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Public Health Agency

# SOUTHERN HEALTH & SOCIAL CARE TRUST CERVICAL CYTOLOGY REVIEW

## Activity and Outcomes Report

## 11th December 2024

# Contents

# Foreword

The Southern Health and Social Care Trust provided a cervical cytology laboratory service until October 2023, as part of the Northern Ireland Cervical Screening Programme. This was commissioned by the Public Health Agency (PHA). The screening programme looks for changes in cells in the cervix which, without treatment, could develop into cervical cancer.

Unfortunately, performance in some steps of the Trust's cervical cytology laboratory screening system fell below standard. Although this underperformance was identified and actions were taken to deliver improvement, the performance of some screeners did not reach the required standard for a number of consecutive years and was not recognised.

Following receipt of a report from the Royal College of Pathologists Consulting, the Southern Trust in partnership with PHA initiated the Cervical Cytology Review (CCR) as a precautionary measure to check the slides of more than 17,000 women to reduce the risk of developing cervical cancer in those who may have had an incorrect result. To ensure public confidence in the process and to avoid any perception of conflict of interest, the Southern Trust cervical cytology laboratory did not participate in review of cytology slides; this was undertaken in cervical cytology laboratories in Belfast, Western and Northern Trust.

The CCR is now complete, and two key reports have been published by the Trust and PHA. This first report details findings from the CCR and the second report focuses on cervical cancers in the Southern Trust area and across Northern Ireland.

The CCR findings show that the vast majority of previous smear results have been reconfirmed as normal. Whilst it is reassuring that no further follow up is required for these women, a small number of women's smear results were incorrect, and they have been offered follow up and treatment if required.

The report by the Royal College of Pathologists (Consulting) and the CCR provided significant learning for both Trust and PHA. The Trust and the PHA acknowledge that the failings in the cervical cytology laboratory extended beyond individual staff members and included wider system failings. The Southern Trust and PHA are committed to ensure these failures never happen again. A number of significant improvements have been put in place, including the introduction of Primary HPV screening and the centralization of cervical screening laboratory services to a single laboratory in Belfast Trust.

The Trust and the PHA remain mindful of the anxiety this process has caused and are sincerely sorry for any distress that the impacted women and their family may have experienced as a result of the Cervical Cytology Review.

Dr Stephen Austin
**Medical Director**
**Southern Health & Social Care Trust**

Dr Joanne McClean
**Director of Public Health**
**Public Health Agency**

# Executive summary

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. The decision was taken in response to the 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. The report concluded that while the majority of results issued by the laboratory were correct, a significant number of women were likely to have received negative screening results on tests that would have been identified as abnormal in other laboratories.

The Cervical Cytology Review (CCR) was overseen by SHSCT and the Public Health Agency. 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.
iv. Ensure that appropriate follow-up care and treatment was provided if and as required.

For the whole of the review period 2008-2021, the Northern Ireland Cervical Screening Programme (NICSP) used cytology-based screening, which involves making a slide from the smear test sample and looking at it under a microscope. It is well known that cervical cytology screening will only detect around three in four abnormalities. In December 2023, Northern Ireland introduced primary HPV screening. This tests for the presence of a virus called Human Papilloma Virus (HPV). HPV is a common virus which causes almost all cases of cervical cancer. Women who test negative for high risk strains of HPV are at extremely low risk of developing cervical cancer. This is a more sensitive screening method and is expected to find nine out of ten abnormalities.

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**.

It is important to note that the Review *did not include women who already had a confirmed cervical cancer diagnosis*. A separate companion report, Cervical cancers in the Southern Health and Social Care Trust: A summary report (PHA, November 2024), has been produced which describes the

cervical cancers reported within the Trust between 2009-2023. This aligns to screening that took place during the period covered by this Cervical Cytology Review (CCR).

## Outcomes

- The total number of women[1] included in the CCR was **17,425**.

- **93.8%** (n=16,346/17,425) of women included in the review completed a slide review and / or call forward pathway and have a reported outcome. **6.2%** (n=1,079) of women either opted out of the review, did not respond to a call forward invitation, or did not attend a scheduled Call Forward appointment.

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

- **14.1%** of women (2,542/17,425) included in the review were called for a new smear in **Pathway 2** either because there was no suitable slide to review or because there was a change to their original result on review.

