Southern Health and Social Care Trust

TOGETHER, IMPROVING CARE, TRANSFORMING LIVES

Summary Learning Report

This report has been developed following
anonymisation and redaction of the
multi-patient SAI for women with Cervical Cancer

November 2025

Contents

1. EXECUTIVE SUMMARY 3
2. THE REVIEW TEAM 5
3. SAI REVIEW TERMS OF REFERENCE 5
4. REVIEW METHODOLOGY 6
5. BACKGROUND 7
6. DESCRIPTION OF CASES 16
7. FINDINGS 17
8. CONCLUSIONS 32
9. LESSONS LEARNED 33
10. RECOMMENDATIONS 34
Appendix 1: Definition of terms 39
Appendix 2: Abbreviations 41

1. EXECUTIVE SUMMARY

This Serious Adverse Incident (SAI) was commissioned following the completion of the Audit of Invasive Cervical Cancer for 12 patients in the Southern Health and Social Care Trust (SHSCT) over the period 2018-2024. These 12 women were found to have "unsatisfactory" findings in the Audit.

The Audit of Invasive Cervical Cancer is undertaken when a woman is diagnosed with cervical cancer. This audit is led by the Hospital Based Programme Coordinator (HBPC) and directed by the Public Health Agency (PHA). The purpose of the audit is for education and learning. This is done through review of cervical screening histories. The cervical screening process involves many steps which aim to find and treat abnormal cells on the cervix to prevent cancer from developing. It is important to emphasise that cervical screening is not a diagnostic test. The smear test collects a sample of cells which are checked for pre-cancerous changes. If detected, these pre-cancerous changes can be treated, preventing the potential progression to cancer.

Northern Ireland has an effective cervical screening programme. The effectiveness of the programme is reflected in cervical cancer case data, with 8.8 cases/100,000 person years in Northern Ireland compared with 11.35 cases/100,000 person years in the Republic of Ireland and a global average of 13.3 cases/100,000 person years. Over 1.9 million smears have been reported in Northern Ireland since April 2008, 400,000 of these were reported by the SHSCT. Northern Ireland has around 81 diagnoses of cervical cancer per year, with on average, 15 of those within the SHSCT. The women included in this SAI had diagnoses of varying types of cervical cancer including: Adenocarcinoma (6), Squamous Cell Carcinoma (4), Adenosquamous Carcinoma (1) and Adenocarcinoma of Endometriod Type (1).

The SAI review team examined the clinical records, laboratory records, PHA policies, Trust policies and all relevant guidance relating to cervical screening to inform this report. The review team met with a number of the 12 women to better understand their personal histories and their experience of the disclosure process.

The review team found that there was underperformance over many years of a small number of cytology staff and the management of this underperformance was inadequate, this underperformance was also highlighted in the Royal College of Pathologists (RCPath) report (2023). This failure of effective oversight allowed this

poor performance to persist resulting in significant harm to some of these women. Staffing levels in the laboratory were insufficient to deal with the workload leading to long delays and excessive use of overtime. The review team found evidence that the quality of the service suffered because of these shortfalls.

The review team found an overreliance by SHSCT on the annual quality assurance visits from the PHA and confusion relating to lines of responsibility for staff underperformance.

The review team also found a poor understanding of the clinical governance systems from the laboratory staff and a lack of adequate oversight from central governance in the Trust. The Hospital Based Programme Coordinator (HBPC) was not recognised in the Trust as a key quality assurance role and was not afforded the support required to discharge this role as envisaged by the PHA.

The review team did not find a pattern of underperformance specifically relating to the 12 women. However, a small number of cytology staff have had a disproportionate input into the false negative results for these women, resulting in a delayed cancer diagnosis and timely treatment. It must be noted that the screeners identified also screened up to 3 times more cases than other staff.

The review team were told by all women interviewed that the disclosure process was clumsy, distressing and retraumatising. Finally, the minutes for their disclosure meetings caused offence and women interviewed stated that the whole process re-traumatised them.

This report would not have been possible without the cooperation of the women involved and the staff at SHSCT and PHA. The team would like to take this opportunity to thank everyone for their patience, openness and honesty in helping the team understand in detail the sequence of events leading to this incident.

2. THE REVIEW TEAM

Olive MacLeod – External Independent Chair

Margaret Morgan – External Cytology Expert

Naomi Allen – Risk Midwife (SHSCT), SAI facilitator

3. SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this SAI review are:

1. To carry out a systematic review of cervical screening process (to include relevant cervical cytology, histopathology, gynaecology and administrative processes) of the twelve patients arising out of the Audit of Invasive Cervical Cancer in the period from 26/11/2018 to 07/05/2024 determined to have category 3 outcomes and as such identified as SAIs.

2. Using Root Cause Analysis (RCA) Methodology, determine how the *Framework for the Audit of Invasive Cervical Cancer and Disclosure Findings (v 18 Feb 2019)* with the Public Health Agency (PHA) Framework Update dated 10 June 2024 was followed for each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.

3. To listen to patients' experience of the disclosure meetings / process to establish learning that to inform future Audit of Invasive Cervical Cancer disclosure protocols and practice in the future.

4. Share the draft TOR of the SAI with individual patients / families to elicit specific questions for the review team to where possible answer / address within the review process and finalise the TOR thereafter.

5. To review the governance and oversight of the cervical screening process(es) within the Southern Trust to identify areas of good practice and opportunities for learning.

6. To make recommendations to reflect what lessons are to be learned and how our systems can be strengthened to minimize the possibility of similar adverse events occurring in the future.

7. To prepare one overarching report drawing together learning arising from the review, but to also provide a customized individualized (sub)report for individual patients/families to include specific learning for the respective patient.

8. To share the written report(s) with patients and families involved as well as the Director of Surgery and Cancer Services, Medical Director of Southern Health and Social Care Trust (SHSCT), Staff involved, Strategic Performance and Planning Group (SPPG), PHA.

9. To escalate any matters of concern arising out of the review to Trust Directors, and PHA if appropriate.

4. REVIEW METHODOLOGY

The review followed the Regional Serious Adverse Incident Framework and were cognisant of the rights of all involved to privacy and confidentiality.

The medical records held in respect for the 10/12 patients were secured in advance of the review and were used to facilitate a timeline account of each woman's involvement in the cervical screening process. These timelines have been included in the individual reports given to each woman and summarised in the main body of this SAI under the section "Description of the Incident".

As discussed in the Executive Summary, those patients who had attended their disclosure meetings were invited to meet with the SAI Chair and to provide written questions to address their specific issues and concerns. These questions were included as part of the review methodology.

The methodology of Root Cause Analysis was used to analyse information collected during the review.

The Root Cause Analysis considered:

1. The audit findings relating to each patient.
2. The cervical screening history for each patient.
3. The application of the 2019 "Framework for the Audit of Invasive Cervical Cancers and Disclosure of Findings"

4. The disclosure process.
5. All laboratory data has been provided by the SHSCT

Please also see the reference list for all guidelines and reports analysed as part of the review process.

5. BACKGROUND

A formal cervical screening programme was established in 1988, the purpose of which was to reduce the incidence of cervical cancer and to prevent women dying from it (morbidity). National Health Service (NHS) cervical screening is offered to all women every three years for those aged 24-49 and every five for those aged 50-64.

An average of 5000 – 10,0000 cells are manually examined at any one time by the operator during the screening process (6 - 8 minutes) and all slides are quality assured (60-90 seconds) by a second operator. A full check of the slide is required in some, but not all, cases. Abnormal cases are referred to a consultant for a final opinion.

