Guidance

Cervical screening: implementation guide for primary HPV screening

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Contents

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1. Introduction

This guidance has been developed to aid local providers of the NHS Cervical Screening Programme (NHSCSP) in implementing high-risk human papillomavirus (hrHPV) testing as the primary screening test in the programme.

Infection with a high-risk strain of the human papillomavirus has been established as a necessary but insufficient cause of cervical cancer[1]. This has led in recent years to the inclusion of hrHPV testing as an adjunct to cytology in organised cervical screening programmes. In the English programme hrHPV testing has been used since 2011 to help manage women with low grade cytology abnormalities and as a follow up test of cure in women who have received treatment.

Four large European randomised controlled trials have considered the use of hrHPV testing as a primary screening test.[2345] Compared to cytology, hrHPV testing has been shown to reduce the risk of developing cervical cancer through increased sensitivity for underlying disease. As natural history work suggests that at least 10 years elapses between acquiring hrHPV and developing cancer, the high negative predictive value of hrHPV testing and lower false negative rate means screening intervals can be lengthened in women who test negative for hrHPV. In addition, detailed modelling studies based on the ARTISTIC trial have since shown primary hrHPV screening to be cost effective[6].

This evidence provides the rationale for moving to primary testing with hrHPV, reserving cytology for women testing hrHPV positive. In 2013, English pilots of primary hrHPV screening began and in 2015 the first report confirmed the feasibility of use and improved performance of primary HPV screening within the NHSCSP. Following an evidence review and public consultation the UK National Screening Committee (UK NSC) recommended the implementation of primary hrHPV testing (https://legacyscreening.phe.org.uk/cervicalcancer) to replace primary cytology and on 4 July 2016, the Public Health Minister announced the implementation (https://www.gov.uk/government/news/changes-to-cervical-cancer-screening) across England.

The implementation of primary HPV screening is a major undertaking that will impact upon all elements of the programme and require significant service redesign. This implementation guide aims to support these processes drawing on experience gained from the pilots.

2. Roles and responsibilities

2.1 UK National Screening Committee

The UK NSC advises ministers and the NHS in the 4 UK countries about all aspects of population screening and supports the implementation of screening programmes. Subsequent to the recommendation to implement primary HPV screening the UK NSC has been considering the evidence on a number of ancillary issues to support and maximise the benefits of primary hrHPV testing offers.

2.2 Public Health England

Public Health England (PHE) is an executive agency sponsored by the Department of Health and Social Care (DHSC). Its role is to protect and improve the nation’s health and wellbeing and reduce health inequalities. The PHE Screening division sits within the Health Improvement directorate of PHE. Its role

is to lead the population screening programmes that are delivered by the NHS.

2.1.1 Young Person and Adult Screening Programmes

The Young Person and Adult Screening Programmes (YPA) is a section of PHE Screening that is responsible for the national coordination and implementation of the 3 cancer screening programmes (cervical, breast and bowel), plus the abdominal aortic aneurysm and diabetic eye screening programmes. YPA has led the programme of work to implement primary HPV screening, working closely with NHS England and other stakeholders. The main elements of this work include:

- developing quality standards and guidance for the cervical screening programme
- developing the Section 7a service specification no.25 for cervical screening using primary HPV screening
- options appraisal to inform the footprint of laboratory services (https://phescreening.blog.gov.uk/2017/01/31/deciding-how-best-to-roll-out-hpv-testing-as-the-primary-cervical-screening-test/)
- information materials for public and professionals
- training for staff working in the programme

2.2.2 Screening Quality Assurance Service

The Screening Quality Assurance Service (SQAS) in PHE is responsible for checking that quality standards for the screening programmes are met by NHS providers, and encouraging continuous improvement. The SQAS provides practical advice and support to NHS services during the transition to primary HPV screening and centralisation of screening laboratories.

2.3 NHS England

NHS England (NHSE) leads the NHS in England. Much of the work performed by NHSE involves the direct commissioning of health care services and holding providers to account for spending this money effectively. NHSE also supports local health services that are led by groups of GPs called Clinical Commissioning Groups (CCGs). CCGs plan and pay for local services such as hospitals and ambulance services.

NHSE works closely with PHE and DHSC to provide and commission a range of public health services according to the NHS public health functions agreement and associated public health national service specifications (https://www.england.nhs.uk/commissioning/pub-hlth-res/). The commissioning of the national screening and immunisation programmes is performed by NHSE's 27 area teams linked to local authorities.

NHSE will commission all screening laboratory services required to implement primary hrHPV testing and cytology triage.

2.3.1 Screening and immunisation teams

Screening and immunisation teams (SITs) comprises public health specialists that are employed by PHE and embedded in NHSE area teams. SITs provide the local system leadership for screening and immunisation services within the NHSE area teams.

2.4 Cervical screening programme boards

Cervical screening programme boards are local multidisciplinary groups comprising representatives from all professional aspects of the local programme, SQAS and SITs. The role of the programme board is to assess programme performance and agree action plans where this falls short of the requirements specified in the cervical screening service specification. They also have a role in ensuring that new guidance is implemented locally.

Programme boards will have a central role in leading the process of primary HPV screening implementation once contracts have been awarded by NHSE. They may also find it helpful to appoint a number of sub-committees with the appropriate bodies to manage individual work streams for the duration of the transition.

2.5 Provider organisations

Provider organisations include:

- NHS Trusts
- NHS organisations
- primary care
- private companies commissioned by NHS England

They provide one or more of the following services to the cervical screening programme:

- call/recall
- hrHPV testing and cervical cytology services
- cervical histology services
- colposcopy services.

The services provided by these organisations must be consistent with national guidance and standards for the cervical screening programme (https://www.gov.uk/government/collections/cervical-screening-professional-guidance).

Primary HPV screening will lead to the centralisation of hrHPV and cytology services. Some current providers will therefore no longer host these services but are likely to retain other services such as colposcopy or histology. The new footprint of services will require organisations to implement new ways of working both within the organisation and across organisation boundaries.

3. Service reconfiguration

The implementation of primary HPV screening into the cervical screening programme will lead to a reduction in the amount of cervical cytology performed. Due to this development, it has been necessary to consider the future screening laboratory footprint required to deliver a sustainable and quality service for women.

PHE and NHSE commissioned an options appraisal with extensive stakeholder involvement, to inform the planning process with regard to the optimal size and number of hrHPV testing laboratories and associated cytology services required post implementation. The outcome of the options appraisal and

subsequent NHSE due diligence exercise was the intention by NHSE to commission up to 13 laboratories across England.

