



Public Health
England



NHS public health functions agreement 2019-20

Service specification no.25
NHS Cervical Screening Programme

NHS England and NHS Improvement



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Cervical Screening Programme

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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement values. Throughout the development of the policies and processes cited in this document, we have

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic and those who do not share it (as required under the Equality Act 2010); and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).

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Service specification No.25 Cervical Screening Programme

This is a service specification to accompany the 'NHS public health functions agreement 2019-2020 (the '2019-2020 agreement').

This service specification is to be applied by NHS England and NHS Improvement and NHS Improvement in accordance with the 2019- 2020 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2019-2020 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-2020 agreement in accordance with the procedures described in Chapter 3 of the 2019-2020 agreement.

Please always refer to the service specification online to ensure you are using the latest version.

The 2019-2020 agreement is available at www.gov.uk (search for 'commissioning public health').

1 Purpose of the screening programme

Purpose of the Specification

- 1.1 To ensure a consistent and equitable approach across England, a common national service specification must be used to govern the provision and monitoring of cervical screening as part of the NHS Cervical Screening Programme (NHSCSP).
- 1.2 The purpose of the service specification is to outline the service and quality indicators expected by NHS England and NHS Improvement and NHS Improvement for the population for whom it is responsible, and which meets the policies, recommendations and standards of the (NHSCSP)
- 1.3 This specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. of the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.
- 1.4 This service specification should be read in conjunction with the current NHS Cervical Screening Programme (NHSCSP) guidance and recommendations. These can be found on the population screening programmes pages of the gov.uk website.

Personal informed choice

- 1.5 All screening is an individual choice. The UK NSC has published [guidance for screening programmes in the 4 UK countries](#) to follow. Everyone must be given the opportunity to make an informed choice about whether or not to be screened. The decision should be based on an understanding of:

- why they are being offered screening
- what happens during the test
- the benefits and risks of screening
- the potential outcomes (including types of result, further tests and treatment)
- what happens to their screening records

If someone is provided with the above information about the programme and chooses not to attend screening, then this is a valid choice and must be respected.

Opting out

- 1.6 Screening Providers should respect the decision of any individual choosing to opt out of screening, either on a single occasion or permanently. No pressure should be put on people to be screened and services should not require the individual to justify their decision. Guidance on opting out can be found [here](#).

The role of PHE Screening

- 1.7 Public Health England (PHE) advises the government and the NHS so England has safe, high quality screening programmes that reflect the best available evidence and the UK National Screening Committee (UKNSC) recommendations. PHE also develops standards and provides specific services that help the local NHS implement

and run screening services consistently across the country. Screening Providers should subscribe to the [PHE Screening blog](#) for the latest national news and updates. National documentation and guidance is published on [GOV.UK](#).

Public information

PHE Screening uses published best practice processes to develop public information leaflets. It also works with NHS Digital to ensure that information on the NHS.UK website for the public is accurate.

1.8 Screening Providers must:

- use the public information leaflets from PHE Screening at all stages of the screening pathway
- involve their NHS England and NHS Improvement local commissioning teams and PHE Screening team in the development of any local awareness campaigns
- not duplicate clinical information from the PHE screening leaflets on local websites
- involve PHE if they want to move from providing printed leaflets to electronic and online sources of information

1.9 Using the [leaflets](#) provided by PHE ensures accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening must be consulted and involved before developing any other supporting materials.

1.10 Screening Providers must involve PHE in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.

1.11 Screening Provider websites must not duplicate clinical information about screening but should be restricted to contact and logistical information. Links should be provided to the national information on [NHS.UK](#) and [GOV.UK](#).

1.12 To support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, Screening Providers are encouraged to send PHE Screening the results of any local patient surveys which contain feedback on these national resources.

Ordering leaflets

1.13 Screening Providers can order [leaflets](#) developed by PHE Screening for free for core screening purposes.

1.14 Leaflets are regularly updated so Screening Providers should not order more than 3 months' supply, or stockpile leaflets, as they could become out of date and need to be destroyed. Leaflets for non-core activities, such as local health promotion purposes, can be bought from the national print provider.

1.15 PHE can only provide one leaflet per person per screening episode. A screening episode is defined as an invitation (with any subsequent reminders) for a particular screening test. People who are referred for further assessment following a screen should get a single copy of the appropriate follow-up leaflet.

1.16 This means that duplicate copies should not be provided with reminder letters or if people lose or forget their leaflet. They should be signposted to electronic sources of information instead.

Sharing personal information

1.17 Under the [2010 Equality Act](#), screening services are required to anticipate and prevent discrimination against people with learning disabilities.

1.18 The duty of care to share information can be as important as the duty to protect patient confidentiality. GPs and other health professionals should have the confidence to share relevant information with screening services in the best interests of their patients. For example, a GP may know that an individual with a learning disability requires accessible information about screening in easy read format or needs a longer than normal appointment slot. See [NHS England's information sharing policy](#) for more detailed guidance.

1.19 PHE Screening's [privacy notice](#) has more information about how screening data is shared within the legal requirements, including those of the General Data Protection Regulation (GDPR).

Reasonable adjustments

1.20 Under the [2010 Equality Act](#) Screening Providers have a legal duty to make [reasonable adjustments](#) to make sure services are accessible to disabled people as well as everybody else.

1.21 Screening Providers must follow the [Accessible Information Standard](#) by law. The standard aims to make sure that people who have a disability, impairment or sensory loss are provided with information they can easily read or understand with support, so they can communicate effectively with health and social care services.