Reflex HPV testing of borderline and low grade samples was regional screening policy from January 2013.

In December 2023, HPV was fully implemented as the new primary screening test due to its increased sensitivity. Cytology became a reflex test (see glossary of terms) and only performed on HPV positive cases. Cytology is used to identify abnormal cervical cells and importantly grade into negative, low grade (which includes borderlines) and high-grade abnormalities. Accurate cytological grading helps determine the management which the patient will be offered in colposcopy. It is worth noting that it is possible to have a HPV positive result and a cytology negative test. Many women will clear the HPV virus hence a management of repeat testing in one year is given to allow time for the HPV virus to regress.

Persistent HPV positive/cytology negative cases are referred to colposcopy on the third test.

The recall ranges are currently under review by the NHS Cervical Screening Programme (NHSCSP). The primary screening test in NI up until December 2023 was cytology, where cells taken from the cervix are examined under a microscope by highly trained staff (cytologists) who are mostly Health and Care Professions Council (HCPC) registered Biomedical Scientists specialising in gynaecological cytology.

The UK National Screening Committee states that it is important to have realistic expectations of what a screening test does, and that it will not identify all cases of disease. False negative and false positive tests occur in all screening programmes.

The cervical screening service in NI is commissioned by the Public Health Agency (PHA). From November 2024 all screening is carried out at Belfast Health and Social Services Trust (Trust 2). Prior to this there were four cervical screening laboratories in NI. The SHSCT ceased reporting cervical samples in October 2023.

Many elements must come together to provide a high-quality cervical screening service, and these will be discussed in detail in this report. The NI programme, with a few exceptions (derogations), aligns closely with the wider programme in England. The exceptions include: working standard is ≥98% of samples authorised within 14 days from the date the sample is taken, and minimum laboratory workload numbers (minimum of 35,000 slides) in the English programme.

Quality assurance, ongoing performance monitoring and a robust clinical governance framework underpin a high-quality service. Regular data collection and submission to Trust and PHA provides reassurance and oversight that the laboratory and staff are performing to recognised standards. Equally, data will identify trends and raise “red flags” if there is a shift in performance which impacts quality of the service and potentially could cause patient harm.

The role of the Hospital Based Programme Coordinator (HBPC) is a key role within a cervical screening service and has oversight of performance in cytology and histology laboratories as well as colposcopy services. The HBPC aligns to the Cervical Screening Provider Lead (CSPL) in England but with less authority and accountability. In NI, it is more of an “audit co-ordinator” for the audit of invasive cervical cancer.

Following a change in clinical leadership at the laboratory (March 2019), SHSCT senior management received formal notification (October 2021 and July 2022) raising concerns of poor performance within the laboratory. The new management also raised the issue of poor performance in other forums in November 2021, December 2021 and January 2022 to the Trust, and February 2022 to the PHA. This triggered a series of meetings involving the Trust and PHA. The SHSCT approached the RCPath to undertake a Risk Assessment, and a report was received in May 2023 which found there to be significant performance issues with a number of screening staff.

The SHCST and PHA considered the recommendations from the report and reviewed the records of about 17,000 women screened during the period in question. The review became known as the **Cervical Cytology Review (CCR)**. No cervical cancers were identified during the "CCR" and also went someway to diminish concerns in the RCPath report which stated, "that while most results issued by the laboratory were correct, a significant number of women were likely to have received negative screening results on tests that would have been identified as abnormal in other laboratories".

The CCR report concluded:
96**%** of women (n=14,951/15,566) who had a slide reviewed had no change to their original result and required no further follow up.

64 women were invited to attend colposcopy or gynaecology review and were discussed at MDM. Of these, 56 women attended their colposcopy appointment.
Of these 56 women:

- 21 women had a negative (normal) result and therefore required no treatment and were discharged.
- 24 had evidence of pre-cancerous changes to their cervix which did not require treatment. These changes usually go away on their own without treatment. However, these women have been invited for gynaecology/Colposcopy follow up.
- 11 women had pre-cancerous changes to their cervix or another significant incidental finding which required treatment. These women have either completed or are undergoing a treatment pathway.

A second report "**Cervical Cancers in The Southern Health and Social Care Trust"** is a comprehensive review at cancer rates in Northern Ireland from 1997 – 2021. The report

concluded that “when adjusted for the population, data from the registry show that there is no statistical difference between trusts in the number of cases of cervical cancer, the stage at which they have been diagnosed, deaths from cervical cancer or the number of cases of pre-cancerous changes of the cervix. The incidence of cervical cancer in Northern Ireland has also been reported as being similar to the UK average”.
Both reports should be read together and not in isolation by following the link below:
https://southerntrust.hscni.net/cervical-cytology-review-reports-published/

Human Papilloma Virus and Cervical Cancer

Persistent infection with human papillomavirus (HPV) is the principal cause of cervical cancer and it is a precursor of cervical intraepithelial neoplasia (CIN)1-3. The presence of HPV has been implicated in greater than 99% of cervical cancers, worldwide. Regular attendance for cervical screening will reduce the risk of developing cancer by identifying pre- cancerous changes so that they can be monitored for regression or treated if necessary.

There are two main types of cervical cancer associated with persistent high-risk HPV infection: squamous cell carcinoma which affects cells on the cervix and adenocarcinoma which usually arises in cells which line the endocervical canal. Adenocarcinoma precursors/pre-cancer can be more difficult to identify on cytology but over the last two decades there has been considerable improved learning and education in this area. (Please see Appendix 4.0)

Grading and Management of Cervical Disease in Cytology

The table below (PHA) sets out the grading and management of abnormalities found on cytological examination at time of CCR audit review. Incidental findings can occur such as the presence of infections and endometrial cells. These may form part of the cytology report but are not directly related to cervical cancer.

RESULT REPORTED	DESCRIPTION	ACTION/FOLLOW UP
Cytology Normal (or Negative)	No abnormalities seen in cervical cells.	Return woman to routine screening within the NI Cervical Screening Programme (i.e. they are called for another smear in 3 to 5 years depending on age and date of screen).
Low-grade abnormalities (borderline and low-grade cell changes)	This result suggests there are some abnormalities in the cells within the cervix. Research suggests that around half of borderline and low-grade abnormalities return to normal within 18–24 months without treatment.	These samples underwent a further test using **HPV testing**. If the HPV test was positive, the woman was referred to **colposcopy** for further investigation. If the HPV result was negative the woman would have been returned to routine recall (i.e. 3 to 5 years depending on age).
High-grade abnormalities (moderate or severe cell changes) and **query glandular Neoplasia of endocervical type**	This result means that there are likely to be abnormal cells in the woman's cervix. These abnormal cells have a greater potential to develop into cancer if left untreated.	Woman referred to gynaecology services for colposcopy investigation/treatment.
Borderline endo-cervical changes	This result means that there are small changes in the glandular cells of the cervix. These are often due to the HPV virus. These changes are usually minor and return to normal on their own. However, there is a risk that changes could progress and may require treatment.	These samples were managed in the same way as low-grade cervical changes until 2019. From 2019 onwards, these women would have been referred directly to colposcopy.
Inadequate	A smear is deemed to be inadequate when the slide is unreadable. This can happen for a number of reasons (e.g.: not enough cells in the sample, or too much blood on the slide to view the cervical cells.	Woman invited to attend for a further smear in 3 months.

