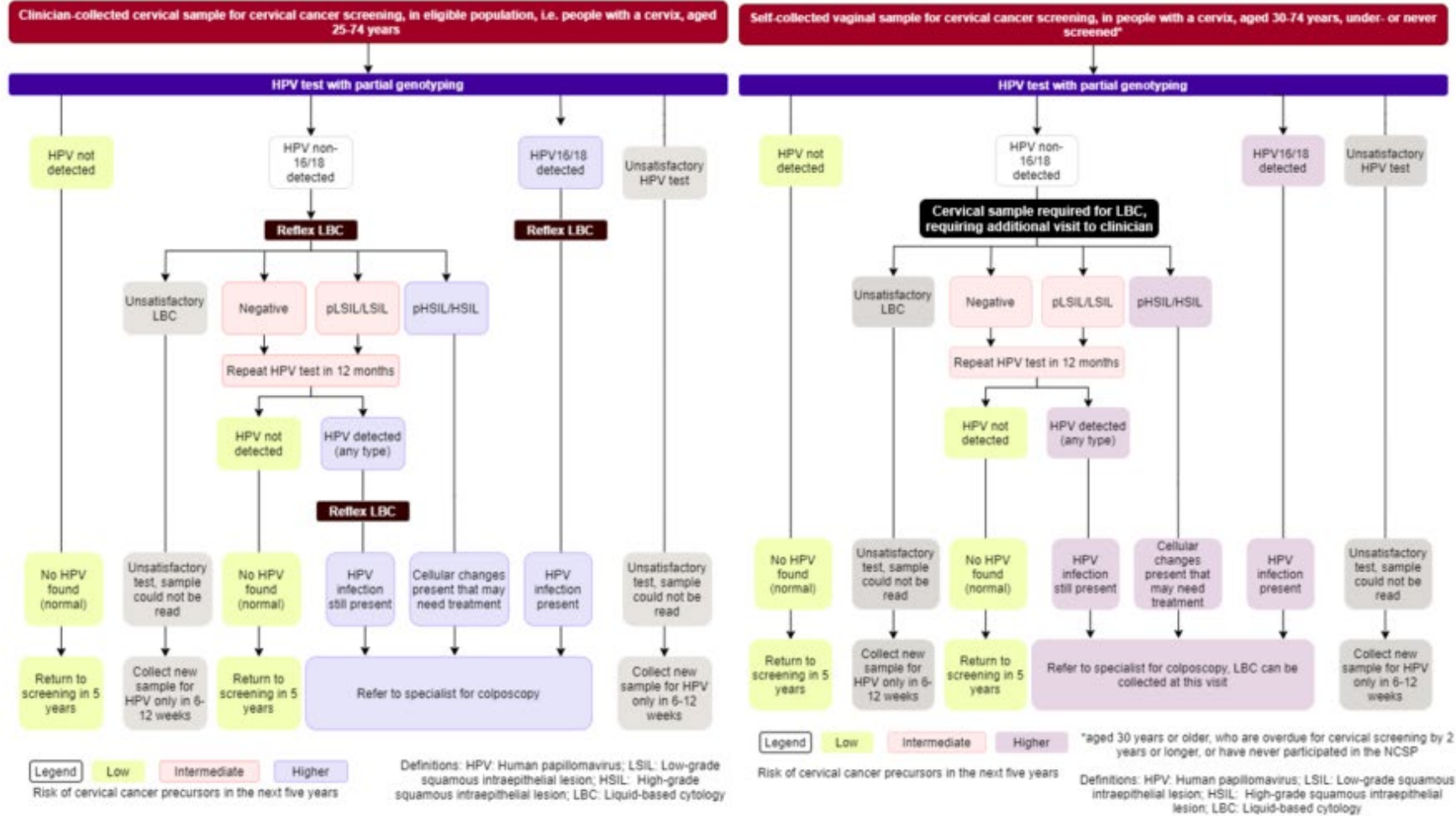


Figure 1 Current clinical management algorithm – clinician-collected cervical sample and self-collected vaginal sample by eligible people

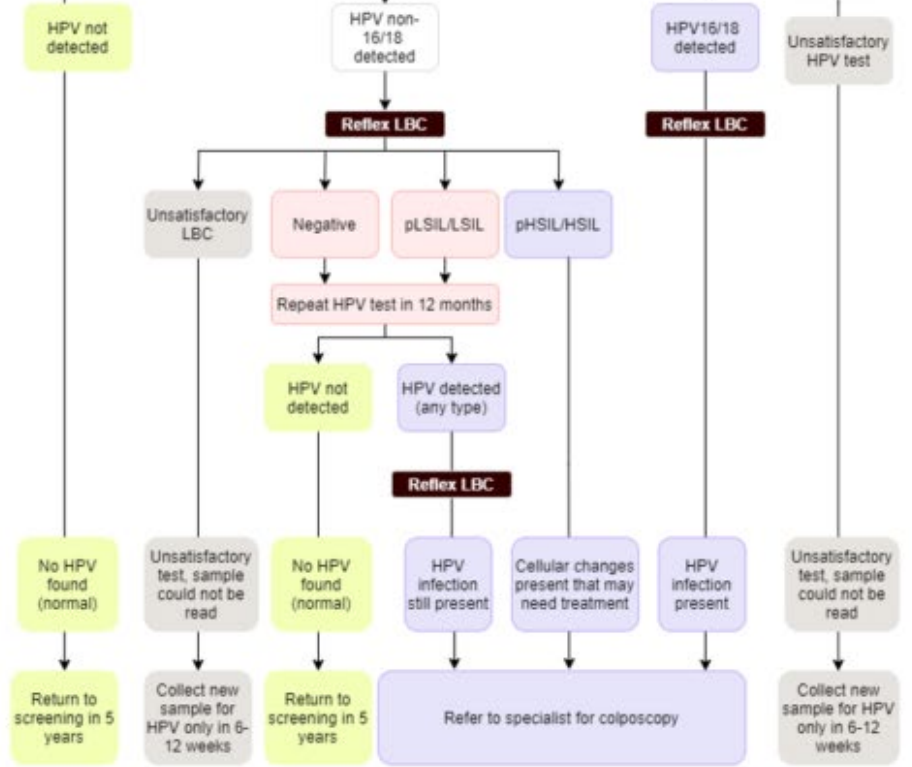
Adapted from Department of Health's "Understanding the National Cervical Screening Program Management Pathway: A Guide for Health Providers" (2017).

