

# Review of processes, systems and governance for exclusions from the national cervical screening programme in Scotland

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# Contents

- Executive Summary ..... 2
- Recommendations ..... 5
- Background to this review..... 9
- How we approached the review ..... 11
- Cervical Screening in Scotland ..... 13
- Oversight and assurance of cervical screening ..... 16
- Scottish Cervical Call Recall IT System (SCCRS) ..... 18
- Review findings ..... 20
- Glossary ..... 38
- Appendix 1..... 40
- Appendix 2..... 42
- Appendix 3..... 45
- Appendix 4..... 46

# Executive Summary

In Scotland, all women and people with a cervix<sup>1</sup> aged 25–64 are invited for a cervical screening (smear) test, even if they've had the HPV (human papillomavirus) vaccine. The cervical screening programme saves thousands of lives every year. This free health check can stop women from ever getting cervical cancer. It is therefore vitally important that women are able to have confidence in cervical screening and that the screening programme is delivered to the highest quality possible.

This review was commissioned after an audit in 2020–2021 identified that two women who had a subtotal hysterectomy (where some cervical tissue remains) had been mistakenly excluded from the cervical screening programme and subsequently developed cervical cancer. This was identified as an adverse event and a national adverse event management team (AEMT) was established, which identified that this was not an isolated issue. The national AEMT was separate to this review and we understand that work is ongoing to ensure that all women with a subtotal hysterectomy have been appropriately invited for cervical screening.

Further information and advice regarding the incident and the work being undertaken can be found at <https://www.nhsinform.scot/healthy-living/screening/cervical-screening-smear-test/cervical-screening-incident>.

The focus of our review was on the processes, systems and governance for the application of exclusions from the cervical screening programme, with the aim of identifying learning and informing improvements. The review did not examine any individual patient records. The review team reviewed over 2000 documents and conducted focus group meetings with a range of individuals with experience of all aspects of the cervical screening programme. We took a person-centred approach to this review, with those impacted by the adverse event and the participants who use cervical screening always at the forefront of our thinking.

The review found that there were a number of instances of incorrect application of exclusions which were identified over a number of years prior to 2020, and that there was a failure to recognise the risk associated with the issue and to implement solutions. The main findings of this review are as follows:

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<sup>1</sup> The cervix is a part of the female reproductive system. It joins the top of the vagina to the lower part of the womb. Women are usually born with a cervix. Someone may also have a cervix if they are: (i) a trans man or non-binary person who was assigned female at birth or (ii) a man who has a difference in sex development (DSD) or is intersex. In rare cases women may be born without a cervix. A woman who has had surgery, such as a hysterectomy, may have had their cervix removed. For brevity and clarity, this report will primarily use the word 'women' to refer to all people that have a cervix.

- There was little evidence that women have been actively engaged in the design, development and delivery of exclusions in the cervical screening programme at a national level. The impact on women of the decision and process to exclude them from the cervical screening programme was not fully understood or considered at that level.
- While there is some evidence of assurance and monitoring activity at a national and local level, this is an area that needs to be strengthened. Permanent exclusions within the cervical screening programme have not been routinely monitored, with no national or local benchmarking taking place.
- While there have been many changes in national governance structures and processes for the cervical screening programme, these have not always been implemented in a consistent manner, nor clearly communicated to all staff involved in programme delivery.
- There was confusion amongst organisations (NSS, NHS boards and primary care providers) who have a role in delivering the cervical screening service regarding who was responsible for monitoring and reporting of exclusions within the cervical screening programme.
- The nationally agreed procedures (NAPs), which set out the functionality and use of the IT system used by the cervical screening programme, the Scottish Cervical Call Recall System (SCCRS), were felt by some healthcare professionals using the system to be confusing and complex.
- The value of the National Invasive Cancer Audit (NICA), and its role in assuring quality, was not fully understood by some NHS boards working within the programme. The NICA was being used mainly at local NHS board level rather than results being aggregated and considered nationally for benchmarking, learning and improvement. We understand that Public Health Scotland is undertaking work to achieve national aggregated analysis.
- NHS boards are not routinely advising women that they are part of the NICA, and they are not routinely offering participants the opportunity to receive results from the NICA.

The processes, systems and governance arrangements for the management of exclusions require significant changes which should be focused on delivering a person-centred cervical screening programme. We spoke with many hardworking, diligent, experienced and expert staff but we identified that in managing the complexity of the programme, the person-centred focus which should be at the heart of cervical screening had been lost or overlooked.

The recommendations arising from this review span the processes, systems and governance of the management of exclusions from the cervical screening programme. They should be taken together as a package for improving the management of exclusions from cervical screening. While the recommendations are specific to cervical screening, we have written to

Scottish Government to advise that they should be considered and applied where appropriate across other Scottish screening programmes.

The review team believe that it is for Scottish Government to decide which organisations and governance groups are best placed to take forward and implement the recommendations made in this report. We would suggest that the Scottish Government considers convening a working group with relevant expertise to explore specific actions required to implement the recommendations, assign these actions with timelines and monitor delivery against the recommendations.

During this review, we observed a very committed workforce across the cervical screening programme. We very much appreciate the high levels of engagement and openness from all staff we met, who gave us an insight into the work they do to deliver cervical screening on a daily basis. We wish to acknowledge their professionalism and honesty throughout the review process.

# Recommendations

## **Recommendation 1: Engagement with women**

All organisations who deliver aspects of the cervical screening programme, at national and local level, must ensure the active engagement of women in the design, development and delivery of the cervical screening programme, particularly regarding exclusions. This requires a shift to a more person-centred approach that meaningfully engages with women and is respectful of, and responsive to, their needs.

## **Recommendation 2: Informing and consulting women about exclusion**

Where a decision has been made to exclude a woman from the cervical screening programme, they should receive written communication about this. This should inform them of their exclusion, the reasons for this, and invite them to question this if they believe they should not be excluded. This should be in an accessible format and available in a range of languages. This will help aid understanding and contribute to failsafe mechanisms.<sup>2</sup>

## **Recommendation 3: Nationally Agreed Procedures**

There should be an in-depth multidisciplinary and clinical review and revision of the Nationally Agreed Procedures for cervical screening. The Nationally Agreed Procedures must be regularly monitored, reviewed and updated with clear version control practices and made easily accessible to all staff working with the system.

## **Recommendation 4: Training for Scottish Cervical Call Recall System**

A rolling national training programme for the Scottish Cervical Call Recall System should be developed and delivered for all clinical and non-clinical staff who use the system as part of their role within the cervical screening programme. User guidance should also be developed as an accompanying document to the Nationally Agreed Procedures, which should include an overview of what they are for and training guidance.

## **Recommendation 5: Reporting and benchmarking exclusions**

Routine reporting and benchmarking of exclusions should be adopted by the cervical screening programme and led by national governance arrangements. Routine consideration of call and recall and laboratory data should take place so that the performance of the programme is managed and monitored.

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<sup>2</sup> A failsafe is a backup mechanism. This makes sure that if something goes wrong in the screening pathway, processes are in place to identify what is going wrong, and what action should follow to ensure a safe outcome.

### **Recommendation 6: Management of exclusions**

A clearly documented process should be put in place for the management and application of exclusions from the cervical screening programme. This process should include as a minimum: criteria for exclusions; how they are monitored; failsafes; communication of decisions to women; and governance arrangements.

### **Recommendation 7: Scottish Cervical Call Recall System oversight**

The specification of the Scottish Cervical Call Recall System should be considered and regularly reviewed. Any further software updates should be mapped against the core specification and aims of the original commission.

### **Recommendation 8: Discharge Communication**

A national template for the discharge communication provided to patients and GPs following a hysterectomy should be developed, ensuring that women have an accurate record of their discharge and that primary care colleagues are clear regarding any further actions required. The template should be developed in partnership with those with lived experience. This should be in an accessible format and available in a range of languages. Local screening programmes should also work closely with gynaecology and obstetrics departments to ensure that the cervical screening programme is considered during patient discussions and in any patient communication materials for those who have had a hysterectomy.

### **Recommendation 9: National and local governance structures**

The broad range of multidisciplinary clinical and non-clinical staff involved in the delivery of the cervical screening pathway should be represented in all local and national governance structures, ensuring that the views and experience of a range of staff inform the decision making by governance groups.

### **Recommendation 10: Sample takers group**

Work should be undertaken to further develop a sample takers group or find other ways to capture the views and voice of this important staff group.

### **Recommendation 11: Oversight and assurance**

The current national governance arrangements for cervical screening should be reviewed as a matter of urgency to ensure they are robust, responsive and person-centred. Governance arrangements should include clearly documented:

- Lines of accountability between and across governance groups
- Processes for escalation and decision making and recording agreement
- Processes for the systematic identification, assessment and evaluation of risk, and
- Roles and responsibilities in relation to governance and quality assurance.



### **Recommendation 12: Quality management system**

A formalised quality management system should be implemented to support a consistent and coordinated approach to delivering high-quality cervical screening services, with focus on continuous improvement. The quality system should clearly describe the assurance methods used, the processes for escalation, and any additional support for quality and safety concerns.

### **Recommendation 13: Local quality assurance arrangements**

NHS boards should review their local processes, systems and governance arrangements for quality assurance of cervical screening. This includes:

- Monitoring and review of programme management and delivery, and
- Monitoring performance against Healthcare Improvement Scotland cervical screening standards (2019).

### **Recommendation 14: Management of Adverse Events**

The *Management of Adverse Events in National Screening Programmes Policy* should be implemented consistently across Scotland, including the management, reporting and review of incidents and near misses, to ensure learning and improvement takes place.

### **Recommendation 15: National Invasive Cancer Audit**

A review, and associated work, should be undertaken to ensure that the role and purpose of the National Invasive Cancer Audit as a mechanism for learning and improvement is fully understood and accepted by all staff working in the cervical screening programme. In addition to this the audit process should be reviewed to ensure that planning, execution and reporting against the audit are supported by rigorous due process.

Audit reporting should be strengthened to ensure that data are presented in a meaningful way, drawing conclusions and findings that support learning and improvement.

### **Recommendation 16: Communication with women regarding the National Invasive Cancer Audit**

National Screening Oversight should complete their ongoing review of communication arrangements, including disclosure, with women regarding the National Invasive Cancer Audit. This communication review should be undertaken in association with organisations such as Jo's Cervical Cancer Trust to ensure that the needs of women are central to the process. All women diagnosed with cervical cancer should be made aware of their participation in the National Invasive Cancer Audit and given the opportunity to receive their results.

**Recommendation 17: Duty of candour**

Specific duty of candour guidance for screening should be finalised and implemented as a matter of urgency to ensure that a consistent approach is taken across all screening programmes.