1.22 As part of the Accessible Information Standard, Screening Providers must do 5 things:

1. Ask people if they have any information or communication needs and find out how to meet their needs.
2. Record those needs clearly and in a set way.
3. Highlight or flag the person's file or notes so it is clear that they have information or communication needs and how to meet those needs.
4. Share information about people's information and communication needs with other providers of NHS and adult social care, when they have consent or permission to do so.
5. Take steps to ensure that people receive information which they can access and understand and receive communication support if they need it.

National accessible information materials

- 1.23 PHE Screening has published national easy read versions of screening information leaflets and screening appointment letter templates. Screening Providers should use these national materials when inviting individuals for screening who have been identified as needing information in an easy read format.
- 1.24 Large print and audio (MP3) versions of standard information leaflets are also available to download from [GOV.UK](#) for people with sight loss.
- 1.25 [Translations](#) of the screening leaflets are available in alternative languages
- 1.26 Screening Providers should send any individual requests for hard copy Braille versions of PHE Screening leaflets to the [screening helpdesk](#).

Education and training

- 1.27 PHE screening provides a variety of education and training for NHS screening staff. Evidence based, up-to-date e-learning resources, study days and courses can be accessed [here](#).
- 1.28 In addition, each screening programme will have specific guidance for the initial training and ongoing learning for sample takers, and laboratory screening staff. This learning should be facilitated, supported and monitored by Screening Providers. In line with professional regulations individuals have a responsibility to ensure their practice is up-to-date and evidence based. Local programmes can use the national programme training guidance and resources to support this.

Equality

- 1.29 Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:
- screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary
 - a Health Equity Audit should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations
 - the service should be delivered in a culturally sensitive way to meet the needs of local diverse populations
 - user involvement should include representation from service users with equality characteristics reflecting the local community including those with protected characteristics
 - Screening Providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow equality, health inequality and screening guidance when making such decisions
- 1.30 The Screening Provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent

diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the [2010 Equality Act](#).

- 1.31 The Screening Provider will have procedures in place to identify and support those persons who are considered vulnerable or hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups, sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The Screening Provider will comply with safeguarding policies and good practice recommendations for such persons.
- 1.32 All screening providers should ensure they have included members of the armed forces who are registered with Defence Medical Centres within their responsible population boundaries and ensure test results are managed in the appropriate way as set out in their local agreements.
- 1.33 Screening Providers are expected to meet the public-sector [Equality Duty](#) which means that public bodies must consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees.

It also requires that public bodies:

- have due regard to the need to eliminate discrimination
- advance equality of opportunity
- foster good relations between different people when carrying out their activities

2 NHS Outcomes Framework Domains and Indicators

2.1 This specification will meet the following domains in the NHS Outcomes Framework:

Domain 1	Preventing people from dying prematurely	x
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill health or following injury	
Domain 4	Ensuring that people have a positive experience of care	x
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	x

3 Scope

- 3.1 This programme operates from identification of the eligible cervical screening population, to the taking of samples in GP practices (or other community facilities), to the testing of samples, further assessment if required and up to the point of return to routine recall or diagnosis of cervical cancer.
- 3.2 The NHSCSP identifies the eligible population which comprises all women in the appropriate age groups who are either:
 - registered on the National Health Application and Infrastructure Services (NHAIS) system with specified GPs, or
 - resident in the specified area and not registered with the NHS but entitled to NHS care
- 3.3 Subsequent elements of the process such as staging, investigations, management and treatment of cervical cancer are outside the scope of the programme and are not included in this specification.

Background

- 3.4 The NHSCSP was introduced in 1988 and since then has acted on evidence to improve the screening methodologies and outcomes for women.
- 3.5 Persistent infection with a high-risk strain of the human papillomavirus (hrHPV) is associated with the development of cervical intraepithelial neoplasia (CIN). CIN is the abnormal growth of cells on the surface of the cervix which have the potential, if left undetected and untreated over many years, to develop into cervical cancer. hrHPV is found in 99.7% of cervical cancers. 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.

Further evidence provided 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 from the pilots confirmed the feasibility of use and improved performance from utilising primary HPV screening within the NHSCSP. Following an evidence review and public consultation the UK National Screening Committee (UKNSC) recommended the implementation of primary hrHPV testing to replace primary cytology within the NHSCSP.

Following the acceptance of this recommendation by ministers in 2016 the programme is currently transitioning to the HPV primary screening pathway across the whole of England. This transition is scheduled to be completed by the end of December 2019. Samples taken in Primary Care settings will follow the HPV primary screening pathway during 2019 in line with transition plans.

- 3.6 This service specification therefore covers both the:
 - primary cytology screening pathway with HPV Triage and Test of Cure (TTOC)
 - primary HPV screening pathway with cytology triage.

Screening Providers must ensure that they are compliant with the correct suite of guidance documentation for the pathway that is currently being delivered to their population.

Aims and objectives of the service

Aim

- 3.7 The aim of the NHSCSP is to reduce the incidence of and mortality from cervical cancer by delivering a systematic, quality assured, population-based screening programme for all eligible women.

