Public Health England

NHS

NHS Cervical Screening Programme

Short term mitigation using primary HPV screening

Version 1.1

Public Health England leads the NHS Screening Programmes

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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Contents

1. Introduction

This guidance provides practical assistance for laboratories and their associated local providers of the NHS Cervical Screening Programme (NHSCSP), where commissioners and the Screening Quality Assurance Service (SQAS) have agreed that primary HPV screening for mitigation is appropriate[1].

Using primary HPV screening can generate extra cytology capacity in laboratories to enable them to reduce cytology screening backlogs and meet the 14 day turnaround time standard for women receiving their screening results. This will then ensure a safe and timely screening service for women until primary HPV screening is fully implemented across England in 2019. This is not the first stage of wider primary HPV screening implementation. Information on national primary HPV screening will follow in due course.

Moving new populations of women to primary high risk (hr) HPV testing needs to be performed in a consistent and coordinated manner. This guidance document sets out the principles which must be followed, drawing on the experience gained in the primary HPV pilot sites.

2. Primary HPV screening for the purpose of mitigation

In practice, the introduction of primary HPV screening means screening samples will be tested first for hrHPV, rather than cytology. Cytology then becomes a ‘triage’ test which is only performed if hrHPV is detected in the sample. Primary HPV screening typically leads to a reduction in the requirement for cervical cytology by approximately 85%. The associated increase in hrHPV testing is easily managed by high throughput analytical platforms.

Local public health commissioning teams that decide to introduce primary HPV screening for mitigation should work with local providers of the NHSCSP to agree a plan to outline how this will be achieved, in line with this guidance. The plan must also detail:

[1] This document **does not** cover information for providers that need help with their cytology capacity, and are looking to send work to another laboratory with excess capacity. If this is a requirement please liaise with local public health commissioning team and SQAS for the process and application to the Mitigation Prioritisation Group.

- the population of women and proportion of the screening laboratories workload to be converted
- an assessment of effect on turnaround times locally

Commissioners should share any plan they receive to use primary HPV testing with SQAS. SQAS will then assess whether the plan meets the quality requirements of the programme, including the need to maintain 35 000 cytology screens per laboratory. Plans with SQAS support will then be considered for approval at the joint NHSE/PHE Mitigation Prioritisation Group.

SQAS may ask for more information during the process but plans should include, as a minimum:

- cytology laboratory details
- details of important personnel
    - Lead cytopathologist
    - Laboratory manager
    - HBPC
    - Lead colposcopist(s)
- HPV testing arrangements
    - Transfer of results from hrHPV testing platform to LIMS
- arrangements for HPV16/18 genotyping testing and recording (where applicable)
- colposcopy services and capacity planning
- training of important staff groups
- population of women to be moved to primary HPV testing and projections for mitigating turnaround times and cytology capacity
- projected cytology workload (>35 000)
- proposed timeline for implementation
- plans for implementing new reporting codes within the laboratory

Detailed assessment will be based on the requirements detailed in this guidance document.

Once a laboratory starts primary HPV screening in a new population of women this is a permanent arrangement. It will not be possible to revert back to primary cytology screening in this population, even if backlog work and capacity issues cease.

3. Preparation

It is essential to engage with all elements of the local programme well before the introduction of primary HPV screening to a new population of women. Sites must ensure:

- start dates are agreed with all elements of the local programme, such as GP practices and colposcopy clinics
- there is enough colposcopy capacity, with plans to increase capacity in line with the requirements of the primary HPV screening protocols for referring women with persistent hrHPV infection in the absence of abnormal cytology
- training resources are provided to all staff who are new to primary HPV screening prior to the start date, including primary care and other sample takers, laboratory and colposcopy staff
- the call/recall service is engaged at an early stage to:
    - identify the cohort extension to the primary HPV screening population and ensure the correct system set up
    - ensure appropriate invitations/information for women and result letters are in place to support the new reporting codes
- local protocols are rewritten to reflect all the changes required for primary HPV screening
- laboratories invest in consumables associated with the increased number of hrHPV tests

4. Screening samples for primary hrHPV testing

hrHPV testing is performed on the liquid based cytology (LBC) sample that is taken when a woman attends for cervical screening. Samples should continue to be taken in the same way, (as per guidance for the training of cervical sample takers) ensuring that the cervix is visualised and sampled appropriately. The sample requirements for hrHPV testing depend on the LBC technology and type of hrHPV test employed. However one LBC sample is sufficient for hrHPV testing and subsequent cytology if the hrHPV test result is positive.