**Recommendation 18: Implementing the recommendations**

Scottish Government should consider which organisations are best placed to deliver the recommendations set out in this report. We recommend that Scottish Government should convene a working group with relevant expertise to explore the specific actions required to take forward the recommendations in this review and agree clear roles, responsibilities and timelines for implementation.

# Background to this review

1. During 2020–2021, a number of NHS boards undertook an invasive cancer audit, where clinical teams review the management of women with invasive cervical cancer to make sure that no gaps in care have existed. This is an important audit, that boards are expected to undertake annually, as it seeks to understand why invasive cancers develop in spite of cervical screening and to ensure that any learning leads to modifications to the programme that may help prevent invasive cancers from occurring.
2. A local NHS board audit found that two women with cervical cancer had been erroneously excluded from the national cervical screening programme up to 24 years ago. Exclusion from the programme means that a potential participant will not be called or recalled to attend and access a cervical screening test. As a result of the findings from the audit a national adverse event management team (AEMT) was established and convened in March 2021 to consider the issue and work to ensure that women who had been erroneously excluded were identified and invited to attend screening. The AEMT consisted of stakeholders from across the screening pathway including representatives from Scottish Government, Healthcare Improvement Scotland, Atos who provide the screening IT system and Public Health Scotland.

## Exclusions

The cervical screening programme in Scotland routinely invites women and anyone with a cervix (aged 25 – 64) for screening at standard intervals. The Scottish Cervical Call Recall System (SCCRS) manages the invitation process and ensures that women are invited at the correct time. Women who are no longer eligible are not included in call and recall. A woman who is excluded from call and recall will not receive invitations or reminder letters from the screening programme.

Exclusions from the cervical screening programme can be temporary or permanent. The Process section of this report (page 22) explores how exclusions are applied in the programme, and by whom.

### Temporary exclusion

A woman for whom a cervical screening invitation is temporarily inappropriate will be temporarily excluded from call and recall. Exclusion is achieved by postponing the screening invitation for a number of months or years. The call and recall system will re-invite the woman for screening after this time is complete, provided that they remain eligible. Reasons for temporary exclusion from cervical screening include pregnancy or undergoing treatment which will affect the sample-taking process.

### Permanent exclusion

A woman will be permanently excluded from the cervical screening programme if they do not have a cervix. Women who have been permanently excluded will no longer receive invitations or reminder letters from the screening programme. Women who have undergone a total hysterectomy (including removal of the cervix) no longer require screening and will be permanently excluded from recall.

**The focus of this review is on permanent exclusions from the cervical screening programme in Scotland.**

- 3.** The initial national AEMT investigation found that some women had been excluded from the programme mistakenly, after being incorrectly recorded on the national Scottish Cervical Call Recall System (SCCRS) as having a total rather than a subtotal hysterectomy (whereby some cervical tissue remains). This error was initially identified as happening in the following instances:

  - Pathology reporting to cervical screening labs/programme stating that total hysterectomy had taken place
  - Application of exclusions at GP practice, following discharge from hospital teams, and
  - Application of exclusions by sample takers.
- 4.** The NHS board that initially identified the issue went on to interrogate local invasive cancer cases within the board against Scottish Morbidity Record (SMR) data to understand the root causes of the error. They found that from a sample of 60 invasive cancer cases reviewed, 14 had been erroneously excluded from the cervical screening programme. This was found to have happened due to inaccurate reporting from pathology or discharge reporting to GP practices.
- 5.** As a result in March 2021, all other NHS boards in Scotland were asked by the national AEMT to similarly undertake an audit of women who had been excluded from screening and recorded as having had a hysterectomy. This identified other women who may have been required to be recalled and provided an indication of the numbers of women erroneously excluded from screening. Call and recall offices and GP practices were also advised not to apply the exclusion status until failsafe procedures had been devised. An urgent audit was undertaken of records of women who had a no cervix exclusion applied.
- 6.** On 15 September 2021, the Minister for Public Health, Women's Health and Sport announced that Healthcare Improvement Scotland would be commissioned to undertake an independent review of permanent exclusions from the cervical screening programme in Scotland, considering the processes, systems and governance for the application and management of permanent exclusions. Healthcare Improvement Scotland was instructed to consider the evolution of these processes, systems and governance over time, including the lessons from relevant significant adverse events, and an assessment of potential learning from other screening programmes in Scotland or elsewhere in the UK.

## How we approached the review

- 7.** Healthcare Improvement Scotland convened an expert review group, comprising individuals who have key roles within cervical screening. The review was chaired by Dr Karin Denton (Consultant Pathologist, North Bristol NHS Trust). The chair of the review was supported by an expert review group with membership drawn from public health screening fields. This included members with expertise in screening policy, quality assurance and processes, systems and governance. There was also representation on the expert review group from Jo's Cervical Cancer Trust. Further details of the expert review group membership are provided in Appendix 1.
- 8.** The expert review group gathered evidence for this review by requesting data and evidence submissions from organisations who have a direct responsibility for the oversight and delivery of cervical screening in Scotland. The review group examined over 2000 documents and data supplied by the organisations involved in cervical screening, including Scottish Government, NHS National Services Scotland (NSS) and NHS boards.
- 9.** During the review, the expert review group met with a broad range of stakeholders and staff involved in the delivery of cervical screening in Scotland. These were representatives of:

  - National Specialist Services and Screening Directorate (NSD) of NSS
  - National Screening Oversight (part of NSS)
  - Public Health Scotland
  - Atos (the company who deliver and support the SCCRS system)
  - General Practice Managers
  - General Practice Nurses
  - Directors of Public Health
  - Board Screening Coordinators, and
  - Call and Recall Managers.
- 10.** As the focus of the review was on processes, systems and governance for the application of exclusions from the screening programme, the engagement carried out by the review group was focused on those that have responsibility for delivering these components of the system, as described above in paragraph 9.
- 11.** The review scope did not include the handling of any individual cases of exclusion of women from the programme, as this was already being addressed through the AEMT processes outlined above.
- 12.** The review also engaged with clinicians and other staff involved in the delivery of the screening programme to consider any learning from other screening programmes across the UK, drawing on relationships with other organisations and specialities.

**13.** The aims of the review were agreed with Scottish Government and sought to:

- Explore previous iterations of cervical screening in Scotland (from 2000 onwards) in terms of call and recall, participant management processes and system governance.
- Explore previous work undertaken to clean and manage data, including any exclusions, through the use of audits or data management exercises.
- Explore data and system governance arrangements, specifically permissions, change requests, reporting, audit and escalation.
- Explore the roles of acute and primary care in the systems and processes used by the national cervical screening programme.
- Consider the adequacy of systems, guidance and policy for ensuring that women are appropriately involved in, and informed of, decisions to exclude them from the national cervical screening programme.
- Consider whether there are identifiable lessons learned and make any recommendations which will support the improved safety and quality of the programme going forward.
- Draw on lessons from previous audits and adverse events in relation to inappropriate exclusions, as well as the learning from other screening programmes in Scotland, the UK and beyond.

**14.** Prior to the commencement of the national call and recall based programme in 1988, there was some delivery of screening through boards and exclusions recorded. However, in order to maximise the value of the review in terms of learning and improvement, only those systems and processes for exclusions used from the year 2000 onwards were considered.

**15.** The following areas were outwith the scope of the review:

- Matters under the remit of the current AEMT. This includes the identification of affected women and resolution of errors in exclusion for individual women.

**16.** Full terms of reference are included in [Appendix 2](#).

# Cervical Screening in Scotland

- 17.** Screening tests identify certain diseases and conditions before symptoms appear so that treatment can be started early and health outcomes are improved. If a condition is found early:
- It is less likely to become severe, and
  - It is less likely to need major treatment.<sup>3</sup>
- 18.** Currently all women and people with a cervix aged between 25 and 64 are eligible for cervical screening, which includes trans men and non-binary people. Uptake of cervical screening is the percentage of eligible women who were screened adequately within the specified period. The uptake rate in 2020–2021 was 69.3%, with just over one million eligible women having participated.<sup>4</sup> Further information on cervical screening in Scotland is available from NHS Inform (<https://www.nhsinform.scot/healthy-living/screening/cervical-screening-smear-test>).
- 19.** Some trans men and non-binary people may have had surgery that involves removing the cervix, and so will no longer be eligible. Trans women do not need cervical screening. Further information regarding cervical screening for trans men and non-binary people is available from Jo’s Cervical Cancer Trust.<sup>5</sup>
- 20.** Cervical screening in Scotland has been available for some time, and since 2000 the programme has been coordinated by National Specialist Services and Screening Directorate (NSD, part of NHS National Services Scotland (NSS)). Prior to March 2020 women were invited to attend a smear test, where samples of cells from the cervix were taken and assessed by a cytology lab. If there were pre-cancerous cells, then women would either be recalled and monitored or referred to colposcopy departments for treatment. Likewise, if cancerous cells were found, women would be immediately referred for treatment.
- 21.** In March 2020, the cervical screening test in Scotland changed. Although the test itself, where a sample is taken from the cervix, remains the same, the programme now looks to identify whether a woman has human papillomavirus (HPV). HPV primary screening is the best way to find out who is at higher risk of developing cervical cell changes or cervical cancer. Almost all cervical cancers are linked to high-risk HPV. By knowing who has high-risk HPV, women can be monitored to find any cell changes early, before they potentially develop into cervical cancer. HPV primary screening is a more accurate test than cytology. This means it is better at detecting cell changes overall, as well as detecting them earlier.

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<sup>3</sup> <https://www.nhsinform.scot/healthy-living/screening>

<sup>4</sup> <https://www.publichealthscotland.scot/publications/scottish-cervical-screening-programme-statistics/scottish-cervical-screening-programme-statistics-annual-update-to-31-march-2021/>

<sup>5</sup> <https://www.jostrust.org.uk/information/cervical-screening/trans-non-binary>

- 22.** Some women will not be eligible for cervical screening even though they fall in the eligible age range. These individuals are permanently excluded from the programme for a number of reasons. For example, total hysterectomy, where the cervix has been removed means screening is no longer required. Women are also temporarily excluded from the programme, for example if they are pregnant or undergoing treatment which will affect the sample-taking process.
- 23.** Calling participants to attend cervical screening is the responsibility of call and recall offices in local NHS boards, who use the national Scottish Cervical Call Recall IT system (SCCRS). The system identifies eligible women using their community health index number (CHI) and invites them to attend screening. This is detailed in appendix 3. Depending on whether they attend and any outcomes of the screening test, the system manages their further recall into the programme.
- 24.** Screening policy in Scotland lies with Scottish Government, which considers recommendations coming from the UK National Screening Committee. 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 Scottish Screening Committee (SSC). The recent changes to the cervical screening programme were overseen by the SSC.
- 25.** NSD provides national coordination of the cervical screening programme, which is delivered locally by NHS boards. NSD supports the implementation and delivery of screening, including managing change or the introduction of new screening programmes and also nationally commissions the two cervical laboratories and the cervical training school.
- 26.** NHS boards are responsible for ensuring the local delivery of cervical screening services for their residents. This means:
- NHS boards are responsible for the provision and delivery of screening services within their local area.
  - NHS board directors of public health, in addition to their oversight and assurance role, are also accountable officers for screening locally.
  - Board screening coordinators have a remit to oversee the delivery, quality and effectiveness of the screening programme for their resident eligible population and are directly accountable to their NHS board's director of public health for this work.
  - NHS boards are expected to work within national screening governance structures, outlined in appendix 4.
- 27.** GP practices deliver cervical screening tests for their local populations, with practice nurses and GPs taking samples which are sent to a laboratory. Sometimes cervical screening tests are undertaken in sexual health centres. Sample takers in primary care are



a key component of service delivery, providing the participant with the screening test and information about cervical screening.

