RCPATH CONSULTING REPORT

For: The Southern Health and Social Care Trust

18/05/2023

Contents

1) Executive Summary

RCPath consulting (RCPC) was engaged by Southern Health and Social Care Trust (SHSC) to undertake a focused analysis of screening performance. The scope of the review, including the questions to be addressed, was agreed in advance, as were the resources.

RCPC advisers engaged closely with staff at SHSC and conducted a careful analysis of data provided to assess performance issues in cervical cytology screening. Responsibility for providing full and accurate data rested with SHSC. Multiple opportunities for SHSC staff to clarify or explain data findings were given. RCPC believes this report is as accurate as possible, based on the information submitted.

We recognize that this is a dynamic situation and some changes may already have been made. This report represents a "snapshot" based on information provided to us at the time.

RCPC has completed the report to the agreed scope. We recognize that there is further work which could helpfully be undertaken but this would be in addition to the report which is detailed below.

Cervical screening is an extremely important public health initiative. It is important to note that many women have had cervical abnormalities detected, and subsequently treated, and therefore had cancer prevented, by screening undertaken in this laboratory.

Cervical cytology is a screening test and can never prevent 100% of cases, however the focus of screening programmes in the UK is to maximise the effectiveness of screening, by optimising performance at all levels within the pathway.

In this laboratory there was significantly poor performance over many years by more than 2 cytology staff.

Mechanisms for identifying this were flawed but when it was identified actions taken were inadequate.

Improved performance monitoring has now been implemented but requires careful ongoing focus.

The laboratory does not have adequate cytology staff to screen their current workload and ongoing quality of cytology performance cannot be assured.

There has been a failure to implement HPV primary screening and the current pathway for dual testing does not allow efficient use of cytology screening capacity, precludes any benchmarking with other UK providers and is not in line with recommendations of the national screening committee.

Whilst the majority of Negative results issued by this laboratory over the specified time period were correct, a significant number of women are likely to have had negative screening results on tests which would have been identified as abnormal in other UK screening laboratories using the same pathway (Cytology screening with HPV Triage and Test of Cure). Concerns do cross the threshold where other such laboratories have undertaken a screening review. However as far as we are aware no laboratory in the UK currently has capacity to undertake a review and no non-UK laboratories should be considered as quality may not be equivalent.

Cytology reviews are imperfect and retesting with a more sensitive test would be a more effective approach.

We recommend that the best strategy to reduce risk is to fully implement HPV primary screening, together with public health initiatives to increase uptake, including consideration of early recall for women considered most at risk, so that they can be reassured by a negative HPV test. Broadly, these women are those who have a negative or inadequate result during the period of the review, and have had no repeat cytology or further investigation.

Adequate cytology capacity needs to be in place before any additional invitation occurs, so implementation is dependent on switching from co-testing to HPV primary screening.

Recommendations – see section 7

Recommendation 1:

Introduce measures to ensure all cytology staff at all grades who do cervical cytology screening, checking or reporting achieve the minimum workload standards set out by the NHS CSP **Recommendation 2:**

Determine a safe and sustainable approach to ensure the staffing capacity matches the laboratory workload.

Recommendation 3:

Ensure all persistent underperformance is managed appropriately and promptly.

Recommendation 4:

Revise the 'Management of Potential Screener Underperformance 'policy to include appropriate thresholds and timescales for action, and of escalation routes in the event that measures employed do not lead to improved performance to the required standards.

Recommendation 5:

If standards used for performance monitoring by SHSCT are going to deviate from NHS CSP published standards, all standards used and explanations for any applicable derogations should be formally documented in a Trust policy.

Recommendation 6:

There must be adequate resources and full compliance with requirements of the NHS CSP cervical cancer audit in review and in full disclosure, in line with the audit protocol and women's wishes.

Recommendation 7:

This UK NSC recommendation should be escalated to the Northern Ireland Department of Health as a priority and a formal plan developed for the implementation of HPV primary screening in Northern Ireland. The change to a Primary HPV cervical screening programme must be coordinated across NI and the implications for service delivery, sustainability and quality must be considered before implementation.

Recommendation 8:

Despite the likelihood that significant numbers of women screened in this laboratory have had abnormalities missed which would have been detected elsewhere, we cannot recommend a review of previous cytology, because there is no suitable capacity in the UK to deliver this. We strongly recommend that HPV primary screening should be implemented in a quality-controlled manner, with consideration of early invitation of women considered to be most at risk.

18/05/2023

2) The Advisor Team

Advisor 1 Dr Paul Cross B Med Sci, MB BS, FRCPath, retired Consultant Cellular Pathologist, Chair RCPath Cytopathology Subcommittee

Advisor 2 Nichole Villeneuve, Consultant Biomedical Scientist, MSc, ASD Cervical Cytology, FIBMS

3) Scope of the Project

In accordance with the RCPath Consulting policy, attached, RCPath Consulting Advisors in accordance with the specification (Appendix 1) will act under the auspices and oversight of RCPath Consulting according to an agreed and signed contract for these services between CLIENT and RCPath Trading Ltd. RCPath Consulting will quality assure the process according to the Quality Policy (Appendix 2)

RCPath Consulting is requested to produce a report for SHSCT; first contact is [redacted]

Objectives / methodology

- To review the available evidence on Cervical Cytology performance relating to screeners [redacted] compared to each of the Cytology screeners working in SHSCT over the past 10 years
- To work with the Trust Operational Team to provide any further data / evidence which may be helpful in further clarifying whether under performance has occurred
- To comment on the adequacy of those data, local procedures and processes and make any recommendations for change
- To review the findings raised by the SHSCT audit of invasive cancer relating to screeners [redacted] and comment on the compliance of those audits with the Northern Ireland protocol and Framework on the audit of invasive cervical cancers and make recommendations, if necessary, to strengthen that process going forward
- To provide an assessment of risk to the screened population in SHSCT due to under performance of screeners [redacted] in the context of a Screening Programme which cannot prevent all cases of cervical cancer, and where the sensitivity of the test will always be less than 100%
- To consider the risks of undertaking such a review, including for example in anxiety and additional recall to women who may not have significant disease
- To make a recommendation based on these findings on whether there should be a review, and if so, what number of slides over what time period should be reviewed.

4) Introduction and Background

Background

The Southern Health and Social Care Trust (SHSCT) has for many years provided a Cervical Cytology Service as part of the Northern Ireland Cervical Screening Programme. This programme currently uses Cervical Cytology as the primary screening test. HPV primary screening has not yet been implemented, as it has been in the rest of the UK.

In October 2021 [redacted] Biomedical Scientists who had been primary screening and / or checking Cervical Cytology ceased screening after concerns were raised about performance including the review of highgrade sensitivity data and findings raised through the audit of invasive cancers. These screeners are known as [redacted] Up to October 2021, performance against high grade sensitivity data for all screeners, was managed in line with Trust protocols.

The Lead Consultant for Cervical Cytology and the deputy lead Biomedical Scientist escalated their concerns in relation to the performance of screeners [redacted] to the Laboratory Senior Management Team. The Senior Laboratory Team agreed that the immediate actions taken where appropriate and that a paper needed to be prepared detailing the performance of screeners [redacted] as compared to all the screeners in the service in order to determine what further actions may need to be taken.

A paper was brought to Trust Senior Management Team in July 2022 raising the concern about the potential impact on women in the screening population in the SHSCT area relating to the performance of screeners [redacted] The paper suggested that Public Health Agency needed to be informed and that a risk assessment needed to be considered. Subsequent to discussions at Senior Management Team in July 2022, two meetings were held with the Trust and the Public Health Agency in August 2022. It was agreed that a Steering Group would be established in line with the regional Lookback Review process Stage 1a and a risk assessment be progressed at the earliest opportunity. At the meetings with PHA in August 2022, it was noted that PHA had raised concerns about one screener based on Trust performance data in its QA report dated 20/09/2019. The QA report stated : "*Concern regarding screening data indicating under performance of a screener who, despite intervention, has missed a number of high grades over a 3 year period. Trust to consider this persons role within the screening programme.*"

The key question to be considered through a risk assessment process is, whether the women in the screening population in SHSCT that had smears reported by screeners [redacted] have a higher risk of a false negative report and therefore a missed opportunity to treat pre-cancerous changes.

Purpose

The purpose of the work to be progressed through this review / risk assessment is to determine whether the women in the screening population in the Trust that had smears reported by screeners [redacted] have a higher risk of a false negative report and therefore a missed opportunity to treat pre-cancerous changes. The review will also consider if the screener performance data and department performance management processes are appropriate.

This is the output expected from the initial review. If any further advice is required upon receipt of the final report, this will be specified separately in an incremental fashion.