Objectives

- 3.8 The objectives are to achieve the above aim across NHSCSP by delivering evidence-based interventions that:

- identify the eligible population and ensure efficient delivery with maximum coverage
- are safe, effective, of a high quality, equitable, externally and independently monitored and quality assured
- lead to earlier detection of HPV infection, cervical abnormalities, appropriate subsequent treatment of cervical intraepithelial neoplasia (CIN), cervical glandular intraepithelial neoplasia (CGIN) and improved outcomes
- are delivered in suitably equipped accommodation, and supported by suitably trained, competent and qualified, clinical and non-clinical staff who, where relevant, participate in recognised ongoing Continuing Medical Education (CME), Continuing Professional Development (CPD), and External Quality Assessment (EQA) schemes
- ensure sample taking and colposcopy clinics are both provided close to the individual
- make sure laboratory services that provide HPV testing and cytology are delivered from a single centralised laboratory on the same site
- have audit or interventions that have audit programmes embedded within them to ensure quality service
- operate strictly within the existing published national standards and guidance, including any updates or new documentation that are subsequently published.

These objectives will be achieved by:

- making the best use of screening resources for the benefit of the whole population
- minimising non-attendance at screening/clinics
- ensuring effective and timely communication with:
 - women being invited, screened, assessed, or have abnormality treated
 - clinical MDTs
 - primary care support services

- NHS England and NHS Improvement regional and national teams
- Screening Quality Assurance Service (SQAS) teams within PHE
- the national office team within PHE
- NHS Digital
- Clinical professional bodies and relevant cancer charities
- working to develop a seamless, integrated care pathway
- building robust failsafe measures into all key stages of that pathway
- dealing with complaints in accordance with relevant protocols
- using the programme IT systems to capture key screening data/outcomes promptly and accurately, supporting local and national SQAS and cancer registration processes and programme evaluation
- complying fully with NHS information governance requirements relating to the confidentiality and disclosure of person identifiable information and system/ information security - PHE Office of Data Release (ODR) application for data processes should be followed
- full records must be retained to assist with audit, incident investigations and service improvement

Service description and care pathway

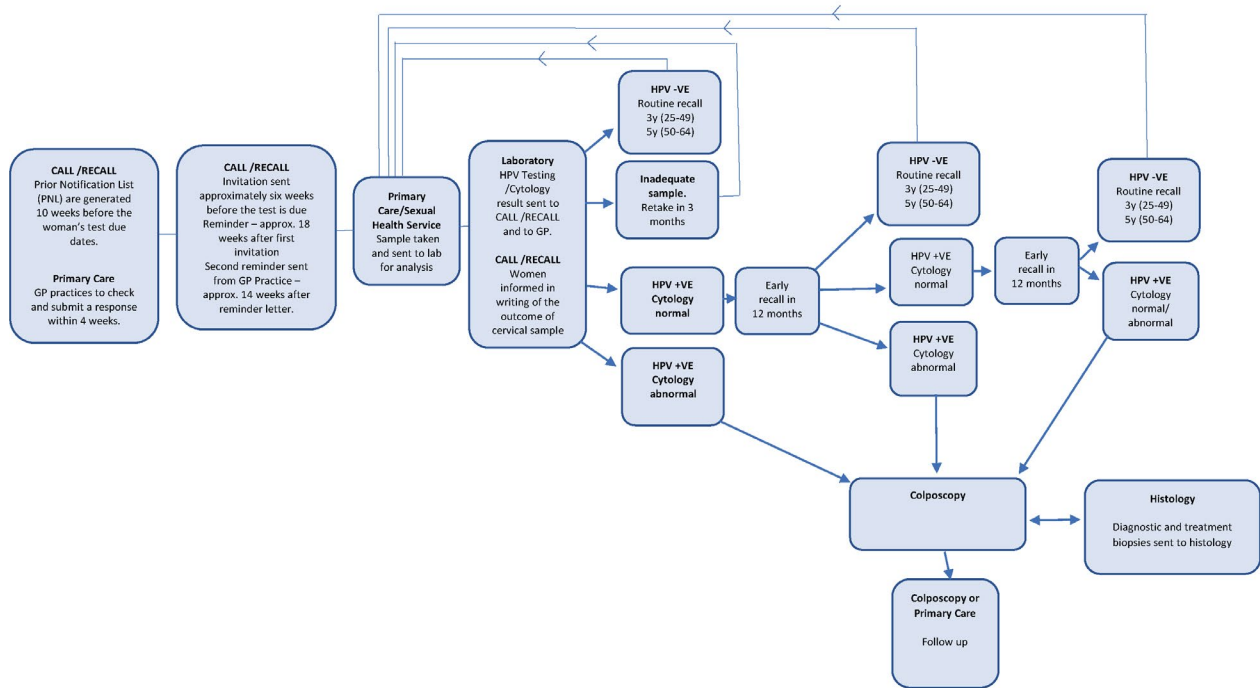
Screening pathway for the NHSCSP

3.9 During 2019/20 there will be two screening pathways in place as the programme transitions from primary cytology, Triage Test of Cure (TTOC) and primary HPV testing.

The pathway flowchart for the triage and test of cure features in the appendix of the colposcopy and programme management guidance.

3.10 The HPV Primary screening pathway flowchart is as follows:

HPV Primary screening pathway flowchart



The screening pathway is divided into the following stages:

- Identification
- Invitation
- Inform
- Test
- Diagnose
- Treatment/intervention
- Monitor outcomes

Identification of target population

3.11 The target population comprises all women in the eligible age groups below that meet the criteria identified in the Scope section of this Specification.

