**BACKGROUND INFORMATION ON THE NHS CERVICAL SCREENING – SELF-SAMPLING IN SERVICE EVALUATION**

**This background document explains:**

* **the current arrangements for the NHS Cervical Screening Programme in England (Section 1-4)**
* **the requirements and purpose of the upcoming In-Service Evaluation, which is the main purpose of this RFI (Section 5-5.1)**
1. The NHS Long Term Plan outlines a commitment to detecting more people at risk of developing

cancer and facilitating their treatment to prevent cancer.

The aim of the NHS Cervical Screening Programme (NHS CSP) is to reduce the incidence of and mortality from cervical cancer through a quality assured, population-based screening programme for women and people with a cervix aged 24.5 to 64. Up until December 2019, cervical screening was based on cytology, however, a national programme of primary HPV screening was [fully implemented in England in December 2019](https://phescreening.blog.gov.uk/2020/01/23/significant-landmark-as-primary-hpv-screening-is-offered-across-england/)

Primary HPV screening is when the first test carried out on the sample looks for high-risk strains of the human papillomavirus (HPV). If HPV is detected a cytology test is used as a triage, to check for any abnormal cells. For further information please refer to <https://www.gov.uk/topic/population-screening-programmes/cervical>

1. The NHS Cervical Screening Programme offers screening at different intervals, depending on an individual’s age:

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| --- | --- |
| **Age group (years)** | **Frequency of invitation** |
| Under 24.5 | No invitation |
| 24.5 | First invitation (to ensure that women can be screened forthe first time by their 25th birthday) |
| 25 to 49 | Every 3 years |
| 50 to 64 | Every 5 years |
| 65+ | Invitation as required for women who have had recent abnormal tests. Women who have not had an adequate screening test reported since age 50 may be screened on request. |

1. **Current service model**

Currently the NHS CSP is delivered by many provider organisations:

* the cervical screening administration service manages the call/recall service, issuing invitation and results letters,
* GPs, other primary care organisations and Community Sexual Health Clinics are commissioned to provide sample taking facilities
* screening laboratories and colposcopy/histology services are largely hosted in NHS trusts

Additional elements have been added and changes made to the programme over the years, future development with this programme is likely to occur.

The current model involves screening laboratories supplying sample taking organisations with sample pots. Samples are taken in primary care and forwarded to regional screening laboratories for HPV testing. Those testing positive for HPV have cytology performed. Individuals referred to colposcopy for further examination/treatment are referred to their local colposcopy clinic, usually located at the nearest NHS Trust, through a process of direct referral undertaken by the laboratory. Biopsies taken at colposcopy are usually examined at the local NHS Trust histopathology service.

1. **Responsibilities in the current service model are as follows:**

Call and recall service:

