Independent expert opinion on findings of the Cervical Screening Review relating to the cervical cytology laboratory in the Southern Health and Social Care Trust

20 March 2025

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Introduction

This report provides independent expert opinion on the findings of the Cervical Cytology Review (CCR) relating to the cervical cytology laboratory in the Southern Health and Social Care Trust (SHSCT). For brevity, the details of the review are not repeated here.

The terms of reference (see appendix) for this report outlined three key objectives:

- to assess if the intended objectives of the CCR were met;
- to provide an expert opinion on whether the CCR identified a significant difference in the number of abnormalities detected than would be expected in a routine review of cervical cytology screening results in a typical screening laboratory in the UK;
- to consider the summary report of cervical cancers in the SHSCT and provide an expert opinion on the profile of cancers over the time period and the effectiveness and limitations of the cervical screening programme in relation to prevention or earlier detection of these cancers.

This report is structured in two parts. The first considers the profile of cervical cancers in the SHSCT and the latter section considers the objectives and process of the CCR review.

The authors met to discuss both review reports and share findings before preparing the two sections of this report respectively.

PART 1: Cervical Cancers in the SHSCT Area

Profile of cancers

The analysis of cervical cancers in the SHSCT area uses data published by the Northern Ireland Cancer Registry (NICR) as well that collected through the Audit of Invasive Cervical Cancers (AoICC) undertaken by the screening programme. These are considered reputable sources that collate and report routinely collected data.

The data show that the profile of cervical cancer in the SHSCT area mirrors that of Northern Ireland as a whole, with no statistically significant differences of note in terms of incidence, stage at diagnosis, or mortality. At the population level, this suggests that the region does not deviate significantly from the broader trends observed across Northern Ireland.

In terms of overall epidemiology, comparator regions are taken from within Northern Ireland. Whilst a wider comparison could have been sought, it is recognised that in terms of screening processes and pathways the comparator regions are appropriate and provide equivalence in this regard.

The relatively small number of confirmed cervical cancers involved and variation between years has been accounted for by inclusion of standardised 5-year-interval incidence rates.

Data from the Northern Ireland Cancer Registry (NICR) are not available for the most recent years (2022 onward). Given the time between the identification of cytological changes and the diagnosis of cancer, followed by a further interval before these cases are recorded in official statistics it is recommended that this routine data continues to be reviewed annually to identify any emerging trends.

The age profile of cases reported in the AoICC shows a broadly similar trend to that seen across the UK.[1]

The analysis of type of cancer aligns to that seen in England as identified through a comparable audit process. Similarly, the screening history data is also comparable when reviewed against England's.

In summary, the epidemiological analysis uses routine data from reputable sources, adopts standard epidemiological methods and uses appropriate comparators. There

[1] https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/cervical-cancer/incidence#heading-One

are no remarkable findings to suggest the profile of cervical cancer in the SHSCT area is an outlier when compared to similar regions within Northern Ireland and is aligned with the broader regional trends.

Effectiveness & limitations of the screening programme in relation to prevention or earlier detection of these cancers

In determining whether the screening programme in the SHSCT region was effective in relation to prevention or earlier detection of the cancers identified in the review, it is important to be clear on the intent and limitations of screening more generally.

Screening programmes aim to separate a defined population into two groups: those who are at higher risk of disease, and those at lower (but not no) risk. People who are at higher risk progress along the screening pathway which usually involves early recall or further investigation and/or intervention. Those at lower risk remain on routine recall until such time as they are no longer eligible for screening.

The inherent limitations of screening mean that there will inevitably be false negative and false positive results. These are not unique to cervical screening and are considered in making recommendations at UK level as to whether to screen for any given condition and how this should be undertaken. For this reason, screening programmes advise participants that a negative result does not guarantee the disease is not present.

The challenge herein is therefore to determine whether there were factors aside from the inherent limitations of screening that had a bearing on the effectiveness of the screening programme in SHSCT in the years in question and ultimately influenced outcomes in the cases identified. This is very difficult to unpick from the profile of cancers alone.