Centralisation of screening laboratory services will lead to laboratories serving a larger number of GP practices, colposcopy clinics, sexual health services and histology laboratories, with many residing in different trusts.

Screening laboratories will need to maintain strong links with all of these services to ensure continuity and provision of a high-quality service. This includes the timely referral of women using direct referral, electronic transfer of results to Primary Care Support England (PCSE), IT links enabling the screening laboratory to look up colposcopy outcomes or histology results and representation at colposcopy multidisciplinary team (MDT) meetings. The role of the cervical screening provider leads is vital in bringing these aspects of the programme together.

NHS England has put a resilience plan in place which aims to maintain the delivery of a high-quality service to women during the transition to primary HPV screening. NHSE is working with NHS Improvement and SQAS to give all laboratories working with their emerging pathology networks the opportunity to implement primary HPV screening ahead of the start of the procurement process. This is dependent on laboratories meeting defined quality criteria and having a robust plan in place to ensure primary HPV testing is implemented in accordance with this guidance and continues to meet quality standards. Providers participating in the resilience process will continue to deliver primary HPV screening in the interim until the commissioned centralised laboratory services begin.

4. Preparation for implementing primary HPV screening

All elements of local cervical screening programmes will need to be engaged well in advance of implementation. Local cervical screening programme boards will be central in leading this process and addressing the various work streams required.

Consideration should be given to the following areas prior to implementation.

1. Start dates must be agreed with all elements and disciplines of the local programmes and any programmes where work is being transferred or centralised prior to implementation. This includes all laboratory screening services that will be transferred or centralised and their associated primary care services via CCGs. Plans and agreements will also need to be made with local colposcopy, genito-urinary medicine (GUM) and histology services that will remain in trusts no longer hosting a hrHPV/cytology laboratory.
2. The sequencing of events with respect to work transferring from one screening laboratory to another needs careful planning. Laboratories will need to generate excess cytology capacity by converting their own screening work to primary HPV screening prior to receiving work transferred in from laboratories ceasing to provide cervical screening.
3. Where implementation is staged, GP practices and colposcopy services that are not yet involved in primary HPV screening but straddle other programme areas that are, need to be alerted to the possibility of being contacted by patients about primary HPV screening.
4. PCSE must be engaged at an early stage (around 12 weeks ahead) to ensure that they are ready to identify cohorts of women and issue appropriate invitations (6 weeks in advance of the start date), information and result letters to support the new reporting codes.

5. Adequate sample logistics are required where work has been transferred or centralised to ensure the continued supply of sample test kits to primary care services and the timely collection and relay of samples to the laboratory (see section 6.2). The screening laboratory should ensure that systems and contracts are in place in time for the start date for a new population of women.
6. An understanding of the primary HPV protocol and procedures required is essential and training must be provided and completed by all staff, including primary care and other sample takers, laboratory and colposcopy staff (see section 11).
7. Cervical screening programme approved platforms for hrHPV and liquid based cytology must be selected, and arrangements made with suppliers to ensure supply of sufficient consumables, capacity planning, and the installation, checking, verification, validation and training on any new equipment is completed in advance (see section 8).
8. Programmes should be alert from the outset to the full implications of primary hrHPV testing for local IT processes. Additions to laboratory information management systems (LIMS), middleware and messaging will be required to support the new reporting code set (see section 12.2).
9. Screening laboratories must be able to send results electronically to the national call/recall using a secure messaging system which supports the necessary fields and codes for primary HPV screening tests. Results sent by other methods (for example email or paper) will not be accepted by PCSE.
10. Arrangements must be made prior to the transfer of laboratory services to address issues relating to backlogs, access to archival slide material and screening records (see section 15).
11. Ensuring capacity in all organisations providing colposcopy, to accommodate additional colposcopy appointments required to support the primary HPV screening pathway (see section 13 and section 14).
12. Local protocols in primary care, laboratories and colposcopy services must be rewritten to reflect all the changes required for primary HPV screening.
13. New programme standards and guidance will to be implemented alongside primary HPV screening and appropriate data flows created to ensure compliance can be demonstrated.

5. Information materials

5.1 Information for women

The cervical screening programme offers primary hrHPV testing to women as an improvement to the screening service. It is not possible for women to request a cytology test instead.

It is the sample taker's responsibility to ensure that the woman to be tested has received 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.

5.1.1 Standard invitation and result letters

The introduction of primary HPV screening requires standard screening invitation and results letters. The NHSCSP has produced templates for the screening invitation and result letters associated with each type of result. These are available with the NHSCSP suite of letters.

Call/recall offices (PCSE) send most correspondence to women and, as noted in sections 4 and 12.1, they must be engaged at an early stage to ensure the appropriate letters are implemented at the correct time for women according to the implementation plan.

Where second reminder invitations are sent by GPs, the text of these letters must be revised accordingly. PCSE will only amend call/recall system parameters and new letters as part of an approved mobilisation plan.

5.1.2 Screening information leaflet

Women having primary HPV screening must be sent the screening leaflet ‘NHS Screening: Helping you decide’ and a copy of the leaflet for primary HPV screening together with their invitation letter.

These leaflets must be sent with all screening invitations for a period of 6 weeks before the introduction of primary HPV screening protocols for that population in the laboratory. This will help to ensure that women attending for screening receive the correct information in time for the switch from cytology to hrHPV testing.

Once a revision of the ‘NHS cervical screening: helping you decide’ leaflet is available, it will replace the 2 separate leaflets in current use.

6. Cervical screening samples

6.1 Sample requirements

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 in accordance with programme guidance. One LBC sample is generally sufficient for hrHPV testing and subsequent cytology triage where indicated.

6.2 Sample logistics

Providers of screening laboratory services to the NHS Cervical Screening Programme are responsible for providing systems to transport screening samples from primary care into the laboratory.

Sample logistics are an important consideration for the implementation of primary HPV screening. The centralisation of cervical screening including hrHPV testing and cervical cytology means many samples will need to be transported over greater distances to reach the screening laboratory, whilst still providing an efficient and timely service for women. In addition, cervical screening laboratories have traditionally supplied GP practices with liquid based cytology (LBC) consumables.

Careful planning is required to maintain and streamline the provision of these services over the new cervical screening programme footprint with increased ratio of GP practices to hrHPV/cytology screening laboratories.

6.2.1 Sample transportation to centralised HPV/cytology screening laboratories

Requirements of sample transportation systems

Samples must be transported from primary care providers to the centralised screening laboratory in a timely manner, enabling women to receive their screening results in line with the 14-day turnaround time core programme standard.

