Healthcare Improvement Scotland | Evidence
Advice, guidance and intelligence

Cervical screening

Draft Standards

October 2024

NHS SCOTLAND

We are committed to advancing equality, promoting diversity and championing human rights. These standards are intended to enhance improvements in health and social care for everyone, regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socioeconomic status or any other status. Suggested aspects to consider and recommended practice throughout these standards should be interpreted as being inclusive of everyone living in Scotland.

We carried out an equality impact assessment (EQIA) to help us consider if everyone accessing health and social care services will experience the intended benefits of these standards in a fair and equitable way. A copy of the EQIA is available on request.

Healthcare Improvement Scotland is committed to ensuring that our standards are up to date, fit for purpose and informed by high quality evidence and best practice. We consistently assess the validity of our standards, working with partners across health and social care, the third sector and those with lived and living experience. We encourage you to contact the Standards and Indicators team at his.screeningstandards@nhs.scot to notify us of any updates that might require consideration.

Healthcare Improvement Scotland 2024

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Introduction

Background to the cervical screening standards

Despite generally being a preventable disease, cervical cancer remains a global health concern and is one of the most common cancers affecting women in Scotland.[1] On average, six women in Scotland are diagnosed with cervical cancer each week and cervical cancer accounts for 2% of all new cancer cases throughout the UK.[1, 2] It is predicted that approximately 50% of women diagnosed with cervical cancer will survive their disease for ten years or more.[1]

The aim of NHS cervical screening is to identify and treat changes in the cervix before cancer develops.[3]

The main risk factor for cervical cancer is infection with the human papilloma virus (HPV).[4, 5] Screening can detect changes even in the absence of symptoms, allowing early treatment.[6]

Regular screening is still required after vaccination with the HPV vaccine. This is because the HPV vaccine protects against many, but not all, of the different types of HPV virus that cause cancer.[7]

Scottish cervical screening programme

The Scottish Cervical Screening Programme (SCSP) is a population-based screening programme which aims to reduce mortality and incidence rates from cervical cancer.

NHSScotland offers cervical screening to women every five years, between the ages of 25 and 64 years. Every woman who is within the screening age range is eligible for NHS cervical screening regardless of their gender identity. Screening continues to be offered following a partial hysterectomy.[8, 9]

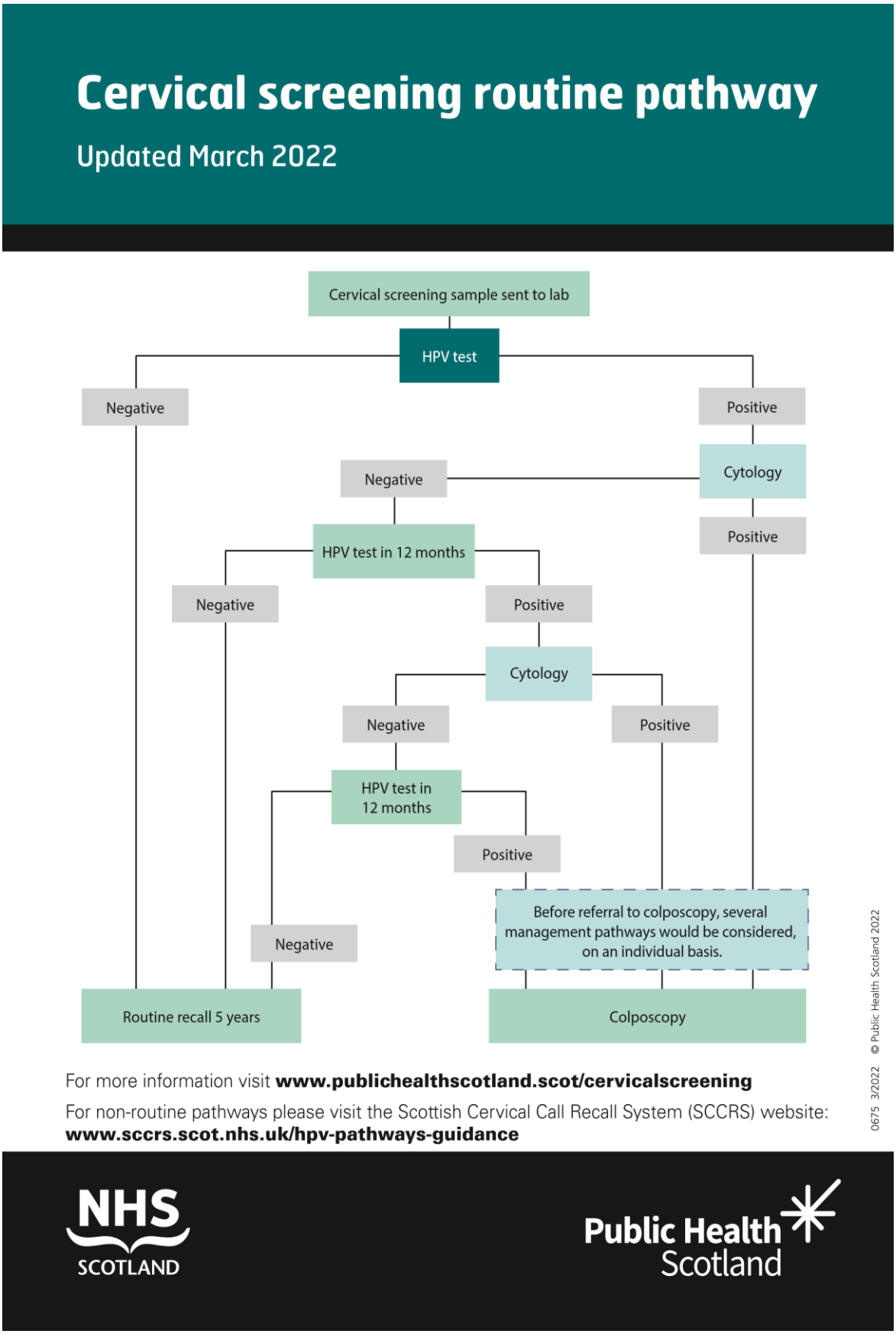
The cervical screening test, previously called a smear test, involves:

- primary HPV screening to identify people with HPV
- liquid-based cytology (if HPV is found) to detect and triage early abnormalities of the cervix, which if untreated may lead to cervical cancer.[6]

Further investigation includes colposcopy to diagnose and treat abnormal changes in the cells that line the cervix.