From the information available, there is indeed no clear epidemiological signal that there is any significant variation in the profile of cancers in the SHSCT area when compared to other Northern Ireland Trust areas and that of Northern Ireland as a whole. As such, the epidemiological analysis of cancers is reassuring in terms of overall population-level cancer incidence and suggests that in very broad terms screening was having the desired effect. However, it is potentially too broad an analysis to be able to determine the effectiveness of the screening programme per se.

In considering the question of effectiveness, the agreed standards and performance measures across the screening pathway are potentially more helpful indicators in this regard. Such measures account for the limitations of screening and as such, they may be able to provide a more rounded assessment of the programme,

accepting that no measure is perfect nor should be taken in isolation to draw conclusions of overall effectiveness.

Summary of findings

The epidemiology of cervical cancer in the SHSCT area is similar to that of the other Trust areas in Northern Ireland with no significant trends that give rise to concern.

Performance measures and routine review against standards (such as those discussed later in this report) provide a more granular means of quantifying the effectiveness of the screening programme. The cancer profile, whilst a much broader indicator, offers assurance that screening was effective at a population level.

Dr Graham Brown

PART 2: Cervical Cytology Review (CCR)

Identification of cases for review

Women were reviewed in two ways:

1. Pathway 1 Slide Review – their last slide was reviewed to ensure the original report was correct.

2. Pathway 2 Call forward – women were invited to attend for a new smear at a Call Forward Clinic.

The majority of women were reviewed under Pathway 1 Slide Review. Some women had no slide available and went directly to Pathway 2 Call Forward. Other women were referred to Pathway 2 Call Forward when their original test result changed following Pathway 1 Slide Review.

This process appears robust and logical. The two-pathway review outlined above ensures that all available slides from women whose most recent sample had been screened by staff whose performance may have been below the required standard were reviewed. When the slide was not available or technically suitable for review, a repeat sample is the most appropriate approach, the move to HPV primary screening was timely as the women invited to attend for screening would have the additional protection of an HPV test.

The review process

No slide review process can be perfect. Irrespective of whatever blinding process is used, the knowledge of the incident that led to the review inevitably leads to a heightened awareness when the screeners are reviewing the slides leading to potential “over-reporting” and an increase in false positives. This is a common finding in the review of slides for the invasive cancer audit.

The process was designed to identify any woman whose last slide had been reported as cytology negative or inadequate by one of the potentially underperforming screeners during the period 2008-2021.

The review rationale, procedures and delivery described in the CCR document appear to have been robust and logical. I have reviewed the comprehensive standard operating procedure (SOP) used for the CCR and the review process involves multiple checks and referrals for additional reviews where appropriate and is clearly well designed to detect any possible “false negatives”. Using staff from the

other three labs provides assurance of the external nature of the review and the data collection systems and analysis of the data appears comprehensive and effective.

Review of the CCR outcomes

Management of the women identified who required further follow-up as described in the CCR document appears to be appropriate and effective. The move to HPV primary screening has assisted with the risk assessment for those women on pathway 2.

From the slide review data there appears to have been six high grade misses (0.04%) and 24 borderline glandular abnormality (BGA) misses (0.15%). All of these cases were referred for colposcopy thus a 0.19% colposcopy referral rate from the slide review. There was also a 2.07% low grade (LG) detection rate in cases initially reported as negative. This would suggest a 99.96% high grade sensitivity from the original screen. This is at the upper end of the accepted range for high grade sensitivity which is currently sitting at above 95%. Low grade sensitivity for the original would be 97.7%, again at the higher end of the accepted range for overall sensitivity which is above 90%.

The relatively high sensitivity of the original screen is in contrast with the outcome of the performance review which suggested that screeners “did not reach the required standard for a number of consecutive years”. The SHSCT, when reporting on the original slides had in place a process where in effect slides were given two full screens, as opposed to a primary screen followed by a rapid review which is the method used in the UK to generate sensitivity data. It would seem reasonable to predict that a full rescreen should have detected more “false negatives” than a rapid screen.