Note: the current clinical management pathway changed from that shown here in February 2021. For details of the updated clinical management algorithm, please see: Department of Health (2021) [Important changes to the National Cervical Screening Program's Clinical Guidelines pathway for women at intermediate risk](#).

Source: based on DCAR, Figure 5.

Clinician-collected cervical sample for cervical cancer screening, in eligible population, i.e. people with a cervix, aged 25-74 years

HPV test with partial genotyping

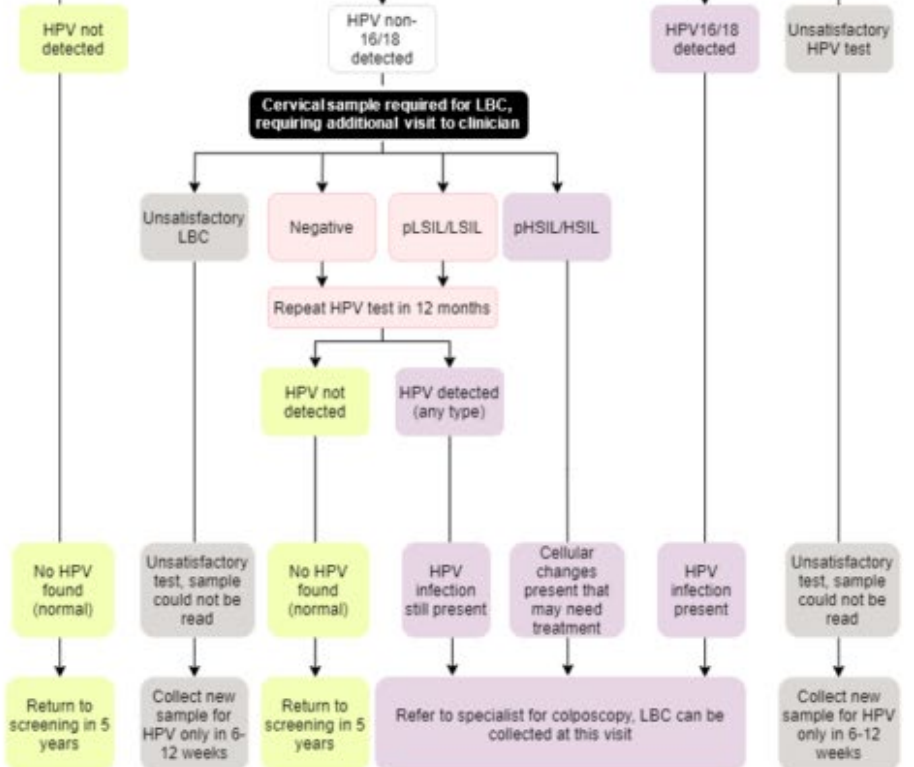


Legend Low Intermediate Higher
Risk of cervical cancer precursors in the next five years

Definitions: HPV: Human papillomavirus; LSIL: Low-grade squamous intraepithelial lesion; HSIL: High-grade squamous intraepithelial lesion; LBC: Liquid-based cytology

Self-collected vaginal sample for cervical cancer screening, in eligible population, i.e. people with a cervix, aged 25-74 years

HPV test with partial genotyping



Legend Low Intermediate Higher
Risk of cervical cancer precursors in the next five years

Definitions: HPV: Human papillomavirus; LSIL: Low-grade squamous intraepithelial lesion; HSIL: High-grade squamous intraepithelial lesion; LBC: Liquid-based cytology

Figure 2 Proposed clinical management algorithm – clinician-collected cervical sample and self-collected vaginal sample

Adapted from Department of Health's "Understanding the National Cervical Screening Program Management Pathway: A Guide for Health Providers" (2017)
Source: based on DCAR, Figure 6]

The current primary cervical screening test comprises testing for the presence of oncogenic HPV types, followed by reflex LBC of HPV-positive cervical specimens. Because the LBC is performed on the same cervical sample used for HPV testing (when a clinician-collected sample is used for HPV testing), it is termed a 'reflex LBC'. The current algorithm uses a risk-based approach to managing people in the NCSP:

- Those with HPV types 16/18 detected in their clinician-collected cervical sample are considered at higher risk, and always referred for colposcopic assessment, after a reflex LBC.
- Those with HPV non-16/18 detected in their clinician-collected cervical sample, also undergo a reflex LBC.
 - If the reflex LBC is either negative or identifies a low-grade squamous intraepithelial lesion (LSIL) or probable LSIL (pLSIL), these people are considered at intermediate risk of developing cervical cancer, and asked to repeat the HPV test in 12 months.
 - If the reflex LBC identifies a high-grade squamous intraepithelial lesion (HSIL) or probable HSIL (p-HSIL), indicating cellular changes in the cervix that require treatment, these people are considered high-risk and referred for colposcopic assessment.
- Those with no HPV detected in their sample are considered at low risk of developing cervical cancer, and are recommended to rescreen in 5 years.
- Those whose sample was deemed unsatisfactory, i.e. could not be read for detection of HPV, are invited to provide cervical samples for an LBC in 6 to 12 weeks.