The transportation of samples must comply with the guidance detailed in the Recommended code of practice for cytology laboratories participating in the UK cervical screening programmes (http://www.britishcytology.org.uk/resources/BAC-Code-Of-Practice-2015.pdf) and relevant clauses of ISO15189:2012 (https://www.iso.org/standard/56115.html), which requires a system to track samples from source through to receipt in the laboratory.

Where a centralised screening laboratory uses a third party (for example the local NHS trust) to receive and sort samples from local GPs for onward transportation, service level agreements must be in place detailing the requirements of the service.

All staff involved in the process of sample transportation must receive training.

Existing methods of sample transportation

Existing services involve:

- local hospital trust operated laboratory transport systems collecting samples from GPs at least once a day and delivering to the sample reception at the local trust pathology department
- sorting of cervical screening samples at the local trust
- provision of transportation by the trust hosting the centralised laboratory to collect samples from local trusts and transport to the centralised laboratory service sample reception, at least once per day

The application of lean principles (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/437141/cytology-14day-tat.pdf) to transport processes is common, for example in the use of colour coded transport boxes and specimen bags.

Opportunities to improve the transportation of samples

Commissioners and providers may want to explore opportunities to speed up transportation and improve the tracking of samples. These include:

- electronic (barcode) tracking of sample bags can be facilitated with some LIMS systems, providing additional security and an audit trail of the transportation process
- universal implementation of GP electronic test requesting, including a process to provide the past screening history as detailed on Open Exeter (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/669132/Guidance-for-acceptance-of-cervical-screening-samples.pdf) at sample taking source, to support sample log in process
- Royal Mail or external courier delivery of samples from local trusts to centralised screening laboratories in terms of speed, costs, environmental impact and regulation compliant packaging (http://www.britishcytology.org.uk/resources/BAC-Code-Of-Practice-2015.pdf)

6.2.2 Consumables distribution

Requirements of consumable distribution systems

LBC consumables must be stored and distributed in accordance with conditions specified by the manufacturer and relevant clauses of ISO15189:2012 (https://www.iso.org/standard/56115.html).

Where a centralised screening laboratory uses a third party to distribute consumables, there must be a service level agreement in place detailing the requirements of the service.

The model of distribution implemented must:

- be reliable and efficient
- provide a means for sample takers to order consumables
- record batch numbers on consumables to enable identification, should any issues or incidents arise

Existing methods of consumables distribution

Models of distribution exist within the cervical screening programme. These are:

- consumables delivered by the manufacturer direct to local trust pathology departments where staff manage distribution to GP practices
- consumables delivered by the manufacturer direct to the centralised screening laboratory for onward distribution to GP practices, usually once per year or once per quarter, including arrangements for ad hoc delivery if required
- centralised supplies solution with no laboratory involvement

6.3 Sample storage

Centralised screening laboratories will require appropriate and sufficient storage capacity to accommodate large numbers of LBC vials received for screening. Once all testing is complete and the results have been reported, LBC samples can be discarded according to the normal laboratory retention, storage and disposal procedures.

The long-term storage and retesting of LBC samples used for hrHPV tests will not be possible. However, where cytology slides are produced following primary HPV screening, they must be stored for 10 years (https://www.rcpath.org/uploads/assets/uploaded/97364ab3-b679-43ab-8afb47be199e1d3c.pdf).

6.4 Self collection devices

The use of self-collection devices is not currently supported in the NHSCSP.

7. Screening laboratories

7.1 Laboratory configuration

The hrHPV testing service will be co-located on the same site with cervical cytology to provide a single seamless service. hrHPV testing will be provided within the cytology laboratory, virology or the department of molecular pathology. Electronic download of hrHPV test results into the LIMS cytology

screening record is essential and the cytology component of the screening service will be responsible for the issuing of all screening results, including those where the result is hrHPV negative.

7.2 Screening process

On receipt, all screening samples must be booked onto the cytology LIMS system that will produce the screening report.

The hrHPV test will be the initial test performed on all cervical screening samples. Those testing hrHPV negative will require no further testing (excepting samples taken by novice samples takers (see section 11.1.1). Samples testing positive for hrHPV will be forwarded for LBC processing to produce a cytology slide. Those testing hrHPV unavailable should be repeated in no less than 3 months, unless this is the second consecutive hrHPV unavailable or inadequate cytology result when a referral to colposcopy will be made (see section 13.6).

Cytology slides will undergo a full cytological examination as well as internal quality control by rapid preview or rapid review. Samples considered potentially abnormal will be examined by checkers and forwarded to a cytopathologist/consultant biomedical scientist (BMS) for reporting as necessary.

Cytology results must be reported together with the hrHPV test results in a combined screening report from the cytology laboratory. hrHPV negative results and hrHPV positive results with negative 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.

7.3 Staffing

The requirement for cytology screeners across the programme will reduce as fewer samples require cytology under the new protocols.

The requirement for checking and abnormal reporting is not expected to reduce in the initial years following implementation. In the pilots of primary HPV screening approximately one third (range 26.9% to 41.7%) of all samples having cytology following an hrHPV positive result at the baseline primary HPV screen were reported as abnormal. The requirement for checking and cytopathologist/consultant BMS reporting will, therefore, be greater in a laboratory that is centralised to maintain minimum cytology workloads once hrHPV testing is the primary screening test.

8. Screening tests

8.1 hrHPV tests

There are a number of hrHPV tests available in the UK which screen for the range of hrHPV types associated with the development of cervical cancer.

PHE has evaluated available hrHPV tests with appropriate LBC samples and has accepted a number of these for use in the cervical screening programme. Details of the acceptable tests including methods to be employed, sample requirements, platforms and permitted modifications to protocols detailed in kit inserts are published on GOV.UK (https://www.gov.uk/government/collections/cervical-screening-professional-guidance).

Acceptable hrHPV tests, platforms and LBC systems can be purchased through the NHS Supply Chain framework agreement.

8.2 Liquid based cytology

Laboratories providing NHS cervical screening services must use one of 2 LBC systems that are currently approved for use in the programme. These are Hologic ThinPrep and BD SurePath.

8.3 BD Focalpoint slide profiler

This system has not been evaluated for use in a setting where the primary screening test is an hrHPV test and is not currently approved for use in clinical practice in the NHSCSP.

9. Quality assurance of HPV testing

hrHPV testing within the NHSCSP must be undertaken in laboratories accredited to ISO standard 15189:2012 for hrHPV testing (https://www.iso.org/standard/56115.html).

