Accuracy of self-collection in human papillomavirus-based cervical screening: An evidence-based review

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Background
As there is a large body of evidence confirming its accuracy, human papillomavirus (HPV) self-collection has been introduced to the Australian National Cervical Screening Program (NCSP). Self-collection also offers an opportunity to engage under-screened (including never-screened) individuals. Under-screening remains a significant risk factor for cervical cancer, with over 70% of Australian cases involving individuals who are under-screened or have never been screened.

Objective
This article provides an in-depth, evidence-based examination of the clinical accuracy of self-collection in cervical screening and provides recommendations for general practice. The discussion also includes a brief overview of self-collection adoption in under- and never-screened people.

Discussion
Many studies have demonstrated that self-collection is similar to clinician-collection for detecting clinically significant HPV infections. However, some general practitioners (GPs) still have concerns about self-collection, including holding the misconception that self-collection is less accurate, possibly because of older studies that were undertaken using less sensitive testing technologies. Understanding self-collection accuracy, devices, quality control methods and the implications for general practice can encourage GPs to offer it to eligible patients, potentially engaging more patients in cervical screening, preventing devastating diagnoses, increasing equity and saving lives.

AUSTRALIA is on track to be the first country to eliminate cervical cancer as a public health problem; however, screening coverage remains a challenge. The Australian National Cervical Screening Program (NCSP) introduced self-collection as a choice for all eligible (asymptomatic) participants in July 2022 based on evidence demonstrating that self-collection is as effective as clinician-collection in detecting human papillomavirus (HPV) infections associated with histologically confirmed cervical intraepithelial neoplasia grade 2 or above (CIN2+).

This review presents current evidence of the clinical accuracy of self-collection and its management in general practice.

Aim

The aim of this review is to provide an overview of the current evidence on the accuracy of self-collection for cervical screening, address concerns with self-collection and provide up-to-date recommendations for general practitioners (GPs) to use in practice.

Accuracy of self-collection

A meta-analysis published in 2014 found that self-collection was less sensitive and less specific for CIN2+ than clinician-collected samples.[1] Although the analysis included 36 studies, it was identified retrospectively that these results might be attributed to the dominance of studies using signal amplification technology.

The 2014 meta-analysis was the best available evidence when the transition to a HPV-based cervical screening program was undertaken prior to 2017. This resulted in a limited introduction of self-collection under restricted eligibility criteria during the 2017 renewal of the NCSP. Simply put, a slightly less accurate test was better than no test, and this was the basis for the restriction to under-screened individuals who refused clinician-collection.

In 2018, Arbyn et al updated their meta-analysis and included an examination of the testing technologies, in which the older signal amplification tests were compared with the newer polymerase chain reaction (PCR) tests. This analysis demonstrated that self-collection is as clinically sensitive and specific for CIN2+ as clinician-collection when processed using PCR-based assays.[2]