The requirements of the project were discussed by the advisors, in collaboration with the RCPath Consulting Lead Dr Karin Denton. The advisors also discussed the project initiation by teleconference (13/02/23) with key senior staff from the hospital prior to undertaking their review of documentation provided by the hospital.
Attendance on site by the advisors was not required for this review. We are grateful to all concerned for the spirit of open and friendly collaboration in which the entire process was conducted, for providing the requested documentation, and for responding to questions from advisors by email.

5) Data Received for RCPath Consulting Review:

Data upload 1 (17/02/23)

- Individual screener HG sensitivity (2007-2021)
- Staffing list and WTE equivalents and laboratory workload figures (2009-2022)
- Lab sensitivity and specific data (2010-2022)
- Primary screener time profile and workloads (2010-2022)
- Primary screener sensitivity and specificity (2010-2022)

Data upload 2 (27/02/23)

- An overview of laboratory and individual performance data with actions taken (2006-2021)
- Record of performance issues and actions taken (2006-2021)
- Cellular pathology Q Pulse document which includes all Cytology Quality Indicators linked to cervical screening (dated 29/04/22)
- Copy of Cytology updates attended (2010-2022)
- The Southern Trust Protocol for managing underperformance (dated 24/02/23)
- Letter sent by Interim Assistant Director of Acute Services (Nursing) for Cancer & Diagnostics to Interim Network Manager, Northern Ireland Pathology Network, advising on an action plan following SAI [redacted] (dated 27/10/22)
- Cover sheet re laboratory and individual performance data and action taken (dated 23/02/23)
- KC61 Returns which cover a 10-year period (2011-2022)

Data upload 3 (1/3/23)

- SHSCT SOPs for identifying and managing poor performance. 17 versions, various years/dates, regional letter, and SOP version control document.

Data upload 4 (3/3/23)
- Revised 'Screening Staff Timeline (recorded as whole time equivalents) WTE 09-22 'to include explanations for the gaps in the screening staff timeline/workload data
- Priority 5 SHSCT Protocol for the Management of Underperformance
- Policy for Managing Under Performance prior to 24 February 2023 – includes copies of the 16 revisions
- Spreadsheet summarising changes made to the policy over time
- Consultant Pathologist Sessions allocated to Cervical Screening
- Mandatory Performance Measures from 1 Apr 2010 to 31 Mar 2022 for Consultants 1, 2, 3 and 4

Data upload 5 (8/3/23) Priority 8 - EQA Participation Data
- Record of External Quality Assurance Data Visits or Reviews by QARC (YPAST)
- EQA Interpretative Assessment Summary Table
- EQA Interpretative Assessment – Proficiency Testing – Gynae Cytology
- AUD2423-3 Attachment 4.2
- AUD2423-2
- AUD2284
- AUD1902
- AUD1902 Response to Laboratory Report
- AUD2008

Priority 10 – Report on High Grade Misses
- Outcome of False Negative Cases for Screeners Listed [redacted]

Priority 7 – Service Profile
- Cellular Pathology Lab Description
- Management and Laboratory Staffing Structures
- Number of Cervical Cancers identified annually
- Number of Smears Screened per Year
- Documents relating to the provision of Cervical Screening in Northern Ireland

Data upload 6 10/3/23 Priority 11 – Northern Ireland Policies, Guidance/ Protocols on Cervical Screening
- NI Protocol Audit of Invasive Cervical Cancer
- Framework for the Audit of Invasive Cervical Cancer

SOP and Clarification re Deviation
- Current SOP used by SHSCT, NHS CERVICAL SCREENSTSTS CSP-S04-S07
- Deviations NI CSP, as documented by [redacted]
- Copy of a letter from PHA letter2015-application of NHSCSP guidelines and how agreed deviations are taken forward. Provided by [redacted]

Data upload 7 13/3/23
- Paper to SMT Feb 2021 – focusing on demand / capacity, explained the plan for cell path linked to the pathology modernisation programme, sought an expedited path to implementation of Primary HPV testing or co-testing and highlighted the issue of non-disclosure between 2009-2018.
- Briefing Paper to SMT May 2022 – detailing the potential underperformance issues in SHSCT Cervical Cytology
- Cervical Cytology Position paper – for corporate SMT – July 2022 – highlighting potential issues in relation to performance with screeners [redacted]
- SAI [redacted] – the SAI investigation document

- Early Alert- Cervical Cytology performance – July 2022 – highlighting potential issues in relation to performance with screeners [redacted]
- Briefing Paper to PHA – articulating concerns re underperformance and the requirement of support to facilitate a risk assessment
- Early alert update 1 – Cervical Cytology performance – 8 September 2022 – potential issues in relation to performance with screeners [redacted]
- Cervical Cytology update for Trust Board confidential – 27 October 2022 (cover sheet) and position paper 27 October 2022
- Updated early alert – Cervical Cytology - potential issues are performance with screeners [redacted] – 17 November 2022
- Further update to Trust Board – Cervical Cytology – 13 December 2022 (cover sheet)
- Further update to Trust Board – 26 January 2023 – Cervical Cytology – screener performance and references concerns about the screening reporting backlog
- Updated Early Alert – 3 February 2023

6) RCPath findings

The Advisors have reviewed and assessed the data provided by the Trust and accept this as a reasonable description of the current services at The Southern Health and Social Care Trust.

In response to the project objectives of assessing the performance of screeners [redacted] to determine whether underperformance has occurred, and whether the women in the screening population in SHSCT that had smears reported by screeners [redacted] have a higher risk of a false negative report and therefore a missed opportunity to treat pre-cancerous changes, the workload and sensitivity data for all screening staff over the period from 2010/11 to 2021/22 were reviewed.

Workload

After the draft report was issued, SHSCT have indicated that the workload figures do not differentiate between screening and checking staff. This distinction as to staff roles was not made apparent on the original data provided. As such, the comments and interpretation made below cannot always differentiate between these staff roles.

Screeners [redacted] reported > 3000 samples per annum for each of these years, until 2021/22 when they both ceased screening and had only reported cases for part of the year. The workload for both [redacted] as a percentage of the overall lab workload was high. For 8 of these years, they screened over 25% of the total workload between them, and this percentage increased as the total number of screeners in the laboratory decreased. From 2017 to 2021 this rose to between 36% and 47% of the total workload.

Between 2010 and 2022 there is evidence of persistent underachievement of the 3000 minimum numbers screened workload standard by most screeners.

During this time period, only one other screener achieved this standard consistently. Two screeners failed to achieve 3000 during all twelve years, and the remaining screeners all persistently failed to achieve this standard for most of the years in which they worked. During many of these years, the numbers screened by these staff fell to less than 50% of the required standard. (See Appendix Three: Workload Data Summary)

The SHCST 'Ongoing Review of Primary Screening Performance 'policy notes that 'sample sizes under 1,500 smears are unreliable and should be interpreted with caution 'but there are no details or actions included for the management of failure to achieve the minimum workload standards for screeners, checkers, or consultants.

Quarterly audits of performance (20232702 *Summary of Underperformance Findings and Actions Taken 1.3, 2.3 and 3.3)* from as early as 2008 note the failure of screeners to achieve the minimum workload standard of 3000 samples screened.

The initial actions taken to manage underperformance state that the 'Lead BMS was instructed to take the appropriate action to ensure targets are met'. There are no further records of action being taken to address this issue, and there is little mention of the persistent issue in records of underperformance from 2012 to 2019.

The situation as of 2021/22 shows the issue of screeners not achieving this standard persists. Data for this year (*Screening Staff Timeline 20230301*) shows there are currently 4 screeners (1.25 whole time equivalent) employed at SHSCT. None of these screeners are achieving the standard: [redacted] has apparently screened zero samples, and the workload of [redacted] others is significantly below 3000.

The total laboratory workload for 2021/22 is recorded as 25,663 samples. The current staffing is insufficient to maintain this workload. If all screeners achieved the minimum 3000 per annum, the staffing would still only cover less than 50% of the current laboratory workload.

Screener Sensitivities

Sensitivity data provided (Individual Sensitivity for High Grade Dyskaryosis and All Abnormalities 01.04.2010 – 31.03.2022) was generated using Cyres Cinergy software and has been summarised into two tables by advisors (see Appendices 4 and 5).

The data provided shows that screener [redacted] failed to achieve the high-grade sensitivity standard of 95% or greater for 3 out of 5 years between 2014 and 2019, including persistent, consecutive quarters, and again from 2020 to 2021. Screener [redacted] failed to achieve the minimum standard for all-grade sensitivity standard of 90% or greater for 7 consecutive years between 2014 and 2021.