- **95.6%** (n=1,145/1,198) of those who attended for a smear had a normal result and were returned to the NI Cervical Screening Programme for *normal recall* (within 3 to 5 years depending on the age of the woman).

- **64** women (from the Slide Review Pathway and the Call Forward Pathway) were invited to attend colposcopy or gynaecology review and were discussed at **MDM.** Of these, **56** women attended their colposcopy appointment; 8 women opted out of attending. The outcomes for the 56 women who attended for a colposcopy appointment are in 3 categories as follows:
  1) **37.5%** (21) had a Negative (normal) result and therefore required no treatment and were discharged.
  2) **42.9%** (24) had evidence of **pre-cancerous** changes to their cervix which did not require treatment. These changes usually go away on their own without treatment. However, these women have been invited for gynaecology follow up.
  3) **19.6%** (11) had **pre-cancerous** changes to their cervix or another significant incidental finding which required treatment. These women have either completed or are undergoing a treatment pathway.

- In summary, around **1 in 1,500** women reviewed (n=11/16,346) required treatment for pre-cancerous cervical cell changes or another significant incidental finding.

- Finally, in addition to the 17,425 women followed up within Northern Ireland, the precautionary review was able to successfully locate **513** women who had moved outside Northern Ireland who

[1] Exclusions included people who had recently moved outside NI, women who had had total hysterectomies and women who had recently had a smear taken within the Northern Ireland Cervical Screening Programme which was reported as normal.

were still located within the UK. To date, **97.1%** (n=501) have been successfully followed up by their local screening provider with no cervical cancers confirmed. The remaining 12 are currently in the process of being followed up by their local cervical screening provider.

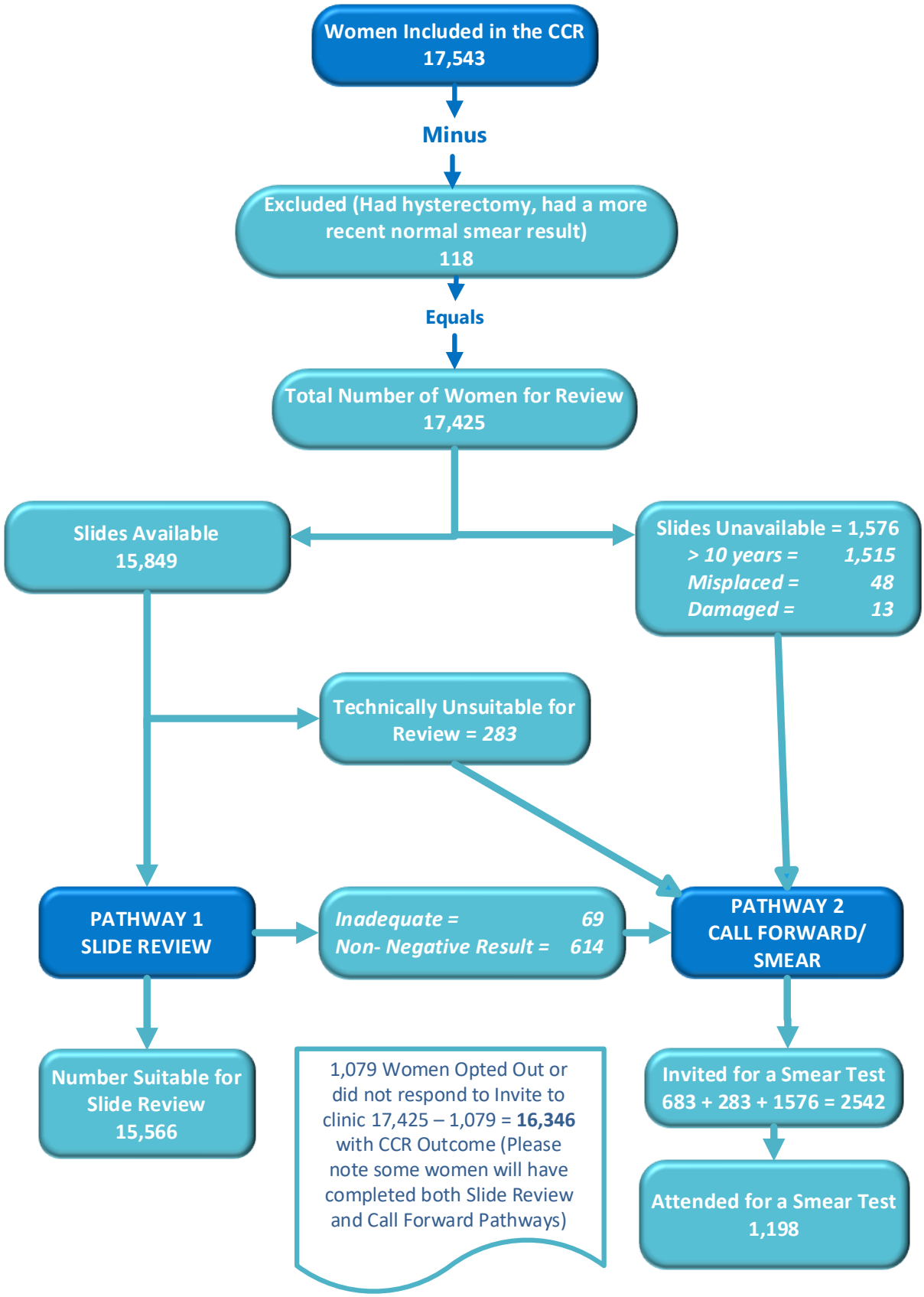
- It should be noted that while no cervical cancers were identified as part of this review for any woman during their individual slide review (Pathway 1) and/or call forward smear (Pathway 2), the Slide Review Pathway used cytology screening methods. As noted above, no screening test will detect all abnormalities. While every effort has been made to ensure slides were thoroughly and accurately reviewed, cytology screening will never find every abnormality and it is possible that a very small number of abnormalities may remain undetected. A small number of women reviewed may still go on to be diagnosed with a cervical cancer at a later date. Therefore, it is important that women who are within the screening age range (i.e. 25-64 years) continue to attend routine screening when invited to do so. Similarly, any women with symptoms should attend their GP for assessment.