**28.** Two laboratories test the samples for HPV and cytology for the cervical screening programme. These are hosted in NHS boards and are nationally commissioned by NSD (NSS) for the cervical screening programme.

**29.** A diagram explaining the cervical screening programme is included as [Appendix 3](#).

## National Cervical Screening Standards

**30.** Healthcare Improvement Scotland publishes national clinical screening standards and can also provide independent quality assurance of screening programmes. National clinical standards for screening are very important as they set out the standards which NHS boards and other organisations should meet in delivering the programme. This is a key component in assuring the quality of screening.

**31.** The Healthcare Improvement Scotland cervical screening standards were first published in 2001 and were recently revised and published in 2019. The standards apply to local NHS boards where cervical screening is provided and set out the quality of screening that should be delivered. There are elements of the standards that will also apply to other special health boards where appropriate. The standards cover the following areas of the participant pathway:

- leadership and governance
- information and support
- call-recall
- attendance and uptake
- screening processes
- laboratory service, and
- colposcopy.

**32.** Monitoring and improving performance against these standards, at a local and national level, aims to improve the quality of the national and local screening programme. Assessment against the standards should be considered as part of a quality management system, allowing boards to assure their own services and provide assurances to national governance structures.

**33.** In the context of this review we considered the use of the standards and how they related to national and local governance arrangements. The screening standards relate to a number of our recommendations and will be an important part of monitoring any improvement work going forward.

# Oversight and assurance of cervical screening

- 34.** Oversight and assurance of screening at a national level is provided by National Screening Oversight (NSO), which is hosted within National Services Scotland (NSS). The function was established in August 2020 following a national review of screening (2018) which recommended strengthening governance in screening.
- 35.** The function is led by the Scottish director of screening who chairs the national screening oversight board (NSOB) and, supported by the NSO team, provides whole system leadership and national oversight of all aspects of screening, namely commissioning, quality management and implementation. Programme and operational delivery organisations are accountable to the national screening programme boards (for 6 screening programmes) and these are all represented on the national screening oversight board, reporting to the Scottish director of screening.
- 36.** The NSOB is the governance group which provides leadership, direction, oversight and assurance of operational matters in relation to screening in Scotland. This includes the introduction of new screening programmes and major changes to existing programmes. The NSOB meets twice a year and is supported by:
- The NSO digital board, which oversees all digital changes and developments and provides direction for the digital roadmap (the plan for IT and technology in screening), and
  - The NSO research and innovation group, which facilitates a consistent strategic approach to research and innovation across all screening programmes in Scotland.
- 37.** Oversight and assurance of screening at the programme level is provided by the national screening programme boards. Each of the six national screening programmes has its own programme board which:
- Is accountable to the NSOB for quality assurance, quality improvement, adverse event management and the ownership of risks and issues within their respective national screening programmes.
  - Contributes to the identification of research priorities and the approval process. They are responsible for the management, implementation and governance of any research that occurs within their programme.
  - Is supported by a number of sub-groups with responsibility for a specific area within that programme. These may include:
    - board screening coordinators group
    - monitoring and evaluation group
    - quality assurance / national IT user groups, and
    - clinical directors or lead clinicians groups.
  - Can make recommendations to NHS boards or can escalate issues to NSOB.

**38.** Oversight and assurance of screening at local NHS board level is provided by the director of public health, as the designated NHS board accountable officer.

**39.** Directors of public health:

- Are advocates and accountable officers to NHS boards for the oversight and assurance of all required elements of screening.
- Hold professional, and corporate, responsibility for local oversight to ensure equitable access to high quality screening pathways for eligible resident populations within geographical NHS board boundaries (including components delivered by other NHS organisations).
- Monitor and assure delivery of high quality screening programmes, support continuous service improvement, and respond to identified issues of concern to maximise the intended benefits for population health, while minimising the risk of harm for screening participants.

**40.** A diagram showing the current governance structure for the cervical screening programme in Scotland is included as [Appendix 4](#).

# Scottish Cervical Call Recall IT System (SCCRS)

- 41.** SCCRS was introduced in May 2007 after a review undertaken in 2000 found that cervical screening was being delivered in an inconsistent way by the 14 territorial NHS boards, each with their own local programme. This inconsistency in delivery had led to a number of issues within the programme and it was recommended that national guidance, procedures and standards should be developed. This was undertaken by National Services Scotland's National Specialist Services and Screening Division (NSD, NSS). Following this, a further review recommended that a national call and recall IT system be explored. This led to the specification, development and implementation of the SCCRS system. SCCRS was designed to replace local systems which were being used to call and recall participants, and which were being used differently between NHS boards. It was thought that a nationwide system would bring cohesion and consistency in practices across Scotland.
- 42.** Since 2007, SCCRS has been the central IT system used to support the delivery of the cervical screening pathway in Scotland. It facilitates:

  - the identification of the eligible cohort
  - the invite and follow up process, including issuing results to participants and service staff
  - the participant management pathway
  - electronic screening test requesting and results reporting, and
  - data reporting and record keeping, with all eligible women having a participant record.
- 43.** SCCRS provides one Scotland-wide database to support the Scottish cervical screening programme and provides programme monitoring data, such as practice uptake, or unsatisfactory rates from individual sample takers.
- 44.** The system is accessed daily by a wide range of NHS staff including GPs, nurses, sexual health clinicians, colposcopists, gynaecologists, laboratory scientists, cytopathologists, virologists, consultants in public health and call and recall office staff.
- 45.** SCCRS was developed and delivered by Atos, who continue to support the delivery of the system, releases and updates. NSS procures this from Atos and undertakes a contracts management role, working closely with Atos and its developers to monitor and manage the system and its functionality. This currently happens through NSS governance arrangements, although previously this function was undertaken by a Scottish Government ehealth portfolio management group.
- 46.** Monitoring and management of a complex IT system such as SCCRS is an ongoing process, with digital governance arrangements working with users and stakeholders to consider system bugs or any change requests which may arise. Stakeholders with governance responsibility for the system also oversee topics such as disaster recovery work and

service issues, and manage the timing and implementation of system updates. Through the life of the system a number of groups have contributed to system monitoring and management. Evidence submitted showed that this fell to various groups including a programme board, a portfolio management group, Solution Stewardship and key governance groups. This is further described in the rest of this report.

- 47.** Over the lifespan of the cervical screening programme there have been a number of changes and updates to the system. These have been supported by nationally agreed procedures (NAPs), which set out the functionality and how the system should be used. The NAPs have been updated and revised in conjunction with system releases.

## Review findings

- 48.** The review group worked to understand the historical delivery of the cervical screening programme and the current position of the management of exclusions. The review group held meetings to discuss the evidence in order to reach consensus on the findings and recommendations for the improvement of the cervical screening programme. It is noted by the review group that the three focus areas for the review – processes, systems and governance – are interlinked and interdependent. As such, some of the recommendations from this review span these three themes.
- 49.** While this review has found areas that require improvement, it recognises that the cervical screening programme, and those working within it, are delivering life-saving screening services to women in Scotland on a daily basis. By successfully implementing HPV primary screening, women are now offered a test which is a more sensitive and effective test for identifying women who are at risk of cervical cancer than previous tests. Cervical screening has proven to be effective in reducing the incidence of cervical cancer, with an estimated 5,000 lives saved in the UK each year.<sup>6</sup> Deaths from cervical cancer have decreased by 70% since the introduction of the cervical screening programme in the UK.<sup>7</sup> After the HPV vaccine, cervical screening remains the best tool for preventing cervical cancer.

## Process

- 50.** The importance of clear and accessible information for women to enable informed choice and decision making is reflected in the national cervical screening standards.<sup>8</sup> The review considered evidence submitted to demonstrate the processes used to exclude women from the cervical screening programme. This included the identification of women to be excluded, the actual application of an exclusion status and the approach to communication with women excluded from the programme. The process of excluding women from the cervical screening programme should be person-centred, ensuring women are fully engaged in decisions about their own care and treatment, and offering appropriate safeguards to ensure that exclusions are applied correctly. Any process which removes the opportunity to attend for screening must be focused on women, their needs and any risks to them.
- 51.** There was little mention in the evidence submitted to the review group of the needs of women, their experiences of the programme or communications from the programme

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<sup>6</sup> <https://www.nss.nhs.scot/specialist-healthcare/screening-programmes/cervical-screening/#:~:text=Every%20year%2C%20cervical%20screening%20saves,10%20cervical%20cancers%20from%20developing>

<sup>7</sup> [New national cervical screening campaign launches – as nearly 1 in 3 don't take up screening offer - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

<sup>8</sup> [https://www.healthcareimprovementscotland.org/our\\_work/standards\\_and\\_guidelines/stnds/cervical\\_screening\\_standards.aspx](https://www.healthcareimprovementscotland.org/our_work/standards_and_guidelines/stnds/cervical_screening_standards.aspx)

about exclusions. It was not clear from this evidence how views from patient groups and women who may be participants in the screening programme have been taken into account in the development of programme processes and systems relating to exclusions from the programme. There was little evidence in the minutes and meeting papers of a number of national governance groups that the impact on women of the decision and process to exclude them from the screening programme was fully understood or considered. This was confirmed by staff working in the delivery of the screening programme during our engagement work. We understand that there is an intention to undertake work to assess and improve communication regarding exclusions from the programme, but we are unclear who within screening governance structures is taking this work forward or when it may be implemented or completed.