Figure 1 provides an overview of the routine pathway for cervical screening.

Figure 1: Cervical screening routine pathway



Public Health Scotland produces screening information to support health professionals, including informed decision making for the Scottish cervical screening programme. publichealthscotland.scot/cervicalscreening A toolkit is provided to support General Practitioners (GPs), practice nurses and other practice staff. This toolkit includes measures to optimise the uptake of cervical screening, reduce barriers and enable people to make an informed choice.[10]

Information to support informed choice for the public is available from nhsinform.scot/cervicalscreening.

Information is available in English and other languages, British Sign Language, audio, Easy Read and Large Print. The information covers the cervical screening pathway, details about the test, what the test results mean and what to expect if further investigation is required.[11] Women should be offered support to enable informed decision making, and given advice about how to access information in a format and language that is suitable for their needs.

Health inequalities

Health inequalities are the unfair and avoidable differences in the health of individuals or groups within a population. Health inequalities can affect how people engage with the SCSP across all parts of the cervical screening pathway. The Scottish Government has set an ambition to encourage and support people to reduce their risk of cancer by living healthier lives, through the reduction of health inequalities and improving access to screening.[3]

The Scottish Equity in Screening Strategy 2023-26 aims to reduce inequalities across the screening pathway.[3] It seeks to achieve equity of opportunity to access screening, and equal benefit from screening for all eligible individuals.

Screening policy and strategy in Scotland

Many stakeholders participate in the strategic and operational delivery of screening programmes across Scotland, including the Scottish Government, the Scottish Screening Committee (SSC) and NHS boards. The Scottish Government sets screening policy for Scotland and approves policy changes, taking into consideration recommendations for new and existing programmes from the UK National Screening Committee, and the advice of the SSC. Key partners include NHS National Services Scotland, PHS, and NHS Education for Scotland. Further information on the roles and responsibilities of these stakeholders and on national screening governance structures can be found in National screening oversight: A guide to population screening in Scotland.

Related guidance and policy

The standards for cervical screening should be read alongside other relevant legislation and guidance including, but not limited to:

- Adults with incapacity (Scotland) Act 2000[12]
- Cancer strategy for Scotland 2023-2033[13]
- Healthcare Improvement Scotland learning from adverse events framework[14]
- Health and social care standards[15]
- National health and wellbeing outcomes[16]
- National screening oversight: A guide to population screening in Scotland[17]
- NHS Scotland climate emergency and sustainability strategy 2022-2026[18]
- Organisational duty of candour guidance[19]
- Realistic medicine: taking care[20]
- Scotland's public health priorities[21]
- Women's health plan[22]
- Other related Healthcare Improvement Scotland guidance, including SIGN guidelines and cervical cancer clinical quality performance indicators.[23, 24]

Key performance indicators for SCSP

Key Performance Indicators (KPIs) for the SCSP are developed, reviewed and monitored by the Quality Performance Monitoring Group (QPMG).[24] The cervical screening standards do not reference the specifics of each KPI but should be read alongside the KPIs. The KPIs provide a retrospective assessment of the effectiveness of screening, evaluating quality and performance. KPIs act as a driver for continuous improvement and direct specific review of any areas that appear to be underperforming.

The KPIs are reported annually by PHS, reviewed by the SCSP's QPMG and reported to the SCSP's programme board.[24]

Scope of the cervical screening standards

The cervical screening standards have been developed to ensure that there is a consistent and equitable approach to the provision and monitoring of the cervical screening pathway in Scotland.

The standards are consistent with the SCSP participant pathway and apply to all organisations involved in the delivery of cervical screening.[25]

The standards cover the following areas:

- call-recall
- attendance and uptake
- sample taking
- laboratory services
- colposcopy.

Throughout the standards, the terms **woman** and **women** are used to refer to people with a cervix. This includes transgender, non-binary and intersex people.

Healthcare Improvement Scotland's core screening standards for Scottish screening programmes

In 2023, Healthcare Improvement Scotland, in partnership with stakeholders, developed core screening standards for the national screening programmes in Scotland. These core screening standards apply to all screening programmes in Scotland, minimising duplication and supporting consistency. The core screening standards cover leadership and governance, training and education, and information and support.

Note: The cervical screening standards should be read and applied in conjunction with the core screening standards.

Format of the standards

Healthcare Improvement Scotland standards follow the same format. Each standard includes:

- an overarching standard statement of the level of performance to be achieved
- a rationale explaining why the standard is important
- a list of criteria describing what is needed to meet the standard
- what the standards mean if you are a person participating in the cervical screening programme
- what the standards mean if you are a member of staff
- what the standards mean for organisations
- examples of how the standards should be achieved in practice.

Further information about the development of the standards is available in Appendix 1 and the standards development group membership is outlined in Appendix 2 .

Implementation

The standards for cervical screening have been developed in collaboration with key stakeholders from the cervical screening participant pathway. The standards support and inform organisational self-evaluation and improvement.

Implementation of the standards by the SCSP and NHS boards will ensure the delivery of safe, effective and person-centred services across the cervical screening pathway.

Quality of care approach and framework

The cervical screening standards are a key component in supporting the approach of the SCSP to quality assurance. Monitoring performance against these standards, at a local and national level, aims to improve the quality of the SCSP.

External quality assurance (EQA) of screening programmes will be delivered using the Healthcare Improvement Scotland quality assurance system and framework. This approach specifies how Healthcare Improvement Scotland will design and deliver EQA activity to support improvement in healthcare.

The approach emphasises the importance of regular, open and honest programme self-evaluation, using the quality framework as a basis. This should be combined with other relevant data and intelligence, including performance against these standards.

Healthcare Improvement Scotland quality management system

The Healthcare Improvement Scotland Quality Management System Framework supports health and social care organisations to apply a consistent and coordinated approach to the management of quality in health and care services. More information about this framework is available on the HIS website.

Terminology

Wherever possible, we have used generic terminology, which can be applied across the cervical screening pathway. The following terms are used throughout this document:

Carer/representative refers to the person whom the individual wishes to be involved in their care.