- Since the individual slide review and/or call forward smears were completed in the CCR, a small number (less than 5)[2] of women have subsequently attended for routine cervical screening through the NICSP and have been diagnosed with cervical cancer. These women will be reviewed as part of the Audit of Invasive Cervical Cancer.

- Should any woman reviewed go on to develop a cervical cancer in the future, she will be included in the ongoing Audit of Invasive Cervical Cancers. This would include a review of their cervical screening slides where a woman has attended for a smear test in the previous 10-year period.

[2] *Unable to give exact number as this could potentially identify individual patients.*

**Figure 1: Summary of Cervical Cytology Review Pathways**



# 1.0 Purpose of the Cervical Cytology Review (CCR)

In May 2023, a report, commissioned by Southern Health and Social Care Trust (SHSCT)[3], concluded that there was a risk that underperformance within the SHSCT **cervical cytology laboratory** between 2008-2021 may have led to women being given an incorrect cervical **smear** test result.

In October 2023, the Trust announced that it was going to undertake a Cervical Cytology Review (CCR) which would look at the slides of women whose most recent cervical screening programme smear had been screened by staff whose performance may have been below the required standard. The aim of the CCR was to undertake a precautionary review to ensure women had been given the correct result and to minimise the risk of developing cervical cancer for anyone who may have been given an incorrect result.

There were **17,425** women included in the Review. This report describes the findings of the CCR process.

Because the main aim of the CCR was to reduce the risk of developing cervical cancer in the review group for women who had an incorrect result, it did not include women who already had a confirmed cervical cancer. A separate companion report has been produced, *Cervical cancers in the Southern Health and Social Care Trust: A summary report* (PHA & SHSCT, November 2024), which describes the cervical cancers reported within the Trust between 2009-2023. This aligns to cervical screening that took place during the period covered by the CCR (i.e. 2008 – 2021).

It is important to note that this document does not seek to establish further information about screener performance in the laboratory. This document summarises the outcomes for the women who were included in the review.

***Please note, all words that appear in bold are defined in the glossary.***

[3] RCPath Consulting Report, For the Southern Heath & Social Care Trust, May 2023. Redacted version available at Cervical Screening Review | Southern Health & Social Care Trust

## 2.0 Background

The Southern Trust cervical cytology laboratory processed and reported cervical screening tests on behalf of the **Northern Ireland Cervical Screening Programme (NICSP)** until October 2023. In October 2021, senior staff within the SHSCT laboratory identified a concern in relation to **screener performance** and some **screeners** were removed from working within the cervical screening programme. The issue was escalated and a detailed review of all screener performance from 2008 was undertaken.