Screener [redacted] failed to achieve the high-grade sensitivity standard of 95% or greater for 5 consecutive years from 2014 to 2019, and again from 2020 to 2021. Screener [redacted] failed to achieve the minimum standard for all-grade sensitivity standard of 90% or greater for 7 consecutive years between 2014 and 2021. Screener [redacted] also failed to achieve this standard for 2 previous consecutive years between 2011 and 2013.

Sensitivity data provided, shows periods of persistent underperformance for several other screeners during the period from 2008 to 2020. The most significant underperformance relates to screener [redacted] who failed to achieve the 95% standard for high grade sensitivity for 4 consecutive years between 2008 and 2012, and again during 2013/14 to 2014/15. Screener [redacted] failed to achieve the 90% standard for all grades of abnormality for 3 consecutive years from 2011 to 2014, and again during 2015/16. Performance concerns for this screener were highlighted in a serious adverse incident (SAI) investigation which took place in 2021 relating to samples reported in 2011. (SAI [redacted] Final Report REDACTED). [redacted]

From the evidence provided as part of the SAI investigation, it was identified that the individual involved in the screening of one cervical screening tests in the cervical cancer audit case from 2011, was not meeting the required performance standards at that time. The individual who reported the cervical screening test in 2011 had a sensitivity for high grade abnormalities of 81.81% which is significantly below the required standard of ≥ 95.0%.

It is not evident from the documentation provided to inform the SAI investigation that any increased quality control or targeted training took place for the underperforming staff member. One corrective action is documented and that was for the individual to attend an external update training course, which was completed in 2012. There is no evidence of a formal rescreening exercise taking place in 2011. There is no evidence that the individual screener's work volume was reduced. There is no evidence that the individual screener's work was confined to core hours, or that out of hours working was discontinued. There is no evidence of any additional monitoring being implemented. This screener's underperformance had been identified by the SHSCT in 2011. There was evidence of limited corrective and preventative action taken by the Trust at that time but action commensurate with the level of underperformance was not taken.

Screener [redacted] failed to achieve the high grade sensitivity target for 3 consecutive years from 2008 to 2011. There are gaps in data for this screener for all grade sensitivities, but underperformance was documented during 2010/11.

Isolated years of failure to achieve the 95% standard for high grade sensitivity for [redacted] other screeners was documented between 2010 and 2019. Persistent failure to achieve the 90% standard for all grades of abnormality were documented for [redacted] screeners between 2010 and 2020. Some of these also involved multiple, persistent years of failing to achieve the required sensitivity for all grades of abnormality.

While persistent underperformance in achieving the 90% standard was documented during previous years for [redacted] screener/checker staff currently employed at SHSCT, all are currently achieving the required sensitivity standards for both high grade and all grades of abnormality.

An audit of false negatives for screener [redacted] for cases reported between 2007 and 2021 shows 54 high-grade misses. High-grade disease was confirmed histologically in approximately 75% of cases and in approximately 25% of the cases, low-grade disease was confirmed.

An audit of false negatives for screener [redacted] for cases reported between 2012 and 2021 shows 30 high-grade misses. High-grade disease was confirmed histologically in approximately 90% of cases and in approximately 10% of the cases, low-grade disease was confirmed.

Summary of Screener Performance

The available evidence on Cervical Cytology performance relating to screeners [redacted] compared to each of the Cytology screeners working in SHSCT over the past 10 years has been reviewed and assessed by the advisors.

The purpose of the work undertaken through this review / risk assessment was to determine whether the women in the screening population in the Trust that had smears reported by screeners [redacted] have a higher risk of a false negative reports and therefore a missed opportunity to treat pre-cancerous changes.

In our opinion, based on the evidence provided, the women in the Trust's screening population are at risk of missed opportunities to detect and treat pre-cancerous changes. The most significant and persistent underperformance during the past 10 years relates to screeners [redacted] but also to screener [redacted] Data provided shows these [redacted] screeners had multiple and consecutive years where they failed to achieve the required sensitivities for both high grade and all grades of abnormality. The period of underperformance is longer for screeners [redacted] as screener [redacted] whereas screeners [redacted] continued in their roles until 2021. While most of the performance concerns pertain to these [redacted] screeners, the data also highlights multiple periods of underperformance, some persistent, for several other screeners during the past 10 years.

Performance Data and Performance Monitoring Processes

The review also considered whether the screener performance data and departmental performance management processes are appropriate.

Evidence was provided of screener sensitivities for high-grade and all grades of abnormality generated using Cyres software, which are currently, and were, during the 10-year period under review, produced quarterly on a rolling annual basis, in keeping with recommended practice. From July 2020, an additional rolling monthly audit has been performed on screener sensitivity for all high-grade and all grades of abnormality, and primary screener and checker screening workload numbers. The audit data is saved in the Q-Pulse Quality Management System (QMS) in the form of quarterly audits where it is accessible to the Lead Consultant in Cytology. Documentation provided states that any exceptions in meeting the sensitivity standards are discussed with the Lead Medical Consultant who is responsible for advising on any required remedial actions, in accordance with the management of underperformance protocols.

The 'SHSCT Laboratory Services Quality Indicators '(issued 29.04.2022) note that a quarterly review of compliance with mandatory performance indicators for the laboratory, and individual screeners and consultants is undertaken by the Cervical Cytology Clinical Lead. This is good practice. Quality Indicator documentation for previous years was not provided.

Identified underperformance with actions taken is currently, and during the 10-year period under review, recorded in the following ways:

- Notes in audits on Q-Pulse
- Incidents raised in Q-Pulse
- In a record keeping document on Q-Pulse (CYTSUBOPTPERFPRIMSCREV)
- In a document on Q-Pulse (*CYTSUBOPTPERFPRIMSCREV*) which is a record of all false negatives including review comments and any actions taken.

Some of the previous instances of poor performance relating to screeners who had failed to achieve the 95% standard for high-grade sensitivity had been identified through quarterly performance monitoring and documented in the QMS system.

From the evidence provided, it appears that underperformance related to screeners who were persistently not achieving the 90% standard for the sensitivity of all grades of abnormality was not considered a concern and was not being proactively documented or managed.

There is evidence that false negative slides were reviewed, that feedback was given to individual screeners, and that screeners were made aware of underperformance concerns. Measures taken to address underperformance of the sensitivity for high-grade abnormalities included short rescreening exercises, requirement to attend an update course, monitoring of time spent screening individual slides, and implementing a more stringent method for rapid review of smears where this QC step was increased to 3.75 minutes, rather than the typical 1.5 minutes. It is unclear whether this additional time spent on rapid review has led to improved screener sensitivities.

Short term removal from overtime screening appears to have been instigated on occasion. Approximately 20% of the total departmental workload is done in overtime and this has been the situation for a considerable timeframe. From the evidence provided, it appears that none of the underperforming screeners were removed completely from overtime screening to improve performance. It is noted however, that the most recent version of the policy for managing underperformance issued 24.02.2023 states that 'out of hours should not occur where there is a possible underperformance issue'.

A policy for managing underperformance (*Southern Trust Protocol for Managing Underperformance*) has been in place since 2006, but prior to the version issued 24.02.2023 it did not contain appropriate thresholds or timescales for action to be taken when national performance standards are not being met. The previous protocols did not include appropriate measures of competency assessment, or of formal actions to be taken, or any detail of escalation routes in the event of persistent underperformance.

Prior to the latest version of the policy for managing underperformance, there was no evidence of linkage to the Trust Clinical Governance Framework or Trust policy on the Performance Management of staff.

The current version (24.02.2023) notes that 'to ensure transparency KPIs should be discussed at the relevant Specialty Meeting and be the first point of escalation 'but no further details of relevant meetings or escalation procedures are documented, and no evidence was provided of discussion or review of performance at relevant operational or governance meetings.

From the evidence provided, it would appear that timely and appropriate action commensurate with the severity and persistence of screener underperformance has not been undertaken during the period under review. In conclusion, there are several clinical governance issues related to performance monitoring in the cytology laboratory which have resulted in an increased risk of false negative reports for the population screened by SHSCT and these require improvement.

<u>Standards Applied to Monitoring of Performance</u>

A document entitled '22032022 Coverage Page Summary of Underperformance and Actions Taken' states that 'generally the Northern Ireland Cervical Screening Programme (NICSP) generally follows the guidance issued by the NHS Cervical Screening Programme (NHSCSP), including that in regard to the monitoring of laboratory, screener and pathologist performance'.