Staffing Within SHSCT Laboratory

Staffing in UK cytology laboratories during the last decade has not been without challenges. From staff interviews within SHSCT, they experienced difficulties in recruitment and retention. This position is thought to be mostly due to the pending switch from cytology primary testing to HPV testing. An air of uncertainty loomed over cytology screening services as science graduates were reluctant to enter the profession as career progression was deemed uncertain and retention became an issue as staff relocated to other Trusts for promotion and job security. In addition, the laboratory in SHSCT operated a unique service model of joint histology and cytology service with some staff working across both. This is not a service model recognised across other laboratories in Northern Ireland.

The following section from the British Association of Cytopathology (BAC) Code of Practice is included to help the reader understand the regulations which are applied to cervical screening laboratories in the UK and explain the findings in section 7.0 of this report.

Staffing and Workload

Staffing requirements, as directed by the BAC Code of Practice, state that laboratories are expected to report a minimum of 35,000 samples per annum (not applicable to NI). Primary screeners are expected to screen a minimum of 3000 cases per annum (under review by NHSCSP), checkers who also perform primary screening duties are expected to screen 1000 and check 750 slides per annum. Checkers and consultants 750 cases per annum. Workload figures are in place to ensure staff report enough samples to maintain competency. As laboratories reconfigure and centralise in the new era of HPV testing and the impact of HPV vaccination, it is expected that less cervical disease will be present in the population. For this reason, workload figures are currently under review by the NHSCSP and are likely to reduce. It is worth noting that as long as quality standards are met, the BAC make no evidence-based recommendation regarding a maximum number of slides per annum. Members of staff may perform many different duties and the amount of time available for primary screening varies between departments. Screeners can safely undertake primary and rapid screening for up to five hours in any working day.

Training of Staff

BAC Code of practice sets out the guidance clearly on training and post registration training of staff employed within the NHS Cervical Screening Programme. Cells are carefully screened by a team of professionals who are highly trained and are a heavily regulated workforce. All cytologists must undergo rigorous training, a minimum of two years in a fully UKAS accredited laboratory and a recognised Institute of Biomedical Science (IBMS) training laboratory. At the end of two years cytologists must pass a specialised examination in cervical cytology before they can independently report samples. Post qualifying all screening and reporting staff must:

- participate in the national external quality assessment (EQA) scheme,
- undertake mandatory update training in line with NHSCSP requirements
- undergo mandatory retraining after a prolonged period of absence and,
- participate in continuing professional development (CPD) and educational activities as required for their role.

There is a continual performance monitoring of individuals against national standards through quarterly reviews which include workload, sensitivity and specificity rates.

Quality assurance

Good quality assurance provides the foundation for a high-quality cervical screening service. The BAC states that the lead consultant is responsible for the quality of the work, including the establishment of monitoring procedures and maintenance of efficient working practices, although some duties can be delegated to other consultants and biomedical scientists.

Departments must have a named quality manager in line with UKAS ISO 15189 requirements. There must be internal quality control (IQC) systems to ensure that appropriate quality checks are in place, undertaken and documented at all stages in the receipt, processing and reporting of cervical samples. Quality checks should be appropriately designed to be able to identify possible quality problems should they exist. Trend analysis must be carried out to identify any persistent issues and all remedial actions recorded. All potential quality issues that arise must be documented, fully investigated and action taken as required to address any shortfalls.

External quality assessment (EQA) schemes

Participation in EQA schemes is integral to assuring a quality cervical screening service. The BAC endorses the national requirements that any performance issues identified at either laboratory or individual level must be documented and investigated, with any associated corrective actions recorded.

Performance monitoring

The lead consultant is responsible for performance monitoring of the laboratory as a whole and of individual staff, although national Cervical Screening Programmes (CSPs within England, Scotland, Wales and NI) may vary with respect to governance and monitoring arrangements.

The mandatory key performance indicators (KPIs) currently in use for England, NI and Wales include inadequate/unsatisfactory rates, positive predictive value (PPV) and referral value (RV) and consultant KPI's. It should be noted however, that these indicators should not be looked at in isolation and may be influenced by local practices in histology and colposcopy as well as cytology performance. KPI data should be produced at least quarterly with an annual summary, this usually is the responsibility of the Cervical Screening Provider Lead (CSPL) or Hospital Based Programme Coordinator (HBPC) in association with the laboratory manager.

Individual performance monitoring

Screener sensitivities and specificities, as determined from rapid screening and rates of abnormal results, should be regularly monitored, and ideally calculated on a 12-month rolling basis to ensure statistical validity.

The current high grade sensitivity rate is equal or >95.0% and the all-grade sensitivity rate is equal or greater than 90.0%.

In NI, the PHA produces annual statistical reports. Laboratory performance is formally reviewed at annual laboratory visits. This can be found at:
Cancer Screening Northern Ireland | Cancer Screening Northern Ireland

It is the individual Trust's responsibility that all staff should receive their individual performance profile at least quarterly, with the opportunity provided to discuss issues arising with a senior member of staff. There must be a mechanism detailed in a Standard Operating Procedure (SOP) for identifying and managing persistent poor performance and instigating remedial action where required.

Managing substandard performance

Underperformance of an individual can be identified through Internal Quality Control (IQC) or EQA and must be managed in accordance with the laboratory's SOP on managing substandard performance and/or appropriate employer policies.

The workload and reporting profile of the individual should be reviewed, and an action plan agreed with the individual detailing the support required. This may include double screening of their work for an agreed time. Further advice may be sought from the Cytology Training Centres (CTC) and a suitable plan devised which may include attending a relevant formal training course/courses.

False negative results

False negative results occur in any screening programme for various reasons including: sampling, technical issues, low number of abnormal cells or an interpretative error by screener or pathologist. The aim of the cervical cancer audit is to look back and try to understand the reasons for a miss or an interpretation error which delayed referral and treatment. This review has focused on cervical cancers which have been classified as category 3 (unsatisfactory), to report on the audit review results and identify trends which will support future learning and improvement in cervical screening in NI.

In 2019, "*The Northern Ireland Framework for the Audit of Invasive Cervical Cancers and Disclosure of Findings* was published and was to be implemented across Northern Ireland. The purpose of the audit is to monitor the overall effectiveness of the screening programme, to identify areas of learning, and highlight areas where further improvements can be made. It is the responsibility of the relevant Health and Social Care Trust to inform a woman diagnosed with an invasive cervical cancer that her screening history will be reviewed, and to offer appropriate feedback on the outcome of that review. The audit will

review a woman's screening pathway, including a review of any previous screening tests, diagnostics, and any clinical treatment.

Findings are classified as either Category 1, Category 2, or Category 3 outcomes.

Category	**Description**
Category 1: Satisfactory review	No untoward findings
Category 2: Satisfactory review with learning points	False negative cases or minor process or management shortcomings but considered to be within the limitations of the screening programme.
Category 3: Unsatisfactory review	False negative cases or significant process or management shortcomings that constitute a patient safety incident.

Where the audit finds no adverse or limited changes in previous cervical screens, they are classified as Category 1 and 2 outcomes. In these cases, patients are notified that an audit review has been completed and if the patient agrees, the outcome disclosed.

6. DESCRIPTION OF CASES

The review team conducted individual reviews on 12 patients identified as having a Category 3 outcome from the Invasive Cancer Audit from 2018-2024.

These individual case descriptions have been redacted to preserve confidentiality of the individual patients.