The proposed clinical management algorithm for a clinician-collected cervical sample is the same as the current algorithm for cervical screening testing on clinician-collected cervical sample. The proposed algorithm for cervical screening testing using a self-collected vaginal sample is different from the current algorithm in the following ways:

- a) the option to self-collect a vaginal sample will be offered to all people eligible for cervical cancer screening under the renewed NCSP, as opposed to being offered only to people with a cervix aged 30 years or older who either are overdue by more than 2 years, or have never screened; and
- b) because a vaginal sample cannot be used for LBC testing, the detection of HPV non-16/18 in the vaginal sample will result in an appointment with the healthcare provider to obtain a clinician-collected cervical sample.

The DCAR stated that of the people who opt for the self-collection pathway, an estimated 6.5% (the proportion who test positive for HPV type non-16/18¹⁹) might need this follow-up LBC appointment.

ESC noted that the cervical screening pathway for intermediate risk women had changed on 1 February 2021: women with a 12-month follow up HPV (non-16/18) result with LBC prediction negative, pLSIL or LSIL (intermediate risk result) are now recommended to undertake a further HPV follow up test in 12 months' time following their previous HPV test,

¹⁹ AIHW (2020) [National Cervical Screening Program monitoring report 2020](#). Cancer series no. 130. Cat. no. CAN 138. Canberra: AIHW.

instead of referral to colposcopy²⁰. This could change the proportion who come back for self-collection if positive once, in both current and proposed clinical management algorithms.

9. Comparator

The proposed model would change the eligible population and uptake, not the test itself. As a comparator, the DCAR used self-collected sampling under current eligibility criteria: only people with a cervix who are 30 years of age or older, who are either overdue by more than two years, or have never screened.

10. Comparative safety

Comparative safety was not assessed by the DCAR.

11. Comparative effectiveness

Clinical claim

The clinical claim was that HPV-testing using polymerase chain reaction (PCR) methods on self-collected vaginal samples is non-inferior in diagnostic accuracy, compared with testing of clinician-collected cervical samples.

A second claim tested in the assessment was that providing the option to participate via self-collection is superior in terms of impact on screening participation rates, compared with requiring clinician-collected cervical samples.

Diagnostic accuracy

Detection of cervical intraepithelial neoplasia (CIN) of Grade 2 or higher (CIN2+) is used to direct clinical management of cervical cancer in the Australian healthcare setting. The DCAR conducted a meta-analysis of the diagnostic accuracy of self-collected samples versus clinician-collected samples, in supporting HPV testing to detect CIN2+ as the reference standard (Table 3). This meta-analysis of cross-sectional studies found that the sensitivity and specificity of the self-collection method was non-inferior compared to the reference standard, clinician-collected samples. Certainty of the evidence for the studies included in the DCAR's meta-analysis was moderate to low.

²⁰ Department of Health (2021) Important changes to the National Cervical Screening Program's Clinical Guidelines pathway for women at intermediate risk. Source: [Department of Health](#).

Table 3 Summary statistics for diagnostic accuracy of self-collection and clinician-collection, against reference standard

Accuracy	Self-collection	Clinician-collection	Self-collected versus clinician collected RR	Published meta-analysis ^a	Number of participants, studies	Quality of evidence (GRADE) ^b	Comments on quality of evidence
Sensitivity, % [95% CI] for CIN2+	0.87 [0.82-0.90]	0.88 [0.85-0.90]	0.98 [0.96-1.01]	0.99 [0.97-1.02]	n=3,890; k=29; cross-sectional	⊕⊕⊕⊖	Downgraded by 2½ points overall, due to serious concerns about study methodology, applicability (indirectness)
Specificity, % [95% CI] for CIN2+	0.61 [0.51-0.70]	0.62 [0.71-0.52]	0.99 [0.98-1.01]	0.98 [0.97-0.99]*	n=36,163; k=28; cross-sectional	⊕⊕⊕⊖	Downgraded by 2½ points overall, due to serious concerns about study methodology, applicability (indirectness)

*Statistically significant difference

CI = confidence interval; CIN2+ = cervical intraepithelial neoplasia (CIN) Grade 2, Grade 3 or cancer; RR = risk ratio.

^a Values from Arbyn *et al.* (2018)'s meta-analysis of self-collected versus clinician-collected samples are included for comparison.

^b GRADE Working Group grades of evidence²¹:

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊖ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊖⊖ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕⊖⊖⊖ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Source: DCAR, Tables 1 and 2

A published meta-analysis found statistically significantly lower specificity of PCR-based testing for CIN2+ in self-collected versus clinician-collected samples ($k = 17$)²². The DCAR noted that the lower specificity found in its meta-analysis compared to the published meta-analysis is likely due to the DCAR's inclusion of more studies with high-risk populations, whereas the published meta-analysis focussed on screening populations.

Participation rate

The participation rate in cervical screening was 46.3% over the two years 2018-19²³. The DCAR stated that allowing individuals a choice of how they participate in the cervical screening program – either by providing a self-collected vaginal sample or a clinician-collected cervical sample – is likely to lead to an increase in participation in screening compared with the current program policy.

The DCAR conducted a meta-analysis of participation rate, using the intention-to-treat (ITT) approach because this reflects the real world situation (Table 4). This meta-analysis found that when individuals were offered a kit for self-collection of vaginal samples for HPV testing they were 2.07 (95% CI: 1.78-2.41) times more likely to participate in the screening program, compared to individuals who were only offered clinician collection of their cervical

²¹ Guyatt, G., *et al.* (2013) GRADE guidelines: 11. Making an overall rating of confidence in effect estimates for a single outcome and for all outcomes. *J Clin Epidemiol*, 66(2), 151-157.

²² Arbyn, M., *et al.* (2018) Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. *BMJ*, 363, k4823.