A comprehensive internal report was prepared which included collated data on screener performance and actions that had been taken to manage any underperformance. This report was presented to the **Southern Trust Senior Management Team** in July 2022. A decision was taken that a risk assessment would be required. Because the cervical cytology laboratory was providing services to the NICSP, the **Public Health Agency** (PHA) was informed of their concerns, and meetings were held between the SHSCT and the PHA in August 2022 to agree a way forward.

In September 2022, a *Cervical Cytology Steering Group* was established by the Trust. This was a director-led working group to review the issue and make a recommendation on a way forward. This group included membership from organisations outside SHSCT, including the PHA and the **Strategic Planning and Performance Group (SPPG)** of the Department of Health (formerly the regional Health and Social Care Board).

Recognising the significance of the issue identified by the laboratory, the recommendation of the group was that the Trust should commission a formal independent risk assessment through **RCPath Consulting.** The outcome of the risk assessment would then inform whether a patient review was required. The risk assessment commenced in February 2023.

RCPath Consulting reported in May 2023 and made 8 recommendations. In order to deliver on the recommendations, a *Cervical Cytology Report Implementation Steering Group* was established in June 2023. The group was chaired jointly by SHSCT and the PHA. The group oversaw implementation of recommendations from the RCPath Consulting Report.

Recommendations 1– 6 related to ensuring improvements were made in cervical cytology laboratory screening processes, management of screener underperformance and audit compliance.

Recommendation 7 related to implementation of Primary HPV within the cervical screening programme in Northern Ireland which was subsequently implemented on 11th December 2023.

Recommendation 8 related to the key finding of the RCPath Consulting Report, which was that, during the period 2008 to 2021, data relating to the performance of a number of screeners indicated that their performance fell below the recognised standard. This underperformance had been identified by the Trust and the expected steps were taken to address it (for example, provision of update training, peer support and repeat audit) across the years. However, the report found that despite the required update training and support, the performance of some screeners was not maintained above the required standard for a number of consecutive years. While the RCPath Consulting Report did not quantify the level of risk, recommendation 8 of the Report stated:

> *"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….."*
> *(RCPath Consulting, May 2023, page 3)*

and concluded that a review should be undertaken to minimise the risk to women.

The *Cervical Cytology Report Implementation Steering Group* considered this recommendation and determined that although the risk to the women screened was likely to be small, a **precautionary review** to provide an updated assessment of the risk of progression to cervical cancer, should be undertaken to provide women with assurance that their screening result was reported correctly. Work for the precautionary review commenced in October 2023.

# 3.0 Cervical cancer and screening

## 3.1 The purpose of the Northern Ireland Cervical Screening Programme

Cervical screening aims to prevent cervical cancer from developing but will not prevent all cases of cervical cancer. The test (smear test) looks for early (pre-cancerous) changes in the cells of a woman's cervix (the lower part of the womb). It is designed to pick up any changes to the cells in the cervix so that they can be monitored or treated. In many cases cervical cell changes return to normal by themselves but in some cases they do not and **preventative monitoring and/or treatment** is required.

Most cervical cancers are caused by the Human Papillomavirus (HPV). There are over 100 types of HPV. Most types are harmless, but some 'high risk' types are known to cause cancer. HPV is a very common infection, and most women get it at some time in their life. There are no symptoms, and it usually clears up without the need for treatment. However, in some women the virus persists and causes changes in the cells of the cervix which may need treatment to prevent them going on to become cancerous.

Each year about 81 women in Northern Ireland are diagnosed with cervical cancer and each year about 20 women die from it. Screening, coupled with examination of the cervix looking for pre-cancerous changes and treatment of these, can prevent 7 out of 10 cancers[4]. Although cervical cancer is rare, cellular abnormalities of the cervix are common. Approximately 7% of all women who have a cervical screening test will have an abnormal test result and go on to have either a repeat cervical screening test or referral for a colposcopy examination (examination of the cervix using a colposcope – a type of magnifying glass, which looks more closely at the changes in the cervix and determines if treatment is required).