7. FINDINGS

The SAI review team were tasked with carrying out a systematic review of 12 patients with category 3 outcomes arising from the Audit of Invasive Cervical Cancer from 2018-2024. The SAI review team looked in detail at how processes were followed and, where they have occurred, identified adverse factors which have contributed to clinical outcomes. Governance, leadership and oversight of screening processes were investigated with areas of good practice and opportunities for shared learning documented in this report. The screening data presented within this report is complex, however the SAI review team endeavoured to explain the interdependencies which must be aligned to deliver a high-quality cervical screening service.

The SAI review team recognise that some of the recommendations made in this report no longer apply to the SHSCT as the cervical screening in NI is now centralised into one regional laboratory at Belfast Health and Social Care Trust. It is anticipated that the new service will take on board the shared learning and recommendations from this report where applicable.

The focus of this SAI report is different and limited to 12 patients, but the investigation concurs with RCPath findings published in May 2023.

Findings of Good Practice

During this SAI, the review team noted some evidence of good practice:

- The cytology laboratory was able to produce good quality data at laboratory and at individual level as far back as 2007/2008.

- Training within the cervical screening programme is highly regulated. SHSCT training records showed a good level of compliance and participation in EQA and attendance at mandatory updates. Any gaps were explained during management interviews and mostly due to prolonged periods of absence. One cytology screener was identified as having a total of 5 unavoidable rounds of non-participation in EQA due to 2 periods of maternity leave and one period of sickness absence.

- Implementation of primary HPV testing on 11 December 2023 across Northern Ireland.

- SHSCT acted with integrity by commissioning a *Cervical Cytology Review Outcomes* report (CCR) of over 17,000 samples. The report concluded that 96% of cases concurred with the original report, 11 individuals were identified as having an abnormal sample which required further treatment. No new cases of cancer were found during the CCR.

- PHA publication (Dec 2024) *Cervical Cancers In The Southern Health and Social Care Trust Area* provides reassurance there is no statistically significant difference in the number of cervical cancers diagnosed in the SHSCT between 1997-2021 compared with the Northern Ireland average. The data from the SHSCT is similar to audit findings in England.

Finding 1: Disclosure of the Audit Process

As per the "Framework for the Audit of Invasive Cervical Cancers and Disclosure of Findings", all women diagnosed with invasive cervical cancer must be given the information leaflet *'Reviewing your Cervical Screening History'* (printed in 2010 and updated in 2024) at the time of diagnosis. This leaflet explains that an audit will be undertaken, and why. This information leaflet also explains that the audit results will be made available to the patient upon completion. The PHA recommend that this is documented in the patient's notes on an "Audit Disclosure Record Sheet" and that good practice would be to check the patient's understanding of the audit process at their next appointment. The SAI review team could not find any evidence either in the patients' electronic records or paper medical records that these recommendations were followed. The SAI review team met with a number of women, both at the beginning of this SAI and following the initial sharing of the draft report, and none of the women could remember ever being informed that an audit was being undertaken into their cervical screening history. Therefore, they were never aware that there was a delay in the commencement of their audits, nor a delay in the completion of the same. It must be considered by both PHA and Trusts, when is the most appropriate time to inform women of the audit process as the time of diagnosis can be a time of "information overload".

The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) (2015) have published a joint report on the duty of candour for Health Care Professionals requiring them to be open, honest and transparent with the patients in their care. Therefore, once the audit into the patient's cervical screening history is completed, the MDT should agree an outcome category and the disclosure process should be agreed. It is entirely the patient's prerogative if they do not want to know the findings of the audit and the patient is also entitled to change their mind at any time.

As per the guidance by the PHA (2019), 10 of the 12 women included in this SAI were written to, advising that the results of the audits were available, and an appointment was offered to discuss these with the Consultant if they so wished. An example of the letter sent is detailed below:

> *As you may be aware the Trust carries out a review of cervical screening histories in all women diagnosed with cervical cancer. This is normal practice and the review looks at your involvement in cervical screening. It is an important part of the cervical screening programme providing an opportunity for us to learn and improve our service.*
>
> *This process is now complete for your case.*
>
> *Please tick one of the boxes below and return this form in the envelope provided to let them know whether you would like to know the outcome of your review.*
>
> □ *I want to know the results of my cervical screening history review.*
> □ *I do not want to know the results of my cervical screening history review now, but would like you to remind me of this offer in 6 months' time.*
> □ *I do not want to know the results of my cervical screening history review. I understand that I can change my mind at any time.*

However, two women, whose care was provided in another Trust outside of the Southern Trust, received routine outpatient appointment letters, giving them no warning of the serious results that were to be conveyed to them. Both women received generic Gynaecology appointment letters which stated that the reason for the visit was "Review Patient Appointment", giving absolutely no indication what this appointment was for or

that information that was going to be shared had the potential to cause great emotional distress.

As part of the review process, all of the women were invited to engage with the SAI process through their Liaison Officers and had the opportunity to meet with the chair of the SAI and the Risk Midwife. The review team found that this initial letter caused confusion. One patient thought that the letter was regarding a survey, another thought it was in connection with the cancer treatment received. One patient described that the letter was misleading as it did not "allude to the gravity of the information that was going to be disclosed". Another woman informed the SAI team that she felt the letter was inviting her to a meeting to 'talk about my cancer journey'. When she tried to find out more about the purpose of the meeting, she received a call from her Cancer Nurse Specialist but found it difficult to process the information that she was given regarding the purpose of the disclosure meeting. This woman was informed that she would be receiving information regarding 'a misread smear' and was left to wonder and worry what more they would learn. Vague and ambiguous information only served to cause confusion and worry. To summarise, the letter has been described as vague, misleading, and ambiguous. The SAI review team learned that one patient threw their first letter in the bin as they thought it was a junk letter looking for her to participate in a survey, another woman did complete the letter but "only to fill a morning", she also thought she was participating in a survey so opted to receive her disclosure meeting over the telephone so she would be at home for her child returning from school.

Those patients who wished to learn the audit findings were invited to attend a disclosure meeting. The 2019 Framework also provides advice on how the disclosure meetings should be organised:

- Check the patient's understanding of the audit
- Ascertain how much information she wishes to know
- Discuss the relevant reports and implications
- Invite her to voice any concerns or ask any questions
- Offer an appropriate apology
- Explain the Trust's complaints procedure

The patient must be helped to understand the reasons for any missed abnormality, suboptimal processes or management, and where appropriate the limitations of the screening programme. Providing a contact point for any follow up questions should also be considered.

The SAI review team learned that the patients were invited to attend a disclosure meeting either face to face, by telephone or in writing. These meetings were held on Fridays in Craigavon Area Hospital. Prior to attending, Liaison Officers made contact with the women and it was this contact that persuaded some of the patients to attend their disclosure meeting. The Liaison Officers were limited in what information they could provide in advance of the disclosure meetings, but their encouragement of the women to attend the meetings is what convinced the women that the information going to be shared was not just relevant, but of great importance. One woman jokingly described being "hounded" by her Liaison Officer to attend the Disclosure Meeting but on reflection, she was very grateful for this encouragement. The Southern Trust Liaison Service was made available to Trust 2 caring for two women outside of Southern Trust, but this service was declined by Trust 2.