If a woman's LBC sample is unsuitable for hrHPV testing for reasons such as containing insufficient material, it should be reported as inadequate and a repeat screening sample taken in 3 months' time. Cytology should not be undertaken in the absence of a hrHPV positive test result.

Once all testing is complete and the screening results have been reported, there is no requirement for the long term storage of LBC samples used for hrHPV testing, frozen or otherwise. LBC samples can be discarded according to the normal laboratory retention, storage and disposal procedures. Cytology slides produced from LBC samples testing positive for hrHPV should continue to be stored for 10 years.

5. Laboratories

5.1 Laboratory configuration

hrHPV testing is required to be co-located with the cytology service, either within the cytology laboratory or within the microbiology/virology department. hrHPV test results must be downloaded electronically into the laboratory information system (LIMS) cytology screening record. The cytology component of the service is responsible for the issuing/reporting of all screening results, including those where the result is hrHPV negative.

5.2 Screening process

The hrHPV test is the initial test performed on all cervical samples from women who are being screened according to primary HPV screening protocols. Women testing hrHPV negative will require no further testing and will be assigned to routine recall at 3 or 5 years, depending on their age. Samples testing positive for hrHPV will be forwarded for LBC processing to produce a cytology slide. The slide will then be cytology screened and reported in the usual way according to current national guidance.

Cytology results will be reported together with the hrHPV test results in a combined screening report. hrHPV negative results and hrHPV positive results with normal cytology can be reported by competent cytology screeners according to screening protocols, irrespective of whether the action code is routine recall, referral or early recall. All results that include abnormal cytology will be reported with the appropriate management recommendation by a cytopathologist/ consultant BMS.

Some hrHPV platforms provide genotyping for HPV16 and HPV18. In the pilots of primary HPV screening some sites have used this genotyping result to assist in the management of women attending for 12 month repeat tests, following an initial screening result of hrHPV positive and cytology normal, where it helps to prioritise and smooth referrals to colposcopy. The UK National Screening Committee is considering the evidence, including pilot data, with regards to the optimal management of women with these screening results.

In the interim, for the purposes of introducing primary hrHPV testing for mitigation, laboratories and commissioners should agree whether to employ the pathway including genotyping for HPV16/18 or the pathway without genotyping. One pathway must be chosen for all women receiving primary hrHPV testing in the laboratory. It is not currently possible to report genotyping results to the call/recall system but genotyping results, where used to inform the management of women, must be recorded on the LIMS and be available to SQAS as part of the data monitoring set.

Until the functionality to record genotyping is added to the call/recall system, it will not be possible to inform women of their genotyping result, only that they have tested positive for hrHPV. Information will be provided to women in the HPV leaflet that accompanies the invitation for screening, to inform women that HPV genotyping may be undertaken and the results will be used to change policy and improve the programme.

6. Screening tests

6.1 hrHPV tests

The NHSCSP has evaluated the available hrHPV tests with appropriate LBC samples and published details of approved tests for use in the NHSCSP. Details of approved tests are available . This is an ongoing process. Laboratories are advised to check with PHE if their proposed platform is approved for primary HPV screening.

Laboratories employing genotyping for HPV16 and HPV18 to assist in the management of women with persistent hrHPV positive and cytology normal screening results must employ an approved hrHPV test that provides this added functionality.

6.2 Liquid based cytology

All NHSCSP laboratories must use one of two LBC systems currently approved for use in the programme, either Hologic ThinPrep or BD SurePath.

7. Quality assurance of hrHPV testing

hrHPV testing must be undertaken in laboratories registered with the United Kingdom Accreditation Service (UKAS) seeking accreditation to ISO 15189:2012. All laboratories providing hrHPV testing must also participate, and show adequate performance in an accredited external quality assurance scheme such as the UK National External Quality Assessment Service (NEQAS) scheme for HPV.