* identifies women who are due for a cervical screening invitation
* sends, receives and acts on prior notification lists of women due for a cervical screening test, which general practitioners (GPs) have updated to ensure women are not invited inappropriately
* invites eligible women for cervical screening tests at the routine screening interval
* invites women for an early repeat test before the routine screening interval
* sends women information to assist them to make an informed choice about whether to participate in screening
* receives, validates and confirms receipt immediately of screening results sent by the laboratory
* records screening results
* informs women in writing of their screening results
* sends reminder letters to women if no test result has been entered on the system after the test due date
* provides non-responder notifications to the woman’s GP if no test result has been entered on the system after the test due date has passed and reminders have been sent
* operates a failsafe system which ensures that eligible women are invited for screening again at an appropriate interval even if no other action is recorded on the system
* operates a failsafe system which ensures that women referred to colposcopy are invited for a further cervical screening test at 12 months following the referral if no further results or outcome is entered on the system
* receives, receipts and updates the system with next test due dates from discharge lists sent from colposcopy clinics, and queries with colposcopy any dates not meeting validation criteria
	1. Primary Care (or alternative sample taking facility):
* make sure that the woman is provided with the necessary information and advice to assist her in making an informed choice about whether to participate
* respect the wishes of women who wish to be ceased from screening, supporting them in making their decision, and notifying the call and recall service where necessary
* act on non-responder notifications for women who have not responded to an invitation for a routine test or early repeat test
* invite women who have not responded to their centrally produced invitation and reminder letters (sending a third invitation)
* make sure that women no longer eligible for screening (due to absence of cervix or pelvic radiotherapy) are notified to the call and recall service promptly
* review prior notification lists from call and recall services and revising accordingly
* make arrangements for taking an appropriate cervical screening sample in line with programme guidance and according to the woman’s circumstances
* arrange for a woman to be informed of her test result
* discuss the test result in person with the woman if required for cases of high-grade dyskaryosis/ ?invasive squamous carcinoma or ?glandular neoplasia of endocervical type
* give a woman her test result in person where an urgent referral is required for ? glandular neoplasia (non-cervical)
* ensure that arrangements are made for women who fall outside the call and recall system to receive their test results
* make sure that the test result is known and followed up appropriately
* for intersex individuals with a cervix, female to male transgender (trans) men, and for individuals who identify as male but require cervical screening, the GP should take responsibility for and arrange the screening process, as the call and recall service is not commissioned to send invitations or results to people registered as male – the GP should also notify the laboratory that the results should be returned to the practice directly
* refer a woman for further investigation and treatment where necessary (for example, a woman needing colposcopy who has moved from another area, or a woman who has been discharged following a previous non-attendance at colposcopy)
* act on the non-responder notification from the colposcopy clinic for women who have not attended for colposcopy
* cooperate promptly with failsafe enquiries from the laboratory about a woman who requires further investigation and treatment
	1. Screening laboratories:
* transfer test results and recommendations for management to the call and recall system using standard result and action codes
* notify the sample taker and GP (or responsible clinician) of test results and recommendations for management
* operate a direct referral system for women who need a referral to colposcopy – this will include daily communication with each colposcopy clinic
* inform GPs and responsible clinicians about women who require referral for colposcopy
* make sure that histology results are collated with cytology results
* keep a record of all test results which are subject to laboratory failsafe
* ensure that the woman’s GP (or responsible clinician) is notified of test results which require urgent referral
* send the GP (or responsible clinician) sufficient and timely information to respond to queries from women about their urgent referrals (this may be covered by existing result notification in which case the laboratory is not required to phone the GP)
* record colposcopy attendance and outcome (as defined in the KC61), such as histology results following tests which are subject to laboratory failsafe
* initiate failsafe enquiries to the woman’s GP (or responsible clinician) if no colposcopy attendance or outcome is notified to the laboratory
* keep a record of all failsafe enquiries (including letters, phone calls, emails)
* send the GP (or responsible clinician) a closure letter when laboratory failsafe enquiries have been made and actions are closed
* keep records of communications from the call and recall service confirming receipt of laboratory test results, and make enquiries of the call and recall service if no receipt is received so that prompt action can be taken as needed
* act immediately in response to call and recall queries on test results
* audit the laboratory failsafe procedures on an annual basis
	1. Colposcopy:
* confirm receipt of all referrals sent by the laboratory on a daily basis (or confirm no referrals received)
* have an auditable system to ensure an appointment is allocated to all referrals received
* send invitation letters or appointments to women directly referred for colposcopy
* have a system to make sure women can have their appointment rebooked for a more suitable time
* send a letter to all women who do not attend for their appointment advising how they can be re-referred to colposcopy
* send a non-responder notification to the GP (or responsible clinician) and the laboratory if a woman does not attend a first appointment for colposcopy
* send a non-responder notification to the GP (or responsible clinician) and the laboratory if a woman does not attend a follow-up appointment for colposcopy
* have systems in place to make sure a result is received for all cervical screening or histology specimens taken in colposcopy
* send a clinician-validated template (see the colposcopy discharge notification template in [NHS Cervical Screening call/recall: guide to administrative good practice](https://www.gov.uk/government/publications/cervical-screening-call-and-recall-administration-best-practice)) of the next test due dates for all women discharged from the colposcopy clinic to the call and recall service and the laboratory
* keep records of communications from the call and recall service confirming receipt of the discharge template and make enquiries of the call and recall service if no receipt is received so that prompt action can be taken as needed
* inform the woman and her GP (or responsible clinician) of the future management plan for all women, make the appropriate arrangements for further colposcopy appointments where indicated (including MDT discussion and agreed outcome) or onward referral, and make sure the GP is aware that they will be responsible for future follow-up for women who are being discharged
* respond to failsafe enquiries by laboratories
* have a system in place to make sure women deferring appointments are re-invited at the correct interval
* perform a continuous audit (and produce audit reports) of referrals received against outcome to make sure all women are accounted for
1. **Self-sampling service model for the ISE (Purpose of the RFI)**