Present at the disclosure meetings for 10 women were a Consultant Gynaecologist, Consultant Pathologist, Lead Nurse, Assistant Director for Integrated Maternal and Women's Health and a Liaison Officer. Having the meetings on a Friday caused some concern to the women, they described being left over the weekend without anyone to contact which only increased their worry and stress. Some women also described how the location of the meetings was unfair. Given the geographical size of the SHSCT, some women had to travel long distances to attend their disclosure meetings and felt that this was also unfair. One patient had to travel more than one hour to attend her disclosure meeting and she had attended the meeting alone as she did not realise the seriousness of what she was going to hear. This long journey home alone on a Friday afternoon exacerbated her fears, anxiety and emotional distress. Similarly, one patient who received their disclosure outside of the SHSCT, had to travel a long distance to the hospital hosting her meeting and found that having four health care professionals hosting this meeting created an intimidating environment. The SAI review team are of the opinion that there should have been more flexibility to arrange more suitable venues across the whole of the Trust to meet these women closer to their home environments.

Some women chose to attend their meeting via telephone. These women also described this as cold and impersonal as they were so shocked by the news of their disclosure that they were unable to think of what to say. Being conducted on a telephone made this worse as they felt pressured to end the call. One woman explained that if she had realised the magnitude of this information to be shared, that she would have opted for face to face so that she could have had the emotional support of a partner with her, rather than being the only voice on the telephone line. It had been assumed that the telephone appointment was routine and therefore was at home alone with no support. Women described being 'distraught' and 'tearful' following the telephone call and found that the information shared was 'unbelievable'. One woman advised the SAI review team that had she been aware that an audit was being conducted and what this may mean that, whilst the disclosure discussion would still have been difficult, she may have been more prepared for this.

As outlined above, the PHA does provide guidance on the content of the disclosure meetings: i.e. to discuss the outcome of the audit, to address any questions, to provide support and to apologise for any failings in care. The PHA does not provide guidance on the tone of these meetings, nor is there specific training available regarding how to make a disclosure. Those patients who engaged with the SAI team, described feeling intimidated by being in a room with five health care professionals, perhaps without a family member present. A number of women described how it was very difficult to receive the information whilst alone at the meeting, except for the professionals, and were upset that they had no prior indication that the information could be of such a magnitude. Women used words such as "flabbergasted", "shocked" and "horrified" to describe the impact of receiving the outcome of their Audit. Women were supported by having a Liaison Officer, but again, the lack of preparation beforehand permitted this opportunity for surprise and shock to overwhelm them. One woman thought she was attending a routine check-up and received an automated text message reminder with confirmation of appointment and location as 'obs @ gynae' department. This lady attended the Gynaecology ward but the nursing staff were unaware of any appointments and there was no information on any computer system regarding her appointment. Following a series of telephone calls, the health care professionals came to her, and conducted her disclosure meeting in a ward sister's office in the Gynaecology department. This was described as a very intimidating experience as she had been

expecting a routine appointment, not a meeting with five people, in a cramped office to inform her of the outcome of her audit. Women have described the disclosure process as being cold, lacked compassion and appeared to be routine to those sharing the news.

One woman who had her disclosure meeting outside of the Southern Trust had a very different experience. As previously mentioned, this patient had only received a generic appointment letter so had no prior warning what the appointment was for. She attended this meeting alone and met her Gynaecologist who she had only met on one occasion prior to this meeting, there were no other health care professionals at this meeting. Having had no knowledge that an audit had been carried out in the first place, this lady was horrified to learn the outcome of her audit. The SAI review team learned that the information shared with this patient was brief and rather than give the specific details of the Audit results, she was informed to contact the Southern Trust for further information and was given the contact details of a Southern Trust Laboratory clinician.

Following the disclosure meetings, women received a summary of the information shared. This also caused distress, as the information received was a clinical summary rather than a minuted account of what was discussed. One woman described this information as being “sanitised” and felt that like the rest of her story, it was a washing away of the truth. The SAI review team also learned from another woman who had had her Disclosure Meeting over the telephone, that she had requested the minutes of the meeting as she found it difficult during the meeting to take on board what had been discussed, however the minutes shared with her were “impersonal” and “scant”. There are many lessons to be learned from the experiences these women have shared.

There is a clear consensus among the team members that the time and effort given to these disclosure meetings fell below an acceptable standard. Whilst on paper they may have been open and transparent, the level of sensitivity and compassion was clearly lacking as reported by the women and the impact of this was witnessed by the team. Whilst this report has described the experience of women who received their treatment from SHSCT, we also found the experience of one woman in another Trust to be similar.

The SAI review team must acknowledge that they did meet with one woman who had a relatively positive disclosure experience. This woman had her disclosure in Trust 2 and present at that meeting was her Gynaecologist and a representative from the Southern

Trust's Governance team. Having a known health care professional deliver this information reassured this woman and her family that the information shared was open, honest and transparent. They expressed how they were shown sympathy, support and genuine care. Whilst there was some comfort from the familiarity of the Gynaecologist, this woman told the SAI Review Team that she feared that there was further bad news coming. Another woman who had her disclosure meeting outside of the Southern Trust felt that although she had met the Gynaecologist previously, she did not know him and had a greater relationship with her Oncologist who may have been better placed to have shared this clinical information.

The women who met with the SAI review team ultimately described the whole process of the Audit of Invasive Cervical Cancer as traumatising as this experience was retriggering. From the moment of diagnosis, these women experienced traumas associated with treatments, psychological distress and, for some women, life-long debilitation as a result of both the disease and the impact of the radical treatments. Having to go through the audit process many years after diagnosis and treatment only served to re-traumatise them and cause even greater psychological distress. Women have described their anger following the audit, disclosure and involvement in the SAI process, and that for some women, they no longer "feel like themselves", there have been personality changes described, emotional distress and physical impairment. The SAI team learned that for some women, the Audit process and this SAI has had a significant impact on their mental health and that they feel as if "they are back to zero".

The SAI team were also informed that the cancer diagnosis, treatment received, the Audit and Disclosure have also impacted on personal and physically intimate relationships, the ripple effect for women is truly widespread into all areas of their lives. As a region, there must be lessons learned that the audit and disclosure is performed with sensitivity, compassion and in a time appropriate manner so that there is safety and protection for the women they are serving. When there are incidents involving inter-trust audits, the HBPC in each site must ensure that communication is unambiguous, time sensitive and the clinician with the most contact with the patient should be present. Use of DATIX (incident reporting software) is the safest method of ensuring inter-trust working, transparency and accountability for this communication and investigation.

Comprehensive retrospective audits (CCR Outcome Reports and Cervical Cancers Summary Report, 2024) have been completed by the SHSCT and PHA in 2024, but there is no evidence provided to the Review team of annual audits being conducted as set out in the 2014 and 2019 NI Framework guidance. The Framework for the Audit of Invasive Cervical Cancers and Disclosure of Findings v1.0 Feb 2019 states that each Trust is expected to undertake an annual audit of their compliance with the audit and disclosure pathways. Completion of timely audits would likely have identified an issue with delays in disclosure sooner.

Finding 2: Patients

Twelve patients were diagnosed with cancer between 2018 and 2024. 8 out of the 12 cases were diagnosed as adenocarcinoma (glandular), 3 of which are rare variants (2 neuroendocrine and 1 of endometrioid type). 4 cases of squamous cell carcinoma were diagnosed. The cytological reviews of 29 slides dating from 2011 – 2021 were carried out in the knowledge a cancer diagnosis had been made and, despite best efforts of the reviewers, there is always a risk of hindsight bias which can influence the review outcome. In 5 of the 29 slides there was a difference of professional opinion in the findings of the slide in the audit. Again, this shows the challenge for professionals in determining the slide findings and it must also be noted that there may be hindsight bias when reviewing a slide following a cancer diagnosis.

9 screeners and 2 consultant staff were involved in the original reporting of 29 slides.