²³ AIHW (2020) [National Cervical Screening Program monitoring report 2020](#). Cancer series no. 130. Cat. no. CAN 138. Canberra: AIHW.

sample, though the certainty of this evidence according to GRADE was low, and substantial heterogeneity was observed.

Table 4 Summary of quality of evidence on cervical screening participation rate comparing self-collection of vaginal samples to clinician-collected cervical samples, using ITT analysis

Outcome	Number of participants, studies	Quality of evidence (GRADE)	Relative participation (95% CI)	Participation difference (95% CI)	Comments on quality of evidence
Participation rate (ITT analysis)	n=223,095; k=24	⊕⊕⊖⊖	2.07 (1.78-2.41)	14% (11%-16%)	Downgraded by 2 points overall due to some concerns about the methodological quality of the studies (risk of bias), concerns about the inconsistency, and some concerns about the indirectness.

CI = confidence interval; ITT = intention-to-treat; RD = risk difference; RR = risk ratio
 Effect estimates obtained from meta-analysis using random effects model
 Source: DCAR, Table 3

The DCAR’s meta-analysis found that relative participation rate and participation difference estimates were affected by the study invitation scenario. The three invitation scenarios were:

- i) opt-out studies in which all participants assigned to the intervention arm received a self-collection kit in the mail;
- ii) opt-out studies where participants were given an option to order or pick-up a self-collection kit; or
- iii) opt-in studies in which study participants were enrolled into the study prior to being randomised.

Relative participation was highest in the scenarios where participants had to first sign up for a trial. In these studies (k=5), individuals assigned to self-collection arm were 2.17 times (95% CI: 1.28 to 3.68) more likely to participate in cervical screening (Table 5). Similar findings were observed for participation difference.

Table 5 Relative participation and participation difference in self-collection versus clinician collection by invitation scenario

Invitation scenario	Number of participants, studies	Relative participation (95% CI)	Participation difference (95% CI)
All sent a kit	n=153,706; k=18	2.15 (1.82 – 2.54)	13% (10-15%)
Option to order a kit	n=67,720; k=8	1.88 (1.35 – 2.62)	8% (4-13%)
Opt-in studies	n=1,669; k=5	2.17 (1.28 – 3.68)	35% (7-63%)

CI = confidence interval
 Effect estimates obtained from meta-analysis using random effects model
 Source: DCAR, Table 4

The DCAR noted that this result differed from that of Arbyn *et al.* (2018)’s meta-analysis, which reported no statistically significant difference in relative participation or participation difference by invitation scenario amongst ITT studies. The DCAR suggested this difference may be attributable to differences in study selection, and inclusion of more recent studies in the DCAR’s meta-analysis.

Adherence to follow-up

The DCAR also conducted a meta-analysis to examine adherence to follow-up amongst people with an HPV positive result on a self-collected vaginal sample. The DCAR found that of all the people who provided a self-collected vaginal sample for HPV testing, 80.8% (95%

CI: 75.5%-85.1%) people followed up with the health-care provider to complete cervical screening, though inter-study heterogeneity in this analysis was high ($I^2 = 93\%$).

This follow-up adherence rate is similar to the 80.6% (95% CI: 67.0%-91.5%) follow-up adherence rate reported in Arbyn *et al.* (2018)'s meta-analysis. Though it is higher than the 62% follow-up rate for self-collected samples observed in NCSP activity data since the commencement of self-collected HPV testing in December 2017 under the current restrictive access policy.

12. Economic evaluation

An economic analysis was not in-scope for the DCAR, and so was not undertaken.

13. Financial/budgetary impacts

Utilisation

The DCAR stated that total cervical screening participation would be expected to increase under the proposed expanded eligibility criteria, from 690,000 in 2021 to 758,000 in 2025, compared with utilisation increasing from 687,000 to 739,000 under current eligibility criteria over the same period. This results in a predicted overall net increase in participation of approximately 0.5 percentage points in 2021, increasing to 2.5 percentage points in 2025. The proportion of self-collected primary screening would also be anticipated to increase from 1.3% in 2021 up to 6.6% in 2025 if the proposed expansion of self-collection is supported, compared with 0.4% in 2021 increasing to 2.1% in 2025 under current eligibility criteria (Table 6). Estimates of self-collection utilisation were based on historical NCSP participation data for the period December 2017 to June 2020.

Table 6 5-year net implications for NCSP participation: proposed and current eligibility criteria (number and %)

Item	2021	2022	2023	2024	2025
Participant numbers by HPV test collection method (MBS item number)					
Proposed					
Clinician (73070)	681,121	689,304	696,884	703,399	708,122
Self-collected (73071)	9,146	13,980	21,354	32,600	49,726
Total	690,267	703,284	718,238	735,999	757,848
Current					
Clinician (73070)	684,030	693,730	703,615	713,634	723,680
Self-collected (73071)	2,878	4,379	6,661	10,133	15,400
Total	686,908	698,109	710,276	723,767	739,080
Participant % share by HPV test collection method (MBS item number)					
Proposed					
Clinician (73070)	98.7%	98.0%	97.0%	95.6%	93.4%
Self-collected (73071)	1.3%	2.0%	3.0%	4.4%	6.6%
Total	100.0%	100.0%	100.0%	100.0%	100.0%
Current					
Clinician (73070)	99.6%	99.4%	99.1%	98.6%	97.9%
Self-collected (73071)	0.4%	0.6%	0.9%	1.4%	2.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

HPV = human papillomavirus, MBS = Medicare Benefits Schedule, NCSP = National Cervical Screening Program.