It also, however, refers to applicable derogations from the NHSCSP guidance and notes that 'this is not always a direct read across'. These applicable derogations were not easily understood from the documentation provided and the advisors requested clarification. Further information was provided in a document entitled '20230309 Clarification re Deviation' which advised that the standards for minimum laboratory sample numbers (35,000 per annum) (see BAC Code of Practice - https://www.britishcytology.org.uk/uploads/files/BAC-recommended-code-of-practice-for-cytologylaboratories.pdf) and the 14-day turnaround time did not apply to Northern Ireland. The document states that these two derogations were not determined by SHSCT, but by the NISCSP Quality Assurance team. This Underperformance and Actions taken document did not address the following issues identified by this review:

1. According to the 'Management of Underperformance Protocol' and highlighted in the 'Summary of Changes to the SHSCT Protocol for the Management of Underperformance' In 2019, an internal change was made to the standard applied for screener sensitivity of all grades of abnormality. The national standard remained at 90% but the SHSCT adopted an operational target of 85% and an

actionable threshold of <85% (Review of IQC Statistics Date of Issue 02.17.2019). This is contradicted in the QMS quarterly monitoring audits which suggest the 90% standard was applied.

2. The summary of changes to this policy states that on 14.12.22 the sensitivity standard for all grades of abnormalities was reverted to >90%. However, in the section on 'Evidence of Individual Competency and Performance' in the most recent version of the policy for the 'Management of Potential Primary Screener Underperformance' issued 24.02.2023, the action threshold for required improvement in performance against the standard is <85%.

3. KC61 returns for the 10-year period being risk assessed were provided. The national Performance Standards for PPV, APV and RV which has been applied for returns calculated from 2010 to 2022 are all the same. These standards are the ones published in the Statistical Bulletin for 2015-16, all other years are incorrect on the KC61s provided.

Laboratory Overview and Consultant Data

The cervical cytology laboratory at SHSCT reported an average of 24886 cervical cytology samples annually between 2009-2021. The data produced is discrepant for 2021-22 in that the KC61 data has a figure of 25645 but the total primary screener workload figure is given as 16252.

After the initial draft of this report, the Trust provided new information that there was an SLA with another Northern Ireland trust, for cytology reporting. The outcomes and data relating to this trust have not been provided for review.

The published NHS CSP standard for a cervical cytology workload per laboratory used is 35000. This figure was not used in NI. It should be noted that SHSCT has never reached this annual workload figure, and as far as we are aware no laboratory in NI has.

The data produced for this report was, in general, of individual years' worth of data, with very little presented in the format of year on year trends or shown as benchmarked against NHS CSP standards for comparison. This required much of the data having to be re-formatted to allow for such comparisons. Some of the reports provided were partly redacted, including action points and outcomes following nonachievement of performance standards.

The laboratory (on the KC61 data produced, see Appendix 6) has had a slowly declining high grade (HG) cytology reporting rate over 10 years - from 1.6% in 2012-13 to 0.51% in 2021-22. The low grade (LG) has varied over the same time frame from 5.05% and up to 8.06% in 2019-20 but has fallen back to 4.49% in 2021-22. The PPV over the period since 2010 has varied between 91.99% (2011-12) and 75.3% (2016-17) but has in general remained around the 80% level. The APV has fallen from 38.14 in 2020-11 down to 9.55 in 2021-22 and the RV has risen from 1.48 to 5.15 over the same time frame.

The change to reflex HPV testing was introduced in NI around 2013, and this may have affected pick up rates to a degree. However, the falling HG rate (effectively down by two thirds over 10 years) is most unusual. Whilst it might reflect population/coverage changes (including HPV immunisation) and hence a true decrease in HG cervical abnormalities in the community, this would need to be proven. Our concern would be that it might represent chronic under reporting of HG abnormalities by the SCSHT laboratory as a whole. We are not aware of any laboratory in England that has shown such a significant downward trend even with a change in screening method.

The documents seen indicate that in NI there were agreed local deviations from the QA standards used in England and that these "deviations or derogations are not determined by the individual Trust organisations but under the auspices of the NI Cervical Screening Programme." The documentation seen indicates that there were deviations for some cytology result codes (partly an IT issue), as well as the overall laboratory workload figure of 35000 samples. There is no indication of any deviation from the standards relating to pick up rates, individual workloads, or values for PPV, APV or RV used in the NI CSP from those in use in the English CSP.

The English CSP has for over 20 years used a minimum Consultant reporting workload of 750 cervical cytology samples/year. The data produced for SHSCT shows (when reformatted) that of the 4 consultants listed, Consultant 2 never achieved the 750 annual workload figure (range 174-684) over a 12 year period. Of the others (not all active over the 12 year period) Consultant 1 achieved the 750 figure or greater 8/10 years (2010-2020), consultant 3 4/9 years (2010-2020, excluding 2018-19) and consultant 4 1/4 years (2017-2022). See Appendix 7.
Additional information provided after the preparation of this report, but not at the time of writing, was that some of the consultant staff reported cervical cytology for other Trust(s). As such, the data provided reflected only work done at the SHSCT site. The additional data of other site reporting not provided or reviewed.

The consultant PPVs are in general in line with the English CSP values for most years, but where the differences when not achieved are relatively minor.

Involvement in the CSP cervical cytology EQA is mandatory for all staff reporting in the CSP. The data produced shows most staff have participated within the EQA scheme. Any potential poor performance identified though participation in the EQA scheme would be addressed by the EQA scheme, and the individual/laboratory depending on the frequency of poor EQA performance and the grade of the staff. No indication has been given that any such issue has arisen for the SCSCT laboratory/staff since 2010 from participation in the CSP EQA scheme.

The CSP EQA scheme does allow for acceptable reasons for non-participation on occasions (such as maternity leave, sickness). The data indicates a Consultant Pathologist (pathologist 5) who took part in the scheme in 2010-11 but no workload appears ascribed to this individual. One of the screening staff [redacted] had 6 non-participations between 2010 and 2019, despite reporting significant numbers of cervical cytology over this time period. They ceased screening in 2020. There are also several screeners listed as reporting cervical cytology who do not appear to have taken part in the EQA in the years listed [redacted] There are also at least two screeners who have taken part in the CSP EQA over many years [redacted] despite only reporting 814 and 4 cervical cytology samples over these periods respectively. It is unusual for screening staff to continue doing the CSP EQA if they are not actively reporting.

Information provided after the draft report, but not provided at the time, was that some of these explanations are for accepted valid reasons, such as extended periods of leave.

External Quality Assurance Reports

The SCSCT laboratory has shown several documents relating to external NI Quality Assurance (QA) review of data and of a visit report (also covering other aspects of the CSP) dated 20th September 2019. As to the appropriate standards with which to assess the CSP it states:

STANDARDS
The standards used to measure performance during the quality assurance visit are those that currently apply to the NHS Cervical Screening Programme (NHSCSP) in England, as published in the various NHSCSP guidelines (www.cancerscreening.nhs.uk). These include:

- *Achievable Standards, Benchmarking for Reporting and Criteria for Evaluating Cervical Cytopathology. NHSCSP Publication No 1 (3rd edition), January 2013.*
- *Programme Specific Operating Model for Quality Assurance of Cervical Screening Programmes PSOM (and)*
- *Colposcopy and Programme Management, Guidelines for the NHS Cervical Screening Programme. NHSCSP Publication No 20 (3rd Edition), May 2016.*

In addition to the specific NHSCSP documents, laboratories are expected to operate within the relevant guidance published by the British Association for Cytopathology (BAC), Institute of Biomedical Science (IBMS) and the Royal College of Pathologists (RCPath).

It does not indicate that any deviation from these standards are used.

Within section 2.6.1 - Laboratory data - of this report it states:

However, there are concerns about the performance of an individual screener, who has missed a number of high grades over the last 3 years. Despite QA and QC procedures being followed, including following protocols for under performance, workload review and completion of update courses, there has been no noticeable improvement. The QA visit team recognise that steps have been taken to try and address this issue, however it is recommended that the Trust consider this staff members role within screening.

It appears that subsequent to this external QA report that the individual screener was ceased from cervical cytology screening.

The same report also highlights that the laboratory has a significant cytology backlog, and that some 20% of the screening work is done as overtime. A plan to address this high use of overtime and the back log was required within 3 months.

The report also noted that there were no trainees in the department. The staffing levels provided in other data indicates that the laboratory had 6.2 WTE in 2009-10 (13 actual staff) but that this dramatically fallen to 1.25 WTE by 2020-21 (4 actual staff).

The laboratory QA data review meeting report (dated 25/01/19 on data for 2017-18) indicates many overall parameters were in range. However, it also noted that:

The lab protocols were discussed. Reduced sensitivity is noted across screeners. This is similar to the pattern seen in other labs and possibly due to changing practice with HPV testing. To be discussed at next regional lab QA meeting.
The Trust advised that all high grade misses have been reviewed and protocol followed.
It was noted that there is a large proportion of the staff with 100% sensitivity and 100% specificity. The Trust stated that they are confident their QC is working well. It was confirmed that no QC is done out of hours.