Service leads in the form of a lead virologist and lead scientist for hrHPV testing are required. These individuals will have specific responsibility for clinical governance and are directly accountable for the quality of their own work and that of their departmental teams.

Cervical cytology laboratories must have an SLA(s) in place for virology services. This can vary depending on where the hrHPV test is carried out (whether within the cytology department or a virology department). Appropriate consultant virologist support must be provided to a cytology service performing hrHPV testing and be available when required. A consultant virologist or lead scientist appointed to provide external advisory services to a cytology laboratory must hold an honorary contract with the host provider.

All laboratories providing hrHPV testing must participate and maintain adequate performance in an accredited external quality assurance scheme such as the UK NEQAS scheme for hrHPV. Further to this, all laboratories providing hrHPV testing should refer to the guidance on laboratory quality control and assurance for human papillomavirus testing (https://www.gov.uk/government/publications/cervical-screening-laboratory-testing-for-human-papillomavirus/nhs-cervical-screening-programme-laboratory-quality-control-and-assurance-for-human-papillomavirus-testing).

10. Reporting hrHPV tests and use of HPV unavailable (HPV-U) category

We aim to develop a new standard for unavailable hrHPV test results, coded ‘U’ for HPV infection on the call/recall system.

In 2018, SQAS began to monitor and collect data on unavailable hrHPV tests in laboratories employing primary HPV screening with a view to establishing reporting thresholds. Criteria will be established for the use of the unavailable hrHPV test reporting code to make sure there is consistent reporting across laboratories.

10.1 Sample internal control (endogenous): definition

The internal control signal in samples serves to confirm that each sample has sufficient cell input for accurate hrHPV detection, was processed correctly, and to indicate whether inhibitors of amplification are present.

10.2 Test run control (exogenous): definition

Test run controls include a positive and negative control provided with the kit and one of each is required with every run. The negative control serves to verify that hrHPV contamination did not occur during the sample preparation and set-up of the amplification reaction.

10.3 Sample internal control not detected

HPV platforms that have sample internal controls report an invalid result when the sample internal control (for example β-globin) result is negative or invalid in hrHPV negative samples. A repeat test is performed starting with sample preparation. If still no valid result the sample will be reported as HPV-U.

Where the sample internal control is negative or invalid an hrHPV positive result remains valid and will be reported as such.

HPV genotyping for HPV 16/18 is provided automatically by some HPV platforms alongside an hrHPV positive result. HPV16/18 results have only been used to manage women in a small number of laboratories participating in pilots of primary HPV screening.

For platforms which genotype, a positive result for HPV16, 18 or HPV O (other HPV types) can still be reported despite the internal control returning a negative or invalid result. These should be reported as HPV positive.

10.4 Failed samples note

HPV platforms will report error codes or flags due to insufficient volume or clot detected as failed samples. Insufficient samples will be reported as HPV-U. A repeat test is performed on clot detected samples starting with sample preparation. If the sample fails again the sample will be reported as HPV-U.

When samples cannot be reported due to failure of test run controls, or fail due to instrumentation errors and failures, a flag or error code is generated to alert the user to the problem. The problem should be addressed and once resolved the samples can be re-tested. If subsequently no result is obtained due to insufficient sample, this should be reported as HPV-U as above.

10.5 SurePath samples with broom head missing or ThinPrep samples with broom head present

Samples testing hrHPV positive should be reported as HPV positive. Subsequent cytology should be reported as inadequate unless abnormal cells are found.

Samples testing hrHPV negative should be reported as HPV-U, an error log made, and the sample taker informed.

10.6 Out of programme samples and major labelling discrepancies

These are defined in NHSCSP guidance for accepting samples in laboratories (https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories) and should be rejected. They must not be reported as HPV-U.

10.7 Cervix not visualised, no 5 X 360-degree sweep

Samples will be hrHPV tested and reported as HPV-U if hrHPV negative. If hrHPV positive, cytology triage will be performed which will be reported as inadequate unless abnormal cells are identified.

10.8 Samples taken into out of date vials or vials expired before testing

These samples should be rejected. They must not be reported as HPV-U.

10.9 Samples beyond the recommended or approved storage time for an hrHPV test, and within vial expiry date.

These samples should be hrHPV tested and the result reported if hrHPV positive. Subsequent cytology should be reported.

Samples testing hrHPV negative should be reported as HPV-U.

10.10 Sample vials that have leaked

Provided there is sufficient volume according to the manufacturer's advice, these samples should be hrHPV tested and the result reported if hrHPV positive. Subsequent cytology can be reported providing there is sufficient residual sample for processing. If there is insufficient volume it should be reported as cytology inadequate.

Samples testing hrHPV negative should be reported as HPV negative.

11. Training

The implementation of primary hrHPV testing places special demands on a range of staff working within the NHSCSP, in particular:

- primary care/ sexual health services staff taking samples and counselling women
- laboratory staff providing hrHPV testing or cytology
- gynaecology oncologists/colposcopists/nurse colposcopists receiving hrHPV referrals
- cervical screening provider lead

All staff must be trained and competent to meet the requirements of cervical screening based on primary hrHPV testing. Specific training requirements are outlined below.

Local training will be required to cover changes to processes required for primary HPV screening, including but not limited to the ordering and supply of sample taking materials, sample transport, sample processing in laboratories and use of IT platforms.

11.1 Sample takers

Engaging primary care is crucial if primary hrHPV testing is to be successfully implemented. Sample takers have an important role in ensuring that women understand the concept of hrHPV testing and the results of their screen. A national primary care eLearning module (https://www.e-lfh.org.uk/programmes/nhs-screening-programmes/) on screening using primary hrHPV testing has been developed for sample takers working in the NHSCSP. It may also be a useful resource for colposcopy staff as women often have questions about hrHPV testing on attendance at colposcopy.

It is recommended that all sample takers complete the e-learning, which includes a question and answer section and certificate of completion, prior to the sample taker participating in screening with primary hrHPV testing. The eLearning resource is hosted on the eLearning for Health website (https://www.e-lfh.org.uk/programmes/nhs-screening-programmes/).

Completion of the online training can be recorded on the local sample taker register, according to local requirements.

Sample takers may also require system specific training if the LBC vial type used changes with the move to the centralised laboratory service.

11.1.1 Novice sample takers

Sample taker training must continue to be offered to staff in areas and practices which have converted to primary HPV screening, including assessing novice sample taker competency within the programme guidance.