The target age group and frequency of screening is currently:

- First invitation is issued at 24.5 years
- Ages 25 – 49: 3 yearly screening
- Ages 50 – 64: 5 yearly screening
- Ages 65+: screening of those who have not been screened since age 50, or those who have not yet met the criteria to be ceased from the programme

Invitation and Inform

3.12 NHS England and NHS Improvement is responsible for commissioning the call and recall system for the local delivery of cervical screening and for monitoring its effectiveness. It is the responsibility of the call and recall service to:

- issue the women invited with the information they require, in an accessible format, so they can make an informed choice about whether or not to participate in the screening programme.
- invite all eligible women for screening six months before their 25th birthday in accordance with programme guidance and;
 - then at three-yearly intervals from the previous test recommending routine recall between the ages of 25 and 49 years
 - thereafter, between the ages of 50 and 64, women should be invited at five-yearly intervals from the date of the previous test recommending routine recall
- ensure women who do not require a further screening are ceased after the date of their 60th birthday due to age, as they will be over the age of 65 at their subsequent screen
- invite women who require more frequent follow-up due to the previous screening result in accordance with programme guidance and HPV Primary Screening pathway

- invite women aged 65 or over who remain eligible as part of the screening pathway
- keep supporting documentary evidence for any woman who is ceased from the screening programme to ensure full screening history is maintained
- follow [national guidance](#) on the routine ceasing of women
- co-operate with and/or carry out annual audits of ceased women
- send results in writing to women meeting the national [standard](#) of 14-day turnaround
- Support GP practices with their checks of eligible participants through their registration process in order to provide assurance that women are being screened appropriately

Sample taking

3.13 Women must be eligible for NHS care to participate in NHSCSP and sample takers are responsible for checking this. Full details are found in NHSCSP [guidance](#).

- Samples taken in the GP practice
- GP practices take the majority of cervical samples in England. Registration with a GP is not an eligibility criterion in itself, although non-registration presents the programmes with practical difficulties in identifying and contacting individuals for call and recall and any further follow-up.
- Call and recall services are responsible for recording contact information provided for women not registered with a GP practice and for sending results and appropriate recall invitations when due. In a situation where there is no address, it is the sample takers responsibility to make appropriate arrangements for the woman to receive her test results and follow-up.
- Samples taken in other NHS settings
- Where samples are taken in other settings (e.g. Community and Sexual Health Clinics) the sample taker must ensure they:
 - check the woman's eligibility for screening
 - record accurate information about the woman's identity
 - record accurate contact information

This will ensure that the woman can be followed-up if necessary.

Women screened through this route must be made aware by the sample taker that their contact details will be kept on record by the call and recall services and used to contact them for future screening invitations as well as to provide test results. The programme does not support anonymous screening.

The screening provider must ensure women whose screening samples are taken in sexual health, colposcopy or gynaecology clinics obtain their results in writing.

- Private samples

Women who have a sample taken privately remain eligible for screening under the NHS at the standard intervals. Samples taken by private providers should be recorded in a woman's screening history by the call and recall service when they are made available by the relevant cytology laboratory.

Test

3.14 NHS England and NHS Improvement is responsible for commissioning the laboratory services to support the delivery of the cervical screening service and for monitoring its effectiveness. NHS England and NHS Improvement must ensure that providers of these services will, as a minimum:

- communicate any issues with samples received to the appropriate parties as indicated in the relevant [guidance/advice](#)
- undertake HPV and/or cytology testing as defined by the programme pathways, in accordance with the [NHSCSP](#) or have a service level agreement in place with the virology/department of molecular medicine to provide this service on site.
- receive, book-in, process and examine/report appropriate HPV /cervical cytology samples and provide clinical reports of these tests in line with programme [guidance](#)
- send results securely to the sample taker (including trainee sample takers if appropriate) and the relevant GP (if different)
- send results securely to the call and recall service and ensure that suitable systems are in place to verify that all tests are reported and safely transmitted according to [programme standards](#)
- deal promptly with telephone and email queries in relation to cervical screening activities
- make sample results available at colposcopy
- make cytology slide(s) and/or HPV results available to the histopathologist
- manage a safe and robust direct referral system for women where HPV/cytology results indicate that referral for colposcopy is required, according to programme [guidance](#)
- contribute to multi-disciplinary team (MDT) case discussion meetings to agreed local protocols. These meetings must meet the requirements outlined in relevant NHSCSP [publications](#)
- produce quarterly activity reports, as determined locally, for both Screening Quality Assurance Service (SQAS) teams within PHE and NHS England and NHS Improvement, who will discuss these at local multi-agency cervical screening coordinating groups and programme boards
- work with NHS England and NHS Improvement to maintain a sample taker register, as determined locally, and provide comprehensive feedback both by individual sample taker and by general practice/clinic on reporting profiles, workload, and

sample error issues (for example missing patient identifier), as agreed with NHS England and NHS Improvement

- provide feedback to sample takers and novice sample takers where required locally
- ensure that the performance of all staff involved in reporting cervical cytology tests is monitored according to NHSCSP and relevant professional society [guidance](#)
- take appropriate action where performance is outside national standards/guidelines
- provide a comprehensive failsafe system as defined by programme [guidance](#)
- comply with NHSCSP guidance and with local SQAS processes and audit requests from the SQAS team within PHE
- produce accurate and validated annual KC61 and monthly, quarterly and annual data reports to the SQAS team by the specified deadlines
- undertake regular audits on cervical screening activities, including the review of HPV and cytology tests on samples taken from women subsequently diagnosed with cervical cancer, in line with programme [guidance](#)
- maintain comprehensive quality management and quality control systems, including internal and external QA and processes (which includes participation in EQA schemes). All such activities should be documented in protocols and procedures that comply with programme [guidance](#)

Test – Surveillance Screen

3.15 The Primary HPV Screening pathway requires hrHPV positive women to 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 repeat test at 12 months, and again in a further 12 months (24 months from the initial screen) if these results persist, in line with the HPV Primary screening [pathway](#).