- 52.** It was found through discussions with clinicians and staff working at national and local level within the programme that, in practice, informing participants that they have been excluded from the screening programme was the sole responsibility of discharging clinicians or primary care, and this was not formally documented as a part of the exclusion process. Evidence submitted to the review showed that a decision was made in 2005 at the national level that participants would not be informed in writing that they had been excluded. It was not clear which national governance groups were involved in this decision making. This was a missed opportunity to recognise women as a partner in the cervical screening process, or to recognise their participation as a possible failsafe point in the process. If women had been informed that they were being excluded from the programme and why, it may have prevented some inappropriate exclusions from occurring, by enabling women to question this decision. Communication informing women of their status with a failsafe check question offers the potential to reduce the risks to them, and reduces the likelihood of erroneous exclusion from the national cervical screening programme.
- 53.** The review group has been made aware that an IT change request for an exclusion letter to be produced by the Scottish Cervical Call Recall System (SCCRS) has been made by National Services Scotland (NSS) following the 2021 exclusion adverse event. This will allow the IT system to create and send a letter to women who are excluded. It is important that this action is progressed as a priority.
- 54.** To create accessible and person-centred cervical screening services, it is essential to engage with women who can share a wide variety of lived experiences. This should include women of different ages; different socio-economic backgrounds; different ethnicities; lesbian, gay and bisexual women; trans and non-binary people; and women with disabilities.

55. The importance of people being fully informed and supported to participate in decisions relating to their health and care is reflected in both the *Patient Rights (Scotland) Act 2011*<sup>9</sup> and also the national *Health and Social Care Standards*.<sup>10</sup>

### **Recommendation 1: Engagement with women**

All organisations who deliver aspects of the cervical screening programme, at national and local level, must ensure the active engagement of women in the design, development and delivery of the cervical screening programme, particularly regarding exclusions. This requires a shift to a more person-centred approach that meaningfully engages with women and is respectful of, and responsive to, their needs.

### **Recommendation 2: Informing and consulting women about exclusion**

Where a decision has been made to exclude a woman from the cervical screening programme, they should receive written communication about this. This should inform them of their exclusion, the reasons for this, and invite them to question this if they believe they should not be excluded. This should be in an accessible format and available in a range of languages. This will help aid understanding and contribute to failsafe mechanisms.<sup>11</sup>

## **Nationally Agreed Procedures (NAPs)**

56. SCCRS is a complex paper-free screening programme system, with four IT system modules which span the participant pathway. The modules are:

- Call and recall
- Sample takers (the screening episode)
- Laboratories, and
- Colposcopy.

57. SCCRS uses NAPs which we were told during focus group discussions act as a user manual and standard operating procedure for the system. These are produced and agreed by national governance groups with members who have experience of using the system in practice. These are complemented by an Atos manual for the system. Each NAP is split into the modules within the system, for example laboratories have their own NAPs for use of the system. Exclusions can be applied in the different modules of the IT system, and by different professional roles involved in cervical screening.

58. The NAPs are key documents which were initially developed during the set-up of the system and have been amended to reflect system updates. The review group was provided with drafts and previous versions of the NAPs, spanning the lifetime of SCCRS. The review group found the NAPs difficult to understand, with little in-depth information regarding processes, particularly for exclusions. Previous versions of the NAPs had no

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<sup>9</sup> [Patient Rights \(Scotland\) Act 2011 \(legislation.gov.uk\)](https://www.legislation.gov.uk/ukpga/2011/11/section/1)

<sup>10</sup> [Health and Social Care Standards: my support, my life - gov.scot \(www.gov.scot\)](https://www.gov.scot/Health-and-Social-Care-Standards-my-support-my-life)

<sup>11</sup> A failsafe is a backup mechanism. This makes sure that if the screening pathway has not been followed correctly, processes are in place to identify the error and initiate actions to ensure a safe outcome.



clear failsafe actions outlined. Actions were often described in one short line and there was no indication of any process for reporting exclusions. The NAPs for applying exclusions have been updated since the 2021 exclusion adverse event, providing more detailed instructions regarding exclusions than previous versions.

59. The NAPs guide the safe application of exclusions within the cervical screening programme and are critical to the implementation of the exclusion process. In order to understand how they have been used in the programme, a selection of national and local staff who routinely use them were invited to provide their views. The review group heard mixed opinions regarding how easy the NAPs were to use. Some system users found that the NAPs were clear and concise, whilst others found them to be confusing and complex. Those users who had contributed to writing the NAPs appeared to have a greater understanding of them, while less experienced users found them more difficult to use. The NAPs may not be suitable for new users of the system. Making sure they are accessible, comprehensive, and easy to understand and use will improve the safety and effectiveness of the programme.
60. The NAPs relating to exclusions from the programme were developed by a small group of staff involved in the cervical screening pathway, primarily call and recall managers, over the course of the life of the system. Approval for the NAPs relating to exclusions from the programme appears to have come from a national governance group, the quality assurance Admin (QA) User Group, which is made up of system users. It was not clear from the evidence submitted to the review group that the views of multidisciplinary and clinical roles involved in the screening pathway were sought in the development of the NAPs. As a result the clinical consequences of processes described within these documents may not have been clearly understood or acknowledged.
61. The NAPs submitted to the review were found to be a mixture of process documentation, specification and system functionality. The evidence showed that NAPs have a system focus but provide little guidance on purpose and outcomes or failsafes. The NAPs should be developed to include clear guidance on the application of exclusions, specific to the roles of those applying the exclusions. This should include descriptions of failsafe mechanisms and information regarding the outcomes and implications of any exclusion.
62. The review found poor document management made the NAPs hard to follow. Version control was often unclear or not present, and the authorship and publication dates were not always present. The review group believes that a clear process to oversee the development, assure the content, and manage the implementation of the NAPs is essential to ensure they are fit for purpose and meet the needs of multidisciplinary users.

### **Recommendation 3: Nationally agreed procedures**

There should be an in-depth multidisciplinary and clinical review and revision of the Nationally Agreed Procedures for cervical screening. The Nationally Agreed Procedures must

be regularly monitored, reviewed and updated with clear version control practices and made easily accessible to all staff working with the system.

**63.** There is no clear pathway or consistent approach to training for SCCRS users. Staff groups invited to talk with us told the review that training is undertaken locally by NHS boards, in call and recall offices and within primary care settings. Training was undertaken by Atos when SCCRS was first deployed. However, there was no routine training programme currently in place. The review also noted that there was no system user guidance developed to accompany the NAPs, which should include an overview of what they are for and training guidance. However, during our focus groups, we were informed by multiple participants that call and recall offices are supportive and responsive to any queries users have.

#### **Recommendation 4: Training for Scottish Cervical Call Recall System**

A rolling national training programme for the Scottish Cervical Call Recall System should be developed and delivered for all clinical and non-clinical staff who use the system as part of their role within the cervical screening programme. User guidance should also be developed as an accompanying document to the Nationally Agreed Procedures, which should include an overview of what they are for and training guidance.

#### **Management of Exclusions**

**64.** Permanent exclusions within the cervical screening programme have not been routinely monitored, with no national or local benchmarking taking place. The review group requested a report from SCCRS detailing the numbers of women excluded by NHS board. We understand that a report of this nature and the subsequent analysis of exclusions had never been undertaken by any of the national governance groups. Regular monitoring of this data is viewed by the review group members as essential in identifying and understanding any unwarranted variation in exclusion numbers across Scotland. This should be considered as a routine failsafe measure in the programme's local or national governance arrangements and an inherent part of a robust safety process.

**65.** The review found evidence that there was an underlying assumption that exclusions due to hysterectomy were correct and that they had been appropriately applied. This assumption occurred in different local and national governance groups over the course of several years. These governance groups were reassured that exclusions were applied correctly without taking any additional assurance measures to confirm that this was the case, or to test whether their assumptions were valid. Minutes and papers from one group showed that this assumption was being made in 2019, when the most recent adverse event for exclusions was found.

**66.** Regular monitoring and assurance activity must take place at a local and national level to ensure that exclusions are being applied appropriately. This must be an integrated aspect of the process of the ongoing monitoring and management of exclusions. Routine and

regular reports from the system should be commissioned for use at national and local levels.

### **Recommendation 5: Reporting and benchmarking exclusions**

Routine reporting and benchmarking of exclusions should be adopted by the cervical screening programme and led by national governance arrangements. Routine consideration of call and recall and laboratory data should take place so that the performance of the programme is managed and monitored.

**67.** During the review group's engagement with representatives involved in delivering cervical screening, there was a lack of understanding across different stakeholders about which staff groups were responsible for the process of applying permanent exclusions from the programme. There was a similar lack of clarity about the responsibility for overseeing or monitoring the application of exclusions.

**68.** Relevant individuals, organisations and local and national governance committees were not clear about the responsibility for:

- Monitoring levels of exclusions in GP practices, localities, NHS boards and nationally
- Taking action around exclusions if inappropriate, or
- Reporting concerns.

**69.** The technical process for applying exclusions supported by SCCRS functionality was consistent across Scotland. However, the representatives engaged by the review group did not have a clear understanding of who was responsible for implementing this in practice. The review group understands that in practice, histopathology labs were the predominant area applying exclusions. However, the review found that a mix of roles using the SCCRS system were able to apply exclusions from the screening programme, including primary care staff and call and recall staff. All staff and organisations involved in delivering aspects of the cervical screening programme should be aware of whose responsibility it is to apply exclusions and how this is monitored. Those who apply exclusions should be appropriately trained.

### **Recommendation 6: Management of exclusions**

A clearly documented process should be put in place for the management and application of exclusions from the cervical screening programme. This process should include as a minimum: criteria for exclusions; how they are monitored; failsafes; communication of decisions to women; and governance arrangements.

## **Systems**

**70.** SCCRS is a critical component of the cervical screening programme. Its inception in the early 2000s sought to address issues relating to the call and recall of women in the

cervical screening programme arising from multiple different arrangements and systems across territorial NHS boards.

- 71.** The use of processes and systems to manage and monitor exclusions within the cervical screening programme pre-dates SCCRS, beginning with legacy systems used by territorial NHS boards to call and recall women. These legacy systems held data which was transferred and used by SCCRS when it went 'live' in 2007. However, evidence submitted shows that board coordinators expressed concerns regarding data integrity of records with hysterectomy exclusions in 2002, when these legacy systems were still in operation. A number of issues were identified at that time in relation to potential erroneous exclusions and there was evidence of poor data management practice. For example, women were excluded using a future recall date of 31/12/9999. Instances of the legacy systems and data migration resulting in inappropriate exclusion, particularly for hysterectomy exclusions, have occurred at various points throughout the lifespan of the cervical screening programme, leading to a number of investigations.
- 72.** SCCRS itself has functioned for 15 years and has been updated numerous times. There is evidence of multiple system updates and the changes that these brought. The system was initially specified by various staff who were involved in the delivery of cervical screening and then developed and released. The initial specification for the system was provided to the review group. This early document included the aims of the system, its role in quality assurance and what failsafes might be required.
- 73.** From the evidence submitted, the review found that SCCRS system updates to address changes or fixes did not refer to the source principles outlined within the initial specification. For example, failsafe reporting and checks were clearly specified in the original specification documentation but the evidence submitted does not indicate that the system has them. It is important to consider whether each system update, and release, continues to meet the core specification, and the principles outlined within that. Without this the system will continue to evolve in a piecemeal way. Strategic oversight and evaluation of this important national IT system requires to be strengthened in order to meet the needs of the safe and effective delivery of the screening programme.
- 74.** Whilst a full evaluation of SCCRS was beyond the scope of this review, this should be considered by those with responsibility for oversight of the system. Exclusions were considered in the original specification for the system which included reference to the importance of failsafes and monitoring. Each new update of the system should be considered strategically, with changes being referenced against the original specification and its aims.