Cervix is the lower part of the uterus (womb) that connects the uterus to the vagina (birth canal).

Cervical screening (previously known as a **cervical smear**) refers to the process of taking a sample from the cervix, which is examined in the laboratory for the presence of HPV. The process usually takes less than 15 minutes and can be performed at a cervical screening clinic or GP practice. If HPV is found, the same sample will be examined for cell changes.

Colposcopy is a procedure performed to identify and treat abnormal cells in the cervix or vagina of an individual. It might be required after a routine cervical screening test.

Failsafe refers to the processes designed to ensure that all aspects of the screening pathway are safe and effective, with appropriate mechanisms in place to manage potential issues or adverse events.

Human papillomavirus (HPV) is a common virus which usually does not produce symptoms and clears up quickly in most people. Persistent infection with HPV increases the chance of developing certain types of cancer, including cervical cancer.

Participant/person/people refer to individuals with a cervix or part of a cervix, who access services and receive care or support across the cervical screening pathway. This includes women, transmen, non-binary and intersex people who are eligible for cervical screening.

Patient refers to a person who has a positive screening result and has been referred for further assessment and investigation.

Primary Care refers to the first point of contact with the healthcare system and includes general practice.

Sample taking involves the gentle insertion of a speculum into the vagina to softly brush cells from the cervix for testing.

SCSP Pathway refers to the Scottish Cervical Screening Programme participant pathway, from the identification of those eligible for cervical screening through to discharge, or referral to oncology or gynaecology services.

Under-served groups refers to people who experience social inequality, stigma, discrimination or lack of opportunity, which makes it difficult for them to access services or make an informed choice. This includes people from certain communities and socioeconomic groups, as well as people with disabilities or gender reassignment.

How to participate in the consultation process

We welcome feedback on the draft standards and will review every comment received. We use different methods for consultation, including:

- online and face-to face focus groups across Scotland
- meetings and events to raise awareness and listen to feedback
- an online survey tool: https://www.smartsurvey.co.uk/s/0F85NQ/

Submitting your comments

Responses to the draft standards should be submitted using our online survey: https://www.smartsurvey.co.uk/s/0F85NQ/

The consultation closes on **26 November 2024.** If you would like to submit your comments using a different format, please contact the project team on his.standardsandindicators@nhs.scot.

Consultation feedback

At the end of the consultation period, all comments will be collated, and the project group will respond to each comment received on the draft standards. The response will explain how the comments were considered in producing the final standards.

A summary of the responses to the consultation will be made available on the Healthcare Improvement Scotland website (www.healthcareimprovementscotland.scot).

The final standards will be published in **March 2025.**

Summary of standards

Standard 1: Call-recall

NHS boards ensure all eligible women are invited for cervical screening.

Standard 2: Attendance and uptake

Cervical screening is accessible to all eligible women.

Standard 3: Sample taking

Sample taking is accessible, safe, effective and person-centred.

Standard 4: Laboratory services

All laboratories involved in cervical screening services conform to nationally agreed standards.

Standard 5: Colposcopy

All women have timely access to safe and effective colposcopy services when needed.

Standard 1: Call-recall

Standard statement

NHS boards ensure all eligible women are invited for cervical screening.

Rationale

An effective call-recall system ensures that all eligible women are invited to participate in cervical screening, regardless of whether they are registered with a GP practice. It also allows the tracking and follow-up of women whose results require further investigation.[25]

Call-recall is managed through the Scottish Cervical Screening Call-Recall System (SCCRS).

Women are eligible for routine cervical screening every five years if they are between 25 and 64 years of age. If previous screening results have shown changes that require further investigation or follow-up, the woman will be included on the non-routine cervical screening pathway and invited for screening up to and including 70 years of age.[26]

Each NHS board should ensure that robust and resilient governance arrangements are in place for the effective delivery of a call-recall system. There should be resilience within the call-recall staffing structure.

The effectiveness of the call-recall system should be monitored and reviewed. The NHS board should have established systems and processes for the management and reporting of screening incidents and adverse events.

Inequalities in access to cervical screening should be addressed at both a national and local level.

The invitation for screening includes information about cervical screening and how to access sample taking. Further information is also available from NHS inform cervical screening page.

Clearly defined processes should ensure that women who are not resident at their registered address have access to screening. This includes women in long-stay care settings or in prison. Women who are homeless should also have access to screening.

Women can choose to opt out of the screening programme at any time. Unless they request otherwise, all eligible women will be reminded at regular intervals that they can still attend for sample taking at any time. If a woman opts out of screening, her GP should be notified. The reasons for exclusion from the screening programme should be documented.

Criteria

1.1 NHS boards ensure that the cervical screening delivered within their board is quality assured to ensure safe practice.

1.2 NHS boards ensure that nationally agreed protocols, and locally agreed standard operating procedures (including failsafe mechanisms), are adhered to by all staff involved in call-recall.

1.3 Arrangements are in place to offer screening to all eligible women, including those who:

- are registered with a GP practice
- are not registered with a GP practice
- reside in Ministry of Defence accommodation
- reside in long-stay care settings or prisons
- are registered in Scotland and living in England
- belong to under-served groups.

1.4 SCCRS:

- routinely invites all eligible women for cervical screening in accordance with nationally agreed intervals
- recalls all eligible women who have not responded to cervical screening invitations
- ensures that eligible women who opt out of screening remain on the call-recall system and are aware that they can still attend for screening if their decision changes.

1.5 Invitation letters from SCCRS should include:

- the benefits and risks of cervical screening
- how to access further information, particularly if this is required in an alternative language or format.

1.6 NHS boards use a standardised format to clearly record the reasons for all exclusions from cervical screening.

1.7 SCCRS regularly monitors and reviews the call-recall process, including uptake of screening.

What does the standard mean for the person taking part in cervical screening?

You can be confident that, if you are eligible for cervical screening, you will be:

- routinely invited to participate every five years between your 25th and 64th birthdays
- offered screening up to and including your 70th birthday, if changes were detected by your previous screening test
- able to access information about cervical screening in a suitable language and format
- offered the opportunity to ask questions about cervical screening or discuss opting out
- able to opt out of the screening programme, and you will still have the option to attend for screening at another time, if you change your mind.

