

Trust Board – 26 October 2023

Update on Cervical Cytology Service

1. Background

Due to the concerns raised in relation to the performance of four screeners, the consultancy arm of the Royal College of Pathologists (RCPath) were commissioned as Subject Matter Experts to independently investigate. The RCPath was asked to assess, through a risk assessment process, whether the women in SHSCT that had smears reported by the screeners had a higher risk of a false negative report. A consequence of a false negative could be a missed opportunity to treat pre-cancerous changes. There was no concern about the performance of all current screeners. The RCPath report was completed on the 18 May 2023.

2. Royal College of Pathologists' Report

The Trust and the Public Health Authority (PHA) have had time to consider the findings and recommendations in the report. In summary, the RCPath concluded that there were a number of issues with the screening process and that in particular some pre-cancerous changes could have been missed due to screener underperformance. RCPath made eight recommendations. While the focus of the report was the Southern Trust, some of the issues raised have significance for the PHA and other Trusts involved in the cervical screening programme. The Trust has engaged with the PHA to ensure that any learning is shared across the region and to address specific issues relevant to the PHA. It was agreed that to deliver on the recommendations, a new Steering Group would be established to be co-chaired by SHSCT and the PHA. The Steering Group would then establish a number of sub groups to progress the detailed work on recommendations and link with other groups already established which are working to implement primary HPV testing.

3. Action Plan to Address the RCPATH Recommendations

In light of the RCPATH report, an Action Plan was drawn up and addressed by both a Steering Group and an Operational Group. The recommendations and status of these are summarised below:

Rec No:	Recommendation Description	Owner	RAG rating	Status (complete / in process)
1	<i>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.</i>	<i>Operational group focus</i>		Complete
2	<i>Determine a safe and sustainable approach to ensure the staffing capacity matches the laboratory workload.</i>	<i>Operational group focus</i>		Partial It is planned to implement Primary HPV Screening in December 2023 This will release the requisite capacity and enable this action to be fully implemented
3	<i>Ensure all persistent underperformance is managed appropriately and promptly.</i>	<i>Operational group focus</i>		Complete
4	<i>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.</i>	<i>Operational group focus</i>		Complete
5	<i>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.</i>	<i>Operational group focus</i>		Complete

6	<i>There must be adequate resources and full compliance with requirements of the NI CSP cervical cancer audit in review and in full disclosure, in line with the audit protocol and women's wishes</i>	<i>Operational group focus</i>		Partial An application for the required resource is currently being made. In-year funding allocated by commissioners.
7	<i>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. (Regional HPV Group)</i>	<i>Regional Group focus</i>	N/A	The region plan to implement primary HPV is being progressed with a timeframe of December 2023.
8	<i>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. (For PHA, however the SHSCT is aiding the PHA with a risk stratification approach, see below)</i>	<i>Risk Stratification Group focus</i>	N/A	This is being progressed by the Risk Stratification Task and Finish Group referred to above. Individuals have been identified and letters sent. A review / call forward process is underway.

4. Risk Stratification and communication with those affected

The Risk Stratification Group was set up to identify the cohort of women whose results would require additional assurance. Approximately 17,500 women were identified. Letters of apology and an explanation of what happened were issued to the women affected. The letter was jointly signed by the Trust and the PHA. Information lines were established both at the PHA and in the Trust. Questions or issues that could not be resolved on the PHA helpline were referred to the Southern Trust helpline to resolve. Calls to the PHA Information line peaked at 181 on the 11 October, but are currently reducing – 53 calls to PHA and 13 to the Trust helpline on Friday the 13 October. The information line will remain in place until 20 October in the first instance.

5. Media Coverage, Communications Plan

On the 9 October there was significant BBC coverage of the issue. Other news outlets also picked up the story. The BBC provided helpline numbers. Individuals, other than the women directly affected, were contacted in advance of the media coverage. Staff (both present and retired) were also spoken to in advance of the media releasing the information. A global email was sent out within the Trust. Psychological support has been offered to staff directly impacted by this issue.

6. Laboratory Accreditation for Cervical Cytology (UKAS)

A routine Cellular Pathology inspection was scheduled from the 4 October to the 6 October 2023. Before the assessment started, the lead assessor was advised that an historic underperformance had been identified and assessed by the Royal College of Pathologists. On this basis UKAS decided to issue a temporary suspension of accreditation for cervical cytology testing. All other laboratory functions were not impacted.

It was agreed to pause testing while this suspension was in place. Work is ongoing to have the suspension lifted as quickly as possible.

The PHA and SPPG took the decision that cervical cytology testing should temporarily be sent to other accredited laboratories in NI for testing. The details of this is currently being determined.

7. Cytology Reporting Backlog / Risk Mitigation

There continues to be a significant backlog of Cytology smears (approximately 7,000). These smears have already been tested for HPV and found to be negative. With the planned implementation of primary HPV testing from December, it is expected that a decision will be taken by the PHA that Cytology testing of smears that have been confirmed as HPV negative will no longer be required – thus addressing the backlog issue in the Trust and regionally. Letters will then be issued to women confirming the negative result.

In the interim risks have been mitigated by the co-testing of samples for HPV and the early reporting of any HPV positive cases. Routine smears (i.e. those not triaged for immediate testing) that test positive for HPV will have cytology performed and they will be reported immediately (6-7 weeks from receipt of smear). However, samples are triaged according to the clinical presentation and any concern about delays can be escalated via the GP through to the laboratory where they will be prioritised.

8. Cervical Cytology Review Steering Group

A Cervical Cytology Review Steering Group will oversee the implementation of the review in the coming months. This Steering Group will be chaired by the Trust and the PHA.

An Implementation Sub Group will do the detailed work required as part of the review process. It has been agreed that a number of Task and Finish Groups will be established as follows:

- Slide Review Group
- Early Recall Group
- Information, Data Management and Communications Group

Within the Trust, the Cytology Review will be managed through the Lookback review Team following broadly similar processes that have been used for the Urology Lookback. Additional non recurrent funding has been secured from commissioners to support the Cytology review and this will be deployed into the existing Lookback Team in the Trust.

A Business Case will be prepared outlining the funding required to support Cytology Review plan including the costs of additional clinical work emerging from the review.