### **Recommendation 7: Scottish Cervical Call Recall System oversight**

The specification of the Scottish Cervical Call Recall System should be considered and regularly reviewed. Any further software updates should be mapped against the core specification and aims of the original commission.

- 75.** Governance of SCCRS in terms of spend and prioritisation of change requests was managed within the national screening programme until April 2010, when it was transferred to a central point within Scottish Government. A portfolio management group within the eHealth directorate managed the funding of the system and prioritisation of change requests. The group amalgamated the funding for each national screening programme's IT requirements. This meant that changes sought by particular programmes required to be considered in the context of other programme change requests in decisions for funding. This responsibility reverted back to the NSS Digital and Security function in 2019.
- 76.** Focus group participants raised the role of primary care in applying exclusions to the system during engagement carried out by the review group. There was understanding from some secondary care professionals that exclusions were being applied by GP practices following the receipt of a discharge letter from gynaecology. Exclusions applied by primary care occurred on the basis of information contained in these discharge letters. The processes supported by SCCRS are reliant on the quality of the data that is input. It is therefore imperative that source data, in this case discharge letters, are accurate, clear about the type of hysterectomy undertaken and explicit regarding whether an exclusion should be applied.
- 77.** As a failsafe, women should be informed following surgery whether or not they should be excluded from cervical screening. We found that staff in local programmes were not aware of the quality of patient information being provided to women following hysterectomy. A great deal of emphasis was placed on discharge letters being given to women and their GPs. Many staff stated that that they were not confident that patients were always given a copy of the discharge letter.
- 78.** Patients should receive a copy of a discharge communication which is written in a person-centred way and provides clear information on whether cervical tissue remains and whether exclusion is appropriate. This should follow meaningful discussion and provision of information by gynaecology services. Discussions should take account of the individual needs of patients, any past screening history, and any requirements for additional information or support to enable their participation.

### **Recommendation 8: Discharge Communication**

A national template for the discharge communication provided to patients and GPs following a hysterectomy should be developed, ensuring that women have an accurate record of their discharge and that primary care colleagues are clear regarding any further actions required. The template should be developed in partnership with those with lived experience. This should be in an accessible format and available in a range of languages. Local screening programmes should also work closely with gynaecology and obstetrics departments to ensure that the cervical screening programme is considered during patient discussions and in any patient communication materials for those who have had a hysterectomy.

## Governance

- 79.** The importance of leadership and effective governance by NHS boards in the delivery of the cervical screening programme is reflected in the national screening standards.<sup>12</sup> Our focus on governance was specific to the application of exclusions from the programme. However, we have been able to comment on broader issues from the evidence submitted, such as minutes and papers from local and national governance groups.
- 80.** The cervical screening programme governance arrangements in Scotland were based around the different roles within the participant pathway and the modules of SCCRS. These national governance groups were established and convened by NSS during the period before 2007, when SCCRS became operational. Representatives were drawn from the following staff groups:
- Call and recall managers who attended a quality assurance Admin (QA) User Group and contributed to a national user group for SCCRS
  - Colposcopy quality assurance group
  - Sample takers who attended a sample takers group
  - Laboratory staff who attended a Laboratory quality assurance group, and
  - Board coordinators who initially attended a joint cervical and breast group before moving to the cervical board coordinators group.
- 81.** A programme board also operated, bringing together core staffing groups during the initial development of the SCCRS system. On implementation this changed to a Quality Assurance Reference Committee (QARC) group which appears to have operated as a programme board. This group was established and convened regularly by NSS, as part of that national aspect of the programme. The QARC has now changed to a programme board following the implementation of strengthened governance structures in 2020.
- 82.** Evidence submitted to the review showed that these groups operated and met regularly over the past 18 to 20 years until the new structure was implemented in 2020 (described in [Appendix 4](#) of this report).
- 83.** The review considered a large number of documents from all of the historical governance groups, which provided a clear picture of their operation and the scope of their interest. While terms of references for all of the groups were not available to the review, the levels of documentation provided, and the detailed information within them, provided a good understanding of the scope of the national governance groups.
- 84.** Minutes from the range of national cervical screening governance groups during the period 2007–2019 show that exclusions were often discussed at length. However, it was

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<sup>12</sup>[https://www.healthcareimprovementscotland.org/our\\_work/standards\\_and\\_guidelines/stnds/cervical\\_screening\\_standards.aspx](https://www.healthcareimprovementscotland.org/our_work/standards_and_guidelines/stnds/cervical_screening_standards.aspx)

not always clear what action was to be taken, who would be responsible for the action and whether the situation was resolved.

- 85.** The review found that the national governance groups, convened by NSD, often passed agenda items and programme issues or concerns between them. As a result it was not always clear where ownership lay or what action took place. From the evidence reviewed there was an indication that there was not clinical input into all governance groups. This meant that the clinical implications of decision making and actions were not always fully considered or understood when making changes to systems and processes in the cervical screening programme.
- 86.** There was limited evidence provided to the review regarding risk management within the programme. Whilst a risk register, which was held and managed by NSS, was submitted to the review group, the same risks were present across a number of years, with little evidence of active risk management. From a review of meeting minutes of a number of national governance groups, it appears that discussions regarding risks were often brief and adverse events were not routinely linked to risk identification and management. Erroneous exclusion of women from the programme should have been considered a high risk and managed as such, particularly following repeated adverse events. This could have identified quality assurance actions which would have allowed the programme to monitor exclusions at a national and local level.
- 87.** Escalation of programme issues did not routinely take place, either with NSS or with the local NHS boards themselves. Discussion of issues were noted in minutes of meetings but often did not lead to any proposals as to how these could be addressed or how NHS boards could be encouraged to undertake any required actions. NSD clearly stated in their evidence submission that they provide national coordination of the cervical screening programme but are unable to compel NHS boards to act on directives which are not mandatory. This situation may impact on the consistency and service levels of the programme between each NHS board and this should be considered by Scottish Government.
- 88.** A number of issues relating to inappropriate exclusions were discussed by national governance groups but not identified as adverse events nor were they escalated to more clinically orientated groups. A subsequent adverse events framework for screening was published in 2017.
- 89.** The review identified the sample takers group as a key clinical governance group within the national programme, comprising representation from those undertaking testing within the community and delivering the programme in primary care settings. From the evidence provided we were unable to ascertain who this group was accountable to within the national governance structure. However, this group appear to have stopped meeting in 2019, following issues with lack of attendance and meeting cancellations. There was no evidence submitted to the review which demonstrated efforts to find alternative

mechanisms to engage with this staff group. The review considered the sample takers to be critical to the governance of cervical screening.

- 90.** The delivery of the cervical screening programme involves a broad range of clinical and non-clinical staff at different points in the screening pathway. It is important that there are mechanisms to ensure that the views and experience of representatives across this multidisciplinary cohort inform relevant decisions made by governance groups.

### **Recommendation 9: National and local governance structures**

The broad range of multidisciplinary clinical and non-clinical staff involved in the delivery of the cervical screening pathway should be represented in all local and national governance structures, ensuring that the views and experience of a range of staff inform the decision making by governance groups.

### **Recommendation 10: Sample takers group**

Work should be undertaken to further develop a sample takers group or find other ways to capture the views and voice of this important staff group.

## **Roles and Responsibilities**

- 91.** The review group was provided with comprehensive diagrams outlining the current national governance structure of the cervical screening programme. However, it was evident from discussions with representatives of staff groups working in the cervical screening programme that these arrangements are not yet fully embedded or understood by all. Staff groups do not have a shared understanding of how the programme operates and where responsibility for key delivery aspects lie. We heard two differing views of the programme structure:

- The screening programme is 14 individual programmes managed by NHS boards with support from NSS, and
- It is a national screening programme commissioned by NSS and delivered by 14 NHS boards.

- 92.** This lack of a shared understanding has implications for the operation of the cervical screening programme. Clarity and a common understanding of operational responsibilities is essential for effective quality assurance, performance monitoring, and the management and consistency of delivery of cervical screening. The roles and responsibilities in relation to governance and quality assurance of cervical screening should be clarified and clearly articulated at the national and local level. This is essential to ensure effective management and monitoring of the screening programme.

- 93.** The lack of clarity around governance roles and responsibilities, evidenced during the review, has contributed to gaps in quality assurance activity and the performance management and monitoring of the programme. There were assumptions among stakeholders that key functions and activities were being undertaken by, or were the



responsibility of, others. However, this was often not the case. For example, there was confusion among both national and local NHS board staff regarding the responsibilities for monitoring and reporting of exclusions within the NHS boards and primary care. This confusion was also evident at a national level, with staff groups involved in the national governance structure unable to provide clarity regarding the scope and responsibility across the governance groups for delivering key management and monitoring functions.

### **Recommendation 11: Oversight and assurance**

The current national governance arrangements for cervical screening should be reviewed as a matter of urgency to ensure they are robust, responsive and person-centred. Governance arrangements should include clearly documented:

- Lines of accountability between and across governance groups
- Processes for escalation, decision making and recording agreement
- Processes for the systematic identification, assessment and evaluation of risk, and
- Roles and responsibilities in relation to governance and quality assurance.

### **Quality Assurance**

**94.** Quality assurance is a method of using quality assessment measures in a system-wide manner to deliver safe, high-quality screening services that are continually improving. Effective quality assurance encompasses a range of activities across all levels from national oversight and monitoring through to local service evaluation and audit. During the review we considered a range of documentation from previous and current local and national governance groups within the national structure. While there was evidence that these governance groups met regularly, there was no consistent, structured assessment and reporting of the management of exclusions from the cervical screening programme at NHS board or national level.

**95.** We also found that Key Performance Indicators (KPIs) for the cervical screening programme were limited to basic performance data, such as coverage. This meant that the programme has not routinely considered any KPIs or data regarding exclusions which could have identified issues in the programme. In addition to this, the national *Cervical screening standards*, published by Healthcare Improvement Scotland in 2019, were not routinely used or considered by the groups and the review found that some stakeholders were unaware of the standards.<sup>13</sup> This was of concern to the review group.