Assessment, diagnosis, referral and follow up

3.16 NHS England and NHS Improvement will ensure that in accordance with programme standards and guidance, the Screening Provider within the NHSCSP should undertake to meet the following criteria:

3.17 The GP practice or sample taker provider will:

- counsel women before and after the screening test, where the result is HPV positive or cytology abnormal and this is requested by the woman
- ensure that follow-up/treatment/referral is recommended and initiated in line with national guidance and verify direct referral is in place.

3.18 The colposcopy service will, as a minimum:

- provide services in line with all programme [standards](#) and [guidance](#) and British Society of Colposcopy and Cervical Pathology ([BSCCP](#)) standards and guidance, including accreditation of colposcopists
- appropriately and efficiently manage women referred via direct referral, GP referrals, and tertiary referral within, or between, providers

- undertake difficult and complex cases where cervical screening is unable to be performed in Primary Care.
- make sure women are fully informed and counselled during the consultation
- manage/treat precursor lesions and early stage 1A cancers according to [protocol](#) and retrieve excised tissue for histological evaluation
- ensure that all clinical, operational, and administrative activities are documented in up-to-date service [guidelines](#), and that usual practice avoids unnecessary attendance
- make sure that women are provided with the necessary information and advice in advance of their colposcopy appointment, including information relating to HPV and see-and-treat options (when appropriate). All information given to individuals should conform with programme [standards](#) ensure that the colposcopist to whom the woman is referred takes responsibility for her management, including arranging further follow-up (either in the colposcopy clinic, Primary Care or gynaecology clinic as indicated), and informs the GP (or responsible clinician) and the woman of the outcome of the examination, including any further investigation performed
- meet the NHSCSP standards for attendance by colposcopists at cervical screening MDT meetings as documented in the agreed local protocol. These meetings should meet the requirements outlined in relevant programme [guidance](#)
- carry out an agreed annual colposcopy audit programme and take the necessary action where performance is outside national standards
- produce timely, accurate and validated quarterly and annual KC65 returns for each clinic to the SQAS team
- produce timely, accurate and validated quarterly and annual QA data reports for each clinic to the SQAS team
- carry out service-wide patient satisfaction surveys at least annually. The findings of such surveys should be used to improve the service
- maintain a suitable IT system to enable an accurate electronic record to be made of all activity carried out within the colposcopy service, including colposcopy carried out under general anaesthetic. The IT system should support the audit and quality assurance processes
- ensure that staff working in the programme are trained to meet the required standards of competence and are actively involved in continuing personal and professional development

Where colposcopy is provided on more than one site, there must be consistency of procedures, protocols, accommodation, equipment and IT including robust policies for onward referral. In this situation, the lead colposcopist and lead colposcopy nurse will be responsible, as appropriate to their roles, for colposcopy activities occurring on all sites.

3.19 The histology laboratory will, as a minimum:

- be accredited by the United Kingdom Accreditation Service ([UKAS](#)), or equivalent, and provide a comprehensive [histology service](#) to support the cytology and colposcopy services
- process and report diagnostic and treatment specimens taken by the colposcopy service (including those taken under general anaesthetic) in a timely manner to allow colposcopy to meet reporting time [standards](#) for biopsy results and relevant professional [guidance](#)
- send results securely to the originating clinician and to the cytology laboratory
- participate fully in the cancer registration process for CIN3, (CGIN) and cervical cancer results
- contribute fully to [MDT](#) meetings to the agreed local protocol. These meetings must meet the requirements of the relevant NHSCSP publications
- undertake internal and external quality control measures and regular audits, in accordance with published [standards](#). Take appropriate action to improve such that standards are met where performance is outside national standards/[guidelines](#)
- participate in relevant EQA schemes, where available
- audit all cases where invasive cervical cancer is found in women within the programme run by the laboratory, in line with NHSCSP [guidance](#)
- comply with NHSCSP /[Royal College of Pathologists](#) histopathology reporting guidelines

Failsafe Procedures

3.20 Quality Assurance within the screening pathway is managed by the inclusion of [failsafe](#) processes. Failsafe procedures are back-up mechanisms, designed to ensure that, where something goes wrong, processes are in place to identify the issue and what actions are necessary to ensure a safe outcome.

3.21 All services delivering cervical screening must have a failsafe system in place, consistent with guidance from the NHSCSP within PHE.

The Screening Providers delivering cervical screening services are required to:

- include appropriate failsafe mechanisms across the whole screening pathway for women who participate.
- ensure routine staff training on failsafe procedures takes place and is up to date
- maintain a record of tests taken
- check that results are received from the laboratory for every sample
- ensure women whose samples they report will be notified of results (either via the practice, colposcopy or call & recall)
- ensure women whose screening samples are taken in genitourinary medicine clinics, colposcopy or gynaecology clinics obtain their results in writing

- ensure required colposcopy referrals are made and outcomes recorded for each woman referred
- ensure that the colposcopy service is responsible for informing the call and recall service regularly of the next test due date by completing the discharge template for all women discharged from colposcopy.
- act on non-responder notifications (screening, and colposcopy appointments)
- respond to failsafe enquiries from laboratories in line with screening incident guidance.
- report incidents in line with screening incident [guidance](#).