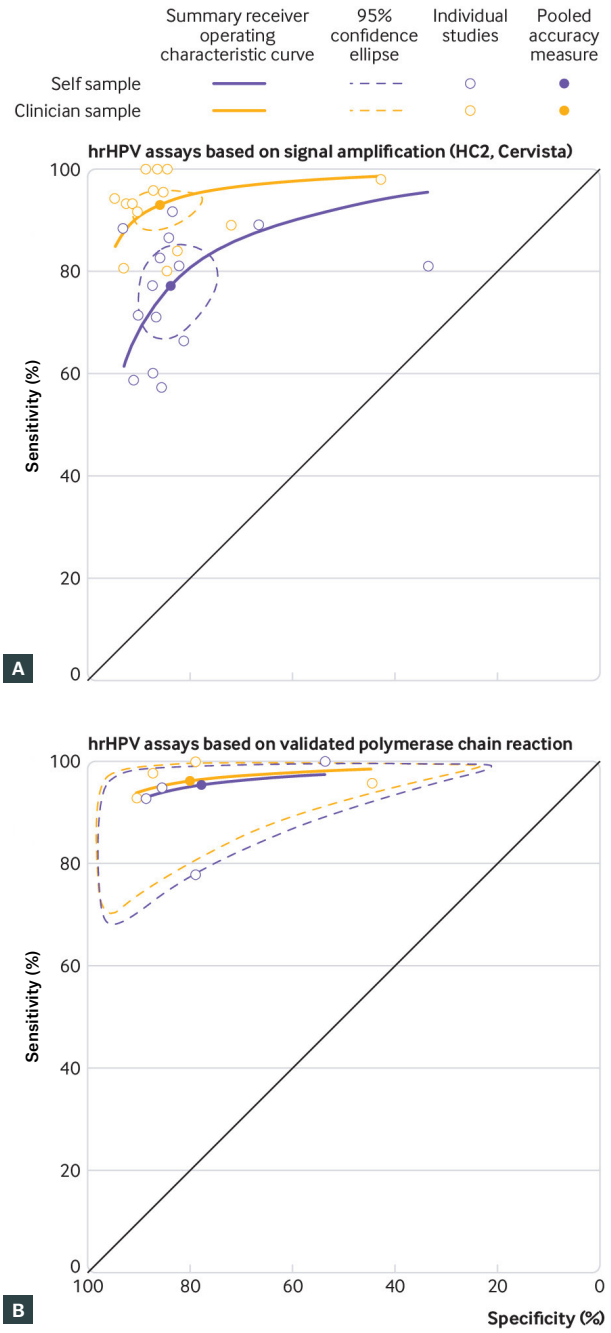

Figure 1. Meta-analysis of the accuracy of HPV assays for CIN2+ based on (**A**) signal amplification and (**B**) PCR for self- and clinician-collected samples in primary cervical screening. Estimates are derived from a bivariate model for pooling of diagnostic data.[2]

Reproduced from Arbyn M, Smith SB, Temin S, Sultana F, Castle P; Collaboration on self-sampling and HPV testing. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: Updated meta-analyses. BMJ 2018;363:k4823. doi: 10.1136/bmj.k4823, with permission from BMJ Publishing Group Ltd.

CIN2+, histologically confirmed cervical intraepithelial neoplasia grade 2 or above; HPV, human papillomavirus; hr, high risk; PCR, polymerase chain reaction.

As shown in Figure 1 and Table 1, PCR-based HPV assays showed non-inferior relative sensitivity for detecting CIN2+ (including CIN2, CIN3, adenocarcinoma in situ, and invasive disease) in self-collected samples compared to those collected by clinicians (0.99, 95% confidence interval [CI]: 0.97–1.02). In contrast, signal amplification-based assays had significantly lower relative sensitivity (0.85, 95% CI: 0.80–0.89).[2]

All Australian laboratories are required to use PCR-based assays for self-collected samples; therefore, GPs can be assured that the sensitivity is comparable to clinician-collected samples.

Safety and controls

One concern with self-collection is the potential for false negatives resulting in missed cervical disease. Robust quality control processes address this risk. Both the International Papillomavirus Society (IPVS)[3] and the World Health Organization (WHO) HPV target product profile[4] have stated a need for an internal cellularity control to reduce risk of false negative results caused by 'empty' samples.

An empty sample can occur when a patient agrees to take their sample, but after opening the swab, returns it to the sheath without having inserted it into the vagina, causing the cellularity control to fail and giving an invalid result (referred to as a 'social invalid'). This can be mitigated by the healthcare practitioner providing the patient with sufficient support beforehand.

The cellularity control ensures the sample has enough human cells for accurate results, especially given that a negative result informs a recommendation not to screen for five years. If the sample is deemed inadequate, the result is reported as 'unsatisfactory', not 'negative'. An invalid result can also occur with an inhibition of the PCR reaction (eg because of high levels of vaginal microbiota or contaminants such as lubricants). It is important to understand that, unlike with Pap smears, the laboratory cannot distinguish between these various causes of invalid results.

The rate of unsatisfactory results for self-collected screening samples in Australia is low, with the most recent national

Table 1. Pooled relative sensitivity and specificity of hrHPV assays based on SA and PCR on self-collected versus clinician-collected samples[2]

			Ratio (95% CI)			
Assay	Outcome	No. of studies	Sensitivity	Specificity	Test positivity	PPV
SA	CIN2+	23	0.85 (0.80–0.89)*	0.96 (0.93–0.98)*	1.14 (1.05–1.24)	0.71 (0.62–0.82)
	CIN3+	9	0.86 (0.76–0.98)*	0.97 (0.95–0.99)*		0.65 (0.57–0.78)
PCR	CIN2+	17	0.99 (0.97–1.02)	0.98 (0.97–0.99)*	1.00 (0.94–1.06)	0.97 (0.90–1.04)
	CIN3+	8	0.99 (0.96–1.02)	0.98 (0.97–0.99)*		0.90 (0.78–1.05)

*Statistically significantly different from unity.