**96.** Throughout the review of evidence we found that governance groups did not routinely consider exclusion data or benchmark performance nationally or across NHS boards. As a result, there has been a lack of robust and data-led routine monitoring of aspects of the programme's performance at local and national level, specifically regarding exclusions. During focus group sessions, we heard that some individuals involved in the national and

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<sup>13</sup> [Cervical screening standards \(healthcareimprovementscotland.org\)](https://www.healthcareimprovementscotland.org/)

local programme believed that other parts of the national structure or local service were undertaking regular monitoring of exclusions, using available data and intelligence.

- 97.** We talked to stakeholders within our focus groups about the cervical screening programme board, which was formed following the national screening review. There was varied understanding about the role and functions of the board in terms of quality assurance. We asked for terms of reference for national governance groups but did not receive a complete set of these for the period under consideration for the review as part of the evidence submissions. We did receive a terms of reference for the most recent iteration of governance groups, dated 2021. As such we were unclear whether the previous governance groups were operating in a way that was intended.
- 98.** Discussions with NSD regarding the commencement of a planned programme of external quality assurance (EQA) had taken place prior to the national review of screening in 2018. However, due to ongoing changes in the delivery of the cervical screening programme in Scotland and the review of the extant Healthcare Improvement Scotland cervical screening standards, the scheduled plan for EQA was halted. A plan for EQA of screening programmes in Scotland is currently being developed by Healthcare Improvement Scotland with input from screening stakeholders.
- 99.** While there is some evidence of assurance and monitoring activity at a national and local level within the programme, this is an area that requires to be further strengthened. The absence of a robust quality assurance system for cervical screening means that there has been no consistent or regular monitoring of the programme at NHS board or national level. This is of concern to the review group. An effective quality management system, underpinned by robust systems and processes and clarity around roles and responsibilities, is essential to driving continuous improvement and ensuring that the essential levels of quality and safety are met. This gap should be addressed as a priority.

### **Recommendation 12: Quality management system**

A formalised quality management system should be implemented to support a consistent and coordinated approach to delivering high-quality cervical screening services, with focus on continuous improvement. The quality system should clearly describe the assurance methods used, the processes for escalation, and any additional support for quality and safety concerns.

### **Recommendation 13: Local quality assurance arrangements**

NHS boards should review their local processes, systems and governance arrangements for quality assurance of cervical screening. This includes:

- Monitoring and review of programme management and delivery, and
- Monitoring performance against Healthcare Improvement Scotland cervical screening standards (2019).

## Management of adverse events

- 100.** An Adverse Event workbook for screening programmes was implemented in 2017 and this is now used to ensure consistency of the management of an adverse event. Adverse events occurring before the implementation of the workbook were considered by the review group given the time span of the review. Prior to 2017, adverse events would have been expected to be investigated and managed in line with NHS board protocol.
- 101.** During 2015 and 2016 two separate investigations into inappropriate exclusions from the cervical screening programme took place. One (2015) was found to have happened as a result of inappropriate exclusions placed on legacy call recall systems by users and one because of a bug (an error in programming and functionality) within SCCRS (2016). This error meant that women who had received a subtotal hysterectomy, which was recorded onto their SCCRS record, were then erroneously marked as 'not for recall'. During the investigation (2016) human error marking of 'not for recall' for subtotal hysterectomy records was also found. The review could find no evidence of learning from the first investigation (2015) being taken into account for the second investigation and therefore both situations were dealt with separately. The review group believe this was a missed opportunity to consider exclusions in the round, including potential failsafes or monitoring to ensure that risk was recognised and mitigated. Root cause analysis was not carried out. The review group believe that if this had been done, the problem with inappropriate exclusions would have been identified at an earlier date. The evidence from submitted documentation shows that, in one incident, a board coordinator suggested that a root cause analysis should be undertaken but this was not taken forward. The evidence provided demonstrated that these incidents were not identified as adverse events by NSD and the national screening programme.
- 102.** The review group considers that a number of incidents within the programme prior to 2017 should have been managed as adverse events and the evidence submitted indicates that when the adverse event policy was implemented, it was often at the request of local NHS board stakeholders. Without a formal adverse event process being triggered, evidence showed that reflection and root cause analysis was not always undertaken for these incidents.
- 103.** We found that prior to 2017 there was no national systematic process to review or act on cervical screening adverse events and enable learning. Adverse events were often recorded as anomalies, using an SBAR communication tool to escalate issues or inform stakeholders, with limited use protocols or reporting mechanisms.<sup>14</sup> This occurred following 2017 despite the availability of the workbook, with one event occurring in 2018. This was linked to a previously managed adverse event regarding exclusions. Instead of managing this using the workbook it was managed using an SBAR.

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<sup>14</sup> SBAR: Situation, background, assessment, recommendation. An easy to use, structured form of communication that enables information to be transferred accurately between individuals.

**104.** Following an adverse event workshop held by NSS in September 2019, a complete review of the screening adverse events policy was undertaken and the *Management of Screening Adverse Events in National Screening Programmes Policy* was brought into use in April 2021.

**105.** In focus group discussions, NHS board representatives were invited to consider how they raised adverse events. It was reported that there was a route to escalate adverse events nationally if required. However, it is unclear how NHS boards' adverse event policies are linked to NSS's policy for screening adverse events.

**106.** The review group believes that there is a lack of knowledge and understanding amongst all levels of staff within the cervical screening programme about screening incidents and adverse event management. Any new policy must be supported by appropriate training for all screening programme staff.

#### **Recommendation 14: Management of Adverse Events**

The *Management of Adverse Events in National Screening Programmes Policy* should be implemented consistently across Scotland, including the management, reporting and review of incidents and near misses, to ensure learning and improvement takes place.

#### **Audit and Disclosure**

**107.** The purpose of the National Invasive Cancer Audit (NICA) is to:

- Monitor the quality and effectiveness of the cervical screening programme
- Compare the screening histories of individuals who develop cervical cancer with those who do not
- Identify areas of good practice and show where quality improvements might be made, and
- Support learning and development for organisations and the cervical screening programme.

**108.** The most recent incident of erroneous exclusion of women from the cervical screening programme was identified through the NICA. The review found that all NHS boards have contributed to the NICA process since 2015. The membership and the frequency of meetings to consider the audit results varies from annual to quarterly at Board level.

**109.** The evidence submitted to the review demonstrated that there was some initial reluctance to contribute to the audit in some NHS board areas. Some NHS boards felt that the process was cumbersome or that there were data privacy issues. From our focus group discussions, it was evident that the value of the NICA, and its role in assuring quality, was not yet fully understood by some staff working within the programme, despite the adverse event taking place.

**110.** The review noted that some NHS boards had contributed to the NICA for many years as pilot sites. These NHS boards continually championed the audit, and its benefits to the

women and the cervical screening programme, as a means of enabling quality improvement.

**111.** We found that the NICA was initially not fully functioning as a national audit, as it did not provide a complete national picture until after 2015. We found that the NICA was mainly being used at local NHS board level rather than results being aggregated and considered nationally for benchmarking, learning and improvement. Among some of the stakeholders engaged in this review there was inconsistency regarding their understanding of the objectives and outputs for the NICA. For the audit to be effective, all the findings drawn from data analysis and the subsequent discussion, including strategies to implement change, should be reported in a detailed account and distributed to all participants of the audit. The principles outlined in the following recommendation should be applied to all audits undertaken within the cervical screening programme.

#### **Recommendation 15: National Invasive Cancer Audit**

A review, and associated work, should be undertaken to ensure that the role and purpose of the National Invasive Cancer Audit as a mechanism for learning and improvement is fully understood and accepted by all staff working in the cervical screening programme. In addition to this the audit process should be reviewed to ensure that planning, execution and reporting against the audit are supported by rigorous due process.

Audit reporting should be strengthened to ensure that data are presented in a meaningful way, drawing conclusions and findings that support learning and improvement.

#### **Recommendation 16: Communication with women regarding the National Invasive Cancer Audit**

National Screening Oversight should complete their ongoing review of communication arrangements, including disclosure, with women regarding the National Invasive Cancer Audit. This communication review should be undertaken in association with organisations such as Jo's Cervical Cancer Trust to ensure that the needs of women are central to the process. All women diagnosed with cervical cancer should be made aware of their participation in the National Invasive Cancer Audit and given the opportunity to receive their results.

### **Disclosure**

**112.** The evidence submitted to the review group included an addendum document (May 2017) noting that the current process does not require the results of the individual NICA to be disclosed to participants unless the review outcome is classed as "unsatisfactory".<sup>15</sup> Evidence provided to the review, in the form of board coordinator group meeting minutes, indicated that the audit was undertaken for educational purposes only and therefore did not require disclosure. We followed this up with national and local board stakeholders. They confirmed that disclosure or offer of disclosure of results did not

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<sup>15</sup> Addendum to NHSSCSP Publication No.20, 3rd Edition- Exceptions Applicable in NHS Scotland

routinely happen, although some noted that it had recently been discussed in national governance groups due to routine offer of disclosure taking place within the English cervical screening programme. We found that most NHS boards had not identified any duty of candour cases arising from the audit, although one NHS board did outline a more proactive approach to disclosure.

**113.** In NHS England the *Cervical screening: disclosure of audit results toolkit*<sup>16</sup> provides guidance regarding disclosure of cervical screening history review results and applying duty of candour. This guidance clearly sets out the responsibilities of organisations providing cervical screening services to offer screening participants disclosure of their audit results. The organisation in which the clinician gives the woman her diagnosis of cervical cancer is responsible for offering her information about the screening history review and how she can receive the audit results if she wishes to have them. The organisation's medical director takes overall responsibility for ensuring this guidance is followed.

**114.** The NICA is a key performance indicator of the integrity of the cervical screening programme. Whilst individual participants have the right to access their personal health data and to request results from the audit, they can only exercise this right if they are aware the audit is taking place. Access to such information should be facilitated in a caring and holistic manner. Such an approach will help promote patient and public confidence in the cervical screening programme.

**115.** The review recognises the importance of a person-centred, open and transparent approach in all areas of the cervical screening pathway. NSS has reviewed and revised Scottish guidance for the NICA. However, at the time of writing this report, the final endorsement of this revised protocol has been delayed. In October 2022, the cervical screening programme board had discussions around enhancing the current process, including reviewing the current communication arrangements with patients diagnosed with cervical cancer. National Screening Oversight (NSO) is leading on developing specific duty of candour guidance for screening to ensure that a consistent approach is taken across all screening programmes.

### **Recommendation 17: Duty of candour**

Specific duty of candour guidance for screening should be finalised and implemented as a matter of urgency to ensure that a consistent approach is taken across all screening programmes.