When comparing the outcomes from the CCR with the sensitivity data from other UK screening labs, the finding of only six high grade “misses” is lower than I would have expected. I have reviewed a summary of Quality Assurance (QA) visits to the SHSCT lab and I note that the calculation used to generate sensitivity was different from the calculation used in other UK labs, this may have led to an under-estimate of individual sensitivity levels.

Comparison with other UK labs.

One of the main objectives of the expert review was to provide an opinion on whether the CCR identified a significant difference in the number of abnormalities detected than would be expected in a routine review of cervical cytology screening results in a typical screening laboratory in the UK. This has proved extremely challenging as comparable data from screening labs in the UK does not exist. It is

also interesting to note that the sensitivity calculation used in the SHSCT lab would not have allowed a meaningful comparison with other UK labs.

I held informal discussions with colleagues working in screening labs in England, Scotland and Ireland and could find no comparable data.

I assessed internal records within my own laboratory when reviews of individual performance had been carried out as part of a performance review or return to work after extended absence. While this data is not comparable to the CCR, there was a significantly higher false negative rate in the internal data compared to the CCR outcomes.

I carried out a limited literature review (see below) to try and find comparable data for the dataset in the CCR document. In summary, while there is no data that is directly comparable, the three studies I assessed all showed a significantly higher variation between the original and the review opinions.

It is therefore difficult to draw any conclusions or to answer this question directly apart from to state that the false negative rate in the CCR was lower than in other studies accepting the limitations of the comparison due to the differences between the starting points of the reviews. It is possible that the method used to calculate sensitivities in the SHSCT lab has led to an under-estimate of the sensitivity in the lab during 2008-2021.

Literature review

Comparable studies describing similar slide reviews are difficult to find and in general laboratories do not publish the outcome of slide reviews. A major incident in the New Zealand screening programme[1] in the 1970's led to an external slide review by an Australian lab. This study reviewed 1.2% of slides originally reported as negative as high grade or query invasive. A further 3.6% of slides were reported as possible high grade.

A more recent Norwegian study compared the performance of four pathologists when reviewing the same set of 100 slides revealed poor comparability. Using high-grade cytology as cut-off, the sensitivity for CIN2+ varied from 68.8% to 93.8% (mean 77.4%) and specificity from 70.6% to 95.6% (mean 81.3%).[2]

A USA study from 1996 where participating laboratories rescreened a total of 3762 previous cases that were originally diagnosed, during the 5 years prior to the current case, as being within normal limits or having benign cellular changes. For the rescreened cases, the overall false-negative rates were 10.1% using a narrow definition and 19.7% using a broad definition.[3]

The above studies are not directly comparable to the review that was undertaken in Northern Ireland, they all demonstrate a considerably higher detection rate of abnormalities in the reviewed slides.

1.McCredie et al. Review of Cytologic Slides from the National Women's Hospital, New Zealand, Cohort of Women with Cervical Intraepithelial Neoplasia 3 Diagnosed in 1955–1976 Acta Cytol 2006;50:632:636.

2. Sørbye et al. Accuracy of cervical cytology: comparison of diagnoses of 100 Pap smears read by four pathologists at three hospitals in Norway. BMC Clinical Pathology (2017) 17:18

3. Tabbara et al. Rescreening in gynaecologic cytology: rescreening of 3762 previous cases for current high-grade squamous intraepithelial lesions and carcinoma—a College of American Pathologists Q-probes study of 312 institutions. Diagnostic Cytopathology 1996, vol 15, (No. I) 7:11

Summary of findings

In summary, the approach to and delivery of the slide review appears logical and robust. This has ensured that either the original slides were reviewed (pathway 1) or the women were invited to attend for further screening (pathway 2).

In the absence of any comparable data set it is difficult to compare the outcomes of the CCR with other UK screening labs. However, the outcome of the CCR indicates a relatively high sensitivity of the original review and this contrasts with the perception of a problem with the performance of the individual screeners.