The same report also notes:

The Trust suggested that the use of CINtec has improved sensitivity. Although it is used at the discretion of the reporting Pathologist.

As part of this it was suggested that this approach be discussed at the regional lab QA group. The use of CINtec has not been approved for routine use within the CSP and any use of it would require full evaluation and QA/CSP agreement.

The Record of QA data visits summary and major findings/actions lists 9 possible visits, some of which appear not to have reports produced. The QA data visit reports provided (for years 2012-13, 2013-14, 2015-16 and 2017-18) do find many parameters as within acceptable values. The QA Record summary document does not list all the points raised by the QA reviews, including around sensitivities of screeners and actions taken, workloads, and variation from any standards. Some reports indicate the need for further review or data, but none is mentioned as having been seen in subsequent reports.

<u>Reporting Data and Invasive Cervical Cancer Audit Review</u>

Documents provided include the NI cervical cancer audit protocol 2014, approved 10/9/14 and Cervical cancer audit and disclosure 8/2/19. Both follow the corresponding English documentation.

Data provided indicates that a total of 196 cervical cancers were identified and audited from SHSCT between 2008-2021. The number per year varies between 9-20, with an average number of 14 cervical cancer cases per year. It is difficult to evaluate how many of this total of 196 involved [redacted] but the

numbers below suggest this could be of the order of at least 15 cases between 2016-2021, out of 83 cases (18.1%). The cervical cancer cases which have been audited may have had cytology available for review up to 10 years previously and so may relate to many years prior to the year to the diagnosis of the cervical cancer. No data has been seen relating to the other cases audited that did not involve [redacted] for comparison.

This must be considered in the context that between 2010-2022, [redacted] screened a total of 48,428 cervical cytology samples, and [redacted] 42,584, out of a total cytology workload of 303,537. Hence, [redacted] screened overall 30% of the total laboratory workload. During this same timeframe, the high grade sensitivity for [redacted] was within the acceptable QA standard during 7 out of 12 years, whilst for [redacted] it was only 5 out of 12 years. For all grade sensitivities, the equivalent comparison against the acceptable QA standard was for [redacted] 5 out of 12 years and for [redacted] 3 out of 12 years.

Although not cervical cancer audit data, data from false negative (FN) reporting is relevant. Data from 'Audit of False Negative Reporting' indicate between 2007-2021 [redacted] had 55 cases classed as FN reporting, with [redacted] having 31 cases. These however appear to cover any suspected FN report, some of which did not have known outcomes. Data on the HG misses (i.e. HG FN reports) with known histological outcomes between 2012-2021 show [redacted] as having 31 such cases, with 22 having histological HG (CIN2 or 3) outcomes out of 27 cases with histological outcomes, and [redacted] having 21 cases with 19 having HG CIN outcomes out of 20 cases with known histological outcomes. From the overall laboratory sensitivity data, during the period 2012-21 there were 98 laboratory HG FN cases. If the cases of HG FN reporting from [redacted] are within this data, then they would represent 52 of these 98 cases (53%) of all lab HG FN when their reporting workload was approximately 30% of the overall laboratory total during this time frame.

The SHSCT laboratory has provided evidence of cases in which [redacted] either alone or on occasions in combination, were indicated as having screened/checked cervical cytology slides that were reviewed as part of the cervical cancer audit. This amounts to: 2016 - 2 cases, 2018 - 3 cases, 2019 - 2 cases, 2020 - 2 cases and 2021 - 6 cases. Of the 10 cases since the introduction of the 2019 protocol and reviewed, 5 were classified as category 2, 1 as category 2/3 and 4 as category 3.

Evidence has also been provided of 8 slides externally reviewed (whose slide numbers do not appear to correlate to those mentioned above and hence may represent other cases).
Of these, 7 were reviewed as category 2, and only 1 as category 3. All appear to have been very recently externally reviewed, in January 2023.

There is one cervical cancer case identified though the cervical cancer audit review which led to the SAI [redacted] report, dated 20/07/22. The review identified three available previous cervical cytology samples, one of which was reported in 2011 at SHSCT with the other two being reported in 2014 and 2017 at another laboratory. The SHSCT cytology 2011 sample (51126265) was reviewed, and felt to be a false negative, and recorded (within the audit criteria) as Category 3 – Unsatisfactory review - False negative cases or significant process or management shortcomings that constitute a patient safety incident. The sample was screened by screener [redacted] and checked by checker [redacted] as they were identified in the SAI report.

The SAI report notes:

From the evidence provided to the SAI team it was identified from the information provided by the SHSCT, that a screener (checker [redacted]) employed by the SHSCT who was involved in the screening of one slide from this patient, was not meeting the achievable benchmarks for high grade sensitivity at that time, however screener [redacted] had reached the target number of 750 checked slides as per recommendation above. The individual checker who reported the cervical screening test in 2011 (51126265) had a sensitivity for high grade abnormalities of 81.81% below the achievable benchmark of ≥ 95.0% as per Table 2.

It would appear highly likely that the Screener [redacted] of the SAI report is screener [redacted] whilst the checker [redacted] is likely to be [redacted]

The SAI report is very detailed and covers most of the points asked of in the RCPath Consulting review. The SAI [redacted] report has detailed Conclusions (section 7), Lessons learned (section 8) and Recommendations and Action Points (section 9). We fully agree with all the points raised and made within this report.

A paper titled, 'Cervical Cytology Service – Trust Board Position paper - Feb 2021', contains the following paragraphs:

SHSCT New Framework outcomes 2019 and 2020
The Trust has completed the new framework approach for the 2019 patient cohort. There are three category 3 outcomes for 2019 and these are being investigated as Level I SAI.
The review team has been established and the process to engage with patients has begun. This new framework approach has a significant additional administrative time commitment, acknowledged in other Trusts also, which is unfunded. So far there are no Category 3 outcomes for 2020.

Cervical Cancer patients 2009 – 2018
Prior to the Framework above Trusts had been asked to carry out a review of the cervical screening history in all women diagnosed with cervical cancer. The Medical Director of the Public Health Agency wrote to Trust Chief Executives to ask that this be done for all cases diagnosed from 2009 onwards and that the NHS Cervical Screening Programme guidance ('Disclosure of Audit results in Cancer Screening, Advice on Best Practice') was to be followed. In 2014 a laboratory specific protocol was introduced but largely resulted in little change to the audit review.

Whilst this audit review has been done in the Southern Trust 2009 – 2018 there is no evidence of patients having been told it was happening and subsequently very few instances of disclosure of outcomes.

No evidence was seen to indicate extra resource was provided for implementation of the cervical cancer audit process. There is documentation which suggests that due to lack of resources, the laboratory is unsure whether they will be able to undertake the audit fully.

This Trust position paper also notes:

Primary HPV testing is a more sensitive test and will eventually replace cervical cytology as a primary screening tool. NI is the only region of the UK not to have rolled out primary HPV testing. It will be difficult to quality assure our service as no national benchmarking will be available. We acknowledge the false negative risk of a cytology based test screening programme and that NI is currently at variance with UK and ROI. Until a policy decision is made to introduce primary HPV testing in Northern Ireland It is proposed that we commence co-testing from 15 March 2021. The cost of this arrangement per year is estimated to be up to £100K.

Routine co-testing on all samples is not advocated in the CSP, and in essence this amounts to cytology and HPV testing on all samples, irrespective of the cytology status. No further detail of this is provided, but if it is not clear if this means cytology and HPV testing on all samples, or HPV testing and cytology only if a HR HPV type is identified, which amounts to Primary HPV testing. No mention is made of QA or other agencies' input to this decision or agreement for it.

In relation to the cases of concern identified through the audit of invasive cancer for 2021 referenced in the initial early alert, it was agreed that these cases will be sent for external review. These were sent to a UKAS accredited NHSCSP provider laboratory in England for external review.

The Trust Board paper dated July 2022 estimates that from [redacted] workload a potential 21,840 women's samples may need to be reviewed, for the time period 1/4/18-31/10/21.

7) Findings and Recommendations

7.1. Finding 1

There is evidence of a longstanding, persistent failure to take appropriate action to manage the underperformance of the minimum workload standard for screening and consultant staff.

Recommendation 1:

Introduce measures to ensure all cytology staff at all grades who do cervical cytology screening, checking or reporting achieve the minimum workload standards set out by the NHS CSP

7.2. Finding 2

The current staffing is insufficient to maintain the total workload of the laboratory and is not sustainable.

Recommendation 2:

Determine a safe and sustainable approach to ensure the staffing capacity matches the laboratory workload.

7.3. Finding 3

Persistent underperformance in achieving screener sensitivities for high-grade abnormalities and all grades of abnormality has not been proactively managed in a timely manner, or at a level appropriate to the degree of underperformance.