See the NHSCSP guidance 'Laboratory quality control and assurance for HPV testing'.

8. Training

Primary HPV screening places special demands on a range of staff working within the NHSCSP, in particular:

- primary care staff taking samples and counselling women
- laboratory staff providing hrHPV testing and/or cytology screening
- colposcopists receiving hrHPV positive referrals

All staff must be trained and deemed competent to meet the requirements of primary HPV screening. The training required to meet these demands successfully is outlined below.

8.1 Sample takers

Engaging primary care is crucial if primary HPV screening is to be successfully implemented. National information and training materials on primary HPV screening have been developed for sample takers working in the NHSCSP. They may also be a useful resource for colposcopy nurses, as women often have questions about hrHPV testing on attendance at colposcopy.

Sample taker primary HPV screening information and training materials are available. They comprise:

- a leaflet for sample takers on primary hrHPV testing
- a PowerPoint training presentation on primary HPV screening
- the screening invitation letter and HPV information leaflet for women
- links to the protocol flowcharts for primary HPV screening and colposcopy management recommendations

- a link to the cervical screening leaflet ‘Helping you decide’ sent to every woman with her screening invitation

Completion of training for primary HPV screening can be recorded on the local sample taker register.

8.1.1 Novice sample takers

Sample taker training must continue to be offered to staff in areas and practices which have converted to primary HPV screening. Whatever method (relating to cytology preparations) is in place locally for assessing competency of sample takers in training must be continued.

All samples taken by sample takers in training **must** be clearly identified to the laboratory. Samples which are hrHPV positive or hrHPV negative should have a cytology sample prepared (dual testing). Samples which give an inadequate or unreliable hrHPV result should be repeated after a period of three months.

All cytology and hrHPV test results must be logged on the laboratory IT system to give a full record of the test result, and so that feedback on cytology adequacy can be given to both sample takers in training and course organisers in the usual way.

Management of women and the transfer of screening results to the call and recall IT system must follow recognised screening protocols. Dual testing of samples may result in a combination of cytology and hrHPV test results which is not currently recognised in the primary HPV screening protocol. Where possible these tests should be recorded as HPV triage samples to facilitate the production of a suitable result notification, and to ensure that women can be managed appropriately in accordance with NHSCSP ‘ABC 3’ guidance. A summary of test result code combinations which cannot be recorded as primary HPV screening tests at present, in particular those which must be recorded as HPV triage tests, is given below.

Note that cytology and hrHPV test result codes which give a valid primary HPV screening code combination should be recorded as such, and transferred as primary HPV screening tests to the call and recall IT system.

Guidance for recording non-standard dual-tested screening results

Cytology result code	HR HPV result code	Action code	HPV PS flag*	Code combination to be used	Special note
0	0	A	N	G0A	
0	0	R	N	G0R	
0	0	S	N	G0S	
1	0	A	Y	X0A	The inadequate cytology result is disregarded for the purposes of recall
1	0	R	Y	X0R	
1	0	S	Y	X0S	
2	0	A	N	N0A	
2	0	R	N	N0R	
2	0	S	N	N0S	
3	0	A	N	M0A	
3	0	R	N	M0R	
3	0	S	N	M0S	
4	0	S	N	40S	
5	0	S	N	50S	
6	0	S	N	60S	
7	0	S	N	70S	
8	0	A	N	B0A	
8	0	R	N	B0R	
8	0	S	N	B0S	
9	0	A	N	E0A	
9	0	R	N	E0R	
9	0	S	N	E0S	

* The HPV primary screening flag will identify a test result being entered as a primary HPV screening result. It must be completed by entering either “N” or “Y”.
N = not primary HPV screening
Y = primary HPV screening test

8.2 Training for laboratory staff handling samples

All staff involved in handling samples for hrHPV testing should undergo training. This should include following the relevant protocols and the correct placing of samples for the screening process.