Reproduced from Arbyn M, Smith SB, Temin S, Sultana F, Castle P; Collaboration on self-sampling and HPV testing. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: Updated meta-analyses. BMJ 2018;363:k4823. doi: 10.1136/bmj.k4823, with permission from BMJ Publishing Group Ltd.

CI, confidence interval; CIN2+, cervical intraepithelial neoplasia of grade 2 or worse; CIN3+, cervical intraepithelial neoplasia of grade 3 or worse; HPV, human papillomavirus; hr, high risk; PCR, polymerase chain reaction; PPV, positive predictive value; SA, signal amplification.

Table 2. Australian Register of Therapeutic Goods (ARTG)-listed validated methods for self-collection for HPV-based cervical screening using Copan FLOQSwabs[10]

Device	Transport	HPV assay	Instrument(s)
Copan FLOQSwab® 552C.80	Resuspended into ThinPrep® vial in clinic	Roche cobas® 4800 HPV test	Roche cobas® 4800 system
Copan FLOQSwab® 552C.80	Resuspended into ThinPrep® vial in clinic	Roche cobas® HPV test	Roche cobas® 5800/6800/8800 systems
Copan FLOQSwab® 5E089N	Dry swab	BD Onclarity™	BD COR™ system

BD, Becton Dickinson; COR, Complete On-line Reporting; HPV, human papillomavirus.

unsatisfactory rate in Q4 2024 being 1.36%.[5] This indicates that most self-collected samples are conducted adequately.

The unsatisfactory rate for self-collected HPV tests is higher than for clinician-collected HPV tests (0.17% in Q4 2024),[5] but is lower than the unsatisfactory rate for cytology (~3–5%).

Opportunistic pelvic exams

Some GPs have expressed concern with the absence of pelvic exams during the self-collection screening process; however, the American College of Physicians (ACP) recommends against performing screening pelvic examination in asymptomatic, non-pregnant, adult women.[6] The American College of Obstetricians and Gynecologists (ACOG) recommends that the decision to perform a pelvic examination should be shared between the patient and healthcare practitioner.[7]

When HPV is detected, follow-up procedures such as liquid-based cytology (LBC) or colposcopy will include a visual examination of the cervix.

The identification of incidental cervical polyps is a commonly cited reason among healthcare practitioners for preferring to conduct a pelvic examination. Polyps are estimated to occur in 2–5% of cervices, and the risk of malignancy increases with age. Cervical polyps are typically benign, with a prevalence of malignancy in 0.1% of cases.[8] Abnormal polyps are typically accompanied by symptoms.[9]

This reinforces the importance of GPs checking for symptoms of cervical cancer when offering a cervical screening test (CST), as symptoms would prompt a pelvic exam and a co-test.

There is no evidence that screening for the presence of polyps by pelvic examination leads to a reduction in any cancer type or an early diagnosis that changes survival. Therefore, there is no evidence to support pelvic examinations for asymptomatic patients undergoing routine cervical screening.

Self-collection devices

Some GPs express confusion about the varying self-collection device instructions and sample transport requirements from different laboratories.

Self-collection requires the use of validated devices and methods. The Copan FLOQSwab® (Copan, Brescia, Italy) and Rovers Evalyn® Brush (Rovers Medical Devices, Lekstraat, The Netherlands) are the devices currently validated by HPV assay manufacturers, but others might be independently validated by pathology laboratories. The most commonly used device in Australia is the FLOQSwab.

Devices are either validated to be transported to the laboratory dry or

transported after resuspension in liquid media (wet), prior to testing. Currently, the Therapeutic Goods Administration (TGA) lists the FLOQSwabs when transported dry for the BD Onclarity™ HPV assay (Becton Dickinson, Sparks, MD, USA) as validated. If the FLOQSwab is resuspended into a Hologic ThinPrep vial (Hologic, Marlborough, MA, USA) in the clinic, the sample is able to be tested using either the Roche cobas® or cobas® 4800 HPV assay (Roche, Basel, Switzerland) (Table 2).

According to the Australian Register of Therapeutic Goods (ARTG)-listed manufacturer validated methods, the dry swab can be transported at up to 30°C (with up to six days at up to 40°C) for up to 30 days, when tested using the Onclarity HPV assay. Comparatively, when the FLOQSwab has been eluted into ThinPrep, it is stable for three months at up to 30°C when tested using the cobas® or cobas® 4800 HPV assays.