Results giving, reporting and recording

3.22 The laboratory will send results to relevant parties within the screening programme, including GPs and the Call & Recall system, using electronic means. Data should be presented with the nationally approved format and codes and follow NHS reporting formats and rules.

Providing results:

- laboratories must notify relevant parties of the result of the screening process in a time period which supports achievement of the overall pathway requirement to issue results to women within 2 weeks of the screening test being taken
- during the transition to HPV primary screening, many laboratory providers are challenged in meeting the 14-day turnaround target. Commissioners and laboratory providers are responsible for implementing plans to ensure local service delivery achieves the programme [standards](#) during the development of planning and introduction of HPV Primary screening
- Commissioners will work with contracted laboratory providers to mitigate any capacity issues and commission HPV primary screening to address turnaround times for screening results

Roles and accountability throughout the pathway

3.23 Accountability and responsibility

The Screening Provider must create clear lines of accountability and responsibility for all cervical screening services carried out under this agreement. This includes identification of the following individuals to undertake the following roles, as defined by programme guidance:

- a Cervical Screening Provider Lead ([CSPL](#)) with delegated responsibility from the chief executive for the quality of all cervical screening activities carried out by the Screening Provider. This role was formerly known as the hospital based programme coordinator HBPC.
- a lead virologist
- a lead cytopathologist
- a lead histopathologist

- a lead scientist for hrHPV testing (a senior member of staff responsible for the delivery of the hrHPV testing service)
- a named laboratory lead (usually a senior biomedical scientist actively involved in reporting cervical screening tests)
- a lead colposcopist
- a lead colposcopy nurse
- a pathway manager (this role may be combined with that of the CSPL)

3.24 Lead staff must be formally appointed and should:

- have sufficient designated sessions
- be able to access sufficient administrative support in order to fulfil their roles
- identify deputies for key roles to provide cover when necessary (and where possible)

3.25 The CSPL must maintain a close working relationship between all parts of the Screening Provider's cervical screening activities with NHS England and NHS Improvement and stakeholders. Where the Screening Provider undertakes HPV testing and cytology, resulting in colposcopy and histology being undertaken in other Trusts, the Screening Provider CSPL must ensure close working relationships with the CSPLs in those Trusts.

3.26 Screening Provider management meetings

The Screening Provider will:

- hold quarterly multi-disciplinary cervical screening management meetings to discuss performance and any issues arising with cervical screening services and where appropriate include representatives from Trusts providing other elements of the screening pathway
- ensure appropriate Trust systems are in place to enable an annual report with six-monthly update from the CSPL can be discussed at a formal clinical governance committee within the Screening Provider's institution, thereby enabling escalation of key issues to the chief executive as required
- convene monthly multi-disciplinary clinical case discussion meetings as outlined in programme guidance ([Link](#))
- ensure that Screening Provider staff attend and support (i.e. through sample review and attendance) meetings convened by other Screening Providers for example where colposcopy and or histology is carried out by other Trusts where the Screening Provider directs referrals
- ensure that all staff involved in cervical screening activities are kept informed of programme performance and issues

3.27 Stakeholder relationships

The NHSCSP is dependent on systematic, specified relationships between stakeholders, including:

- treatment for abnormalities
- laboratories
- external diagnostic services
- Primary Care representatives
- Emerging pathology networks

Laboratory providers will be expected to identify a pathway manager to take the lead and ensure that inter-organisational systems are in place to maintain the quality of the whole screening pathway. This will include, but is not limited to:

- providing coordinated screening across organisations, so that all parties are clear about their roles and responsibilities at every stage of the screening pathway, and particularly where responsibility is transferred from one party to another
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway
- contributing to any initiatives led by NHS England and NHS Improvement or public health screening teams to develop the screening pathway in line with programme expectations
- maintaining robust electronic links/communications with IT systems and relevant organisations across the screening pathway
- agreeing links with primary care, and with secondary and/or tertiary care.

Competencies and ongoing training

3.28 Training and education for all staff groups must be conducted as required by the cervical Screening Programme. The Screening Provider shall ensure all staff groups engaged in providing the Services are trained and complete continual professional development in accordance with guidance and in particular in accordance with the relevant programme requirements. The Screening Provider should ensure training has been completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

All Screening Providers must:

- ensure that staff are appropriately trained and supported by national continuing professional development and skills frameworks, enabling them to develop their skills, competencies, and potential.
- ensure that only approved/accredited training courses are be used
- ensure that all relevant laboratory staff reporting specimens within the NHSCSP must participate in external quality assurance activities (EQA schemes)

Information technology for the call and recall service

3.29 All IT systems across the pathway e.g., NHAIS, LIMS must support the call and recall service to:

- communicate with eligible women by sending all required invitation, reminder and result letters
- maintain electronic communications with GP surgeries and laboratories and colposcopy clinics
- collaborate with laboratories and colposcopy services to enable all parties to capture key screening data/outcomes promptly and accurately in clinical systems, supporting local and national SQAS, cancer registration processes, and programme evaluation including audit
- be able to maintain appropriate record keeping in order to ensure that audit trails of activities undertaken are available and followed
- support the programme and supply accurate and complete data for the purpose of monitoring national standards and KPIs and for quality assurance activities
- ensure that there is business continuity through regular back up and system security
- perform failsafe checks

Population covered

3.30 NHS England and NHS Improvement and the Screening Providers will work together to:

- ensure that up-to-date population registers and lists of GP registered populations are maintained and cleansed to guarantee accuracy and completeness
- optimise screening participation amongst vulnerable and hard-to-reach groups within the eligible population across their catchment area.
- co-operate with regular analysis of coverage to identify groups of women who either access screening at lower levels, or do not access services at all
- ensure that women who are not on the NHS lists have access to screening, and that local arrangements are made to cover residential institutions including prisons.