8.3 Training for laboratory staff undertaking hrHPV testing

Initial training for staff new to hrHPV testing may be provided by the suppliers of hrHPV test technologies or in house by staff previously trained in the technique. Thereafter training will form part of update training.

Suppliers providing training must submit their training protocol for approval by SQAS. Amongst the criteria for approval is that:

- training will be provided on site
- all staff undertaking testing must complete the training
- certification of completed training must be provided

If a laboratory decides to adopt more than one HPV testing method, staff must be trained to this level of competence in each of the tests used.

8.4 Training for laboratory staff undertaking cytology triage

All staff involved in the screening and reporting of cytology samples following primary hrHPV testing should have an up to date knowledge of the primary HPV screening pathway. In house training of staff new to primary HPV screening should include:

- results of randomised controlled trials and primary HPV screening pilots
- primary HPV screening protocols and management algorithms
- hrHPV and cytology workflow through the laboratory
- quality assurance

8.5 Training for colposcopists

All colposcopists who receive primary HPV screening referrals are expected to undertake relevant study and have up to date knowledge of the primary HPV screening pathway and management algorithms.

9. Protocols for screening women with primary HPV testing

The pilot protocol for women having primary HPV screening in the cervical screening programme is available.

This protocol is under review as part of the development of wider guidance for the implementation of primary HPV testing in 2019. Laboratories participating in mitigation should use the pilot protocol until further guidance is published.

9.1 Routine call and recall

Women will continue to be called for routine screening at 3 and 5 year intervals, depending on their age. All women will be tested for hrHPV and those with a negative result will be returned to routine screening.

9.2 Cytology triage

Samples from women found to be positive for hrHPV will have cytology performed (cytology triage). Those women with normal cytology will be recalled in 12 months for a repeat test. In laboratories using genotyping for HPV16 and HPV18 to manage an earlier referral to colposcopy for women who are hrHPV positive with normal cytology, the HPV16 or HPV18 status will be recorded on the LIMS in order for this to be available to SQAS (see 5.2). Women with abnormal cytology (any grade) will be referred immediately to colposcopy.

9.3 Repeat tests at 12 months

Women recalled for a repeat test at 12 months due to being hrHPV positive with normal cytology will have a repeat hrHPV test. Women testing hrHPV negative will be returned to routine screening.

Women testing hrHPV positive will have cytology performed and any abnormal cytology result will lead to a referral to colposcopy. If the cytology is normal again the woman may be asked to come for a further repeat test in 12 months' time. However, if the laboratory is employing genotyping for HPV16 or HPV18 to guide management, persistence of infection with either of these two HPV subtypes will lead to a colposcopy referral, without the need for a further repeat test.

9.4 Repeat test at 24 months

Women returning for a second repeat test, 24 months since the initial screening test, will have a hrHPV test. Women testing hrHPV negative will be returned to routine screening. Women testing hrHPV positive will have cytology triage performed, but will be referred to colposcopy at this stage regardless of whether the cytology result is normal or abnormal. Cytology not only assists the colposcopist, but also defines the urgency of referral required.

9.5 Inadequate tests

Inadequate tests at any screening episode in the pathway will be repeated in 3 months' time. Women with 3 inadequate screening tests (hrHPV and/or cytology) in a row will be referred to colposcopy.

Cytology will not be performed on any sample where the hrHPV test is inadequate. This includes samples from women attending for 12 months repeat tests.

When a hrHPV test result is obtained from a sample but the cytology triage test is inadequate, the repeat sample should be tested for hrHPV and if negative the woman will be returned to routine screening.

9.6 Women entering primary HPV screening whilst in follow up

Women recently treated for cervical intraepithelial neoplasia (CIN) or cervical glandular intraepithelial neoplasia (CGIN) prior to the implementation of primary HPV screening should be managed according to the protocols detailed on page 2 of the primary HPV screening pilot colposcopy management recommendations algorithm (see section 10). Follow up differs to the test of cure protocols used in HPV triage and TOC, most notably in that cytology is not required for hrHPV negative women.

Women who have completed test of cure protocols when primary HPV screening is implemented and are returning for the follow up test 36 months later will begin a new screening episode, according to the primary HPV screening protocol algorithm.