19 out of 29 slides were screened initially as negative; however, 14 out of 19 negative slides were found to contain abnormal cells on review.

8 out of 29 slides were screened initially as abnormal. However, it is worth noting that 2 of the abnormal slides tested negative for high-risk HPV and were returned to routine recall in line with policy at the time. 3 slides screened as abnormal were downgraded to negative 1 by a checker and 2 by a consultant.

2 out of 29 slides were screened as inadequate, however, 1 slide was changed to negative by a checker.

The average workload for this laboratory was 25,000 samples per annum. The team noted that Screeners [redacted] and [redacted] did report a higher number of slides as negative, however they were also found to be reporting a much higher percentage of the overall workload. These two screeners did substantial amounts of poorly monitored overtime and it is the opinion of the review team that this overtime contributed to the poor performance over a period of years.

The scope of this SAI review was limited to 12 patients, but it was noted by the team that most of the cancers were adenocarcinomas. The slide reviews show a trend towards missed glandular abnormalities. It is widely accepted within the profession that glandular lesions can present the cytologist with a diagnostic challenge but with the implementation of primary HPV targeted training, the screening programme has greatly improved the detection rate of glandular disease over the last decade.

Finding 3: Staffing

The service managed as best they could despite recruitment and retention challenges which was common across most laboratories in the UK in the years leading up to the introduction of primary HPV testing. Training of new staff was not encouraged due to pending changes in methodology and the introduction of primary HPV testing. The continued use of overtime became a long-term solution and was culturally embedded in the service. The use of overtime was partially due to difficulty in recruiting staff and reluctance within the NI programme to train new staff.

The team concluded that the delay to implementing HPV primary testing in NI, combined with a lost opportunity to consolidate laboratories, created pressure on the overall cervical screening service. Consolidation from four to fewer laboratories could have addressed workload issues and may have eased the burden of staffing resource in the early years prior to implementation of HPV primary testing.

Finding 4: Performance Monitoring and Management of Substandard Performance

Performance monitoring is complex and dynamic with many factors to be considered especially during a period of change and the introduction of new methodology. HPV reflex testing was introduced from 2013 and HPV primary testing across NI in 2023

It is important not to look at quality indicators in isolation but to understand what might be causing the exceptions (swings) in laboratory and individual screener data. Regular audit is an important part of identifying trends and persistent poor performance.

In this report, the team reviewed:

- **high grade sensitivity**
- **all grade sensitivity**
- **high and low-grade reporting rates**
- **low grade reporting rate**

Laboratory statistics show that the SHSCT laboratory met the national standards for detecting high grade disease. **High grade sensitivity** (ability to detect a true high grade abnormal) remained consistently high >95% from 2007 to 2023. Screening ceased at SHSCT in 2023. The laboratory was described by the PHA as “risk averse” and in 2014 during a QA visit, it was noted that an additional level of checking (full rescreen) was introduced. Although this was outside national guidance and contributed to turnaround times and workload issues, it did not impact quality. A case could be made that a full rescreen would have picked up more disease than rapid review, rescreening could also have had the effect of lowering the laboratory all-grade sensitivity rate.

The **high-grade reporting rate** (percentage of high-grade disease in this population) from 2010 to 2020 was also in line with national reporting standards. From 2016 there was a lowering in high grade reporting rate but an increase in low grade reporting rate was noted the overall abnormal reporting rate from 2009 to 2019 was between 6.6 and 7.7%.

Several factors could have contributed to the changing reporting rates, the impact of more reflex HPV testing and/or a change in consultant staff reporting abnormal cases. The use of HPV as a reflex test is likely to have led to an increase in low grade reporting rate as it is a more sensitive test than cytology alone. The data is comparable to other laboratories across the Region. This may have been influenced by the introduction of HPV and outsourcing of work to the Western Trust to support management of the backlog.

All grade sensitivity (ability to detect all grades of true abnormalities) is one of several performance indicators used by the NHSCSP and is currently set at > 90.0%. Whilst the detection of high-grade disease was consistently above target at 95%, the all-grade sensitivity started to decrease from 2014 over a period of 6 years, up until 2020 ranging from 84.48% – 89.12%.

On closer scrutiny of the data, it is evident that Screeners [redacted] and [redacted] were significantly below 90.0% over a period of seven years and had missed a significant number of high grades. This constitutes persistent poor performance which should have been managed in line with the Laboratory Department's poor performance policy. The lack of review of the performance of individual screeners over a considerable period of time was a missed opportunity by the Trust. The poor performance was flagged by the PHA in their QA visit in 2019 and recommended that the "Trust consider this staff members role within screening", however, they were "reassured that the highlighted screener's performance indicators were within an acceptable range. The Southern Trust also reassured the PHA that monitoring systems in place were robust and all screeners were monitored in accordance with laboratory protocol" (Report on a Quality Assurance visit to cervical screening services provided by the Southern Health & Social Care Trusts, 2019; SOUTHERN QA visit 20/09/19 - list of time limited requirements). Further action was taken in 2021 with one screener being removed from screening due to continued poor performance, a second screener who was underperforming requested to be moved from screening and a third screener was removed to work in a different area (Laboratory QA Data Meeting 2020/21).

In addition to poor performance identified, all-grade sensitivity rate may have been impacted by the introduction of reflex HPV testing for low grade disease (borderline and low grades). Management shared with the review team that at the time of HPV implementation there was a tendency for consultants to report cases as borderline which had previously been screened as negative by a primary screener. This would have had the effect of triggering a HPV test but also lowering the all grade sensitivity of primary screening staff. All laboratories who have converted to HPV primary screening in England have had to manage the impact on laboratory reporting. Regular workshops and microscopy sessions are key to keeping reporting aligned.

The **low-grade reporting rate** (amount of low-grade disease in this population which often resolves without treatment) remained in line with other NI laboratories at 5.0 – 6.72% from 2009-2019. Rates started to increase in 2019/2021 to just above 8.0% which coincided with a dip in high-grade rates. The reasons are unclear but outsourcing of work, new consultant staff and new technologies such as reflex HPV /CINTEC could have contributed to a change in the grading of abnormalities. The positive predictive value (PPV) is a key indicator which measures the correlation between cytology and histological outcomes. The PPV within the laboratory was good and indicative of accurate grading of cytology and histology.

Finding 5: Failure to Manage and Escalate Poor Performance

There was failure by laboratory management to deal adequately with persistent poor performance over many years. Interviews with management staff confirm attempts were made to manage individuals who fell below the target, but documented evidence including histological outcome audits to check against sensitivity data were lacking.

There was a failure by laboratory management to escalate the problem through the clinical governance framework within the Trust and to notify the PHA directly. Escalation of the problem was notified to the Trust Senior Management team in October 2021 and again formally in July 2022.

The focus of PHA scrutiny was at laboratory level rather than individual performance. This led to individual poor performance of some screeners going unquestioned. An earlier intervention would have raised a red flag. A QA visit to the Trust in September 2019 recorded laboratory data to be within expected ranges and met standards. However, the Trust was advised by QA to consider the suitability of one individual within a screening role. A response (recorded in the action log) in January 2020 from the clinical lead to QA confirmed that the individual's performance indicators were within an acceptable range and that robust monitoring systems were in place. The individual continued screening duties until October 2021. The review team found this statement was incorrect, indicators from 2014 – 2021 show that Screener [redacted] was persistently below the national standards of 90% for all grade sensitivities.