Acceptance criteria

3.31 All of the eligible population should be invited for screening. Information on the eligibility of lesbian, gay, bi-sexual and transgender people is [here](#).

Exclusion

3.32 This specification does not include the following activities, or any work or cost associated with:

- women below the current eligible age group
- symptomatic referrals
- post diagnosis follow-up and management of cervical cancer
- the treatment of cervical cancer

Interdependence with other agencies, services and providers

3.33 The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway. Accurate and timely communication and handover across these interfaces are necessary to reduce the potential for errors and ensure a seamless pathway for service users. The Screening Provider will ensure that there are clear, named lines of clinical responsibility at all times, and particularly where there is handover of care.

Increasing attendance

3.34 It is recommended that:

- Commissioners and Screening Providers work with local authorities and third sector organisations to understand and develop plans to address low screening attendance and inequalities. SQAS QA visits include an assessment of the process to develop such plans and their implementation at a local level
- Screening Providers, commissioners and local authorities are encouraged to pilot, evaluate and publish (preferably in peer reviewed journals) local solutions to address inequalities of access. Before piloting, these local proposals must be agreed with the PHE screening team via the Research Advisory Committee process.
- PHE will share new and emerging knowledge via the screening inequalities network and blogs.

Service Model Summary

3.35 Screening Providers should deliver cervical screening services as outlined in national standards to all eligible women within the population defined by NHS England and NHS Improvement. This specification operates up to the point of diagnosis of cervical cancer; subsequent management and treatment is outside of its scope.

- If the optimal deliverable benefits from a screening programme are to be achieved, there must be seamless links between 'screening responsibility' and 'treatment responsibility', so that women at the end of the screening process are referred seamlessly to cancer treatment services where necessary.
- All elements of the screening pathway must be delivered by appropriate trained staff, to national standards and guidelines.

This must include:

Days/hours of operation

- the days and hours of operation of both screening appointments and colposcopy clinics will be locally determined and appropriate for the local populations.
- easy access to initial screening appointments and timely further examination is essential, and this is a key criterion of quality for the entire screening pathway.
- the Screening Provider must be able to demonstrate efficient and effective use of resources

- hours of operation must reflect the procurement contract specification and financial agreement

Staffing levels

- the Screening Provider will ensure that there are adequate numbers of trained, qualified, and competent staff in place to deliver a high-quality NHSCSP, in line with guidance and NHSCSP national policy
- qualified staff deliver the service across the care pathway and are obliged to meet their professional requirements for continuing professional development
- all professionals involved in the screening programme are required to keep up-to-date with nationally approved training programmes and CPD/CME etc. and should participate in educational schemes such as EQA as appropriate
- staffing levels must reflect the procurement contract specification and financial agreement

4 Applicable service standards

Applicable national consolidated programme standards

- 4.1 The national consolidated standards are available [here](#).
- 4.2 The Screening Provider will meet all published programme standards. Where a recommendation for standards are not met as identified by performance management processes, the Screening Provider will be expected to indicate in service plans and what changes and improvements will be made over the course of the contract period.
- 4.3 The Screening Provider shall develop a development plan in line with KPIs, programme standards and the results of internal and external quality assurance checks. The plan will respond to any performance issues highlighted by the commissioners, having regard to any concerns raised via any feedback from women, family or carers. The plan will contain action plans with defined timescales and responsibilities and this will be agreed with the commissioners.

Data and intelligence

- 4.4 The collection, analysis and comparison of good quality data is critical for all NHS screening programmes in England. PHE Screening aims to develop a consistent approach to data collection and reporting across all screening programmes and is committed to making sure that stakeholders have access to:
 - reliable and timely information about the quality of the screening programme
 - data at local, regional and national level
 - quality measures across the screening pathway without gaps or duplications

Performance thresholds are selected to align with existing screening standards and service objectives;

Key performance indicators (KPIs) and screening standards

- 4.5 The Screening Provider should adhere to the requirements as specified on following links where relevant:
 - KPIs: "[Reporting data definitions](#)"
 - Screening programme [standards](#)
 - SQAS QA data [requirements](#)

Please note that indicator definitions are updated regularly and you should always obtain the most recent version available.

Oversight and monitoring of pathway standards

- 4.6 PHE Screening Quality Assurance Service ([SQAS](#)) systems support commissioners and the Screening Provider in the quality and clinical governance aspects of the Services so that core processes are safe and the programme achieves better [outcomes](#).
- 4.7 The Screening Provider shall at all times cooperate and participate fully in national Quality Assurance processes, co-operate in undertaking ad-hoc audits and reviews

as requested and as such may be directed by the commissioner, from time to time. The Screening Provider shall act upon and implement recommendations made as a result of PHE SQAS visits or reviews within a timeframe and in accordance with a plan that has been agreed by the commissioner.