What does the standard mean for staff?

Staff, in line with their role, responsibilities and workplace setting understand:

- the eligibility criteria for cervical screening, including the process for opting out and the option to attend for sample taking at another time
- the governance structures of the SCSP[27]
- the call-recall system, protocols and pathways
- failsafe procedures, including the escalation pathway[17]
- processes for monitoring, reporting and reviewing the call-recall system for their local eligible population.

What does the standard mean for NHS boards and primary care organisations?

NHS boards and primary care organisations, in line with their governance and delivery responsibilities ensure:

- cervical screening is accessible to all eligible women
- governance arrangements are in place for the effective delivery of a call-recall system
- opportunities for women who opt out to review and change their decision
- monitoring and review of the call-recall system
- failsafe and escalation procedures exist, including action plans to manage identified issues or concerns[28]
- resilience in the staffing structure for call-recall.

Examples of evidence for meeting this standard *(NOTE: this list is not exhaustive)*
• Inclusive national protocols for inviting anyone who is eligible to participate in cervical screening. • Protocols for information sharing between staff, which are compliant with General Data Protection Regulations (GDPR). • Records of the number of people who did not attend for screening and exclusions from the screening programme. • Evidence of effective failsafe arrangements and incident reporting. • Action plans demonstrating adherence to Healthcare Improvement Scotland's core screening standards • Assessment of call-recall performance management at NHS board level.

Standard 2: Attendance and uptake

Standard statement

Cervical screening is accessible to all eligible women.

Rationale

NHS boards have a responsibility to ensure cervical screening services are accessible to all eligible women, including those with protected characteristics.[29-31] The benefits of screening should be maximised by identifying and addressing barriers across the entire screening pathway.[32]

Clear information about cervical screening supports women to make informed decisions to participate.[33] Health inequalities can be addressed by raising awareness of cervical screening amongst women within under-served groups, who may be at greatest risk of cervical cancer.[34] Under-served groups include people with learning and physical disabilities, minority ethnic groups, travelling communities, LGBT+ communities and people who reside in areas of deprivation, long-stay care settings or prisons.

NHS boards should identify groups in their area with low participation rates and direct resources to maximise the uptake of screening.[35] Consideration should be given to the provision of appointments dedicated to specific under-served groups.[36] Increased participation might also be achieved by sending personalised letters and providing appointments for screening as soon as practicable after receipt of the invitation.[37]

Healthcare Improvement Scotland's core screening standards address inequalities in screening and support the delivery of effective screening programmes that meet the requirements of all women.[28]

Access to sample taking should be provided for women who require additional support. This includes, but is not limited to, under-served groups, women who require trauma informed care and women with specific needs such as a translator or additional equipment.

Regular feedback from different population groups supports service improvement and equity of access. NHS boards should work in partnership with other service providers to reduce the number of women who do not attend and monitor women who might be excluded from cervical screening.

Criteria

2.1 NHS boards and primary care ensure:

- cervical screening services are accessible to all eligible women
- health inequalities are addressed within under-served groups
- eligible women are provided with the opportunity to discuss their decision about participating in screening and their options if they decide to opt out.

2.2 NHS boards and primary care organisations maximise uptake of cervical screening by:

- identifying groups with low participation rates and targeting resources to increase uptake
- providing a wide selection of appointment times
- obtaining regular feedback from different population groups to support service improvement and equity of access
- working in partnership with other service providers to increase the uptake of screening
- reviewing and monitoring eligible women who might be excluded from cervical screening.

2.3 NHS boards and primary care organisations ensure access to sample taking for women who require additional support, such as clinics which:

- are dedicated to under-served groups
- offer translation services
- offer a female sample taker
- provide a trauma informed service
- provide extra time and additional equipment to facilitate the procedure.

What does the standard mean for the person taking part in cervical screening?
You can be confident that, if you are eligible for cervical screening, you will: • have access to sample taking • be able to request a sample taking appointment that is appropriate for your specific needs • be offered the opportunity to discuss your decision on participating in screening • be able to review your options and change your mind at any time • be asked to provide feedback about the service that you receive.
What does the standard mean for staff?
Staff, in line with their role, responsibilities and workplace setting: • understand and take measures to maximise attendance for cervical screening • can support eligible women to participate in cervical screening and advise about their options if the decision is made to opt out of screening.
What does the standard mean for NHS boards and primary care organisations?
NHS boards and primary care organisations, in line with their governance and delivery responsibilities ensure: • timely access to cervical screening appointments following receipt of invitation, to encourage participation • collaboration with other service providers and stakeholders to increase participation within under-served groups • collection of feedback to increase uptake by identifying barriers to screening • provision of clear information for women who opt out, and support for them to attend for sample taking at another time, if they change their decision.

Examples of evidence for meeting this standard *(NOTE: this list is not exhaustive)*
• Documentation of needs assessment for under-served groups. • Audit of uptake and attendance for screening including, but not confined to, measures of deprivation. • Evidence of efforts to maximise uptake, including use of personalised letters and provision of pop-up clinics, as well as provision of specific arrangements for under-served groups. • Evidence of data sharing with Health and Social Care Partnership colleagues to direct resources towards areas with low participation rates. • Feedback from service users.

Standard 3: Sample taking

Standard statement

Sample taking is accessible, safe, effective and person-centred.

Rationale

All eligible women should have timely access to cervical screening sample taking (previously called cervical smear) following receipt of an invitation or reminder.[38] If required, appropriate support should be provided for women to attend for sample taking.

Facilities that provide sample taking should comply with nationally agreed standards and guidance. All organisations providing cervical screening, including NHS boards and primary care, are responsible for the provision of appropriate and accessible facilities. The NHS board should ensure adequate supplies of sample taking consumables are provided to all facilities.

Equipment and staffing should be adequate to ensure participant safety, comfort and privacy during sample taking. Participants should always be treated with dignity and respect.

Healthcare professionals who take cervical screening samples should receive appropriate training.[39] The sample taker must be a registered healthcare professional who has completed a recognised education programme for cervical screening.[39]

Both the employing organisation and the individual sample taker are responsible for ensuring that appropriate levels of competency for sample taking are maintained by staff within primary care. If the primary care organisation is not able to provide an appropriately trained sample taker, arrangements should be made for the participant to attend an alternative healthcare facility at the earliest opportunity.