**116.** This report makes a number of recommendations at both national and local level to deliver improvements in the management of exclusions from the cervical screening programme. It is important that these recommendations receive prompt attention and that Scottish Government determines which organisations and governance groups are best placed to take forward and implement individual recommendations. Arrangements should

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<sup>16</sup> <https://www.gov.uk/government/publications/cervical-screening-disclosure-of-audit-results-toolkit>

be put in place to establish a group that will have oversight of the process, track progress against the implementation of the recommendations and verify that the action taken has fully addressed the recommendation's original intent.

**Recommendation 18: Implementing the recommendations**

Scottish Government should consider which organisations are best placed to deliver the recommendations set out in this report. We recommend that Scottish Government should convene a working group with relevant expertise to explore the specific actions required to take forward the recommendations in this review and agree clear roles, responsibilities and timelines for implementation.

# Glossary

**Admin QA User Group** – a governance group within the national cervical screening programme structure with membership from Call and Recall management.

**Adverse event** - an event that could have caused or did result in harm to people or groups of people.

**Atos** – the private company which provides and supports the SCCRS system.

**Bug** – an unintended issue within an IT system, usually due to coding of the system. It affects how the system functions.

**Cervical board coordinators group** - A governance group within the national cervical screening programme structure with membership from NHS board screening coordinators, who are consultants in public health.

**Cervical screening programme board** – A key governance group which provides a level of national oversight to the cervical screening programme.

**CHI** – community health index, a number identifying each individual.

**Colposcopist**- a clinician who delivers treatment to women within the colposcopy department.

**Colposcopy** – an outpatient department where treatment of cellular changes on the cervix takes place. Colposcopy departments follow up women who have received treatment until they are back into the screening programme.

**Coverage** – the percentage of the people eligible for screening at a certain point of time. Often this is calculated in screening rounds.

**Cytopathologist** – A healthcare professional who looks at cells from the body to establish a diagnosis or finding.

**Duty of candour** – A legal duty in Scotland which sets out how an organisation should inform a person affected by an incident that has caused harm or death.

**Eligible cohort** – All of the women, and those with cervixes, who are eligible to receive a screening invitation in Scotland.

**EQA** – external quality assurance.

**Failsafe** – a measure, or process, in a system which seeks to address a point of inherent risk.

**Human papillomavirus (HPV)** – a group of viruses which affect cells within the body. High risk HPV in the cervix can cause cervical cancer.

**Key Performance Indicators (KPIs)** – a key indicator of progress or performance towards or against a quantifiable target.

**Laboratory Quality Assurance (QA) group** – a governance group within the national cervical screening programme structure with membership from cervical screening laboratories and pathology professionals.

**National invasive cancer audit - NICA** – an audit undertaken by boards which uses retrospective consideration of cancer patient notes to ensure that care was as it should be for the purposes of learning.



**National Screening Oversight - NSO** – A national function, hosted in NSS, which holds independent governance oversight for screening.

**National screening oversight board – NSOB** – a national governance group, hosted by NSS, which oversees operational aspects of national screening programmes and reports to the Scottish Government’s Scottish Screening Committee.

**NSD – National Specialist Services and Screening Directorate, previously National Services Division, part of NSS** – The commissioning directorate which commissions and oversees national aspects of the Cervical Screening Programme in Scotland, such as national governance and the SCCRS system.

**NSS – NHS National Services Scotland** – a special NHS Scotland health board which delivers key functions for screening.

**Participant management pathway** – a pathway which describes the participant’s journey through cervical screening, including referral and monitoring.

**Participant pathway** – this is the pathway that outlines each step of the screening process for a participant.

**Practice uptake** – the number of eligible women who take up the offer of cervical screening in a GP practice area.

**QA – Quality Assurance** – the process of monitoring and managing the quality and safety of a programme.

**QARC – Quality Assurance Reference Committee**

**Root cause analysis** – an analysis of an issue in order to find the root cause and inform solutions.

**Sample takers group** – a governance group within the national cervical screening programme structure with membership from cervical screening sample takers.

**SBAR – Situation, background, assessment, recommendation** – an easy to use, structured form of communication that enables information to be transferred accurately between individuals.

**SCCRS – Scottish Cervical Call Recall System** – the national IT system which identifies women who are eligible for screening, invites them and manages their journey through the screening pathway.

**Screening programme** – a programme whereby clinically eligible individuals are identified and offered a test to assess whether there is a disease process detected. If this is the case the screening programme will refer the individual to treatment. The aim of a screening programme is to detect disease earlier, so that treatment outcomes are better.

**SSC – Scottish Screening Committee** – a strategic oversight governance group, convened by Scottish Government.

# Appendix 1

## Expert Review Group Member Biographies – Cervical Screening Review

### **Dr Karin Denton (Chair)**

Dr Karin Denton is a consultant pathologist with North Bristol NHS Trust and leads the laboratory service for Cervical Screening in the South West of England. She previously held the role of Regional Head of Screening Quality Assurance for the South of England and has many years of experience in leading, developing and quality assuring cervical screening services. She currently chairs the national Laboratory Clinical Professional Group. Dr Denton also worked with Professor Gabriel Scally on a major review of cervical screening in Ireland.

### **Professor Vasanth Andrews**

Professor Andrews is an NHS consultant in obstetrics and gynaecology working at Lewisham and Greenwich NHS Trust. Clinical areas of interest include advanced minimally invasive gynaecological surgery and postnatal pelvic floor trauma. He was the elected South London members representative on the RCOG council and was also previously the Divisional Medical Director for Women's, Children's and Sexual Health in his Trust. He has been appointed visiting Professor at the University of Greenwich and in this role continues with teaching activities and also aims to improve links with midwifery colleagues.

### **Dr Sue Cohen**

Dr Sue Cohen is a consultant in Public Health Medicine with a special interest in screening programmes. Since 2018 she has been working as a consultant for WHO Regional Office in Europe advising on implementation of screening programmes in the European Region. She is the lead author on several WHO publications on screening.

Before 2018, she worked for Public Health England (PHE) as the National Lead for Quality Assurance, leading the development of a national system for quality assurance for all screening programmes across England. Prior to joining PHE she worked as a consultant in Public Health Medicine in Derbyshire leading on design, implementation and monitoring of screening programmes in the county.

### **Carole Davis**

Carole Davis started working in the cervical screening programme 40 years ago as a screening manager in the South West region, and was involved in the early 1980's in the development and national rollout of the cervical screening call and recall system. At this time, she worked closely with the IT development teams and assisted other regions in the implementation of the system.

In the late 1980's the rollout of the breast screening call and recall began, and she worked closely with regional colleagues to ensure the rollout in the South West region. Later in her career she moved to the quality assurance service as an expert advisor on the call and recall system. She has been involved in several national groups to advise on policy and investigation of incidents affecting the national programmes.

#### **Adv. Nurse Practitioner Gail Oliver**

Gail Oliver is an advanced nurse practitioner who has worked within a gynaecology outpatients setting since 2000. She has been a lead Nurse Colposcopist, accredited since 2002, and also the CSPL (cervical screening provider lead) for her Trust. Gail is a cervical sample taker and colposcopy trainer and she enjoys sharing her knowledge while providing evidence based learning. Gail has also worked as a PCA (professional Clinical Advisor) for the screening quality assurance services (South) and is a member of Colposcopy Clinical Professional Group, Education and Training Group and HPV primary development group. Gail understands the need for a multidisciplinary approach to all aspects of healthcare to ensure quality, improvements and excellent service delivery.

#### **Iona Stoddart**

Iona is the Deputy Head of Information and Engagement with Jo's Cervical Cancer Trust. For the past 16 years Iona's career has focussed on improving health outcomes for young people, and latterly adults who are less likely to engage with health services, within the charity sector and the NHS. Originally from the Western Isles, Iona now lives in Glasgow and leads on Jo's work to address inequalities and improve uptake of cervical screening in Scotland and enjoys working with a wide and varied group of professionals and communities in this role.

#### **Dr Anthony Williams**

Dr Anthony Williams is a Consultant Gynaecological Pathologist at Birmingham Women's and Children's Hospitals; Director of Birmingham Pathology Training Centre; Consultant Cellular Pathologist at University Hospitals Sussex; Honorary Senior Lecturer at Brighton and Sussex Medical Schools and Professional Clinical Advisor (Cervical Screening Programme) for Screening Quality Assurance Service.

# Appendix 2

## Terms of Reference

### Healthcare Improvement Scotland review of Cervical Screening System, Process and Governance

#### Introduction

1. During 2020-2021 an NHS Board undertook an invasive cancer audit, which found that two women with cancer had been erroneously excluded (up to 24 years ago) from the National Cervical Screening Programme. This was reported to the Cervical Screening Programme Board which agreed that an Adverse Event had taken place. As a result, a national Adverse Event Management Team (AEMT) was established and convened in March 2021. The AEMT comprised of stakeholders from across the screening pathway as well as representatives from Scottish Government, Healthcare Improvement Scotland (HIS), Atos and Public Health Scotland.
2. Initial investigation found that women had been excluded from the programme mistakenly, after being coded on the national Scottish Cervical Call Recall System (SCCRS) as having a total rather than a sub-total hysterectomy (whereby some cervical tissue remains). The application of these exclusions was initially identified as happening in the following instances:
  - a. Pathology recording sent to Cervical Screening labs/programme stating that total hysterectomy has taken place,
  - b. Application of exclusions at GP practice, following reports from hospital teams (a failsafe exists in an alert to call and recall teams to check the exclusion) and
  - c. Application of exclusions by sample takers, some of whom had not recorded journal entries for the application or had excluded despite subtotal hysterectomy being stated.
3. The identifying Board went on to interrogate the invasive cancer cases against SMR data to understand the root causes and found that from 60 invasive cancer cases reviewed 14 contained erroneous exclusion due to inappropriate exclusion or from inaccurate pathology reporting or discharge reporting to GP practices.
4. In March 2021, other NHS boards in Scotland were asked by the AEMT to undertake similar work. This identified women who required to be recalled and provided an accurate picture of the numbers of women erroneously excluded from screening. In addition to this, call and recall offices and GP practices were advised not to apply the exclusion status until failsafe procedures had been devised. As an urgent matter, an

audit was undertaken of records which had been excluded despite a subtotal hysterectomy being indicated.

5. As records after 1997 were more easily accessed, audits on these records were completed more quickly and around 474 letters were issued to women for follow-up. This was communicated in a ministerial press release in June 2021. Records where hysterectomies were performed before 1997 were subsequently audited and a further press release was issued in September 2021.
6. Scottish Government colleagues have commissioned HIS to undertake a review, considering systems, processes and systems governance within the cervical screening programme. This will seek to identify learning and inform improvements in the current Cervical Screening Programme. This, in turn, will hopefully improve the quality and safety of the Scottish Cervical Screening Programme.