Recommendation 3:

Ensure all persistent underperformance is managed appropriately and promptly.

7.4. Finding 4

The policy for the Management of Underperformance does not include appropriate thresholds, or timescales for action for underperformance, and does not contain details of escalation routes to be followed in the event of persistent poor performance.

Recommendation 4:

Revise the 'Management of Potential Screener Underperformance 'policy to include appropriate thresholds and timescales for action, and of escalation routes in the event that measures employed do not lead to improved performance to the required standards.

7.5. Finding 5

Not all published screening programme performance standards have been applied to performance monitoring at SHSCT.

There are no published guidelines specific to the NI CSP which define the deviations or derogations from the NHS CSP standards.

Recommendation 5:

If standards used for performance monitoring by SHSCT are going to deviate from NHS CSP published standards, all standards used and explanations for any applicable derogations should be formally documented in a Trust policy.

7.6 Finding 6

There is evidence that the NHS CSP cervical cancer audit protocol has not been fully followed.

Recommendation 6:

There must be adequate resources and full compliance with requirements of the NHS CSP cervical cancer audit in review and in full disclosure, in line with the audit protocol and women's wishes.

7.7. Finding 7

HPV primary screening has not been adopted in Northern Ireland, despite the 2017 recommendation from the UK National Screening Committee (NSC) that the UK Cervical Cancer Screening Programme should adopt the test for Human Papillomavirus (HPV) as a primary screening test. ([ARCHIVED CONTENT] Cervical Cancer (nationalarchives.gov.uk)

Recommendation 7:

This UK NSC recommendation should be escalated to the Northern Ireland Department of Health as a priority and a formal plan developed for the implementation of HPV primary screening in Northern Ireland. The change to a Primary HPV cervical screening programme must be coordinated across NI

and the implications for service delivery, sustainability and quality must be considered before implementation.

8) Recommendations Against RCPath Consulting Brief

8.1 *To review the available evidence on Cervical Cytology performance relating to screeners* [redacted] *compared to each of the Cytology screeners working in SHSCT over the past 10 year* Completed, see main report

8.2 *To work with the Trust Operational Team to provide any further data / evidence which may be helpful in further clarifying whether under performance has occurred*

Completed, see main report

8.3 *To comment on the adequacy of those data, local procedures and processes and make any recommendations for change*

Much data has been given to the reviewing team. Much of this, whilst complete and of use as far as it went, was not in a format that allowed much meaningful data or trend analysis. Some of the SHSCT procedures and documents lacked meaningful objective, monitoring criteria or outcomes. See recommendations 7.1-7.9.

8.4 *To review the findings raised by the SHSCT audit of invasive cancer relating to screeners* [redacted] *and comment on the compliance of those audits with the Northern Ireland protocol and Framework on the audit of invasive cervical cancers and make recommendations, if necessary, to strengthen that process going forward.*

The NI Cervical cancer audit procedure, mirroring that published in England, has been in use since the revised criteria were issued in 2019. The data provided appears piecemeal, and whilst of necessity concentrating on screeners [redacted] did not allow for comparison with other screening staff. The data, and slide review, appeared selective and limited. It is imperative that all cases are reviewed and classified in line with the cancer audit protocol, and that any lessons learned are put in place. Full disclosure appears not to have been fully undertaken where indicated.

8.5 *To provide an assessment of risk to the screened population in SHSCT due to under performance of screeners* [redacted] *in the context of a Screening Programme which cannot prevent all cases of cervical cancer, and where the sensitivity of the test will always be less than 100%*

The data presented and reviewed has shown long standing issues with the performance of screeners [redacted] and [redacted] This poor performance has been poorly addressed, and has shown no meaningful improvement despite the limited interventions. The policies used for addressing poor performance were suboptimal (see findings 7.4-7.6 in particular).

The reviewing team, in consultation with Dr K Denton (RCPath Consulting Lead) have concluded that it is not possible within the resources of this review to calculate a precise assessment of the risk posed to the screened population by this underperformance.

It is possible to conclude that the sensitivity of the laboratory as a whole, both for primary screening and rapid review, is likely to be significantly lower than for other UK laboratories.

For example, a difference of true sensitivity of 80%, vs best achievable with UK practice of triage and test of cure protocol, which is probably about 90%, would result in 10% more cases of CIN2+ being detected. However this would be mitigated somewhat by women who have disease detected on repeat sample, with no adverse effect on outcome.

8.6 *To consider the risks of undertaking such a review, including for example in anxiety and additional recall to women who may not have significant disease.*

There is substantial evidence that the performance of screeners [redacted] was not in line with CSP QA standards for most of the last 10 years. The delivery of the CSP by the SHSCT laboratory has been within QA standards in some areas, but many of the screening staff QA performance parameters were not so, and the trends in the overall laboratory performance and especially the decreasing pick-up rate of HG disease is worrying. The falling, and low, staff numbers, reliance on overtime for backlog management, and lack of trainees means that the delivery of cervical screening at the SHSCT laboratory is not sustainable in its current format. As such, the laboratory cannot manage its own current workload, let alone any additional workload that any potential review exercise might represent. The quality of any cervical screening work review undertaken at the SHSCT laboratory must also be in question given the above issues. It is also important to highlight that the capacity to undertake any large scale cytology slide review would not be an option elsewhere in NI given the current state of the screening programme, and the capacity would also be highly unlikely to exist elsewhere in the remainder of the United Kingdom.

The cervical cytology workload of [redacted] was 91,012 over a 12 year period, some 30% of the overall laboratory workload. Many of these women will have had negative cytology, and these are the ones where a potential false negative may have occurred. Women with positive cytology would have been referred and managed clinically on the abnormal report. Many of the "negative cytology" women will have attended for screening at the prescribed intervals, whether 6 or 12 months, 3 or 5-yearly. Some may have been ceased due to reaching 64 years of age or for other reasons. It is not suggested that this figure of 91,012 would all need a potential review, but even allowing for those who have been rescreened during this time frame (or subsequently) the ones at greatest risk of a false negative report and hence potential inappropriate action, are those with a negative cytology report given by screener [redacted] and who have never been rescreened, or who have been ceased. It is not possible to accurately quantify this number without reviewing the records and outcome of these 91,012 women. However, the overall laboratory data does raise the possibility that the potential for FN reporting was not only from screeners [redacted] but from others, and hence arguable that the review, if undertaken, should be widened to other aspects of the laboratory's workload.

8.7 *To make a recommendation based on these findings on whether there should be a review, and if so, what number of slides over what time period should be reviewed.*

Given the point made under 8.6, a rescreening exercise cannot be recommended at this time. This is largely shaped by the fact that capacity for large scale slide review is highly unlikely within the UK CSPs given the general state of workload and service delivery. Outsourcing overseas is not advocated given the historic issues with quality.

It is our view that the best way to reduce the risk of false negative reports from SHSCT is for the NI CSP to implement HPV Primary Screening. This would offer all the advantages of the NSC recommendations and would also then be consistent with the CSPs of England, Wales, Scotland and Republic of Ireland. We note that the laboratory indicates that it has moved to co-testing since 1st March 2023. This is effectively, if understood correctly, an effort to implement Primary HPV screening.

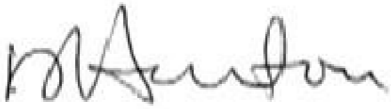
Efforts should be made to encourage more women to attend for cervical screening given the current coverage is of the order of 72%. Conversion to Primary HPV screening, with its move to a more automated testing approach for 100% of the screened women, and reflex cytology rate of typically 15% would mean 85% of women would receive their results within a few days (as they would test negative for high-risk HPV). The 15% cytology workload would amount to approximately 20-25,000 cytology samples per year for the whole of NI. The increased sensitivity of Primary HPV testing would result in more high-grade cervical disease being identified. Women with potential false negative cytology for the workload of screeners [redacted] and those women who have been ceased following a negative cytology by [redacted] should be encouraged to attend for a Primary HPV screening test.

9) Advisor Sign off

Dr Paul Cross Date: 17/05/2023

Nichole Villeneuve, Consultant Biomedical Scientist Date: 17/05/2023

10) RCPath Consulting Quality Assurance Sign off



Dr Karin Denton Date:17/05/2023
RCPath Consulting Lead

Appendix One: Scope and Terms of Reference

Royal College of Pathologists and
Southern Health and Social Care Trust (SHSCT)

Proposed review of Services by RCPath Consulting

Scope and Terms of Reference

1. General background to the Cervical Cytology Service

Background

The Southern Health and Social Care Trust (SHSCT) has for many years provided a Cervical Cytology Service as part of the Northern Ireland Cervical Screening Programme. This programme currently uses Cervical Cytology as the primary screening test. HPV primary screening has not yet been implemented, as it has been in the rest of the UK.