Before sample taking is performed, informed consent should be obtained from the participant, including consent to access any previous health information. The participant should be given a clear explanation of the test, provided with an opportunity to ask questions, and offered a chaperone during the procedure.

Participants should be notified of the test result within nationally agreed timelines. Systems and processes should exist to ensure timely transfer of information from SCCRS to GP information systems. Participant data should be appropriately shared between healthcare organisations, in accordance with GDPR.

There should also be established protocols for exclusion from routine screening during pregnancy and also following pelvic surgery or radiotherapy.

Sample taking and colposcopy may still be required during pregnancy as part of the non-routine screening pathway, as advised by the Royal College of Obstetricians & Gynaecologists

Appropriate systems and equipment should be available to undertake the sample taking procedure for participants with additional requirements. Procedures should exist to accommodate requests for a female sample taker, as well as to provide access to sample taking within a specialist centre, if required.

If the participant has symptoms of cervical cancer and the cervix appears abnormal, a cervical screening sample may still be taken. The woman should immediately be referred for colposcopy and advised to attend the appointment even if she receives a negative cervical screening result.[40]

Although there are studies on the use of self-sampling tests for HPV as a method for increasing participation in cervical screening, self-sampling is not currently part of the national cervical screening programme in Scotland.[41]

Criteria

3.1 NHS boards and primary care organisations ensure that:

- cervical screening sample taking is timely and accessible for anyone who is eligible
- participants are given a clear explanation of the test, provided with an opportunity to ask questions and offered a chaperone during the procedure.

3.2 NHS boards and primary care organisations ensure that staff involved in cervical screening sample taking:

- are registered healthcare professionals who have completed a recognised education programme for cervical screening
- receive appropriate training in the technique of sample taking and the use of relevant equipment, in accordance with national guidelines
- attend regular updates courses, at least every three years, to maintain their knowledge and skills
- engage in ongoing quality assurance processes
- understand and effectively use SCCRS, in line with their roles, responsibilities and workplace setting.

3.3 Sample taking is performed in an appropriate, accessible, safe and private clinical environment.

3.4 NHS boards and primary care organisations ensure access to sample taking within a specialist facility for anyone who requires an alternative method of sample taking.

3.5 Systems and processes exist for the detection and appropriate management of screening samples that are insufficient for analysis, inadequately labelled, or collected in containers that have exceeded their expiration date.

What does the standard mean for the person taking part in cervical screening?
You can be confident that, if you are eligible for cervical screening, you will: • be treated with dignity and respect • able to request a timely appointment at a clinic with appropriate facilities, equipment and staffing • be given a clear explanation of the test, provided with an opportunity to ask questions and offered a chaperone during the procedure • be asked to give your consent, which can be withdrawn at any time during the procedure, if you change your mind • have your cervical screening sample (smear test) taken by an appropriately trained healthcare professional • be offered an alternative method for sample taking, if required • receive the results of your test within nationally agreed timelines.
What does the standard mean for staff?
Staff, in line with their role, responsibilities and workplace setting: • treat participants with dignity and respect • demonstrate the knowledge and skills required to provide safe and effective sample taking • attend appropriate training and regular updates on sample taking • ensure accurate documentation of discussions prior to sample taking, as outlined in the sample taker guidance • ensure timely and accurate input of relevant information to SCCRS • are encouraged to identify areas of improvement and report these within the appropriate governance framework.

What does the standard mean for NHS boards and primary care organisations?

NHS boards and primary care organisations, in line with their governance and delivery responsibilities ensure:

- sample taking is accessible to all eligible women who wish to participate in cervical screening
- facilities, equipment and staffing levels comply with nationally agreed standards and requirements for safe and effective cervical screening sample taking
- robust systems are in place for the distribution of sample taking consumables
- cervical screening samples are taken by registered healthcare professionals who have completed a recognised education programme for cervical screening
- an alternative method for sample taking is available to women with additional requirements, if necessary
- participants receive appropriate information and provide their consent prior to sample taking
- participants receive the results of their screening test within nationally agreed timelines.

Examples of evidence for meeting this standard *(NOTE: this list is not exhaustive)*

- Evidence of provision of appropriate support for participants to attend for cervical screening sample taking.
- Evidence of staff qualifications, competencies and continued professional development.
- Evidence of identification and management of samples that are insufficient for analysis, inadequately labelled or collected in containers that have exceeded their expiration date.
- Evidence that data is appropriately shared between healthcare organisations, in accordance with GDPR.
- Feedback from participants and carers or representatives.

Standard 4: Laboratory services

Standard statement

All laboratories involved in cervical screening services conform to nationally agreed standards.

Rationale

All laboratories involved in cervical screening require formal United Kingdom Accreditation Service (UKAS) accreditation to the International Standardisation Organisation (ISO) standard 15189. The laboratory structure for cervical screening in Scotland consists of processing laboratories, non-processing laboratories and the HPV reference laboratory (HPVRL). Further information about the structure and functions of the laboratory service is available in Appendix 4.

Processing laboratories should have HPV and cytology testing included in their scope of practice, as agreed with UKAS. There should be an established quality management system (QMS) for both processing and non-processing laboratories.[42-44]

It is essential for each processing laboratory to provide evidence of participation and satisfactory performance in national quality assurance schemes, including the gynaecological cytopathology external quality assessment scheme.

Clinical governance processes ensure that cervical screening tests are processed with high reliability and accuracy. The employer is responsible for maintaining adequate levels of staff and professional registration, in accordance with national guidance.

Each laboratory should have a designated clinical lead. The clinical lead, and lead biomedical scientist in the processing labs, have responsibility for ensuring the delivery of both the HPV primary screening test and the cytology triage test for those cases that are HPV positive. The processing laboratory clinical lead will be the primary point of contact for any queries about samples or results.

Accurate input of laboratory data to SCCRS is the responsibility of all the laboratories involved in screening. Systems and processes should be in place to ensure that cervical screening test results are received by the participant within nationally agreed timelines, with GP systems updated accordingly by SCCRS.