Prof Allan Wilson

Acknowledgements

With thanks to colleagues for their insight:

Sharon Hillier (Director of Screening, Public Health Wales)

Gareth Powell (Laboratory Service Manager, Public Health Wales)

Andrew Evered (Laboratory Clinical Director, Public Health Wales)

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Terms of Reference

APPENDIX: TERMS OF REFERENCE

Document History

Document Owner The owner of this document is: Public Health Agency

Document Location The approved document will be made available on the project SharePoint site and held in the Project File on the project manager's networked drive.

Document Status The current status for this document is ***DRAFT***

Revision History Revisions to this document need to be recorded:

Version	Revision Date	Summary of Changes	Revised by:	Signed by:
0.1	12/01/25	Initiation of document	Tracy Owen	
0.2	17/01/25	Inclusion of Trust logo and revisions to background following discussion with Trust colleagues	Tracy Owen	

Approvals This document requires approvals to be signed off and filed in project files

Name	Role	Version	Signature	Date

Distribution This document has been distributed as follows

Name	Role	Date of Issue	Version

APPENDIX: TERMS OF REFERENCE

External opinion on findings of the Cervical Screening Review relating to the cytology laboratory in the Southern Health and Social Care Trust

Terms of Reference

1. Background

1.1. In October 2023, the Southern Health and Social Care Trust (SHSCT) announced that it was undertaking a precautionary review of the cervical screening results of 17,543 women screened within the Trust between 2008-2021 as part of the Northern Ireland Cervical Screening Programme.

1.2. The decision was taken in response to an independent Royal College of Pathologists (Consulting) Report (RCPath) commissioned by the Trust which found that there had been ongoing performance issues within its cervical cytology laboratory. This report concluded that *'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'*.

1.3. The Cervical Cytology Review (CCR) was overseen by SHSCT and the Public Health Agency (PHA). The aim of the CCR was to undertake a precautionary review to:

i) check if women had been given the correct result for their last smear test carried out within the review period 2008-2021;
ii) identify any women who may have been given an incorrect result;
iii) provide an up-to-date risk assessment (with a new smear test) for those women who had a change in their original result or for those women who did not have a slide available to review; and
iv) ensure that appropriate follow-up care and treatment was provided if and as required.

1.4. For the whole of the review period 2008-2021, the Northern Ireland Cervical Screening Programme (NICSP) used cytology-based screening, with HPV testing for triage of low-grade results and test of clearance.

1.5. Women were reviewed in two ways:

i) Pathway 1 Slide Review – their last slide was reviewed to ensure the original report was correct.

ii) Pathway 2 Call forward – women were invited to attend for a new smear at a Call Forward clinic .

1.6. The findings of the review process were published in an 'Activities and Outcomes Report' on 11 December 2024.

1.7. The review did not include women who already had a confirmed cervical cancer diagnosis. These women had their screening history comprehensively reviewed as part of the routine Audit of Invasive Cervical Cancers. A separate companion report was also published on 11 December which described the cervical cancers reported within the SHSCT between 2009-2023. These dates were identified to align to cervical screening that took place during the period covered by the CCR.

2. Purpose of Seeking an Independent External Opinion

2.1 An independent external opinion is being sought to understand the significance of the reported outcomes of the CCR and confirmed cervical cancers in the review cohort, within the context of the known limitations of a cytology based cervical screening programme in the prevention or earlier detection of cervical cancer.

3. Objectives

The key objectives of the Independent Expert Opinion process include:

- to assess if the intended objectives of the CCR were met;
- to provide an expert opinion on whether the CCR identified a significant difference in the number of abnormalities detected than would be expected in a routine review of cervical cytology screening results in a typical screening laboratory in the UK;

- To consider the summary report of cervical cancers in the SHSCT and provide an expert opinion on the profile of cancers over the time period and the effectiveness and limitations of the cervical screening programme in relation to prevention or earlier detection of these cancers.

Further information relating to the CCR and the invasive cervical cancers will be provided at request to support this work.

4. Timescale

A single report for factual accuracy checking should be provided by 7 February 2025. A final report to be submitted by 14 February 2025.