All samples taken by sample takers in training must be clearly identified to the laboratory. All samples with a valid hrHPV result must have a cytology sample prepared and reported, irrespective of whether the HPV result is positive or negative. Samples which give an unreliable hrHPV result do not have a cytology slide prepared and must be repeated after a period of not less than 3 months (and for the purposes of sample taker training recorded as unsatisfactory).

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/recall IT system must follow recognised screening protocols. Cytology slide review in addition to hrHPV testing of samples may result in a combination of cytology and hrHPV test results which is not recognised in the primary HPV screening protocol. Such tests cannot be recorded on the call/recall IT system as primary HPV screening tests. Where necessary these tests should be recorded as HPV triage samples to facilitate the production of a suitable result notification, and to make sure that women can be managed appropriately in accordance with NHSCSP ‘ABC 3’ guidance (https://www.gov.uk/government/publications/cervical-screening-cytopathology-standards-and-evaluation-criteria). For example, a hrHPV negative result in combination with high grade abnormal cytology must be reported using the appropriate HPV triage code combination, to make sure that the woman is referred to colposcopy.

A summary of test result and action code combinations which cannot be recorded as primary HPV screening tests, in particular, those which must be identified and recorded as HPV triage tests, is given below. There is no code combination in either the primary HPV or HPV triage pathway to accommodate

reporting tests which are hrHPV negative with inadequate cytology. In these circumstances, the inadequate cytology result must be disregarded for the purposes of recall. The test can then be reported as a primary HPV test using code ‘X’ to indicate no cytology. The quality of the sample must still be fed back to the sample taker with an explanation that the sample does not require repeating in 3 months and detailing the required management. If following a hrHPV negative result the cytology sample is found to be acellular (casting doubt over the validity of the hrHPV test result) and a decision is made to repeat the hrHPV test in 3 months, this must be reported using code combination XUR, in accordance with section 12.2.

Under no circumstances should a test be repeated in less than 3 months.

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/recall IT system.

Codes for recording screening results for novice sample takers

Cytology result code	hrHPV result code	Action code	HPV PS flag*	Code combination to be used
0	0	A	N	G0A
0	0	R	N	G0R
0	0	S	N	G0S
1	0	A	Y	X0A**
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’ (see section 12.2).
N = not primary HPV screening
Y = primary HPV screening test

** For codes XOA, XOR and XOS, the inadequate cytology result is disregarded for the purposes of recall.

11.2 Training for laboratory staff undertaking hrHPV testing

Training on a new HPV platform must be delivered by the supplier to an appropriate core of staff who can then deliver cascade training to existing and new staff.

SQAS must be provided with evidence that:

- training is provided on site
- all staff undertaking testing complete training
- staff have a certificate of completed training

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

11.3 Training for laboratory staff undertaking cytology triage

All staff involved in the screening and reporting of cytology samples following primary hrHPV testing must have up-to-date knowledge of the HPV screening pathway.

Training courses will be provided by programme approved cervical cytology training centres (https://www.gov.uk/guidance/cervical-screening-education-and-training#cervical-cytology-training).

Course topics include:

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

These elements will need to feature in programme update training.

11.4 Training for colposcopists

All colposcopists receiving primary hrHPV screening referrals are expected to complete training and undertake the relevant study. A national colposcopy e-learning module on primary HPV screening has been developed, which is hosted on the eLearning for Health website (https://www.e-lfh.org.uk/programmes/nhs-screening-programmes/).

A certificate is issued on completion of the eLearning.

11.5 Training for cervical screening provider leads (CSPLs)

The reconfiguration of screening laboratory services associated with implementing primary HPV screening will impact significantly on the role of the CSPL. The scale and complexity of the role will increase in providers with large screening laboratories referring women to multiple external colposcopy units, and the audit of invasive cancers across separate providers will require extra coordination. There will also still be a need for CSPLs in those providers still providing parts of the cervical screening pathway but where there is no longer a cervical cytology laboratory.

The role of the CSPL will, therefore, be vital in ensuring that links are maintained between all elements of the local programme and that individual components of the service function together to provide the best possible service and outcomes for women.

Guidance has been developed to support the requirements of the CSPL role (https://www.gov.uk/government/publications/cervical-screening-role-of-the-cervical-screening-provider-lead). CSPLs new to the role and those requiring further development should attend programme approved training (https://www.gov.uk/guidance/cervical-screening-education-and-training#cervical-cytology-training).

12. IT system changes

12.1 Call/recall

The screening laboratory and local screening and immunisation team (SIT) must establish communication with the call/recall service (PCSE) at least 12 weeks prior to services moving to primary hrHPV testing. The lines of communication should be maintained throughout the transition period.

Discussion should 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/recall system.

Laboratories and screening and immunisation teams 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 – this needs to be provided by the SIT
- the relevant screening laboratory involved
- the anticipated date of transfer to primary hrHPV testing for the cohort defined

At least 12 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 only amend call/recall system parameters and new letters as part of an approved mobilisation plan.

PCSE will need to:

- validate the cohort selection with the SIT
- ensure that the flag defining that primary HPV screening is being utilised is switched on, which will ensure the correct letters 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 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

12.2 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 HPV screening flag as follows, for every individual test (noting the exceptional combinations associated with novice sample takers).

'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' to input 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 the laboratory system or middleware suppliers is available on request from Exeter.helpdesk@nhs.net.

National Health Application and Infrastructure Services (NHAIS) requires a cytology result code for all primary hrHPV screening results, a hrHPV test result code and an action code in accordance with the coding scheme given below. Where the hrHPV test is negative and so no cytology test is required, a dummy code must be used to indicate 'no cytology'. A new cytology result code of 'X' has been introduced for this purpose. 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, featured here in case noted in patient's history)

Action codes

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

With limited exceptions, test results sent to the call/recall service 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 or failsafe recall date in accordance with the primary screening protocol. If a number of months is provided this will be disregarded by the call/recall system. It will not be formally rejected by the system and therefore no automatic warning or a system-generated error message will be provided to the laboratory when the test result is recorded. The laboratory cannot, therefore, specify a non-standard recall interval for any woman.

There is no override facility for individual cases beyond those described below and so it is not possible to recall women at shorter or longer intervals than those defined in the protocol.

Where there is uncertainty over the quality of the sample, these should be rejected, or accepted and reported in accordance with guidance detailed in section 10. Samples accepted but requiring a repeat sample in 3 months must be coded as XUR or 19R as appropriate. Code combination X0R must not be used for tests requiring 3-month repeat as it will be implemented as the default recall interval of 36 months.