All laboratories involved in screening should work collaboratively with other clinical departments, including colposcopy, gynaecology, histopathology and the Scottish HPV Reference Laboratory. This will allow shared learning by facilitating appropriate laboratory

staff participation in multidisciplinary team (MDT) meetings, National Invasive Cancer Audit (NICA) reviews and other relevant forums such as local working groups.

The SCSP should be notified of any QMS issues relating to the cervical screening laboratory service.[45]

Criteria

4.1 All laboratories involved in cervical screening:

- demonstrate formal accreditation to the ISO 15189 standard
- have HPV and cytology testing included in their scope of practice agreement, if they are involved in processing samples
- ensure implementation of an effective QMS.

4.2 All processing laboratories demonstrate participation and satisfactory performance in the relevant External Quality Assessment (EQA) schemes.

4.3 Each laboratory has a designated clinical lead for cervical screening.

4.4 All laboratories ensure a workforce with the required mix of skills and expertise in virology, molecular virology, cervical cytology and pathology.

4.5 All laboratory staff are trained to the required standards of competence, and undertake ongoing training, supervision and assessment, appropriate to their roles, to ensure maintenance of skills and competencies.

4.6 All laboratories have processes in place to ensure:

- monitoring and recording of samples that are insufficient, inadequately labelled or collected in expired containers
- accurate input of laboratory, biopsy and hysterectomy data to SCCRS.

4.7 Cervical screening samples are effectively tested for HPV and examined for cell changes, if appropriate.

4.8 Cervical screening test results are reported to the participant and their GP within nationally agreed timelines, with recommendations provided on the next steps for the participant.

4.9 Screening laboratory QMS issues are constantly monitored, with timely reporting of any relevant issues to SCSP.

4.10 All laboratories work collaboratively with other clinical departments, including colposcopy, gynaecology, histopathology and the Scottish HPV Reference Laboratory, to promote exchange of information and shared learning.

What does the standard mean for the person taking part in cervical screening?
You can be confident that: • your cervical screening sample will be accurately examined in an accredited laboratory • your sample will be tested for HPV and examined for cell changes, if appropriate • you will receive your test results within nationally agreed timelines • you will be advised about what you need to do next, based on your test results.
What does the standard mean for staff?
Staff, in line with their role, responsibilities and workplace setting: • understand and work within the appropriate standards for HPV and cytology testing • ensure that cervical screening tests are processed with high reliability and accuracy • understand the importance of timely reporting of results and recommendations • ensure the accurate input of data to SCCRS.
What does the standard mean for NHS boards and primary care organisations?
NHS boards and primary care organisations, in line with their governance and delivery responsibilities: • demonstrate participation and satisfactory performance in the relevant EQA schemes • have clinical governance processes in place to ensure that cervical screening tests are processed with high reliability and accuracy • maintain adequate levels of staff and professional registration, in accordance with national guidance • ensure that each laboratory has a designated clinical lead • ensure that adequate supplies of sample taking consumables are maintained within specified expiry dates • ensure accurate and timely communication of results to participants • ensure accurate input of data to SCCRS.

Examples of evidence for meeting this standard *(NOTE: this list is not exhaustive)*

- Evidence of UKAS accreditation, or equivalent.
- Evidence of QMS.
- Documentation of laboratory participation in the relevant EQA schemes.
- Regular reporting of Internal Quality Control information and screening test performance within processing laboratories.
- Demonstration of procedures to detect, report and manage issues relating to quality.
- Evidence of staff qualifications, competencies and continued professional development.
- Regular data collection and audit of unsatisfactory (incomplete, spoiled or expired) samples, and actions taken.
- Audit of data entered to SCCRS following biopsies and hysterectomy.

Standard 5: Colposcopy

Standard statement

All women have timely access to safe and effective colposcopy services when needed.

Rationale

An effective cervical screening programme requires an accessible colposcopy service to assess and treat abnormalities of the cervix and lower genital tract. This will reduce the incidence of cervical cancer, and the mortality associated with its development.[46]

Women are referred to the colposcopy service for assessment following abnormal cervical screening test results, or when there is concern about the appearance of the cervix. Colposcopy may also be required if repeated screening tests have been inconclusive or if the woman has symptoms of cervical cancer.[47]

Women referred for colposcopy following an abnormal screening test result should receive an appointment within nationally agreed time frames, together with information about the procedure in an appropriate language and format.[28]

The colposcopy procedure is usually performed within a specialised clinic setting, which might be in a hospital or a community healthcare facility. Colposcopy clinics should provide an accessible, safe environment with areas for private consultation and assessment, as well as changing facilities for patients.

Healthcare professionals who perform colposcopies should be appropriately trained. The colposcopist must be a registered healthcare professional who has completed a recognised education programme suitable for the role.[48]

Appropriate systems and equipment should be available to facilitate colposcopy for patients with additional requirements. Trauma informed care should be implemented in recognition and response to the impact of prior traumatic experiences. Procedures should exist to accommodate requests for a female colposcopist, as well as to provide access to colposcopy within a specialist centre, if required.

Before the procedure, the colposcopist should ask about the patient's medical history and any current medication. The patient should receive a clear explanation of the colposcopy procedure, including the benefits and risks. The potential requirement for biopsy and treatment during the procedure should also be discussed, with an opportunity provided for the patient to ask questions. Consent should then be obtained for the procedure.

Abnormal cells on the cervix are usually identified immediately during colposcopy, although biopsies may be required to confirm the diagnosis. If treatment is required, this is often

performed at the same time as colposcopy. Patients should be invited for follow-up screening to determine the success of the colposcopy.

Biopsy samples should be analysed and reported by a UKAS accredited laboratory within nationally agreed timelines. A copy of the colposcopy results should be communicated to both the patient and their GP or referring healthcare professional. In all cases of cervical cancer, NHS boards should ensure accurate completion of the NICA within nationally agreed timelines. If the patient requires further treatment in a hospital operating theatre, a referral should be made to oncology or gynaecology services.

Colposcopy services should provide a mechanism to facilitate multidisciplinary discussion of complex cases and cancer cases. Collection of data on the National Colposcopy Clinical Information and Audit System (NCCIAS) is also important to allow participation in national audits.[48]

A risk reporting system should be in place to allow investigation of issues arising during colposcopy procedures.[48]

Systems and processes should also exist to follow-up and contact the GP of patients who do not attend their colposcopy appointment.