The aim of the Northern Ireland Cervical Screening Programme (NICSP) is to reduce the incidence of, and mortality from, cervical cancer. Screening does not diagnose cervical cancer. The purpose of screening is to identify apparently healthy people who may have an increased chance of a disease or condition. Cervical screening aims to reduce the chance of developing cervical cancer by identifying pre-cancerous changes and supporting early treatment.

The **UK National Screening Committee** states that is important to have realistic expectations of what a screening programme does. Screening does not guarantee protection from the disease being screened for and receiving a result which indicates the person has a low chance of developing the disease does not prevent the person from developing the condition at a later date.[5]

Similar to every other screening programme, cervical screening will not identify all cases of disease. It is well recognised that a cytology-based screening programme (which was in place in Northern Ireland until December 2023) can expect to pick up approximately 75% of cases with abnormal cells. Screening programmes are designed with a trade-off between detecting the maximum number of potential cases of a disease while not subjecting women to unnecessary diagnostic tests and treatment (benefit versus harm).

[4] Cervical cancer (who.int)
[5] Population screening explained - GOV.UK (www.gov.uk)

## 3.2 The screening pathway during the period 2008 to 2021

Women screened during the review period had their smear test slides screened using **liquid based cytology testing**. This involves making a slide from the sample taken during a cervical smear. This is then looked at under a microscope to see if there are any cell abnormalities in the cervical smear sample. Table 1 outlines how results were reported and the action or follow up that would have taken place at the time the smear was taken.[6]

**Table 1: Cervical screening results and expected follow up during the review period**

| RESULT REPORTED | DESCRIPTION | ACTION/FOLLOW UP |
|---|---|---|
| **Cytology Normal (or Negative)** | No abnormalities seen in cervical cells. | Return woman to routine screening within the NI Cervical Screening Programme (i.e. they are called for another smear in 3 to 5 years depending on age and date of screen). |
| **Low-grade abnormalities (borderline and low-grade cell changes)** | This result suggests there are some abnormalities in the cells within the cervix. Research suggests that around half of borderline and low-grade abnormalities return to normal within 18–24 months without treatment. | These samples underwent a further test using **HPV testing**. If the HPV test was positive, the woman was referred to **colposcopy** for further investigation. If the HPV result was negative the woman would have been returned to routine recall (i.e. another smear in 3 to 5 years depending on age). |
| **High-grade abnormalities (moderate or severe cell changes)** | This result means that there are likely to be abnormal cells in the woman's cervix. These abnormal cells have a greater potential to develop into cancer if left untreated. | Woman referred to gynaecology services for colposcopy investigation/treatment. |
| **Borderline endo-cervical changes** | This result means that there are small changes in the glandular cells of the cervix. These are often due to the HPV virus. These changes are usually minor and return to normal on their own. However, there is a risk that changes could progress and may require treatment. | These samples were managed in the same way as low-grade cervical changes until 2019. From 2019 onwards, these women would have been referred directly to colposcopy. |

[6] *Prior to January 2011, the age range for screening was 25 - 64 years, with smears taken every three years. From January 2011 onwards, following recommendations from UK National Screening Committee, the age range for inclusion was changed to 25-64 years. Frequency of smears changed with three-yearly smears for individuals aged 25-49 and five-yearly smears thereafter. This means that the follow up offered to women in the review cohort would have differed depending on the date that their smear was taken.*

| | | |
|---|---|---|
| **Inadequate** | A smear is deemed to be inadequate when they are unable to read a slide. This can happen for a number of reasons (for example, not enough cells in the sample, or too much blood on the slide to view the cervical cells. | Woman invited to attend for a further smear in 3 months. |

In addition to these cervical screening findings, **incidental findings** may also have been present. Incidental findings do not relate to the main purpose of cervical screening. There are two main types of incidental findings that may occur:

(1) **Endometrial cells (cells from the womb)** - Cervical smear tests are not recommended for screening for endometrial abnormalities. However, endometrial cells can sometimes be visible in cervical smears. Where an incidental finding of *normal* endometrial cells was made in smears from women 45 years old or over, including all post-menopausal women, the woman's GP was informed so they could consider referral to gynaecology for investigation. If *abnormal* endometrial cells were present in a woman aged 45 and over, to include post-menopausal women, the woman was referred directly to gynaecology for further investigation.