In October 2021 two Biomedical Scientists who had been primary screening and / or checking Cervical Cytology ceased screening after concerns were raised about performance including the review of high grade sensitivity data and findings raised through the audit of invasive cancers. These screeners are known as [redacted] Up to October 2021, performance against high grade sensitivity data for all screeners, was managed in line with Trust protocols.

The Lead Consultant for Cervical Cytology and the deputy lead Biomedical Scientist escalated their concerns in relation to the performance of screeners [redacted] to the Laboratory Senior Management Team. The Senior Laboratory Team agreed that the immediate actions taken where appropriate and that a paper needed to be prepared detailing the performance of screeners [redacted] as compared to all the screeners in the service in order to determine what further actions may need to be taken.

A paper was brought to Trust Senior Management Team in July 2022 raising the concern about the potential impact on women in the screening population in the SHSCT area relating to the performance of screeners [redacted] The paper suggested that Public Health Agency needed to be informed and that a risk assessment needed to be considered. Subsequent to discussions at Senior Management Team in July 2022, two meetings were held with the Trust and the Public Health Agency in August 2022. It was agreed that a Steering Group would be established in line with the regional Lookback Review process Stage 1a and a risk assessment be progressed at the earliest opportunity. At the meetings with Public Health Agency in August 2022, concerns were raised by Public Health Agency in relation to the quality of the Trust performance data available including the way screener sensitivity data was calculated.

The key question to be considered through a risk assessment process is, whether the women in the screening population in SHSCT that had smears reported by screeners [redacted] have a higher risk of a false negative report and therefore a missed opportunity to treat pre-cancerous changes.

Purpose

The purpose of the work to be progressed through this review / risk assessment is to determine whether the women in the screening population in the Trust that had smears reported by screeners [redacted] have a higher risk of a false negative report and therefore a missed opportunity to treat pre-cancerous changes. The review will also consider if the screener performance data and department performance management processes are appropriate.

This is the output expected from the initial review. If any further advice is required upon receipt of the final report, this will be specified separately in an incremental fashion.

2. RCPath Consulting input

RCPath Consulting is requested to produce a report for SHSCT; first contact is [redacted] Independent Advisor.

Objectives / methodology

- To review the available evidence on Cervical Cytology performance relating to screeners [redacted] compared to each of the Cytology screeners working in SHSCT over the past 10 years
- To work with the Trust Operational Team to provide any further data / evidence which may be helpful in further clarifying whether under performance has occurred
- To comment on the adequacy of those data, local procedures and processes and make any recommendations for change
- To review the findings raised by the SHSCT audit of invasive cancer relating to screeners [redacted] and comment on the compliance of those audits with the Northern Ireland protocol and Framework on the audit of invasive cervical cancers and make recommendations, if necessary, to strengthen that process going forward
- To provide an assessment of risk to the screened population in SHSCT due to under performance of screeners [redacted] in the context of a Screening Programme which cannot prevent all cases of cervical cancer, and where the sensitivity of the test will always be less than 100%
- To consider the risks of undertaking such a review, including for example in anxiety and additional recall to women who may not have significant disease
- To make a recommendation based on these findings on whether there should be a review, and if so, what number of slides over what time period should be reviewed.

3. Clinical advice schedule

3.1: Preparation (1 day)

RCPath Consulting Lead Introduction to project

This whole day session will offer the opportunity to:

- Read the existing documentation to inform the Scope of Services
- Discuss the requirements by teleconference with SHSCT
- Draft (and if required, redraft) the Scope of Services

3.2: (4 days) 2 RCPath Consulting Advisors, each for 2 days.

Visits and teleconference meetings with managers and key clinical staff members depending on the requirements of due diligence for assessment of working practices and the availability and notice period required for the Advisors and the client.

These 2 days will offer the opportunity to:

- Discuss the evidence and data around laboratory performance with managers and clinical staff
- Review current processes against UK national guidance and standards and relevant local protocols
- Consider the evidence and come to an evidenced conclusion on whether a review of screened slides is required to assure patient safety.

It is expected that the advisors will be a consultant cytopathologist with extensive experience of cervical screening and a biomedical scientist/consultant biomedical scientist with experience of performance monitoring of screening staff. Both members will be experienced in quality assurance.

3.3: (2days) 2 RCPath Consulting Advisors, each for 1 day.

Preparing and writing the review report

- Distill the background information and documentation along with the review undertaken in section 3.2
- Formulate an authoritative report which draws on experience elsewhere of the particular issues which pertain to the service
- Produce a written record of information gleaned and findings of the review
- Produce a written record of recommendations for SHSCT

- Submit the report for RCPath Consulting Lead quality assurance and factual accuracy checking to SHSCT within the timeframe agreed

3.4: Quality Assurance of Advisor input (0.5 days) **RCPath Consulting Lead**

This half-day session will offer the opportunity to:

- Quality Assure the Advisor's input
- Identify any further improvements to RCPath Consulting processes
- Identify any further project needs and ways to continue support if required (see follow up below)

4. Costs

Sessions will be charged at [redacted] per day excluding VAT and excluding all expenses which will be according to the College expenses policy.

- 7 whole days and 1 half-day
- Total anticipated cost: [redacted]

5. Timelines

This output is planned in the within 8 weeks following receipt of a signed contract from SHSCT. If these timelines are delayed due to actions/inaction of SHSCT this could have implications for RCPath input and subsequent costs. Any problems in the implementation of the consulting work should be conveyed to the RCPath Consulting Lead as soon as they arise in order that mitigation can be considered. Failure to raise issues as they occur are likely to result in delay and/or subsequent costs.

6. Key Personnel and Expectations

RCPath Consulting will field an appropriate team to provide clinical advice informed by pathology experience led by the RCPath Consulting Lead. The RCPath Consulting Advisors will attend all agreed meetings or, if unable to attend due to unforeseen circumstances will contact with SHSCT immediately to re-schedule appropriately.

SHSCT will field an appropriate team to provide input on the status of, patient pathways, user requirements and concerns. This will be co-ordinated by a single SHSCT point of contact. SHSCT staff will attend all agreed meetings or, if unable to attend due to unforeseen circumstances will make contact with RCPath Consulting immediately to re-schedule appropriately.

7. Venue

Tele/videoconferencing to be arranged via RCPath Consulting Lead, RCPath Consulting Advisors and SHSCT, for initial discussions. On-site visit at SHSCT

8. Risks and Mitigating Actions

	Risks		**Mitigating Actions**
1	Input from SHSCT is not available in a timely manner.	1	RCPath Consulting Advisor and Lead to contact SHSCT
2	Input from RCPath Consulting is not available in a timely manner.	2	RCPath Consulting Lead to take action to identify alternative resource input.
3	Key SHSCT personnel are unable to complete the work.	3	RCPath Consulting Advisor and Lead to contact SHSCT to facilitate.

4	Key RCPath Consulting personnel are unable to complete the work.	4	RCPath Consulting Lead to take action to identify alternative resource input.
5	The work takes longer than anticipated due to unforeseen circumstances.	5	RCPath Consulting Lead to notify SHSCT senior management immediately to discuss and agree implications for completion of project.
6	All key information and documentation is not provided upfront to assist timely and efficient decision-making.	6	SHSCT to consider the scope of the project and the documentation and information which will be useful. Preparation session will be the opportunity to discuss and agree all information required for the project.

9. 9.

9.

9. Outputs

The output from the review will be a report which will deliver the objectives set out in section 2 with appropriate clinical pathology specialist input framed to accommodate the needs of SHSCT The review report will be made available to •Dr Stephen Austin – Medical Director, SHSCT.

10. Follow Up

Follow up advice may be available, if required by SHSCT and agreed by RCPath Consulting. The follow up advice would be provided via an extended contract on a limited basis and a subsequent extension of this scope of services and schedule would be agreed after completion of the work in the schedule above.

Dr Karin Denton
RCPath Consulting Lead
October 2022

Appendix

Two: Quality Assurance policy for RCPath Consulting

Pathology is the science at the heart of modern medicine, vital for the diagnosis and clinical management of disease. The College's mission statement is to promote excellence in the practice of pathology and to be responsible for maintaining standards through training, assessments, examinations and professional development, to the benefit of the public.

The Royal College of Pathologists was established in 1962 to coordinate this development and maintain the internationally renowned standards and reputation of British pathology. Today, the College advises on a vast range of issues relating to pathology and, responding to unmet demand in the United Kingdom and beyond, the College, through its trading subsidiary RCPath Trading Limited, will provide a range of consultancy services as RCPath Consulting (RCPC).