Women being followed up for untreated CIN1 should also be managed according to the recommendations detailed on page 2 of the primary HPV screening pilot colposcopy management recommendations algorithm (see section 10). Follow up is based on primary HPV testing, and women part way through follow up should be managed by hrHPV testing at their next test and not continue with cytology based follow up.

9.7 HIV positive women

Annual screening of women who are HIV positive will be based on primary hrHPV testing rather than cytology. The management of these women will follow the screening protocol flowcharts for primary HPV screening in all other aspects other than frequency of screening.

10. Protocols for managing women referred to colposcopy following primary HPV screening

The recommended pilot management pathways and follow up for women being referred to colposcopy following abnormal results from primary HPV screening are available.

These protocols are under review as part of the development of wider guidance for the implementation of primary HPV testing in 2019. Laboratories participating in mitigation should use the pilot protocols until further guidance is published.

10.1 Inadequate colposcopy

Women with inadequate colposcopy examination are managed on the results of their referral screening test. Those with high-grade dyskaryosis or worse cytology will be offered a large loop excision of the transformation zone (LLETZ) procedure. Women with borderline changes or low grade dyskaryosis will be invited for a repeat colposcopy examination in 12 months' time. If this second examination is again inadequate, a LLETZ procedure should be considered depending upon the woman's preference to be treated or remain under surveillance.

10.2 Normal and adequate colposcopy

10.2.1 Negative or no biopsy taken

Women with a negative biopsy or no biopsy taken will be recalled in 36 months if their referral cytology results indicated either borderline changes or low grade dyskaryosis. At their next test in 36 months' time, these women will restart the screening protocol for primary HPV screening (see section 9).

Women whose referral cytology was high grade dyskaryosis or worse should have their case discussed and management agreed at the multidisciplinary team meeting within 2 months.

10.2.2 Abnormal biopsy

If CIN is confirmed on biopsy from a woman with a normal colposcopic appearance, she should be managed according to the same protocols as women with an abnormal colposcopic appearance.

10.3 Abnormal colposcopy

10.3.1 CIN1

The follow up management for women who have CIN1 (histologically confirmed or colposcopic impression) is recall for screening at 12 months with primary hrHPV testing. Women testing hrHPV negative at this repeat test can be recalled in 36 months, at which point they will restart the screening protocol for primary HPV testing.

Women testing positive for hrHPV at the 12 month repeat test will have cytology performed on their sample and if this is abnormal (any grade) they will be referred to colposcopy again. Women with normal cytology will be recalled for screening again in a further 12 months' time.

At the second follow up test women who are hrHPV negative can be recalled in 36 months. Those who are hrHPV positive will have cytology performed and those testing normal can also be recalled in 36 months when they will restart the screening protocol for primary HPV testing. Women with abnormal cytology will be referred to colposcopy.

10.3.2 CIN2 and CIN3

Women treated for CIN2 or CIN3 will be called for another test 6 months post treatment. Those testing hrHPV negative will be recalled in 36 months, when they will restart the screening protocol for primary hrHPV testing. Women who test hrHPV positive will have cytology performed, but will be referred to colposcopy regardless of the result (including those with normal cytology).

10.3.3 Adequately treated CGIN

Women adequately treated for CGIN or stratified mucin producing intraepithelial lesions (SMILE) with complete excision margins will be managed according to the pathway detailed on page 2 of the primary HPV screening pilot colposcopy management recommendations algorithm. These women will be invited to attend for the first of 2 follow up tests 6 months post treatment. All will be tested for hrHPV and those who are negative will be recalled for the second follow up test in a further 12 months. Cytology is not required in hrHPV negative women to confirm the presence of endocervical cells.

Women testing hrHPV positive at the first follow up test will have cytology performed. Women with abnormal cytology will be referred to colposcopy. Where cytology is normal a further colposcopy examination will be performed and if this is normal women will be recalled for the second follow up test in a further 12 months.