There are 2 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:

Code combination	**Results/action**	**Default recall interval (months)**	**Allowable recall interval (if provided)**
X0A	No cytology result, HPV negative, routine recall	36/60	none
X0R	No cytology result, HPV negative, early recall – 12 or 36 months	36	12
X0S	No cytology result, HPV negative, refer colposcopy	12 (failsafe)	none
XUR	No cytology result, HPV not available, early recall – 3 months	3	none
XUS	No cytology result, HPV not available, refer colposcopy	12 (failsafe)	none
X9S	No cytology result, HPV positive, refer colposcopy	12 (failsafe)	none
19R	Inadequate cytology, HPV positive, early recall – 3 months	3	none
19S	Inadequate cytology, HPV positive, refer colposcopy	12 (failsafe)	none
39S	Low grade dyskaryosis, HPV positive, refer for colposcopy	12 (failsafe)	none
49S	High-grade dyskaryosis (severe), HPV positive, refer colposcopy	12 (failsafe)	none
59S	High-grade dyskaryosis ?invasive squamous carcinoma, HPV positive, refer colposcopy	12 (failsafe)	none
69S	?Glandular neoplasia of endocervical type, HPV positive, refer colposcopy	12 (failsafe)	none

	HPV positive, refer colposcopy		
79S	High-grade dyskaryosis (moderate), HPV positive, refer colposcopy	12 (failsafe)	none
89S	Borderline squamous, HPV positive, refer colposcopy	12 (failsafe)	none
99S	Borderline endocervical, HPV positive, refer colposcopy	12 (failsafe)	none
09R	?Glandular neoplasia (non-cervical), HPV positive, early recall – 12 or 36 months	12	36
29R	Normal cytology, HPV positive, early recall – 12 or 36 months	12	36
09S	?Glandular neoplasia (non-cervical), HPV positive, refer colposcopy	12 (failsafe)	none
29S	Normal cytology, HPV positive, refer colposcopy	12 (failsafe)	none

Test results will be rejected by the call or 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 and test of cure screening protocol
- include any unrecognised code
- form an invalid code combination
- are incomplete (does not include 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 (code X for cytology)
- an action code is inappropriate with reference to the woman’s screening history, for example early repeat instead of referral after a third consecutive HPV positive/cytology negative test

It is recommended that the laboratory LIMS incorporates basic validation to prevent the issue of these results where possible.

13. Protocols for screening women with primary hrHPV testing

The mandatory protocol for women having screening in the English NHSCSP using primary hrHPV testing is summarised in appendix 1. (https://www.gov.uk/government/publications/cervical-screening-primary-hpv-screening-implementation)

13.1 Routine call/recall

Women will be called for screening from age 24.5 years then at the routine recall interval until aged 64.

Women are currently screened every 3 years between the ages of 24.5 and 49, then at 5 years between the ages of 50 and 64. The UKNSC is considering the evidence to support extending screening intervals for all women in the screening age range.

All women who attend for screening will be tested for hrHPV and those with a negative result (around 85 to 90% initially) will be returned to routine recall.

13.2 Cytology triage

Samples from women found to be positive for hrHPV (approximately 10 to 15% in the first year) will have cytology performed. Those women with negative cytology (approximately 8% of the screening population) will be recalled in 12 months for a repeat test. Women with abnormal cytology (any grade, approximately 4% of the screening population) will be referred immediately to colposcopy.

13.3 Repeat tests at 12 months

Women recalled for a repeat screen at 12 months due to being hrHPV positive with negative cytology at their preceding test will have a repeat hrHPV test. Women testing negative (approximately 40%) will be returned to routine recall.

All hrHPV positive women will have cytology triage performed on their sample. Those with abnormal cytology will be referred to colposcopy. Women with negative cytology will be recalled for a further 12 month repeat test (24 months from the initial screen).

13.4 Repeat test at 24 months

Women returning for a second repeat test, 24 months since the initial screening test, will receive an hrHPV test.

Women testing hrHPV negative (approximately 35%) will be returned to routine recall. Women testing hrHPV positive (approximately 65%) will have cytology triage performed but will all be referred to colposcopy at this stage regardless of whether the cytology result is inadequate, normal or abnormal. Cytology performed here defines the urgency of referral required and assists the colposcopist.

13.5 ?glandular neoplasia (non-cervical)

A gynaecological referral must be made for women with a cytology result of ?glandular neoplasia (non-cervical). These women will be followed up for their hrHPV positive result in the same way as women with negative cytology by repeat screening at 12 and 24 months.

13.6 Screening samples without a valid result

When the hrHPV test result is unavailable or cytology is inadequate at any screening episode in the pathway, the sample will be repeated in no less than 3 months.

Women who have an inadequate cytology test at the 24 month repeat test are an exception and will be referred to colposcopy. Women with 2 consecutive hrHPV unavailable or cytology inadequate screening tests in any combination will be referred to colposcopy.

Cytology will not be performed on any sample where an hrHPV positive result has not been obtained (exception in the case of novice sample takers (see section 11.1.1). This includes samples from women attending for 12 month repeat tests.

13.6.1 Assessing cytological adequacy

Guidance on the criteria for assessing cytological adequacy will be published shortly on GOV.UK (https://www.gov.uk/government/collections/cervical-screening-professional-guidance).

13.7 Women entering primary hrHPV testing protocols whilst in follow up

Women recently treated for cervical intraepithelial neoplasia (CIN) or cervical glandular intraepithelial neoplasia (CGIN) prior to the implementation of HPV primary screening should be managed according to the colposcopy management recommendations for the implementation of primary hrHPV screening (see section 14 and appendix 2). Follow up differs slightly to the test of cure protocols used previously, most notably in that cytology is not required for hrHPV negative women.

Women being followed up for untreated CIN1 should also be managed by hrHPV testing according to the colposcopy management recommendations for the implementation of hrHPV primary screening (see section 13).

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

Women part way through follow up for CGIN/stratified mucin-producing intraepithelial lesions of the cervix (SMILE) or untreated CIN1 should be managed by hrHPV testing at their next test and not continue with cytology-based follow up.

Women part way through follow up for cervical cancer (who still have a cervix) should be managed by hrHPV testing at their next test and not continue with cytology-based follow up.