Quality in delivery of consultancy services is as important to us as the quality of our clinical services, teaching and research. The College's reputation is built on well-informed and considered approach to challenges and a commitment to continuous improvement. In order to ensure that we provide total satisfaction to our clients for consultancy services, RCPath Consulting has put in place the following quality assurance system:

- The RCPath Consulting Lead provides each RCPath Consulting requestor with a single point of contact and management of their consultancy contracts.
- The RCPath Consulting Lead gathers and monitors requestor feedback.
- The RCPath Consulting refers opportunities for service improvement to the Board of the Royal College of Pathologists
- The RCPath Consulting Lead is responsible for resolving requestor complaints.
- Training and development is available to advisors delivering consultancy services.
- Policies and procedures relating to the management of RCPath Consulting and the delivery of consultancy contracts are subject to review by our internal panel, and changed where improvements to customer service can be made.
- The Directors of RCPath Trading, through the RCPath Lead, have ultimate responsibility for the quality assurance of all services provided by RCPath Consulting, but all employees involved in managing and delivering these services have responsibility within their own areas of work, so helping to ensure that quality is embedded within the RCPath Consulting ethos.

Appendix

Three: Workload Data Summary 2010 – 2022

Workloads													
[redacted]	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	>3000/year
	3072	3851	5378	5185	4809	3307	3561	5717	4830	4508	3417	793	11-12
	3786	4087	4249	102	3180	3123	3934	4803	5160	4431	4256	1473	11-12
	416								398				
	1							1	1	1			
	935	1133	1214	1942	1144	1017	709						0-7
	1432	1846	1880	1901	2958	2285	2136	3120	3343	1890	1846	2369	2-12
	1416	2039	1137	1545	1333	34							0-6
	1529	1307	1442	1202	1392	1113	1328	1323	1041	1013	2300	4	0-12
	1543	1624	2174	2963	2223	1240	1524	1203	1485	1732	2593	1740	0-12
	3203	900	2077	5641	4063	3016	2947	726	3002	2595			5-10
	1613	2183	1956	1755	1589	1286	2162	3176	2424	846	1343	1215	1-12
	3641	1223											
	3471	4102	4574	5597	5231	3977	4332	5301	5900	5416	580		10-11
	1		1	2	2								
	3590	3489	1221										
	1												
						6877	2072						
						167							
									344	2577			
												2136	
												6522	
	29650	27784	27303	27835	27924	27442	24705	25370	27928	25009	16335	16252	
	23.1%	28.6%	35.3%	19%	28.6%	23.4%	30.3%	41.5%	35.8%	35.7%	47%	9.1%	

Appendix

Four: Summary of High Grade Sensitivities for All Screeners

Year	[redacted]														
07/08	94.74	76.32	100.00	100.00	50.00	90.00	-	100.00	92.31	100.00	100.00	-	98.21	95.24	-
08/09	97.50	90.54	93.33	100.00	73.81	100.00	-	100.00	96.17	100.00	87.88	-	100.00	96.15	-
09/10	96.30	-	90.70	98.31	95.00	94.34	-	100.00	100.00	100.00	90.48	-	100.00	-	97.67
10/11	92.50	99.61	94.44	95.45	96.43	96.61	-	100.00	100.00	96.15	87.50	-	100.00	96.49	98.46
11/12	100.0	97.10	81.82	100.00	93.44	100.00	-	100.00	100.00	95.65	-	-	100.00	100.00	98.46
12/13	96.43	96.25	100.00	96.77	95.52	100.00	-	100.00	97.30	100.00	-	-	96.88	-	96.15
13/14	96.47	100.00	88.00	96.55	95.35	98.63	-	100.00	100.00	100.00	-	-	100.00	-	-
14/15	91.11	94.74	92.31	100.00	100.00	92.73	-	100.00	100.00	93.75	-	-	100.00	-	-
15/16	96.55	91.49	100.00	100.00	98.31	100.00	92.59	100.00	100.00	95.83	-	-	100.00	-	-
16/17	94.74	93.18	-	95.83	100.00	97.44	96.43	100.00	100.00	100.00	-	-	100.00	-	-
17/18	94.37	94.44	-	100.00	100.00	100.00	-	100.00	-	100.00	-	-	100.00	-	-
18/19	95.92	91.89	-	98.00	96.43	96.77	-	100.00	-	100.00	60.00	100.00	100.00	-	-
19/20	95.00	97.44	-	97.22	100.00	100.00	-	100.00	-	100.00	-	95.00	100.00	-	-
20/21	92.59	94.12	-	100.00	-	-	-	100.00	-	100.00	-	-	100.00	-	-
21/22	100.00	92.86	-	100.00	-	-	-	100.00	-	100.00	-	-	100.00	-	-

Appendix Five: Summary of All Grade Sensitivities for All Screeners

Year	[redacted]														
07/08															
08/09															
09/10															
10/11	90.24	92.59	92.08	97.20	93.65	91.92	-	96.55	94.81	97.89	87.80	-	96.18	93.13	93.59
11/12	93.89	89.18	84.13	96.48	90.55	97.22	-	93.75	100.00	95.42	-	-	97.97	93.33	91.64
12/13	90.56	87.63	88.61	89.74	89.81	95.21	-	94.44	90.51	98.21	-	-	95.42	-	92.31
13/14	91.06	100.00	85.92	92.91	89.32	84.05	-	89.29	93.53	92.45	-	-	95.24	-	-
14/15	85.13	87.76	90.23	92.58	90.56	85.37	-	89.70	92.86	92.59	-	-	92.57	-	-
15/16	85.42	85.19	85.71	90.91	89.55	86.59	86.50	94.23	94.07	88.89	-	-	95.20	-	-
16/17	83.51	82.01	-	90.44	88.61	84.57	83.74	94.09	88.37	91.47	-	-	100.00	-	-
17/18	80.90	80.43	-	85.20	88.92	70.83	-	87.43	-	88.50	-	-	91.44	-	-
18/19	76.50	82.75	-	81.18	90.23	79.41	-	88.17	-	84.71	57.69	81.82	96.36	-	-
19/20	82.12	83.96	-	86.96	91.10	86.06	-	91.54	-	93.61	-	74.81	95.45	-	-
20/21	87.45	81.85	-	92.89	-	-	-	94.46	-	93.15	-	-	96.49	-	-
21/22	91.23	93.15	-	96.07	-	-	-	100.00	-	99.21	-	-	99.41	-	-

Appendix

Six: Laboratory Trends from KC61 Data

KC61 data totals CSP (part B, 20-64), and Part C2 (PPV, lost to FU)

	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22
Total CSP 2064	25711	24246	23974	24976	25422	24749	22214	23134	25773	22931	14649	23792
Inadequate	1044	685	625	618	783	860	816	939	1119	918	762	1047
Total CSP adequate	24667	23561	23349	24358	24639	23889	21398	22195	24654	22013	13887	22745
LG total	1397	1189	1179	1312	1531	1361	1319	1333	1656	1775	1116	1022
HG total	394	385	374	306	358	351	239	215	233	206	104	116
% Inadequate	4.06	2.83	2.61	2.47	3.08	3.47	3.67	4.06	4.34	4	5.2	4.4
% LG	5.66	5.05	5.05	5.39	6.21	5.7	6.16	6.01	6.72	8.06	8.04	4.49
% HG	1.6	1.63	1.6	1.26	1.45	1.47	1.12	0.97	0.95	0.94	0.75	0.51
PPV	89.76	91.99	88.54	83.33	85.14	80.15	75.3	82	84.55	84.34	79.3	80
APV	38.14	37.86	32.16	25.31	21.11	18.07	17.27	15.61	21.45	19.47	13.13	9.55
RV	1.48	1.56	2.08	1.99	2.3	2.45	2.49	2.62	2.56	2.69	3.56	5.15
Lost to FU	0.61	0.12	0	1.93	1.16	1.46	1.52	2.99	1.86	2.66	2.99	4.56

Appendix Seven: Consultant Workload Figures

Consultant workload figures

Year	[redacted]				Cons work total	Lab workload	% Cons work of lab	English CSP level >750
10/11	431	539	749		1719	29650	5.8	750
11/12	666	174	761		1601	27784	5.8	750
12/13	945	545	555		2045	27303	7.5	750
13/14	1057	517	571		2145	27835	7.7	750
14/15	1035	461	818		2314	27924	8.3	750
15/16	1069	631	884		2584	27442	9.4	750

16/17	783	533	929		2245	24705	9.1	750
17/18	1250	584	245	148	2227	25370	8.8	750
18/19	1149	598	0	670	2417	27928	8.7	750
19/20	1102	684	386	504	2676	25009	10.7	750
20/21	221	470	0	959	1650	16335	10.1	750
21/22	1	214	0	1331	1546	16252 or 25645	9.5 or 6	750