4.8 The Screening Provider shall ensure that it submits the following to SQAS and the Commissioner as relevant within the timescales laid out in [guidance](#) or otherwise as directed by the commissioner or PHE SQAS:

- Data and reports from external quality assurance schemes
- Minimum data sets as required
- Self-assessment questionnaires/tools and associated evidence
- Audits or data relating to nationally agreed internal quality assurance processes incidents and serious incidents as they occur in accordance with the policy [guidance](#)
- Incident management occurs in line with [failsafe](#) document and national guidelines for [incident](#) management (NHS England and NHS Improvement/PHE)

4.9 Where PHE SQAS believe there is a significant risk of harm to the population, they will recommend to commissioners to suspend a service.

4.10 The Screening Provider will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.

4.11 The Screening Provider shall, at all times comply with the national screening programme guidance '[Managing Safety Incidents in the English NHS National Screening Programme](#)' as referred to in the Quality Requirements in Schedule 4 and the NHS England and NHS Improvement guidance for the management of incidents. Applicable standards set out in Guidance and/or issued by a competent body

Clinical and corporate governance

Accountability and oversight

4.12 The Screening Provider will ensure that:

- an appropriately skilled and competent named executive officer within its organisation is accountable for, and oversees, the Services;
- the Screening Provider's board of directors is part of the clinical governance procedures and must be responsible for receiving assurance on the quality of the Services;
- there is appropriate internal clinical oversight of the Services and have its own management and internal governance of the Services;
- an internal multi-disciplinary management group is established, that meets quarterly as a minimum. This group will ensure robust operational processes are in place between individuals delivering the Services

Programme board

4.13 It is the responsibility of the commissioner to convene a programme board to maintain governance and monitor the local screening oversight arrangements. The boards will meet regularly at a schedule defined by commissioners and have defined points of escalation within NHS England and NHS Improvement e.g. provider contract meetings. Representation will include Screening and Immunisation Team, CSPL, Screening Provider clinical leads, public health and PHE SQAS representative, call and recall service representative and may also include; Local Authority representatives, Primary Care, CCG commissioners as agreed locally. The programme boards must consider service user engagement and involvement.

The Screening Provider must:

- ensure co-operation with and representation on the local screening oversight arrangements/ structures
- provide representation at screening programme boards which are part of good governance of the programme.
- ensure that service improvements required due to the advice of SQAS to screening commissioners are adhered to in compliance with contractual requirements
- produce an annual report of screening services, which is signed off by the board
- ensure that there is regular monitoring and audit of the screening service and as part of the organisation's clinical governance arrangements, the programme board is assured of the quality and integrity of the screening service

Risk Management

4.14 The Screening Provider must have an internal risk management process for the Services. The process must be reviewed and agreed at programme board and form part of the assurance to the Screening Provider's board of directors.

4.15 The Screening Provider shall:

- review and risk assess local screening pathways in the light of guidance offered by SQAS processes or the NHSCSP
- work with NHS England and NHS Improvement and PHE SQAS teams to develop, implement, and maintain appropriate risk reduction measures
- ensure that mechanisms are in place to audit implementation of risk reduction measures regularly and report [incidents](#) should these occur
- ensure that appropriate links are made with internal Screening Provider governance arrangements, such as risk registers

High scoring risks will be identified and agreed between the Screening Provider and the commissioners and reviewed on an ongoing basis and mitigation plans established. It is expected that Screening Providers will investigate anything outside the acceptable levels.

Governance policies

4.16 The Screening Provider must have an appropriate governance framework in place that has been approved by the Commissioner, prior to the Services Commencement

Date and annually thereafter, covering the following aspects of the services:

- Information governance/records management
- Equality and diversity
- User involvement, experience and complaints
- Failsafe procedures
- Risks & mitigation plans.

The Screening Provider must:

- comply with the statutory data protection requirements of the UK General Data Protection Regulation ([UK GDPR](#)) and the Data Protection Act 2018 ([DPA 2018](#))
- comply with the best practice guidance on collecting, analysing and disseminating confidential patient information set out in the NHS Digital (previously the Health & Social Care Information Centre) [Code of Practice on Confidential Information](#)
- comply with the best practice guidance on the management of screening records set out in the Information [Governance Alliance Records Management Code of Practice for Health and Social Care 2016](#)
- achieve, or have in place an improvement plan to achieve, at least the 'good' performance standard for the [NHS Digital Data Security & Protection Toolkit](#)
- only access screening records held in PHE-controlled IT systems that are to be used for multi-centre audit, evaluation and research purposes through the [PHE Office for Data Release](#)

5 Location of Screening Provider premises

5.1 The Screening Provider will ensure that:

- suitable premises are provided for the screening programme
- there are appropriate and secure premises on which screening activities can safely take place.

6 Equipment specification

6.1 The Screening Provider will ensure that:

- only HPV and LBC technologies and protocols that have been evaluated and accepted by PHE are used in the programme, and that the manner of their use accords with national guidelines.
- all staff are aware that unorthodox use of approved technologies or use of unapproved technologies is prohibited within the NHSCSP except as part of a formal national pilot, or a properly constituted and approved research project.
- appropriate policies are in place for equipment calibration, maintenance, and replacement

7 Safeguarding policies

- 7.1 Safeguarding vulnerable people is at the heart of all health service delivery. NHS England and NHS Improvement and the Screening Provider is required to ensure that services provided adhere to local multi agency safeguarding [policies](#) and procedures, have appropriate training in place and arrangements to work with local authorities and partner agencies through safeguarding boards and other relevant bodies.