13.8 HIV positive women

HIV positive women within the screening age range are eligible to be screened annually and should be invited for screening using hrHPV as the primary test rather than cytology. The management of these women will follow the protocols for primary hrHPV testing in all other aspects other than frequency of screening. It is the sample takers' responsibility to inform the laboratory of the HIV status to make sure:

- the sample will not be rejected for being out of programme
- hrHPV negative results are coded for an early repeat test in 12 months

13.9 Management of women hrHPV positive/cytology negative at their final screen

The UK NSC is reviewing the evidence on how to manage women who are hrHPV positive with negative cytology at their final screen. At the current time, these women remain in the programme according to screening protocols.

13.10 Direct referral of women to colposcopy

Laboratories providing primary hrHPV testing and cytology triage to the NHS screening programme will be required to use a system of direct referral of women to colposcopy. Direct referral reduces anxiety for women by speeding up the patient journey and facilitates improved management of clinics, reducing waiting lists and non-attender rates. An efficient system needs to be in place to correctly identify the appropriate colposcopy clinic to send the referral and ensure it is received.

13.11 Women who have received pelvic radiation

Women with an intact cervix who have received radiotherapy of the pelvic region (for example for anal, cervical, low colorectal and vaginal cancers) which means that an adequate sample cannot be obtained, are not eligible for cervical screening using primary hrHPV testing. They can be ceased from the programme. For further information see guidance for ceasing women from the programme (https://www.gov.uk/government/publications/cervical-screening-removing-women-from-routine-invitations).

13.12 Women attending for screening after defaulting colposcopy/treatment

Where a woman has defaulted colposcopy following high grade abnormalities and attends for screening 12 months later through the failsafe process, she should be re-referred to colposcopy even if her result is hrHPV negative. If, however, she has defaulted colposcopy following low grade abnormalities she does not warrant re-referral to colposcopy if her result if hrHPV negative; her management will follow the usual national protocol.

13.13 Private HPV tests

Women who have a private screening test remain eligible for NHS testing at appropriate intervals (subject to a minimum of 3 months between samples). Primary screening tests taken under private arrangements are managed in the following ways:

- an abnormal cytology result which requires an early repeat test or referral may be recorded on the call/recall system using an R or S action code respectively
- a private primary screening test which is HPV negative or HPV inadequate/unavailable with no abnormal cytology may not be recorded on the call/recall system
- a positive HPV test with a negative, inadequate or no cytology result may not be recorded on the call/recall system

Women who are due or overdue for their NHS test should be encouraged to take up their screening following a private HPV positive result. A GP can request a change to the woman’s recall date if a screening invitation is required.

14. Protocols for managing women referred to colposcopy

The recommended management pathways and follow up for women being referred to colposcopy following abnormal results from primary HPV screening are summarised in Appendix 2. (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/773339/Appendix_2_colposcopy_management.pdf)

hrHPV testing and cytology should not be repeated at first attendance at colposcopy. Follow up screening tests are hrHPV tests with cytology only performed if the hrHPV result is positive.

The implementation of primary HPV screening pathways leads to an increased number of colposcopy referrals. Data from the primary HPV pilots indicated the referral rate at the baseline primary HPV test to be 4.2% of the screened population. This compared to 3.9% with cytology-based screening.

The impact of recalling women at 12 and 24 months following HPV positive results with negative cytology amounted to an extra 1.4% and 0.9% of women being referred, respectively. The first full school-based cohort of vaccinated women entering the programme in 2020 will impact this.

14.1 Inadequate colposcopy

Women with inadequate colposcopy examination are managed on the results of their referral screening test. Those with borderline changes in endocervical cells and high-grade dyskaryosis or worse cytology will be offered a large loop excision of the transformation zone (LLETZ) procedure.

Women with negative cytology, borderline changes in squamous cells 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.

14.2 Adequate colposcopy

14.2.1 No CIN on biopsy, no biopsy taken or no colposcopic impression of CIN

Women with no biopsy taken, a biopsy showing no CIN, or where there was no colposcopic impression of CIN will be recalled in 36 months if their referral cytology results were negative, borderline changes in squamous cells or low-grade dyskaryosis. At their next test in 36 months' time, these women will re-start the screening protocol for primary hrHPV testing.

Women referred with borderline changes in endocervical cells and high-grade dyskaryosis or worse should have their case discussed and management agreed at the colposcopy multidisciplinary team meeting within 2 months.

14.2.2 Abnormal biopsy CIN1+ or colposcopic impression of CIN1 (no biopsy)

If CIN is confirmed on biopsy or there is colposcopic impression of CIN1 without a biopsy, the woman will be managed according to the same protocols as women with an abnormal colposcopic appearance, detailed in the following sections.

14.3 Abnormal colposcopy

14.3.1 CIN1

The management recommendation for women who have a colposcopic appearance consistent with CIN1 or CIN1 confirmed on biopsy is recall for screening in primary care in 12 months with hrHPV testing. Women testing hrHPV negative at this repeat test can be recalled in 36 months, at which point they will re-start 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 negative cytology will be recalled for screening again in a further 12 months' time.

At the second repeat test women who are hrHPV negative can be recalled in 36 months. Those who are hrHPV positive will have cytology performed. Those testing negative for cytology 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.

14.3.2 Treated CIN

Women treated for CIN will be called for a follow up hrHPV test 6 months post treatment in primary care. Those testing hrHPV negative will be recalled for screening 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 all be referred to colposcopy again regardless of the cytology result.

14.3.3 Untreated CIN2

Rarely, women may be offered conservative management for CIN2. Such women must remain subject to close colposcopic follow up in a clinic. If screening samples are taken during this time, they will be primary hrHPV tested by the laboratory with cytology performed if hrHPV positive.

14.3.4 Treated CGIN/SMILE

Women adequately treated for CGIN or SMILE with complete excision margins are followed up with screening at 6 and 18 months post treatment. All samples will initially be tested for hrHPV and those women testing 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 and all will be referred to colposcopy if follow up is in primary care. The cytology samples from these hrHPV positive women must contain endocervical cells to be considered adequate for cytology (unless they contain abnormal cells).

Women who have negative cytology and normal colposcopic appearance 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 testing in 36 months, when they will restart the screening protocol for primary hrHPV testing. Women testing hrHPV positive at the second follow up test will have cytology performed and all will be referred to colposcopy if

follow up is performed in primary care. Women with negative cytology and normal colposcopic appearance will continue to be called at 12 monthly intervals for hrHPV testing and managed according to these protocols for CGIN/SMILE follow up.

Women with abnormal cytology at either of the 2 follow up tests will be re-referred to colposcopy. In those women where colposcopy is found to be normal or re-excision does not occur, 10 years follow up should be completed with annual hrHPV testing.