Other sample transport options can be available through specific laboratories across Australia. For example, for warmer climates, some laboratories have validated in-house methods demonstrating dry FLOQSwab stability at up to 50°C for 28 days.

Therefore, self-collected samples remain accurate and stable throughout a range of conditions. **If GPs are uncertain of the circumstances in which their swabs remain stable, including in cases where the patient is taking their sample at home, they should refer to their laboratory's instructions.**

Table 3 summarises some in-house validated testing and transport methods, aside from those listed by the ARTG. GPs should be aware that these methods can also be used by their pathology provider.

Additionally, there are restrictions on the usage of self-collection devices. For example, the swab cannot currently be used during pregnancy when the manufacturer-validated methods (Roche and BD) are used, as these manufacturers have based their restrictions on the Copan FLOQSwab instructions for use.[11] Copan currently states that vaginal self-collection should not be performed during pregnancy; however, some laboratories have performed in-house validation for using the swab during pregnancy, provided the swab is transported dry. These laboratories can process self-collected samples from pregnant patients. It is important to note that despite these restrictions, the self-collection process itself is safe for patients during all stages of pregnancy when the swab is used.[12]

Therefore, if the patient is pregnant and would like to self-collect their sample, GPs should use a dry swab for self-collection and ensure their laboratory can process the sample or will send the sample to a laboratory that can process it.

In summary, because of the range of validated methods and restrictions, it is critical that GPs contact their laboratory to ensure they have correct instructions.

Management in general practice

Within the NCSP, self-collection can be offered to all asymptomatic cervical screening participants, including those who are pregnant or who have immune deficiency.[12] GPs should ensure that patients with symptoms warranting further investigation receive appropriate care, as self-collection is not recommended for those with symptoms, including post-coital bleeding, unexplained inter-menstrual bleeding or any post-menopausal bleeding. Occasionally, people who have concerns might present for screening and, unless explicitly asked, might not disclose the presence of these symptoms.

If a patient is unable to take their own sample but still prefers a vaginal swab over a speculum exam, the healthcare practitioner can help them or administer their self-collected test. This would still be classified as self-collection, as the sample was not taken from the cervix. If the patient does not require assistance, it is not necessary to observe them taking their sample.

It is important that GPs adequately explain the self-collection process to patients to help reduce the likelihood of unsatisfactory results from insufficient cellular material. The healthcare practitioner can also address patient concerns in a manner that is culturally sensitive and easy to understand. It is helpful to provide printed instructions from the NCSP or laboratories. Translated how-to guides and CST explanations are available for patient consultations (refer to Box 1 for useful resources for both healthcare practitioners and patients).

Follow-up

If a self-collected sample returns an unsatisfactory result, it is recommended that the patient returns within six weeks to retake their sample.[12]

If HPV (16/18) is detected on a self-collected sample, the patient should be referred directly for colposcopy, where a cervical sample for LBC will also be taken.[12]

Table 3. In-house validated testing and transport methods for Copan FLOQSwabs®

Device	Transport	HPV assay	Instrument(s)
Copan FLOQSwab® 552C/552C.80	Dry swab	Roche cobas® 4800 HPV test	Roche cobas® 4800 system
Copan FLOQSwab® 552C/552C.80	Dry swab	Roche cobas® HPV test	Roche cobas® 5800/6800/8800 systems
Copan FLOQSwab® 552C/552C.80	Dry swab	Abbott Alinity m HPV test	Abbott Alinity m system
Copan FLOQSwab® 552C/552C.80	Dry swab	Seegene Anyplex™ HR HPV assay	Seegene systems
Copan FLOQSwab® 552C/552C.80	Dry swab	Cepheid Xpert® HPV test	Cepheid GeneXpert® systems

HPV, human papillomavirus.

Box 1. Useful CST resources for healthcare practitioners and patients

For healthcare practitioners

- To aid healthcare practitioners comparing CST options (clinician-collection and self-collection) for patients, the ACPCC has produced a 'Supporting patients to make the choice' resource. This resource also includes age-based incidence rates for the detection of HPV.

For patients

- The ACPCC has developed an information booklet for patients, addressing common questions on cervical screening, what happens after a test and how to self-collect; this is available in seven languages.
- The Australian Government and ACPCC have produced a resource addressing 'Common questions about cervical screening' for Aboriginal and Torres Strait Islander patients.
- The NCSP has produced many resources for patients, including those tailored to Aboriginal and Torres Strait Islander patients, and are available in various languages.
- The ACPCC has developed a simple, four-step resource on how to self-collect; this is available in 23 languages.

