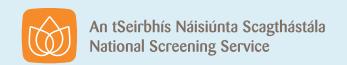


Cervical Screening Results and Management Recommendation Guide







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Introduction

CervicalCheck – The National Cervical Screening Programme provides free cervical screening tests to eligible women aged between 25 and 65 years. From 2020 the primary cervical screening test changes from cytology (examination of the cervical cells under a microscope) to HPV testing (molecular test for the types of high risk HPV associated with cervical cell changes). There is no difference in the procedure for the woman, the test is taken in the same way as a smear test using the same consumables and sent to the designated Programme laboratory.

HPV tests are considered to offer increased sensitivity for high grade cell changes compared to cytology, in addition the high negative predictive value of the HPV test allows women who test negative for HPV subtypes to be recalled at a longer interval.

Because HPV is a very common infection it is important that not all HPV positive cases are referred to colposcopy as there would be a high risk of unnecessary treatment for those women with transient infections. Therefore those samples that are reported as HPV positive are also tested (triaged) using cytology to identify those women who should be referred to colposcopy for further investigation and possible treatment.

In CervicalCheck the result of every eligible screening test is accompanied by a management recommendation. Management recommendations are determined by the HPV result and where applicable the cytology result, the clinical history and colposcopy discharge recommendations available to the laboratory.

This document describes the management recommendations provided by the pathology laboratory.

Healthcare providers are responsible for checking that the management recommendation associated with the HPV result and cytology result, where applicable, is correct with regard to the woman's screening history.

Terminology

HPV testing

HPV is the human papillomavirus. There are over 100 different types of HPV. Most do not cause changes to cervical cells. There are approximately 14 (high risk) types (hrHPV) that are known to cause cervical cell changes and of these, HPV type 16 and 18 are known to be a causative agent in the majority of cervical cancers. All cervical screening tests are now tested for the presence or absence of these 14 HPV types. Where one or more of the 14 high risk HPV types is detected, the sample is further tested (triage test) using cytology which is performed on the residual fluid left in the container. All women who test positive for HPV and show abnormal cytology will be referred directly to colposcopy, however those women who test positive for HPV with normal cytology will be recalled for a repeat test at 12 months. This is because many women will test positive for HPV, but most of these represent transient infections that will clear in twelve to eighteen months. If after 12 months the test result is again HPV positive, these women will be referred to colposcopy at this time regardless of cytology result. If the HPV test is negative the woman can be recalled in either 3 years (age 25-29) or 5 years (age 30+).

Possible results include:

(i) HPV positive/detected

One or more of the 14 high risk HPV types has been detected in the sample. Cytology triage will determine next step.

(ii) HPV negative/not detected

No high risk HPV types have been detected in the sample.

(vii) HPV equivocal/indeterminate result

Some samples give an equivocal result where the sample was tested for HPV but despite a number of attempts a valid result was not achieved.

(viii) Test not processed

The sample was not suitable for HPV testing.

Cytology

CervicalCheck uses the Bethesda classification for cytology.

The Bethesda classification uses a terminology of squamous intraepithelial lesions (SIL). These are divided into:

- (i) Low grade SIL (LSIL) which includes HPV-associated cellular changes and mild dyskaryosis*
- (ii) High grade SIL (HSIL) which includes moderate dyskaryosis*, severe dyskaryosis* and carcinoma in situ
- (iii) Query squamous cell carcinoma
- * Dyskaryosis is identified in cells as nuclear changes. Laboratory reports equate mild dyskaryosis with LSIL and moderate and severe dyskaryosis with HSIL

Cytological changes in squamous cells which are not normal and do not fulfil the criteria for SIL are classed as atypical squamous cells (ASC). In a review of Bethesda in 2001 this category was subdivided into:

- (i) ASC-US 'Atypical Squamous Cells of Undetermined Significance'
- (ii) ASC-H 'Atypical Squamous Cells of Undetermined Significance but high grade changes cannot be ruled out'.

Glandular cell abnormalities are less common and are classified as:

- (i) AGC 'Atypical Glandular Cells' The glandular cell type is specified as endocervical, endometrial, or glandular cells not otherwise specified
- (ii) AGC Favour Neoplastic 'Atypical Glandular Cells Favour Neoplastic Process' The glandular cell type is specified as endocervical or not otherwise specified
- (iii) Endocervical carcinoma in situ (AIS)
- (iv) Query glandular neoplasia