At the second follow up test, women testing hrHPV negative will be recalled for further screening in 36 months when they will re-start the screening protocol for primary hrHPV testing. Women testing hrHPV positive at the second test will have cytology performed. Those with abnormal cytology will be referred to colposcopy. Where cytology is normal a further colposcopy examination will be performed and if this is normal, women will be recalled for a further test in 12 months' time. At this further repeat test they will be managed according to the recommendations at the previous test.
Women referred to colposcopy for abnormal cytology at either of the two follow up tests will be eligible to enter the follow up pathway again if they have further re-excision with

complete excision margins. In those women where colposcopy is normal or re-excision does not occur, follow up with annual cytology testing for 10 years is recommended.

10.3.4 Women attending for post treatment follow up tests

Follow up samples should be taken at least 6 months following treatment and early attendance should be discouraged. Whilst it may be acceptable to test samples taken 3 to 6 months post treatment, samples taken less than 3 months post treatment should not be tested.

10.3.5 Follow up of women with incomplete excision of CGIN/SMILE

Women treated for CGIN or SMILE who are ineligible for the two test follow up pathway above (10.3.3) due to incomplete margins will be followed up for 10 years using annual hrHPV testing.

10.3.6 Follow up of cervical cancer

Women in follow up for cervical cancer (who still have a cervix) will be followed up for 10 years using annual hrHPV testing.

11. IT system changes

11.1 Call and recall

The laboratory and local screening and immunisation team (SIT) must establish communication with the call and recall service (Primary Care Support England (PCSE)) at least 8 weeks prior to services moving to primary HPV screening. The lines of communication should be maintained throughout the transition period.

Discussion must take place as to the cohort definition for the relevant population as this may require a new cohort of the population to be defined on the call and recall system.

Laboratories or SITs need to notify PCSE of:

- the cohort of the population to be included
- the additional text to be used in the invitation and result letters
- the relevant laboratory involved
- the anticipated date of transfer to primary HPV screening for the cohort defined

At least 8 weeks' notice needs to be given to enable appropriate primary HPV screening invitations to be sent to women with the correct information regarding primary HPV screening.

PCSE will need to:

- validate the cohort selection with laboratory or SIT
- ensure that the flag defining that primary HPV screening is being utilised is switched on, which will ensure the correct letters inserts and leaflets are sent to the relevant cohort
- ensure that women receive the correct primary HPV screening invitation letters for the screening technology in use, commencing approximately 6 weeks prior to transfer to primary HPV screening at the laboratory
- ensure that the additional text supplied by the SIT has been applied to the primary HPV screening letters.
- ensure that all of the relevant parameters are set for the women if a new cohort of the population is defined, thus ensuring appropriate and timely communication
- ensure the appropriate delivery times are defined on the parameters which drive the VSA15 turnaround statistics, once switchover takes place

11.2 Laboratory information systems

Primary hrHPV tests must be identified as such when results are reported to the call/recall service. The laboratory system must have the functionality to provide the primary hrHPV screening flag for each test as follows:

- Y = primary hrHPV screening test
- N = not primary hrHPV screening test

Test results which are sent electronically using the standard network messaging system must use the redundant field formerly reserved for 'Excluded from target payments' marker for the primary HPV screening flag. If this field is left blank (null) in the message, it will default to 'N' on receipt at the call/recall service. Technical advice for laboratory system and/or middleware suppliers is available on request from exeter.helpdesk@nhs.net.

All primary hrHPV test results must include a cytology result code, a hrHPV test result code and an action code in accordance with the coding scheme given below. Note that a new cytology result code of X (dummy code) has been introduced to record tests where the hrHPV test result is negative and therefore a cytology test is not required. The laboratory LIMS must be able to support this new result code.

Cytology result codes

X No cytology result
0 ?glandular neoplasia (non cervical)
1 inadequate
2 negative
3 low grade dyskaryosis
4 high grade dyskaryosis (severe)
5 high grade dyskaryosis ?invasive squamous carcinoma
6 ?glandular neoplasia of endocervical type
7 high grade dyskaryosis (moderate)
8 borderline change in squamous cells
9 borderline change in endocervical cells

hrHPV result codes

0 (zero)	HPV negative
9 (nine)	HPV positive
U	HPV result unavailable
Q	no HPV test carried out due to recent HPV positive result (pilot use only – code now retired)

Action codes

A routine recall
R early repeat in 3, 12 or 36 months
S suspend from recall

With limited exceptions, test results coded ‘R’ for action should not specify the number of months for the woman’s recall. This is because the call/recall system will in each case calculate the appropriate recall interval in accordance with the primary screening protocol. If a number of months is provided for a standard R-coded test, this will be disregarded by the call/recall system. It will not be formally rejected by the system and therefore no warning or error message will be provided to the laboratory. The laboratory cannot, therefore, specify a non-standard recall interval for any woman.