(2) **Infection** such as **Herpes Simplex Virus (HSV)** or **Trichomonas** can be evident on review of the cervical cytology slide. If infection was suspected, the woman's GP was informed to enable them to follow the woman up and provide any treatment that may be required.

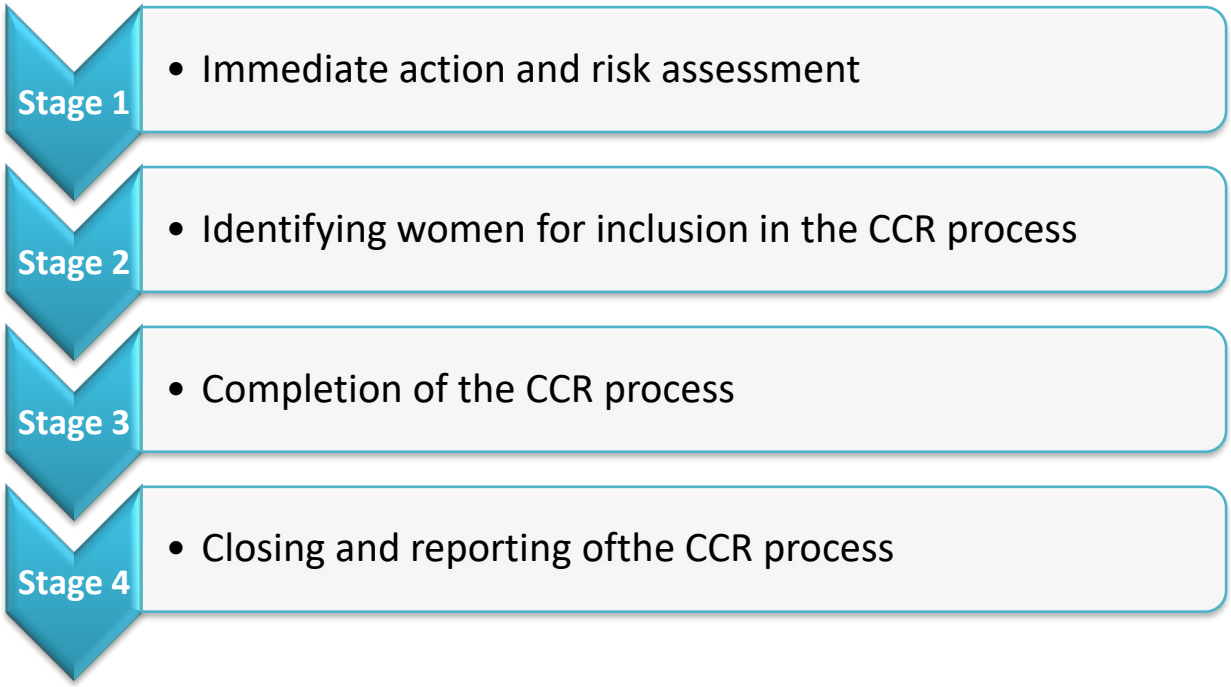
Primary HPV testing was implemented in the Northern Ireland Cervical Screening Programme on 11th December 2023. This service has since been centralised in Belfast Health and Social Care Trust (from 1st November 2024); cervical screening is no longer undertaken in the Southern Health and Social Care Trust laboratory.

# 4.0 Cervical Cytology Review methodology

## 4.1 The process

This Review was a high volume, complex process and therefore the Department of Health **Lookback Review Guidance**[7] was used as a framework for the delivery of the CCR, ensuring a robust and systematic approach to planning this review. This Department of Health guidance outlines four key stages for the completion of a review. The key stages of the CCR process are presented at Figure 1.

**Figure 2: Key Stages of the CCR Process**




## 4.2 Patient and public involvement, information & support

It was recognised that women included in the Cervical Cytology Review may be anxious and there was a need to be sensitive in terms of communication, information and support. Considerable efforts were made to engage and support women, and in particular women who had received letters advising they were to be included in the CCR. Service user representation was included at all levels within the review planning structures and was instrumental in shaping the design and delivery of the CCR and advising on patient support and communication, including the development of information leaflets and outcome letters.