## Role and Remit

7. Through the establishment of an expert review team and External Expert Review Group, Healthcare Improvement Scotland will seek to:
  - a. Explore previous iterations of cervical screening in Scotland (from 2000 onwards) in terms of call and recall and participant management processes and system governance.
  - b. Explore previous work undertaken to clean and manage data, including any exclusions, through the use of audits or data management exercises.
  - c. Explore data and system governance arrangements, specifically permissions, change requests, reporting, audit and escalation.
  - d. Explore the roles of acute and primary care in the systems and processes used by the national Cervical Screening Programme.
  - e. Consider the adequacy of systems, guidance and policy for ensuring that women are appropriately involved in, and/or informed of, decisions to exclude them from the national Cervical Screening Programme.
  - f. Consider whether there are identifiable lessons learned and make any recommendations which will support the improved safety and quality of the programme going forward.
  - g. Draw on lessons from previous audits and adverse events in relation to inappropriate exclusions, as well as the learning from other screening programmes in Scotland, the UK and beyond.

The three themes initially identified are:

- Systems
- Process, and

- Governance.

## Out of Scope

8. The following areas are out with the scope of the review:
  - a. The current Adverse Events Management Team work, undertaken to initially identify and resolve the issue.
  - b. Any action required by the individuals identified as having been inappropriately excluded from the programme.
9. Exclusions within the programme have taken place since 1959 until present day however, in order to maximise the value of the review in terms of learning and improvement, only those systems and processes for exclusions which have taken place from the year 2000 onwards will be considered.

## Review Methodology

10. The review team will:
  - be comprised of persons with the relevant skills and experience to provide key findings and recommendations for improvement,
  - work within the scope of the review and support to reach review timescales,
  - meet with key stakeholders within the screening pathway to gather information and data,
  - where appropriate, seek additional expert advice to complement the knowledge and skills of the review team,
  - consider key documents and data submitted by stakeholders to support the findings of this review,
  - assess best practice guidelines, clinical standards and any other relevant protocols and guidance, and
  - produce a report with key findings and recommendations to support the improvement of the programme.

## Expert Review Group membership

11. The expert review group membership is predominantly drawn from Public Health Screening fields across the UK nations. Membership will also include representatives of relevant organisations supporting women with an interest in cervical cancer and the national screening programme.
12. The chair of the expert review group is Dr Karin Denton, Consultant Pathologist.
13. Healthcare Improvement Scotland's Quality Assurance team will provide all necessary support to the group.
14. The review will be completed within 12-18 months from the date of commencement.

# Appendix 3

## Scottish Cervical Screening Programme Diagram



- Screening services delivered by NHS Boards
- Delivered by host NHS Board(s) on behalf of other territorial boards
- Supported by national delivery partners
- Diagnostic / treatment services
- Nationally commissioned by NSD

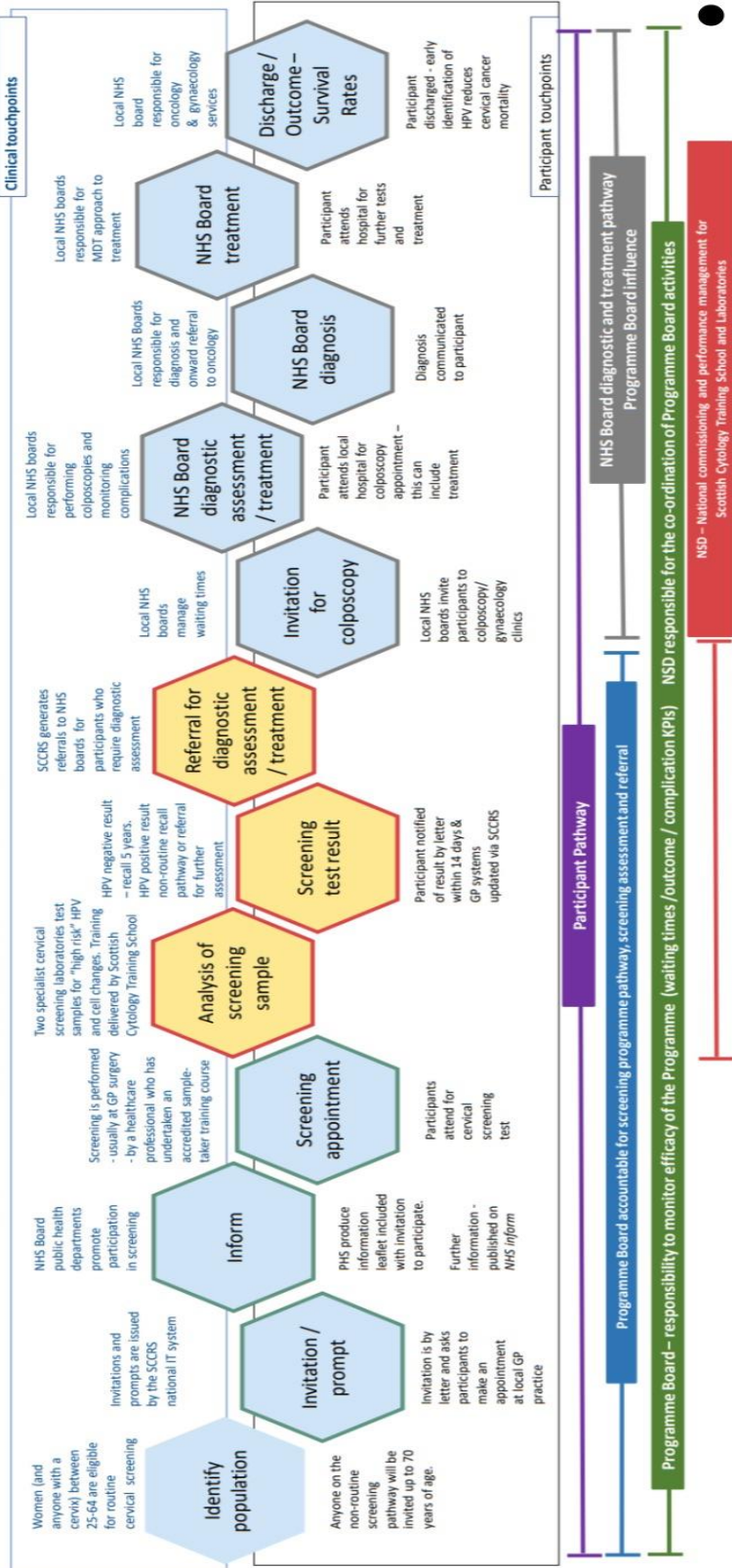
# Scottish Cervical Screening Programme

SCREENING INTERVAL

5 year routine screening interval

AIM

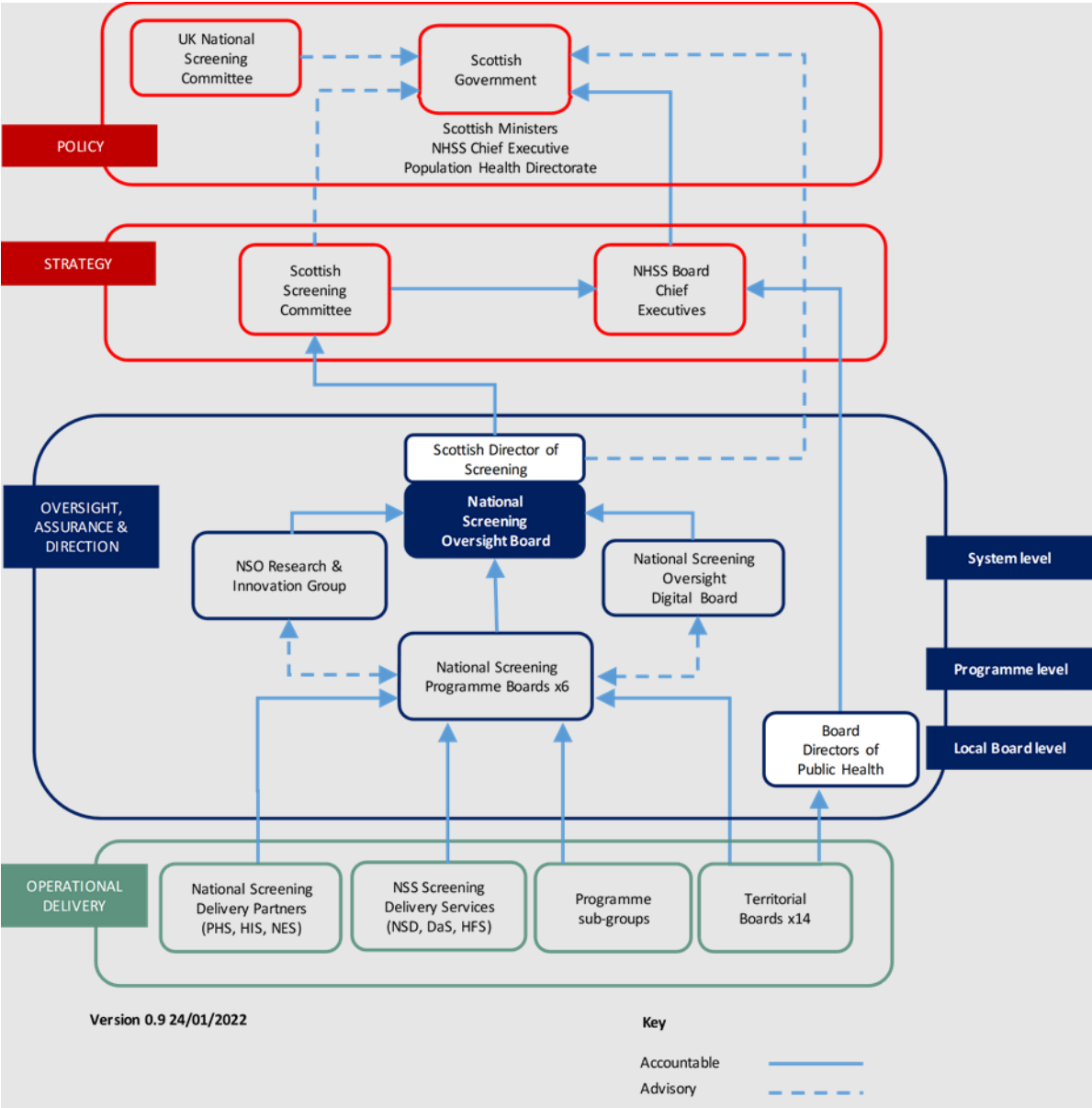
To detect HPV and/or changes in cervical cells early to reduce incidence of invasive cancer of the cervix



# Appendix 4

## Overview of governance and decision making structure

The organisations and groups involved in governance and decision making in the Scottish Cervical Screening Programme and how they relate to each other are set out in the diagram provided by NSD below.





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