Management recommendation table

Result	Reco	mmendation
HPV Not	R1	Woman is aged 61 or older at date of test, no further screening required
Detected	R1	No further screening post hysterectomy unless recommended by colposcopy or oncology
	R2a	If the woman is between 25 and 29 years – repeat in 3 years (includes women discharged for 1 test in 12 months post discharge) from colposcopy
	R2b	If the woman is 30 - 60 years (at date of test) - repeat in 5 years
	R3	Patients who are HIV positive
	R3	If recommended increased surveillance post colposcopy (>1 test required post discharge & discharge date is after HPV primary screening implementation date)
HPV Detected	R7	If cytology triage result is ASCUS or worse- refer to colposcopy – any test
	R6	First screening test with cytology triage test result of unsatisfactory – repeat in three months
	R3	First screening test with cytology triage test result of No abnormality detected – repeat test in 12 months
	R7	Second consecutive screening test with cytology triage test result of No abnormality detected (disregard intervening indeterminate or unsatisfactory results) – refer to colposcopy
	R7	If HIV +ve- refer to colposcopy
	R7	If discharged for increased surveillance (>1 test required post discharge) – refer to colposcopy
HPV indeterminate result	R6	If this is the first or second indeterminate screening test result – repeat no earlier than 3 months
	R7	If this is the third consecutive indeterminate screening test result – refer to colposcopy
	R7	If the woman has had any three screening test results that are not normal in the previous 10 years and has not had a colposcopy – refer to colposcopy
Test not processed	R6	Repeat no earlier than three months

Where a cytology result is present:

Endometrial cells in a woman over 40 (out of cycle)	Refer for gynaecological assessment.
Clinical details of abnormal bleeding (PCB/IMB/ PMB)	Refer for gynaecological assessment.

Note: where the cervix is suspicious for the presence of cancer a screening test should not be taken, instead an urgent referral should be made to the colposcopy service. A detailed description of the cervix should be provided on the referral form.

Cervical Screening results and recommendations table



HPV Test Result	Cytology Pattern (where applicable)	Code	Management Recommendation	Rationale/ Recommendation
Not Detected/	N/A	뜐	Screening completed	Woman is aged 61 or over at date of test OR post hysterectomy and no requirement for increased surveillance
Negative		R3	l year recall	if HIV+. Or as per colposcopy discharge if recommended increased surveillance (increased surveillance = more than one annual test required post colposcopy discharge & discharge date is after HPV primary screening implementation date)
		R2a	3 year recall	If aged between 25 and 29 years (includes women discharged for one test in 12 months post discharge).
		R2b	5 year recall	If aged 30 - 60 years at test date.
Indeterminate	N/A	R6	3 month repeat	First or second indeterminate screening test result
HPV result		R7	Refer to colposcopy	3 consecutive indeterminate screening test results
				Any 3 screening test results that are not normal in previous 10 years & woman has not had colposcopy
Test not Processed	N/A	R6	3 month repeat	Repeat 3 months
Detected/	P1 (Unsatisfactory)	R6	3 month repeat	Repeat 3 months
Positive	P2 (No abnormality	82	1 year re-call	First HPV positive and cytology NAD, repeat screening test in 1 year
	detected)	R7	Refer to colposcopy	Second consecutive HPV positive and cytology NAD (disregard intervening indeterminate or unsatisfactory results), refer to colposcopy
				Any HPV positive test for woman with HIV, refer to colposcopy
				Any HPV positive and increased surveillance (increased surveillance = more than one annual test required post colposcopy discharge & discharge date is after HPV primary screening implementation date)
	P3a+ (ASCUS or worse)	R7	Refer to colposcopy	Any HPV positive result with abnormal cytology, refer to colposcopy

NOTE:

Where cervix is suspicious for invasive disease, refer for urgent colposcopy, do not take screening test.

When current clinical details record Post Coital Bleeding (PCB)/intermenstrual bleeding(IMB)/ Post-Menopausal (PMB) Bleeding it is recommended to refer for gynaecological assessment.

Where there is a cytology result: If there are endometrial cells present out of cycle for a woman over 40 years it is recommended to refer for gynaecological assessment.



Reference list

- (1) Herbert A, Bergeron C, Wiener H, Schenck U, Klinkhamer P, Bulten J et al. *European guidelines for quality assurance in cervical cancer screening: recommendations for cervical cytology terminology.* Cytopathology 2007; 18(4):213-219.
- (2) von Karsa, L., Arbyn, M., DeVuyst, H., Dillner, J., Dillner, L., Franceschi, S. et al, *European guidelines for quality assurance in cervical cancer screening. Summary of the supplements on HPV screening and vaccination. Papillomavirus Res.* 2015;1:22–31.
- (3) PHE publication: Cervical screening: guidance for laboratories providing HPV testing and cytology services in the NHS Cervical Screening Programme.
- (4) NHS CSP Publication No. 20: Colposcopy and Programme Management Guidelines for the NHS Cervical Screening Programme.