ACPCC, Australian Centre for the Prevention of Cervical Cancer; CST, cervical screening test; HPV, human papillomavirus; NCSP, National Cervical Screening Program.

Table 4. Follow-up for positive HPV result by HPV type and collection method[5]

Follow-up type	HPV type detected	Collection method	CSTs (1 Dec 2017 – 30 Jun 2024) (n)	Follow-up within 6 months (n, %)
LBC (any reason)	Not 16/18	Self-collected	36,620	30,483 (83.2)
Colposcopy	16/18	Self-collected	10,596	8616 (81.3)
		Clinician-collected	109,791	88,373 (80.5)

CST, cervical screening test; HPV, human papillomavirus; LBC, liquid-based cytology.

Adapted from The Australian Government Department of Health, Disability and Ageing. Update on cervical screening self-collection uptake. Commonwealth of Australia, 2025, with permission from Commonwealth of Australia. Available at www.health.gov.au/resources/publications/update-on-cervical-screening-self-collection-uptake?language=en [Accessed 9 April 2025].

If HPV (not 16/18) is detected, the patient should return as soon as possible, ideally within six weeks, for LBC to determine risk and further management. If the LBC result is high-grade squamous intraepithelial lesion (HSIL), possible HSIL or any glandular abnormality, the patient should be referred for colposcopy. If the LBC result is negative, low-grade squamous intraepithelial lesion (LSIL) or possible LSIL, the patient should return in 12 months for another HPV test.

Some GPs might be cautious about the loss to follow-up with self-collection; however, there are low levels of participants lost to follow-up when HPV is detected on a self-collected sample.

Table 4 shows data about Australians who received a self-collected HPV (not 16/18) result after 1 December 2017; 83.2% subsequently returned for LBC within six months.

The percentages of patients who received colposcopy within six months of a positive HPV (16/18) result from both collection methods were similar (81.3% and 80.5% for self-collected and clinician-collected exams, respectively).[5]

Self-collection screening rates

Offering self-collection to more eligible patients presents an acceptable alternative to clinician-collection and can engage more patients in cervical screening. In Q4 2024, self-collection formed a higher proportion of CSTs in under-screened people (57.42%) and never-screened people (49.33%) compared to that of those who screened on time (37.72%; Table 5).[5]

Conclusion

Self-collection represents a significant opportunity for cervical screening, offering eligible participants the choice of an acceptable and accurate screening test when using clinically validated PCR-based HPV assays. GPs should be aware of the accuracy, quality controls, practical considerations and opportunities associated with self-collection to effectively integrate it into routine practice. GPs are also strongly encouraged to consult their pathology provider to ensure they have correct instructions for offering self-collection in their clinic.

Key points

- Self-collection is as sensitive as clinician-collection for the detection of HPV infections associated with CIN2+. Clinically validated PCR-based assays ensure reliability.
- Quality controls reduce the risk of false negative results for self-collected samples.
- The use of self-collection devices and transport conditions are regulated by the TGA. Healthcare practitioners are encouraged to contact their laboratories to ensure that they have the approved self-collection devices and instructions for use and transport.
- It is crucial that GPs enquire about symptoms suggesting the possible presence of cervical cancer. If symptoms are present, patients should receive a diagnostic work-up instead of self-collection or screening. Routine pelvic exams are not needed for asymptomatic patients.
- Self-collection provides a valuable opportunity for increasing screening participation and equity.

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Table 5. Count of clinician-collected and self-collected CSTs and percentage of all screening tests that were self-collected in Q4 2024[5]

Screening status	Clinician-collected CSTs	Self-collected CSTs	Total CSTs	Percentage of CSTs self-collected
Under-screened	13,872	18,703	32,575	57.42
Never-screened	12,217	11,895	24,112	49.33
On time	182,735	110,676	293,411	37.72
Total screening population	208,824	141,274	350,098	40.35

CST, cervical screening test; Q4, quarter 4.

Adapted from National Cervical Screening Program. Cervical Screening Test self-collection uptake report. Australian Government Department of Health and Aged Care, 2025. Available at www.health.gov.au/resources/publications/update-on-cervical-screening-self-collection-uptake?language=en [Accessed 9 April 2025], with permission from the Australian Government.

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