It was noted that a request was made by the clinical lead in January 2020 for a formal discussion at a Regional Quality Assurance meeting to discuss the issue of screener

sensitivities and seek confirmation that the same thresholds were being applied to all Trusts providing cervical screening. Discussions on screener sensitivities and management of underperformance took place at regional laboratory QA advisory subgroup meetings on 4 June 2020, 3 March 2021, 16 April 2021 and 12 October 2021 (as per minutes of these meetings).

In Northern Ireland, the CYRES database is used under the direction of the PHA to extract screener performance data. The PHA directed laboratories in NI to calculate statistics using rapid review.

The review panel established during the investigation (from minutes of meetings held in August 2022 and email correspondence) that there was some confusion around sensitivity data and in particular, the inclusion of rapid review cases in the calculation.
NHSCSP and PHA guidance recommends sensitivity be based on rapid review (excluding rapid review could reduce sensitivity for primary screeners). The data could be run internally by individual Trusts and centrally by PHA using CYRES software.
The panel was informed that up until 2019 when an adjustment was made to the CYRES system, the only option was to calculate sensitivity against final report.

All laboratory data was reviewed at an annual data quality meeting led by PHA. A regional meeting was requested by the clinical lead at SHSCT to discuss anomalies and seek reassurance that performance data gathering was consistent across all four laboratories in NI. The SAI panel have been informed that this was not discussed at any regional meeting. The panel also concluded that the way in which the statistics were calculated should not detract from the fact that there was persistent poor performance over many years.

Cervical screening standards valid for data collected from 1 April 2020 - GOV.UK

Persistent poor performance and drop in sensitivity by Screeners [redacted] and [redacted] significantly brought the overall laboratory performance of all grade sensitivity below the NHSCSP target of 90.0% according to the data SHSCT provided to RCPath in 2022.

Screeners/checkers were permitted to work outside of core hours despite poor all-grade sensitivity. Speed of screening may have been a contributory factor leading to false

negative cytology. However, it is recognised that people can work at different rates and maintain accuracy. For this reason, the British Association for Cytopathology (BAC) have never put an upper limit on the number of slides screened: "Provided that staff satisfy NHSCSP quality standards and are not exceeding the hours of screening stated, then the BAC can make no evidence-based recommendation regarding a maximum number of slides per annum." In reference to the time taken to carry out a primary review, the guidance from NHSCSP (2003) is in keeping with: "The BSCC's recommendation of eight slides per hour is a reasonable expectation for this rate." The SAI review team did not find evidence of a robust, accurate method of calculating the time taken for slides to be reviewed as some screeners reviewed in batches, whereas others reviewed and entered slide information individually, it may be that difference in times taken was in connection with data entry rather than quality of screening.

The PHA also considered the laboratory to be "risk averse" and noted during a QA visit in 2014 that an additional level of checking had been introduced. The reason for this intervention was to ensure checkers would meet their workload targets. This practice was over and above national guidance and although its value is unclear, this would have impacted turnaround times and may have impacted sensitivity calculations at a laboratory and individual level. PHA recommended in 2014 that the Trust should consider aligning their protocols to national guidance. The review team found it difficult to confirm the extent of double screening as it could not be captured on the laboratory database.

Finding 6: Hospital Based Programme Coordinator Role

The HBPC is a similar role to the Cervical Screening Provider Lead (CSPL) in English laboratories. Interviews with the PHA confirmed that the HBPC in NI has a limited role and is predominantly an "audit co-ordinator". In NI, the HBPC appears not to have the authority and direct line of reporting to the CEO (or delegated authority). Despite best efforts, the HBPC did not have adequate Trust management support or remuneration. The HBPC role is a key role within any organisation delivering cervical screening and colposcopy services.

Finding 7: Commissioning Contract

The absence of a contract or service level agreement specific for cervical screening services is likely to have contributed to the poor understanding of responsibilities and

accountabilities between Commissioners (PHA) and providers (SHSCT) of the service. This led to a “soft touch” approach by PHA and SHSCT with both lacking in curiosity to investigate further the reasons for persistent below standard performance.

Finding 8: Clinical Governance and Leadership

Clinical Governance was lacking at all levels from laboratory to Senior Trust Management. The review team found that the laboratory acted almost independently, there was little engagement with senior pathology management. Robust clinical governance was lacking and led to a breakdown in communication and a significant lack of understanding by pathology management of their role in the oversight of the cervical screening service. The role of the HBPC was also poorly understood by senior pathology management.

The SHSCT approved long term overtime to support the backlog. Records show that a large proportion of the workload was done outside of core hours, at the expense of quality which is reflected in low all grade sensitivity for the laboratory and several screeners. There was a failure to escalate poor performance until the appointment of a new clinical lead.

8. CONCLUSIONS

Twelve women were diagnosed as having cervical cancer with category 3 outcomes confirmed on audit review.

The slide reviews showed a trend towards missed glandular abnormalities which can be a challenging area for all involved in the screening and reporting of cervical screening. In several of the cases there were different review opinions between experts despite knowing the final diagnosis.

Persistent poor performance of Screeners [redacted] and [redacted] were identified and would have contributed significantly to the laboratory low grade sensitivity from 2014 to 2020.
In total 29 cytology slides were reviewed as part of the Invasive Cancer Audit, Screeners [redacted] and [redacted] primary screened 13 of the slides as negative and were involved in the rapid review of 7 slides equating to involvement of over 50% of all slides reviewed. This must

be balanced against the fact that they also screened up to 3 times more cases than other staff.

Failure by pathology management to address persistent poor performance was unsatisfactory and delayed timely intervention to ensure a safe and effective service. Clinical governance and leadership was lacking, leading to a breakdown in communication and lack of oversight of the cervical screening service until the appointment of new staff in 2019 and 2020 who identified underperformance and immediately flagged this to management.

Data from two publications in December 2024, *The Cervical Cytology Review of 17,000 cases* and a *Summary of Cancers in the Southern Trust by PHA* provides reassurance that the laboratory was performing to acceptable standards and was not an outlier. It is a salutary lesson that a small number of underperforming staff can impact overall laboratory standards and have such a devastating impact on the health and wellbeing of patients as evidenced in the impact on the twelve women's cases examined by this review team.

9. LESSONS LEARNED

In summary, the 12 patients identified within this SAI were failed due to the following reasons:

1. Screeners who were performing below national targets were allowed to continue cervical screening.

2. The management of poor performance, particularly before the changeover of management in 2019 was not robust enough to ensure the safe delivery of service to women.

3. There was a lack of senior management oversight of a laboratory department which was operating in a "silo".

4. The laboratory was running on a reduced number of staff as the program for cervical screening was moving to one centralised lab for the Region, there was a lack of attention given to recruitment and training requirements.

5. The majority of the women involved in this SAI suffered from adenocarcinomas. As discussed, these glandular abnormalities can be challenging and difficult to interpret cytologically.

6. It is the opinion of the SAI review team that the PHA were reassured that at laboratory level, the laboratory as a whole met national targets, however, oversight of the trends regarding individual screener performance over a number of years was lacking.

10. RECOMMENDATIONS

Recommendation 1

Learning identified through the Audits of Invasive Cancer is to be shared annually with each Trust by PHA. These can be used to underpin the educational aspect of cancer audit and feed into a continuous improvement programme to improve the accuracy of the screening programme.

Person Responsible: PHA and HBPC in each Trust
Timeframe: within 12 months of publication of this report.

Recommendation 2

The provider Trust must ensure adequate staffing and succession planning to deliver a high-quality cervical screening service. This should include mitigation steps and a business continuity plan which would consider all aspects of the pathway. To prevent isolation the new provider, supported by PHA, should form links with other service providers.