Criteria

5.1 All women who require colposcopy have timely access to safe and effective colposcopy services, for assessment and treatment during cervical screening.

5.2 Clear pathways and protocols exist for referral of patients requiring colposcopy assessment following abnormal cervical screening results.

5.3 Patients referred to the colposcopy service receive clear information explaining:

- why the colposcopy is required
- what can be expected from the colposcopy appointment
- how to contact the colposcopy facility about the appointment
- details of any potential treatment plans.

5.4 Patients with an abnormal cervical screening test result are offered an appointment with the colposcopy service within nationally agreed time frames.

5.5 Staff working within colposcopy services:

- receive training and updates in the use of SCCRS, appropriate to their roles and responsibilities
- ensure that timely, relevant and accurate data is entered to SCCRS, allowing patients to be placed on the correct care pathway.

5.6 Colposcopy clinics:

- provide an accessible, safe environment with areas for private consultation, changing and assessment
- implement trauma informed care

5.7 Effective processes exist to follow-up patients who do not attend for colposcopy.

5.8 NHS boards:

- have a designated clinic lead for colposcopy, who has protected time and administrative support for identification and review of NICA cases
- ensure all colposcopies are performed by registered healthcare professionals who have completed a recognised education programme suitable for the role.[48]
- ensure timely and accurate completion of the NICA
- participate in national audit systems, such as the NCCIAS, to quality assure colposcopy services
- ensure risk reporting and investigation of issues that arise during colposcopy
- provide opportunities and regular protected time for colposcopy staff to attend multidisciplinary meetings for discussion of cases that involve cancer or other complexities
- ensure that clear information is provided to the patient, explaining the outcome of the colposcopy, any post-colposcopy care required, and the reason for any subsequent investigation or referral to other services
- ensure timely communication of the colposcopy report to the patient's GP, together with details of any further referral or treatment plans, including anticipated time frames.

What does the standard mean for the person taking part in cervical screening?
You can be confident that you will: • be treated with dignity, respect and compassion • be offered an effective colposcopy assessment that is right for you • receive information about what to expect at your colposcopy appointment • be assessed and treated by an appropriately trained healthcare professional • be offered the opportunity to ask the colposcopist questions before your procedure • be asked to give your consent before your colposcopy is performed • receive the results of your colposcopy as soon as possible, together with information about any further treatment you may require.
What does the standard mean for staff?
Staff, in line with their role, responsibilities and workplace setting: • treat patients with dignity, respect and compassion • demonstrate the knowledge and skills required to provide a safe and effective colposcopy service • understand the importance of documenting discussions and obtaining consent prior to colposcopy • are encouraged to identify areas of improvement and report these within the appropriate governance framework • provide timely results to the patient and the referring healthcare professional • follow-up patients who do not attend their colposcopy appointment • are provided with opportunities and protected time to attend multidisciplinary meetings.

What does the standard mean for NHS boards?

NHS boards, in line with their governance and delivery responsibilities:

- ensure timely access to safe, effective and trauma informed colposcopy services for all referred patients
- ensure governance arrangements are in place for the delivery of a safe and effective colposcopy service
- ensure that colposcopies are performed by appropriately trained and competent healthcare professionals
- have effective systems and processes in place to determine roles, responsibilities and lines of accountability, including for the management of adverse events
- have failsafe and escalation procedures, including action plans for the management of identified issues or concerns
- ensure that the results of colposcopy and proposed treatment plans are communicated to the patient and referring healthcare professional within nationally agreed timelines
- have effective systems for the management of patients reviewed at the NICA
- arrange to follow-up patients who do not attend their colposcopy appointment.

Examples of evidence for meeting this standard *(NOTE: this list is not exhaustive)*

- Audit of patients referred for colposcopy following abnormal cervical screening results.
- Documentation describing lines of accountability, roles and responsibilities, and escalation of adverse events.
- Evidence of systems for reporting, reviewing and learning from all types of adverse events.
- Measurement of performance against national standards.
- Evidence of participation in national audit systems, such as NCCIAS.
- Feedback from patients, carers and staff members.
- Evidence of follow-up of patients who do not attend for colposcopy.
- Documentation of NICA and MDT meetings.
- Records of staff attendance at MDT meetings.

Appendix 1: Development of the standards for cervical screening

The standards for cervical screening were developed in accordance with current evidence, best practice recommendations and group consensus.

Evidence base

A review of the literature was carried out using an explicit search strategy devised by an Evidence and Information Scientist from the Research and Information Service. Databases searched include Medline and the Cochrane Library. The year range covered was 2015-2024.

Additional internet searches were carried out on various websites including SIGN, NICE, NHS Evidence and Department of Health websites. The main searches were supplemented by material identified by individual members of the development group. This evidence was also used to inform equalities impact assessments.

Development activities

A standards development group, chaired by Allan Wilson, Consultant Biomedical Scientist, University Hospital Monklands, was convened in **July 2024** to consider the evidence and to review the 2019 standards for cervical screening.

The standards for cervical screening were developed in association with the core screening standards.

Membership of the development group is outlined in Appendix 2.

Each standard reflects the views and expectations of people accessing cervical screening services, healthcare staff, third sector representatives and members of the public. Information has been gathered from various sources and activities, including:

- two development group meetings in July and September 2024
- engagement activities with people with lived/living experience.

Consultation feedback and finalisation of standards

Following consultation, the standards development group will reconvene to review all comments received and make final decisions and changes. More information can be found in the consultation feedback report which will be available at: www.healthcareimprovementscotland.scot/ on publication of the final standards.

Quality assurance

All development group members were responsible for advising on the professional aspects of the standards. Clinical members of the development group also advised on clinical aspects of the work. The chair had lead responsibility for providing formal clinical assurance of the standards for cervical screening. The chair approved the technical and professional validity of the standards, as well as the acceptability of any reports or recommendations from the group.

All development group members made a declaration of interest at the initial stages of the project. Members also reviewed and agreed to the Terms of Reference for the project. Further details about quality assurance are available on request from: his.standardsandindicators@nhs.scot

Healthcare Improvement Scotland performed a final review of the draft standards document to ensure that:

- the standards were developed according to agreed Healthcare Improvement Scotland methodologies
- the draft standards document addresses the areas to be covered within the agreed scope
- the risk of bias was minimised throughout the process of standards development.