Source: DCAR, Table 6

The DCAR stated that, if expanded eligibility for sample self-collection is supported, then between 2021 and 2025 there would be between 2,900 and 15,600 fewer utilisations associated with clinician-collected HPV tests (MBS item 73070) and an additional 6,300 to 34,300 utilisations associated with self-collected tests (MBS item 73071), with a net impact on primary screening item utilisation between 3,400 and 18,800 over this period (Table 7). The increase in overall participation would also be accompanied by changes in the utilisation of other professional attendance items. LBC testing would increase marginally; while for self-collecting participants who test HPV positive there would be a reduction in the follow-up LBC testing due to the lower assumed follow-up rate (approximately 62%). Overall, this would be offset by the additional screening participants proceeding to colposcopy from a positive HPV test only (and thus requiring an LBC test as part of colposcopy).

Table 7 Net MBS item utilisation implications

MBS item	2021	2022	2023	2024	2025
Clinician-collected primary HPV test (73070)	-2,909	-4,426	-6,731	-10,235	-15,558
Self-collected primary HPV test (73071)	6,268	9,601	14,693	22,467	34,326
Follow-up HPV test (73072)	-2	279	452	696	1,068
Test-of-cure (hysterectomy) (73074)	0	1	3	4	6
HPV re-test (unsatisfactory) (73075)	186	285	436	667	1,019
LBC test (including unsatisfactory) (73076)	52	-7	17	35	59
Professional attendance items	3,545	5,743	8,857	13,605	20,869
PEI specimen collection (73938)	3,546	5,744	8,858	13,607	20,872
BBI associated with specimen collection (74998)	3,546	5,744	8,858	13,607	20,872

Results may be subject to rounding.

BBI = bulk billing incentive, HPV = human papillomavirus, LBC = liquid-based cytology, MBS = Medicare Benefits Schedule, NCSP = National Cervical Screening Program, PEI = patient episode initiation.

Source: DCAR, Table 7.

Financial implications

The DCAR forecast that expanding the eligibility criteria would cost the MBS an additional \$350,000 to \$2.1 million per annum over the first five years (Table 8). This is driven primarily by the growth in HPV testing on self-collected vaginal samples (item 73071), with accompanying growth in attendance items, with self-collecting participants requiring additional professional attendance consultations for LBC testing. With approximately 77% of all the forecast treatments for p-HSIL/HSIL (pre-cancerous lesion) patients undertaken on MBS items in outpatient settings, additional treatment of patients does not have significant incremental financial implications. This highlights the importance of early detection and treatment in minimising longer-term cancer treatment costs.

Table 8 Net MBS financial implications

MBS item	2021	2022	2023	2024	2025
NCSP MBS financial implications					
Clinician-collected primary HPV test (73070)	-\$86,542	-\$131,674	-\$200,247	-\$304,491	-\$462,851
Self-collected primary HPV test (73071)	\$186,473	\$285,635	\$437,118	\$668,408	\$1,021,198
Follow-up HPV test (73072)	-\$43	\$8,322	\$13,485	\$20,692	\$31,743
Test of cure hysterectomy (73074)	\$0	\$30	\$60	\$149	\$208
HPV re-test (unsatisfactory) (73075)	\$6,268	\$9,601	\$14,693	\$22,467	\$34,326
LBC test (including unsatisfactory) (73076)	\$2,034	-\$262	\$677	\$1,367	\$2,305
Professional attendance items	\$160,060	\$254,508	\$392,699	\$603,455	\$925,944
PEI specimen collection (73938)	\$24,106	\$39,054	\$60,227	\$92,516	\$141,913
BBI associated with specimen collection (74998)	\$6,026	\$9,763	\$15,057	\$23,130	\$35,477
Total	\$298,383	\$474,977	\$733,770	\$1,127,692	\$1,730,262
Post-NCSP MBS financial implications					
LBC test (HPV positive presenting patients) (73076)	\$7,859	\$18,494	\$28,308	\$43,245	\$66,118
Specialist consultation: initial (104)	\$9,450	\$18,059	\$27,898	\$42,720	\$65,634
Specialist consultation: subsequent (105)	\$727	\$1,301	\$1,913	\$2,869	\$4,437
Colposcopy (35614)	\$4,088	\$7,812	\$12,068	\$18,480	\$28,392
Biopsy (35608)	\$8,191	\$15,652	\$24,179	\$37,026	\$56,885
Biopsy examination (72823)	\$7,599	\$14,455	\$22,467	\$34,196	\$52,699
Biopsy examination (72824)	\$6,488	\$12,496	\$19,104	\$29,557	\$45,176
PEI biopsy (73926)	\$1,155	\$2,191	\$3,367	\$5,145	\$7,910
Large loop excision of transformation zone treatment (35647)	\$1,156	\$2,065	\$2,974	\$4,460	\$6,856
Large loop excision diathermy (35648)	\$120	\$120	\$240	\$481	\$601
Biopsy examination (72830)	\$5,209	\$9,321	\$13,707	\$20,562	\$31,802
Total	\$52,043	\$101,965	\$156,225	\$238,741	\$366,510
Financial implications for the MBS	\$350,426	\$576,942	\$889,995	\$1,366,433	\$2,096,772

BBI = bulk-billing incentive, MBS = Medicare Benefits Schedule, NCSP = National Cervical Screening Program, PEI = patient episode initiation.

Source: DCAR, Table 8.

The DCAR assumed that approximately 23% of treatment occurs in hospital settings. Only 5% of all treatment and 22% of inpatient treatment is assumed to be hysterectomy, the costliest of all treatment options. With the remaining inpatient treatments being cone biopsy and ablation therapy, this results in costs to other Government health spending through treatment of patients increasing from \$17,000 in 2021, to \$105,000 in 2025 (Table 9).