Primary HPV screening provides an opportunity to change the method of sample collection and allow people to self-collect a vaginal/urine sample at home via a self-sampling device. Self-sampling offers opportunities to engage eligible women and people with a cervix in the programme, reduce inequalities, increase participation, and continue to reduce the incidence of cervical cancers. The UK National Screening Committee has requested an in-service evaluation (ISE) is undertaken. The English NHS Cervical Screening Programme will be responsible for implementing the ISE using HPV self-sampling as a primary screening option for eligible people. The ISE will explore several issues including:

* the effect on uptake
* sensitivity for high grade cervical intraepithelial neoplasia (CIN2+)
* rate of uptake in under screened individuals
* rate of switching from clinician to self-sampling
* slightly reduced sensitivity of self-sampling against adherence to a follow up triage test that requires a clinician sample to be taken

The ISE will be an ethically approved research study nested in the English NHS Cervical Screening Programme. Participants will be recruited from the eligible screening population, potentially across the whole of England. More than one type of self-sampling device may be included in the ISE. It is anticipated that the ISE will commence in Autumn 2024.

Participants will be offered a choice of completing a self-sample or to attend for a clinician taken sample (normal care). This could be through an ‘opt in’ or ‘opt out’ regime. Those choosing to take a self-sample will require a kit, with instructions for use, to be mailed to their home address, if one hasn’t already been supplied with the invitation. Participants could also be required to opt out of receiving a self-sampling kit. Participants will complete their self-sample and either post the sample to the HPV screening laboratory in a pre-labelled envelope or return to the laboratory via their GP sample collection services. Participant details will be accessed from the NHS Cervical Screening Programme call and recall service/cervical screening management system.

The self-sampling pathway will negate the need for sample pots and sample taking by clinicians in primary care, for participants choosing to take a self-sample. Alternatively, the participant will be sent a self-sampling kit, or may collect a kit from their GP practice and/or third party supplier. When a participant tests positive for HPV, they will then be invited to attend their GP practice (or alternative provider) for a clinician taken sample. The clinician sample will be tested for HPV and if this is also positive a cytology test will be performed. Patient management will then be dependent on the results of the clinician taken sample according to national programme protocols. The number of individuals invited to complete a self-sample has yet to be agreed but will need to be sufficient to power evaluation studies.

The ISE may also include an opportunistic arm where individuals overdue for screening may be offered the chance to complete a self-sample by their GP practice, when attending their GP practice for another reason. This could involve the GP practice distributing self-sampling kits to patients or requesting a kit is delivered to their home address.

The provider of the self-sampling service model described in this document will be responsible for:

* self-sampling kit design (in line with NHS CSP requirements)
* kit assembly (including printing of supplementary contents and labelling)
* packaging and the accompanying kit instructions/letter
* distribution to participants opting for a self-sample, through interface/download from Cervical Screening Administration Service or ISE portal/app
* participant prompt/reminders
* provision of addressed envelope/packaging for onward postage of completed kit to the laboratory
* helpline for advice/replacement kits
	1. **In Service Evaluation Governance Chart**