For more information about the role, direction and priorities of Healthcare Improvement Scotland, please visit: Healthcare Improvement Scotland .

Appendix 2: Membership of the cervical screening standards development group

Name	Position	Organisation
Allan Wilson (Chair)	Consultant Biomedical Scientist – Pathology	NHS Lanarkshire
Julie Anderson	Portfolio Manager – Screening Services	NHS National Services Scotland
Julieann Brennan	Screening Coordinator	NHS Borders
Celia Briffa Watt	Consultant in Public Health	NHS Lanarkshire
Maggie Cruikshank	Professor in Gynaecology	NHS Grampian
Lucia Codron	General Practice Nurse and Programmer Officer	Tweeddale Medical Practice and NHS Education for Scotland
Kate Cuschieri	Director, Scottish HPV Reference Laboratory	NHS Lothian
Heidi Douglas	Consultant in Public Health	NHS Tayside
Sharon Hanley	Senior Lecturer (Public Health)	University of Aberdeen
Chloe Kelly (until August 2024)	National Screening Programmes Policy Advisor	Scottish Government
Athena Lamnisos	Chief Executive	Eve Appeal
Sari Lievonen	Programme Officer (Practice Management Team)	NHS Education for Scotland
Isabell MacInnes	Health Protection and Screening Nurse Specialist	NHS Western Isles
Diane MacMichael	Specialist Lead General Practice Nurse – Continuing Professional Development	NHS Education for Scotland
Sue Mehew	Consultant Healthcare Scientist in Gynaecological Histology and Cytology	NHS Lothian

Name	Position	Organisation
Rosemary Millar	Consultant in Public Health, Board Coordinator for Cancer Screening Programmes	NHS Lothian
Alison Milne	Team Manager, Cervical Screening Call-Recall Team	NHS Lothian
Joanne Milne-Toner	Senior Programme Manager	NHS National Services Scotland
Rosalynn Morrin	General Practitioner	NHS Ayrshire & Arran
Jane Oliver	Health Improvement Manager (Screening)	Public Health Scotland
Lorna Porteous	Co General Practitioner Lead for Cancer and Palliative Care in Lothian/ Co-Chair of Scottish Primary Care Cancer Group	NHS Lothian
Aileen Primrose (until September 24)	Programme Manager Screening & Immunisation	NHS Dumfries &Galloway
Liz Rennie	Programme Manager - Child Health & Screening Dept	NHS Greater Glasgow and Clyde
Tasmin Sommerfield	Consultant in Public Health Medicine/National Clinical Advisor for Screening	NHS National Services Scotland
Hazel Sommerville	Gender-Based Violence & Sexual Assult Service Lead	NHS Forth Valley
Catherine Thomson	Service Manager for Cancer and Adult Screening	Public Health Scotland
Jennie Young	Psychological Therapies Team Lead	NHS Forth Valley

The standards development group was supported by the following members of the standards and indicators team at Healthcare Improvement Scotland:

- Lola Adewale – Programme Manager
- Stephanie Kennedy – Administrative Officer
- Carolyn Roper – Project Officer
- Fiona Wardell – Team Lead

Appendix 3: Membership of the cervical screening standards editorial review panel

Name	Position	Organisation
Athena Lamnisos	Chief Executive	Eve Appeal
Joanne Milne-Toner	Senior Programme Manager	NHS National Services Scotland
Safia Qureshi	Director of Evidence & Digital	Healthcare Improvement Scotland
Fiona Wardell	Team Lead, Standards and Indicators	Healthcare Improvement Scotland
Allan Wilson	Consultant Biomedical Scientist – Pathology	NHS Lanarkshire

Appendix 4: Structure of cervical screening laboratory service

Structure and functions of the cervical screening laboratory service

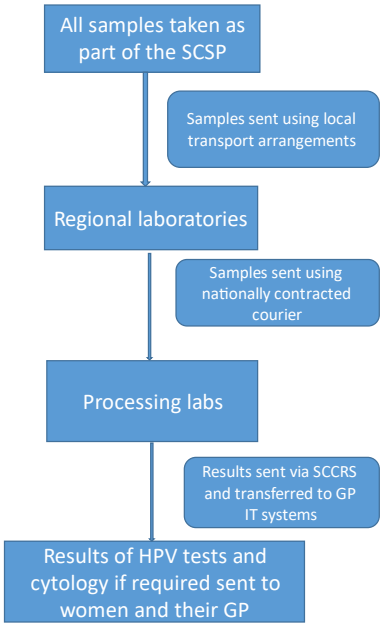
Following the introduction of HPV primary screening to the SCSP in 2020, the laboratory service was reconfigured to deliver the new primary test, with two laboratories (Monklands in NHS Lanarkshire and Queen Elizabeth in NHS GG&C) designated as processing laboratories. The remaining five laboratories were designated as non-processing laboratories.

Processing laboratories

The two processing laboratories receive, process and report all samples taken as part of the SCSP. They also function as non-processing laboratories for their own health board.

Non-processing laboratories

The five non-processing laboratories forward samples taken within their health board to the processing labs for testing.



The role of non-processing laboratories is to:

- ensure continued ordering and delivery of sample taking consumables to distribution points, as well as distribution to sample taking locations
- enter relevant biopsy and hysterectomy information to SCCRS
- contact the processing laboratory to highlight cases of cervical cancer
- respond to the “biopsies not reported” notification and ensure all biopsies are entered on SCCRS
- escalate cases where the colposcopy event is not entered in SCCRS
- identify women who are HIV positive to ensure annual follow-up
- review histology material for presentation/discussion at MDT meetings
- participate in the National Invasive Cancer Audit, including review of histology material
- separate cervical screening samples from other laboratory specimens and prepare for dispatch to the designated cervical screening laboratory
- retrieve and dispatch archival cytology material to the screening laboratories for review purposes.

HPV reference laboratory (HPVRL)

The HPVRL provides expert advice on HPV testing, quality assurance material and specialist testing to the two processing laboratories.

https://edinburghlabmed.co.uk/Specialities/reflab/hpv/Pages/default

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