Person Responsible: The new provider Trust with oversight by the PHA
Timeframe: Within 12 months of this review being published.

Recommendation 3

A reminder to line managers on the active and prompt management of poor performance in line with local Trust policy and national guidance, including clearly documented evidence to demonstrate compliance and a return to normal practice. This memo should be shared with Corporate Governance for evidence of shared learning.

Person Responsible: Assistant Director for Human Resources
Timeframe: Within 6 months of publication of this report

Recommendation 4

PHA to instigate additional checks at individual screener levels as part of annual data checks with the provider laboratories and requests for action plans to reassure that the poor performance is being managed in line with local Trust policy.

Person Responsible: PHA
Timeframe: Within 12 months of publication of this report

Recommendation 5

Consider strengthening the role of the Hospital Based Programme Coordinator by expanding the authority and accountability in line with NHSCSP guidance. Job description of the Hospital Based Programme Coordinator and deputy to be revisited with PHA and Trusts acknowledging the responsibilities and lines of accountability within their organisation in relation to the role of Hospital Based Programme Coordinator.

Person Responsible: PHA and Trusts
Timeframe: Within 6 months of publication of this report

Recommendation 6

Ensure that the contractual arrangements between commissioners and providers must clearly identify responsibilities including clinical governance accountability and escalation pathways.

Person Responsible: PHA
Timeframe: Within 12 months of publication of this report

Recommendation 7

PHA, as the commissioning body, should establish and chair Programme Boards (or equivalent) to meet regularly with representatives from Trusts involved in the delivery of cervical screening including colposcopy services. This will provide oversight and reassurance to all stakeholders including users of the cervical screening service.

Person Responsible: PHA
Timeframe: Within 6 months of publication of this report

Recommendation 8

Disclosure meetings will be built into the responsible consultant's job plan as there are, on average, 3 disclosure meetings per year. There should be a high level of flexibility in relation to venue, date and time to support the women to attend.

Person Responsible: Medical Director
Timeframe: Within 6 months of publication of this report

Recommendation 9

The PHA should develop a regional letter of invitation for involvement in the Audit process with stakeholder involvement in the revision process.

Person Responsible: PHA
Timeframe: within 6 months of publication of this report

Recommendation 10

Sharing of information between the Private Health Care sector and the HSC must be clear and contemporaneous with a focus on working together to ensure safety and transparency within the audit process.

Person Responsible: RQIA
Timeframe: Within 12 months of publication of this report

Recommendation 11

Health care professionals involved in the Disclosure process must engage in a training programme such as that delivered by NHS England at NHSE elfh Hub.

Person Responsible: Medical Director and Director for SCS
Timeframe: Within 6 months of publication of this report.

Recommendation 12

The Hospital Based Programme Coordinator, Clinical Leads and Head of Services must have training on the value of the Risk Register to help support the safety of the service which they are providing.

Person Responsible: HBPC, Clinical Leads and Head of Services
Timeframe: Within 6 months of publication of this report.

Recommendation 13

The PHA should confirm in writing that the calculation of statistics are in line with the NHSCSP using rapid review.

Person Responsible: PHA
Timeframe: Within 6 months of publication of this report.

Recommendation 14

Where there is inter-trust care, a lead Hospital Based Programme Coordinator, must be identified to lead on the Audit and to ensure there are no delays to the disclosure process.

Person Responsible: PHA
Timeframe: Immediately

Recommendation 15

The findings and recommendations of this report should be shared regionally with the Hospital Based Coordinators on each site and with those responsible for delivering the disclosure information.

Person Responsible: HBPC

Timeframe: Within 3 months of publication of this report

Appendix 1: Definition of terms

Adenocarcinoma: is a cancer that starts in the gland cells that produce mucus.

Cervical screening: is a medical screening test designed to identify risk of Cervical cancer.

Cervical smear: A cervical smear test is a sample of cells taken from the cervix and transferred to a glass slide.

CIN: Cervical intraepithelial neoplasia (CIN) is a term that describes abnormal changes of the cells that line the cervix. CIN is not cancer. But if the abnormal cells are not treated, over time they may develop into cancer of the cervix.

Colposcopy: a diagnostic procedure to visually examine the cervix as well as the vagina and vulva using a colposcope.

Cytology: the examination of cells from bodily tissue or fluids to determine a diagnosis.

Cytology laboratory – a laboratory that provides cytology screening for the Northern Ireland Cervical Screening Programme (i.e. which processes and reports on smears).

Cytology Normal (or Negative): No abnormalities seen in cervical cells.

Endometrial cells – the cells or tissue that line the uterus (womb).

Glandular Neoplasia: changes to the glandular cells which line the inside of the cervix.

High-grade abnormalities: there are likely to be abnormal cells in the woman's cervix. These abnormal cells have a greater potential to develop into cancer if left untreated.

Histopathology: diagnosis and study of diseases of the tissues and involves examining tissue under a microscope.

Human papillomavirus: **(HPV)** a viral infection which can cause different types of cancer.

Inadequate: A smear is deemed to be inadequate when the slide is unreadable. This can happen for a number of reasons (e.g: not enough cells in the sample, or too much blood on the slide to view the cervical cells.

Invasive Cervical Cancer Audit- An audit of the cases of cervical cancer established for the purpose of learning and improvement to better understand why some women continue to be diagnosed with cervical cancer despite having effective screening programmes in place.

Low-grade abnormalities (borderline and low-grade cell changes) - This result suggests there are some abnormalities in the cells within the cervix. Research suggests that around half of borderline and low-grade abnormalities return to normal within 18–24 months without treatment.

Primary screening: An initial full screen of a conventional cervical smear.

Process for the screening of cervical slides:

1. Primary screen – full screen of slide
2. Rapid review – a rapid review of the slide, not a full check. If an abnormality developed then passed for full check by a senior screener or consultant.

Rapid screen/rapid review: A re-examination of all cervical smears identified as negative or inadequate at primary screening, as part of the quality control process. This is also known as rapid review. In rapid review, smears are not fully screened.

Reflex test: If a patient tests positive for high risk HPV, a Cytology test is undertaken. Similarly, before Primary HPV testing when cytology was the first test, if the cytology was positive, then this would have generated in some cases, a HPV test.

Screener: A screener is a trained individual who is employed to undertake the primary screening, double screening and rapid screening of cervical smears. A screener may sign out and report negative or inadequate smears that have undergone primary screening and rapid screening.

Squamous cell carcinoma: This type of cervical cancer *begins in thin, flat cells, called squamous cells*.

Appendix 2: Abbreviations

BAC: British Association Cytopathology

CCR: Cervical Cytology Review

CPD: Continuing Professional Development

CSPL: Cervical Screening Provider Lead

CTC: Cytology Training Centres

EQA: External Quality Assessment

GMC: General Medical Council

HBPC: Hospital Based Programme Coordinator

IBMS: Institute of Biomedical Science

IQC: Internal Quality Control

KPIs: Key Performance Indicators

MDT: Multi-Disciplinary Team

NHS: National Health Service

NHSCSP: NHS Cervical Screening Programme

NMC: Nursing and Midwifery Council

PHA: Public Health Agency

PPV: Positive Predictive Value

RCPath: Royal College of Pathology

SAI: Serious Adverse Incident

SHSCT: Southern Health and Social Care Trust

SOP: Standard Operating Procedure

SPPG: Strategic Planning and Performance Group

TOR: Terms of Reference