Table 9 Other net health care system costs

Item	2021	2022	2023	2024	2025
Current					
Treatment	\$6,188,343	\$6,286,470	\$6,391,865	\$6,506,346	\$6,633,547
Total other government health budget costs	\$6,188,343	\$6,286,470	\$6,391,865	\$6,506,346	\$6,633,547
Proposed					
Treatment	\$6,205,606	\$6,317,361	\$6,437,294	\$6,574,490	\$6,738,943
Total other government health budget costs	\$6,205,606	\$6,317,361	\$6,437,294	\$6,574,490	\$6,738,943
Net implications					
Treatment	\$17,263	\$30,892	\$45,429	\$68,144	\$105,395
Other net government health budget costs	\$17,263	\$30,892	\$45,429	\$68,144	\$105,395

Source: DCAR, Table 9.

The DCAR forecast that expanding eligibility for self-collected sampling would cost an additional \$367,000 to \$2.198 million per annum to the Australian health care system over the first five years (Table 10).

Table 10 Overall net cost to the Australian health care system

Item	2021	2022	2023	2024	2025
Net cost to the MBS	\$349,691	\$575,813	\$888,270	\$1,363,796	\$2,092,747
Net cost to other healthcare budgets	\$17,263	\$30,892	\$45,429	\$68,144	\$105,395
Net financial implications for the Australian health care system	\$366,954	\$606,705	\$933,699	\$1,431,940	\$2,198,142

MBS = Medicare Benefits Schedule

Source: DCAR, Table 10.

The DCAR stated that the weighted average cost of screening for participants self-collecting is slightly lower than for those clinician-collecting, \$95.10 compared to \$96.79 (Table 11). However, the DCAR noted that this analysis assumes that self-collecting participants only follow up on a positive HPV non-16/18 result approximately 62% of the time (based on NCSP activity data). If the follow-up rate was 80.7% (as found in the DCAR's meta-analysis) then the weighted average cost of screening per self-collected participant would increase to \$97.18; if follow-up were 100% (as per a clinician-collected HPV test), then the weighted average cost for self-collected participants would be \$99.35.

Table 11 Summary: Weighted-average cost of primary screening – clinician-collected vs. self-collected

Item	Total	HPV test	LBC	Clinician consult	PEI	BBI
Clinician-collected	\$96.79	\$31.45	\$4.96	\$51.39	\$7.19	\$1.80
Self-collected	\$95.10	\$31.80	\$1.95	\$51.85	\$7.61	\$1.90

BBI = bulk-billing incentive, HPV = human papillomavirus, LBC = liquid-based cytology, MBS = Medicare Benefits Schedule, NCSP = National Cervical Screening Program, PEI = patient episode initiation.

Source: DCAR, Table 11.

Sensitivity analyses

The DCAR stated that key parameter categories where uncertainty was present included:

- overall participation rates
- additional uptake resulting from expanded self-collection eligibility criteria
- HPV positive test result rates
- NCSP participant adherence rate, including rate of follow-up amongst those self-collecting participants who test positive and require LBC testing.
- lags in participation in transition to the 5-year screening interval.

The DCAR’s sensitivity analyses exploring these uncertainties (Table 12) showed that the total financial implications are primarily driven by participation rates, switching rates to self-collecting, and any potential impact that causes a slowdown in participation or a lag in transition to the 5-year screening interval. While continued adherence to the NCSP (as measured by follow-up LBC test uptake rate after positive HPV test non-16/18, Table 12) is important to cervical screening outcomes, it does not materially affect financial outcomes, as the majority of costs are incurred upfront during the primary screening step.

Table 12 Financial implications under sensitivity analysis and scenario testing

Scenario tested	Value		2021	2022	2023	2024	2025
Base case		Cost to the MBS	\$349,691	\$575,813	\$888,270	\$1,363,796	\$2,092,747
		Cost to the healthcare budget	\$17,263	\$30,892	\$45,429	\$68,144	\$105,395
		Total financial implications	\$366,954	\$606,705	\$933,699	\$1,431,940	\$2,198,142
Participation rate: year 5 self-collected steady-state uptake rate, as % of all eligible participants (non-participants including never or under-screened and switching)	10%	Cost to the MBS	\$603,604	\$1,301,000	\$2,037,292	\$2,808,718	\$3,611,717
		Cost to the healthcare budget	\$30,892	\$65,418	\$100,852	\$140,830	\$181,716
		Total financial implications	\$634,495	\$1,366,418	\$2,138,145	\$2,949,548	\$3,793,433
	20%	Cost to the MBS	\$1,208,028	\$2,603,606	\$4,077,757	\$5,619,880	\$7,224,956
		Cost to the healthcare budget	\$61,783	\$132,653	\$206,248	\$283,477	\$364,341
		Total financial implications	\$1,269,811	\$2,736,258	\$4,284,005	\$5,903,357	\$7,589,297
	40%	Cost to the MBS	\$2,415,958	\$5,205,201	\$8,155,362	\$11,237,919	\$14,449,799
		Cost to the healthcare budget	\$122,658	\$263,488	\$413,404	\$565,137	\$729,590
		Total financial implications	\$2,538,617	\$5,468,689	\$8,568,766	\$11,803,056	\$15,179,389
	60%	Cost to the MBS	\$3,624,538	\$7,808,351	\$12,232,027	\$16,857,026	\$21,674,099
		Cost to the healthcare budget	\$184,442	\$396,141	\$617,835	\$848,614	\$1,093,931
		Total financial implications	\$3,808,980	\$8,204,492	\$12,849,862	\$17,705,640	\$22,768,030
	80%	Cost to the MBS	\$4,832,912	\$10,410,668	\$16,309,214	\$22,476,153	\$28,899,153
		Cost to the healthcare budget	\$246,225	\$526,068	\$823,174	\$1,133,000	\$1,458,272
		Total financial implications	\$5,079,137	\$10,936,736	\$17,132,388	\$23,609,153	\$30,357,425
	100%	Cost to the MBS	\$6,041,214	\$13,012,249	\$20,382,734	\$28,091,893	\$36,118,081
		Cost to the healthcare budget	\$308,009	\$657,812	\$1,026,696	\$1,416,477	\$1,821,704
		Total financial implications	\$6,349,223	\$13,670,062	\$21,409,430	\$29,508,370	\$37,939,785