All women re-referred to colposcopy due to a hrHPV positive result will be eligible to enter the CGIN post treatment follow up pathway again if they have further re-excision with complete excision margins.

14.3.5 Follow up of incomplete excision of CGIN/SMILE

Women treated for CGIN/SMILE with incomplete excision margins will be followed up with hrHPV testing at 6 and 12 months and then annual hrHPV testing for a further 9 years. Follow up in clinic is recommended, however, should follow up occur in primary care an hrHPV positive result must result in a re-referral to colposcopy regardless of the cytology result.

14.3.6 Women attending for follow up samples

Follow up samples should be taken at least 6 months following treatment and attending early should be discouraged. Samples taken less than 3 months post treatment must not be tested.

14.3.7 Follow up of cervical cancer

Women being followed up for cervical cancer and who still have a cervix will be followed up with hrHPV testing at 6 and 12 months and then annual follow up for a further 9 years. These women are usually on clinical follow up, however, should follow up testing occur in primary care an hrHPV positive result must result in a re-referral to colposcopy regardless of the cytology result.

Follow up after radical trachelectomy for cervical cancer is outwith the remit of the cervical screening programme. The arrangements for follow up of these women remain within the remit of the commissioning of and provision of local gynaecological cancer services.

If the gynaecological oncology services wish to offer cytological follow up for women after radical trachelectomy then this is a local decision.

If cytology is required as the primary test and not HPV, the gynaecological cancer service should negotiate with the relevant cytology laboratory and the cancer service commissioners to find a mechanism to provide this service.

15. Centralisation of screening laboratories

The centralisation of screening laboratory services will require the consideration of a number of issues required for the continuation of the screening service across previous boundaries.

15.1 Screening records management

Where laboratories are to merge, or individual systems are to be decommissioned, providers must provide plans for the safe transition of data into a single system or have alternative plans to ensure continued, appropriate access to data from legacy or decommissioned systems for failsafe, audit and data reporting purposes.

The providers involved must also agree who will complete the KC61 and other outstanding data returns for the population of women transferred to the new service. This may depend upon the time of year when the service transfers and SQAS will be able to advise on the most pragmatic approach. Arrangements must be in place to ensure that the data needed for the retrospective elements of the KC61 can be obtained.

15.2 Cervical cytology slide archive

Cervical cytology slides are retained and stored for a period of 10 years following reporting for review purposes. As screening services relocate to larger centralised laboratories, provision must be made to maintain these slide archives, which remain the responsibility of the trust that reported them. Whether the archive is moved to the new screening laboratory or maintained in the current site an SLA must be put in place to ensure continued prompt access when required.

Any issues arising from these slides in the future, for example, findings from invasive cancer audits, remain the legal responsibility of the provider that reported them.

15.3 Audit of invasive cancers

The responsibility for carrying out audits of invasive cervical cancer will remain with the provider, and thus the CSPL, where the woman was diagnosed. The centralised screening laboratory must agree to arrangements or procedures for providing slide review opinions to the provider hosting the services where women are diagnosed. This may include accessing and reviewing archived slide material originally reported at another provider (as detailed above in 15.2). Where archived material has been produced using a different LBC technology to that used in the screening laboratory, arrangements must be put in place for these reviews to be performed by an individual qualified to report the LBC type.

15.4 Failsafe

The provider must agree who will take responsibility and provide clear arrangements for the provision of laboratory failsafe for women referred to colposcopy during the 12 months prior to the transfer of screening laboratory services. This should be in accordance with the requirements detailed in NHSCSP failsafe guidance (https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe).

IT links must be put in place to enable the centralised screening laboratory to look up colposcopy outcomes/histology results at all colposcopy clinics that the new laboratory provides a referral service for women, both within and across provider boundaries.

15.5 Cytology screening during transition and backlogs

Consideration must be given to the management of samples received shortly before the implementation of primary HPV screening and cytology backlogs present within screening laboratories. These samples must be primary cytology screened and provision must be made to ensure these samples are screened,

hrHPV tested (where applicable) and reported promptly. Services transferring elsewhere may require the continuation of the laboratory service for a period of time purely for the purpose of screening all recent samples and clearing backlogs.

15.6 Cervical screening provider leads

The role of CSPLs will require review to become aligned with the services delivered by the provider following the reorganisation of screening laboratory services. Role descriptions and meeting terms of reference and arrangements may need to be revised to take account of the changes.

15.7 Sample taker registers and feedback

Where the laboratory has traditionally hosted the sample taker register, agreements must be put in place, in collaboration with the relevant SIT, to ensure the provision of this once the laboratory service has transferred to a centralised laboratory.

15.8 Direct referral

Systems of direct referral must be established for women referred from the screening laboratory service to colposcopy services both within and across provider boundaries as defined by zonal commissioning arrangements.

15.9 Colposcopy multidisciplinary team meetings

The CSPL at the provider hosting the hrHPV/cytology screening laboratory will need to ensure the laboratory adequately supports and participates in colposcopy MDT meetings, in accordance with NHSCSP guidance. Videoconferencing or similar should be considered for LEAN working for distant colposcopy MDTs.

16. References

1. Bosch FX, Lorincz A, Muñoz N and others. The causal relation between human papillomavirus and cervical cancer. Journal of Clinical Pathology, 2002, 55. 244 to 265. ↩
2. Bulkmans NW, Rozendaal L, Snijders PJ, and others. POBASCAM, a population-based randomized controlled trial for implementation of high-risk HPV testing in cervical screening - design, methods and baseline data of 44,102 women. International Journal of Cancer 2004; 110(1). 94 to 101. ↩
3. Naucler P, Ryd W, Tornberg S, and others. Human papillomavirus and Papanicolaou tests to screen for cervical cancer. New England Journal of Medicine 2007; 357(16). 1589 to 97. ↩
4. Ronco G, Giorgi-Rossi P, Carozzi F, and others. Efficacy of human papillomavirus testing for the detection of invasive cervical cancers and cervical intraepithelial neoplasia - a randomised controlled trial. Lancet Oncology 2010; 11(3). 249 to 57. ↩
5. Kitchener HC, Almonte M, Thomson C, and others. HPV testing in combination with liquid-based cytology in primary cervical screening (ARTISTIC) - a randomised controlled trial. Lancet Oncology 2009;10(7). 672 to 82. ↩
6. Kitchener H, Canfell K, Gilham C, and others. The clinical effectiveness and cost-effectiveness of primary human papillomavirus cervical screening in England - extended follow-up of the ARTISTIC randomised trial cohort through 3 screening rounds. Health Technology Assessment 2014; 18(23).

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