There are two valid recall intervals applicable to tests coded X0R, 29R and 09R. In each case the woman could require recall in either 12 or 36 months. A default interval will apply to these results although an allowable alternative can be provided by the laboratory which will override the default value. The defaults and allowable override values are:

Result code combination	Default recall interval (months)	Allowable recall interval (if provided)
X0R	36	12
29R	12	36
09R	12	36

Result and action codes will only be accepted by the call/recall system if they form a valid code combination as follows:

Cytology Result Code	Infection Code(s)	Action Code(s)
X	0 or U	R
X	0	A
X	0, 9 or U	S
1	9	R or S
0	9	R or S
2	9	R or S
3	9	S
4	9	S
5	9	S
6	9	S
7	9	S
8	9	S
9	9	S

Test results will be rejected by the call/recall system if they are flagged as primary hrHPV tests and:

- include cytology result codes B, E, G, M or N which relate to the triage & test of cure screening protocol
- include any unrecognised code
- form an invalid code combination
- are incomplete i.e. do not include a separate cytology, infection and action code

Test results will also be rejected by the call/recall system if:

- the primary hrHPV screening flag/field contains an invalid character

- the primary hrHPV screening flag/field is set to ‘N’ or null and the test result suggests a primary screening test i.e. code X for cytology
- an action code is inappropriate with reference to the woman’s screening history e.g. early repeat instead of referral after a third consecutive HPV positive/cytology negative test

It may be helpful for the laboratory LIMS to incorporate basic validation to prevent the issue of these results where possible.

12. Monitoring data

Laboratories participating in primary HPV screening for the purposes of mitigation must be able to supply monthly monitoring data to SQAS. A data template will be provided by SQAS for this purpose.

13. Information materials

13.1 Information for women

13.1.1 Standard invitation and result letters

The introduction of primary HPV screening requires new standard invitation and results letters. Call and recall offices send most correspondence to women and as noted in section 11.1, the offices must be engaged at an early stage to ensure appropriate letters are used at the correct time. Where reminder invitations are sent by GPs the text of these letters should be revised to take account of primary HPV screening.

13.1.2 HPV information leaflet

Primary HPV screening is offered to women as part of an enhanced screening service. It is the sample taker’s responsibility to ensure that the woman to be tested has received all the necessary information and understood it. Once this is confirmed, her consent to primary hrHPV testing and cytology triage (where indicated) is implied by the fact that she attends and accepts the procedure.

Until primary HPV screening is fully implemented across England it will be necessary for an additional HPV information leaflet to be included in all invitation and reminder letters for routine call/recall tests and early recall tests. This will accompany the existing ‘NHS Cervical Screening: Helping you decide’ leaflet. Similarly, any routine invitation letters that are not sent by call and recall offices, for example those sent by GPs, must include the HPV information leaflet. This additional leaflet:

- advises women that their sample will be tested as part of primary HPV screening
- explains why primary hrHPV testing is being used
- advises women of the types of primary HPV screening results

The additional primary HPV screening leaflet must also be sent with all screening invitations for 6 weeks before the introduction of primary HPV screening testing protocols for that population in the laboratory. This will ensure that women attending for screening receive the correct information in time for the start of primary HPV screening.

Once the whole of England has implemented primary HPV screening in 2019 PHE will incorporate information about primary hrHPV testing into the NHS cervical screening leaflet and the need for an additional leaflet will cease.

13.2 Information for sample takers

Primary care and sample taker information materials have been developed to provide cervical sample takers with information on primary HPV screening and to assist with training (see section 8.1).