Scenario tested	Value		2021	2022	2023	2024	2025
Follow-up LBC test uptake rate (positive HPV test non-16/18) (base case ~62%)	20%	Cost to the MBS	\$333,430	\$490,670	\$755,223	\$1,161,192	\$1,782,485
		Cost to the healthcare budget	\$6,360	\$7,269	\$9,994	\$15,446	\$22,715
		Total financial implications	\$339,790	\$497,939	\$765,217	\$1,176,638	\$1,805,199
	40%	Cost to the MBS	\$341,607	\$531,053	\$818,699	\$1,257,413	\$1,930,272
		Cost to the healthcare budget	\$11,812	\$17,263	\$27,257	\$39,978	\$61,783
		Total financial implications	\$353,419	\$548,316	\$845,957	\$1,297,391	\$1,992,056
	60%	Cost to the MBS	\$349,471	\$571,524	\$881,159	\$1,353,792	\$2,078,153
		Cost to the healthcare budget	\$17,263	\$29,075	\$41,795	\$65,418	\$101,761
		Total financial implications	\$366,734	\$600,598	\$922,954	\$1,419,209	\$2,179,914
	80%	Cost to the MBS	\$357,571	\$611,582	\$944,636	\$1,451,176	\$2,226,632
		Cost to the healthcare budget	\$22,715	\$39,069	\$59,058	\$91,767	\$140,830
		Total financial implications	\$380,286	\$650,651	\$1,003,694	\$1,542,943	\$2,367,462
	100%	Cost to the MBS	\$365,272	\$652,643	\$1,008,026	\$1,547,448	\$2,374,499
		Cost to the healthcare budget	\$27,257	\$50,881	\$76,321	\$116,298	\$179,899
		Total financial implications	\$392,529	\$703,524	\$1,084,347	\$1,663,747	\$2,554,398
Scenario tested	Value		2021	2022	2023	2024	2025
Participation progression to colposcopy (base case 100%)	20%	Cost to the MBS	\$308,149	\$479,339	\$739,456	\$1,136,001	\$1,743,064
		Cost to the healthcare budget	\$3,634	\$4,543	\$9,086	\$14,537	\$20,897
		Total financial implications	\$311,784	\$483,882	\$748,542	\$1,150,538	\$1,763,961
	40%	Cost to the MBS	\$319,403	\$504,047	\$775,832	\$1,193,124	\$1,831,081
		Cost to the healthcare budget	\$8,177	\$12,720	\$17,263	\$28,166	\$42,703
		Total financial implications	\$327,580	\$516,767	\$793,095	\$1,221,290	\$1,873,785
	60%	Cost to the MBS	\$329,663	\$527,482	\$813,760	\$1,250,577	\$1,918,198
		Cost to the healthcare budget	\$11,812	\$16,354	\$27,257	\$41,795	\$64,509
		Total financial implications	\$341,475	\$543,836	\$841,017	\$1,292,371	\$1,982,707
	80%	Cost to the MBS	\$339,395	\$550,726	\$850,848	\$1,306,687	\$2,005,228
		Cost to the healthcare budget	\$13,629	\$21,806	\$36,343	\$54,515	\$84,498
		Total financial implications	\$353,024	\$572,532	\$887,192	\$1,361,202	\$2,089,726
	90%	Cost to the MBS	\$344,662	\$563,060	\$868,814	\$1,336,128	\$2,050,020
		Cost to the healthcare budget	\$15,446	\$26,349	\$39,978	\$62,692	\$95,401
		Total financial implications	\$360,107	\$589,409	\$908,792	\$1,398,820	\$2,145,421
HPV positivity rate: equivalent self-collected vs. clinician collected	Cost to the MBS	\$307,740	\$490,852	\$756,513	\$1,163,362	\$1,787,722	
	Cost to the healthcare budget	\$8,177	\$13,629	\$19,080	\$29,983	\$49,063	
	Total financial implications	\$315,917	\$504,480	\$775,593	\$1,193,345	\$1,836,785	
Sudden drop reduction in participation 2021 (recover by 2025)	Cost to the MBS	\$348,268	\$572,580	\$860,947	\$1,291,710	\$1,937,122	
	Cost to the healthcare budget	\$19,080	\$32,709	\$48,155	\$72,686	\$108,121	
	Total financial implications	\$367,348	\$605,289	\$909,102	\$1,364,396	\$2,045,243	
Lag in participation during transition from 2 to 5-year program, bounce back in years 3, 4 and 5	Cost to the MBS	\$218,386	\$359,524	\$1,074,184	\$1,703,142	\$2,617,185	
	Cost to the healthcare budget	\$10,903	\$18,172	\$55,423	\$86,315	\$132,653	
	Total financial implications	\$229,289	\$377,695	\$1,129,608	\$1,789,457	\$2,749,838	

HPV = human papillomavirus; LBC = liquid-based cytology; MBS = Medicare Benefits Schedule.
Source: summarised from DCAR Tables 10, 50-55

14. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Comparative safety and effectiveness	Cervical screening with self-collected samples appears to be as accurate and safe as with clinician-collected samples.
Increase in participation rates	The (heterogeneous) evidence suggests that self-collection will recruit more people into participating in cervical screening. There is no direct evidence looking at the proposed model of care in Australia, but a positive outcome is expected.
Extent to which self-collection will increase participation and main cost drivers	The extent of the increase is unknown and subject to many assumptions. The biggest driver of numbers screened is the likely concomitant switching from clinician-collected samples. The biggest driver of additional budgetary expenditure is boosting participation, which is the intent of this screening program.
Proportion of self-collection patients who test positive who will return for follow up	This is unknown, though studies suggest this follow-up rate to be around 80%. For safety reasons, pre-test education will be crucial for patient engagement with follow up. Those who are less engaged and harder to reach may need other strategies.
Policy issues around education	Long lead-time anticipated, and educational material will need to be developed.
Policy issues around the use of telehealth	To increase participation, telehealth may be useful and should not increase costs if used as a replacement for face-to-face consultations. “Double dipping” may be an issue, if the MBS telehealth is used to call patients in and educate them and then another consultation is billed when the patient comes in to do the test.
Policy issues about readiness of the pathology sector	A commercially available self-collected sample kit is needed to increase capacity of testing.
Lost opportunity for physical examination if patients self-collect	Education by GPs and retaining the use of the primary care setting to manage self-collected sampling should ameliorate this concern.

ESC discussion

ESC noted that the purpose of this application was to examine the evidence to support the change to the Medicare Benefits Schedule (MBS) to expand access to self-collected samples under the National Cervical Screening Program (NCSP). The expansion would allow self-collection (through primary care) to all eligible people with a cervix aged between 25 and 74 years (about 6.8 to 7.23 million people) who have ever been sexually active. Self-collection is currently restricted to people 30 years and over who are overdue for a cervical screening test (CST) by 2 years or more, or who have never screened.

ESC noted the largely positive feedback from the public consultations, and that increased self-collection may lead to increased participation in cervical screening in hard-to-reach communities. ESC noted some concern about education and workflows, and pathology concerns about samples, workforce, lead-time, and the need for internal validation given the lack of commercially available test kits. ESC also noted the concern that less clinician sampling will result in fewer opportunistic findings at a physical examination. ESC noted that consumer groups advocated for the change, stating that it could save lives and reduce shame and embarrassment.

ESC noted that the clinical management pathway for screening patients at intermediate risk had changed in February 2021.

ESC considered that the specificity (0.61 and 0.62, self-collected and clinician-collected, respectively) and sensitivity (0.87 and 0.88, self-collected and clinician-collected, respectively) appeared to be acceptably equivalent and that the pooled differences of these two measures with their 95% confidence intervals appeared to be within acceptable limits. ESC noted that the results of the Department-contracted assessment report (DCAR)'s meta-analysis and Arbyn *et al.*, (2018)'s meta-analysis²⁴ did differ in that Arbyn *et al.* reported higher sensitivity and specificity, however, ESC accepted that these differences across the meta-analyses are explained by different reference standards used for the sensitivity calculations and the DCAR's inclusion of higher-risk patients.

ESC noted that, in the meta-analysed studies of participation rates, the intention-to-treat (ITT) analysis showed that giving patients a choice increased participation in screening and thus had superior effectiveness to clinician-collection only. However, ESC also noted that no direct evidence on the proposed Australian model of recruitment for self-collection was identified.

ESC noted the follow-up rate amongst people with an HPV positive test result on a self-collected vaginal sample, and that the meta-analysis indicated 80.8% (95% CI: 75.5% to 85.1%) people followed up with the healthcare provider to complete cervical screening. These results are very similar to the follow-up adherence rate of 80.6% (95% CI: 67.0% to 91.5%) reported by Arbyn *et al.* (2018), but higher than the 62% follow-up rate for self-collected samples observed in NCSP activity data since the commencement of self-collected HPV testing in December 2017 under the current restrictive access policy. ESC noted the challenges with the implementation of the current policy and the very low number of people currently accessing self-collection.

ESC noted that the DCAR omitted an economic analysis on the basis of MSAC's earlier advice in October 2019 that this had been done as part of [MSAC application 1276](#) and recognising that if it is accepted that self-collection yields acceptably similar screening results as clinician-collection, then it improves health outcomes and is acceptably cost-effective per patient screened. A financial budgetary analysis was presented in recognition that the intent of the proposal is to screen more patients. ESC considered a main driver of cost and overall budget expenditure would be the proportion of patients who "switch" from clinician-collected to self-collected samples, and the extent of "boosted" participation (eligible people who would otherwise not have participated). ESC accepted that the budget should increase, as the aim of expanding access to self-collected samples is to increase participation in cervical screening.

ESC noted that there is no direct evidence to inform an assessment of how many patients would switch, but noted that additional modelling conducted by the Cancer Council New South Wales (CCNSW) used some questionnaire and survey data to estimate numbers. The CCNSW report concluded much higher expenditure than the DCAR, the difference arising from different assumptions, particularly around the number who "switch" and the additional total cost of increased participation. ESC noted that some of CCNSW's sources for its assumptions and calculations were unclear, and that some of its analyses may have included double counting, thus increasing the expenditure inaccurately. ESC considered that both analyses were based on many uncertainties, including in relation to clinician behaviour. ESC

²⁴ Arbyn, M., *et al.* (2018) Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. *BMJ*, 363, k4823.

considered that this proposed increase in access to self-collection will not affect the eligible population and may increase the numbers of patients who present for screening.

ESC noted the policy issues that would need to be considered before implementation, including the need for clinician and patient targeting and education, and commercially available self-collected sampling CST kits. Minority and culturally and linguistically diverse (CALD) groups with higher rates of female genital mutilation may need additional support to access self-collection. ESC noted that the Royal Australian College of General Practitioners (RACGP) has conducted a webinar that highlighted the comparable accuracy of self-collection and clinician collection, and surveys show more than 85% of GPs who did not previously offer self-collection would now do so.

15. Other significant factors

Nil.

16. Applicant comments on MSAC's Public Summary Document

N/A

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)