[7] Department of Health, 2021 *Policy for Implementing a Lookback Review Process* doh-pol-implem-lookback-review.pdf (health-ni.gov.uk)

At all stages of the CCR, steps were taken to ensure that appropriate information and support was provided to the women impacted by the review. This included:

### *Support for Women*

- The establishment of a dedicated telephone helpline which was maintained for the duration of the CCR.
- Women contacting the helpline were supported by the Patient Liaison Team. If a woman was experiencing anxiety, Liaison staff could refer them for individual counselling through the Inspire service.
- A dedicated CCR email address to allow women to email any individual queries.
- A dedicated information page on the SHSCT website with a detailed 'Frequently Asked Questions' (FAQs) section which was updated on an ongoing basis in response to queries coming through the Helpline and other routes.
- Information leaflets were provided at call forward clinics.
- Information updates and bulletins were also provided to GP practices in the SHSCT so that they were equipped to respond to any patient queries and to signpost women as required.

### *Communication with impacted women*

- A letter issued to all women on 17 October 2023 advising of their inclusion in the CCR.
- Second update letter sent to all women on 1 March 2024.
- Women received individual outcome letters when the review of their own case was completed.

### *Media communication*

- Proactive press releases to provide the public with updates on progress.
- Meetings with interest groups (for example MLAs, the NI Assembly All-Party Group on Cancer, local Councillors, and local interest groups such as Ladies with Letters).
- Public reporting on the CCR at the Southern Trust Board meetings.
- Media engagement with interviews by Trust and PHA senior staff with broadcast media.

## 5.0 Stage 1: Immediate action and risk assessment

As referenced above, a risk assessment had already been commissioned via RCPath Consulting and concluded that there were concerns with respect to screener performance in SHSCT cervical cytology laboratory. While the RCPath Consulting Report did not quantify the level of risk, it stated:

*"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 is implemented in a quality-controlled manner, with consideration of early invitation of women considered to be most at risk".*

Having considered the available options, the CCR Steering Group took a decision to undertake a precautionary review of women's smear slides. The RCPath Consulting Report had said that while the concern reached a threshold where other laboratories have undertaken reviews, they could not recommend a review of slides because there was not suitable capacity in the UK to undertake this.

However, the Steering Group, with detailed knowledge of the system in Northern Ireland, determined that the planned introduction of primary HPV would release sufficient capacity to facilitate the review of all slides by cervical cytology screening laboratories within Northern Ireland. This was considered the optimal approach as it would allow a more timely and complete review to be carried out. Importantly, there was concern that uptake of an offer of a new smear would be low and that slide review would provide a definitive outcome for a larger number of women. In addition, it was recognised that women outside the screening age range of the NICSP may find it very uncomfortable and these smears would be technically more difficult to perform.

# 6.0 Stage 2: Identifying women for inclusion in the Cervical Cytology Review

## 6.1 Defining the Review Cohort

A Risk Stratification Group, led by the Public Health Agency, was set up to define the groups of individuals who may be at risk of having a cervical abnormality that had not been detected by one of the screeners identified in the RCPath Consulting Report (screeners X, Z, R or S). The process was designed to identify any woman whose last slide had been reported as **cytology negative** or **inadequate** by one of the underperforming screeners during the period 2008-2021.

The criteria and the rationale used to identify women to be included in the CCR is set out in Table 2.

**Table 2: Criteria used to identify women to be included in the CCR**

| | CRITERIA | DETERMINATION / RATIONALE |
|---|---|---|
| 1 | Screener | To include samples reported by one of four screeners (X, Z, R or S) identified in the RCPath Consulting Report as underperforming over multiple and consecutive years. |
| 2 | Time | To include samples reported between 2008 and 2021 where the screener failed to meet the minimum sensitivity standards for high grade and/or all abnormalities. To include underperformance identified in the RCPath Consulting Report or by the Trust.<br>In order to ensure that all potential periods of underperformance are taken account of, the time frame 1 January 2008 – 31 August 2023 to be included. |
| 3 | Result | To include samples reported as **cytology negative** (see Table 1 for definition) or inadequate at final result and did not have an HPV test.<br>*Samples reported as abnormal are managed through the HPV triage process and referred to colposcopy as appropriate. A negative HPV result provides an assurance of a very low risk of cervical cancer.* |
| 4 | Quality Control | To include samples that did not have a full rescreen by a consultant or another screener (excluding X, R or S).[8]<br>*A full rescreen undertaken by a consultant or another screener meeting the performance thresholds provides assurance that the original result was correct.* |
| 5 | Screening History | To include samples recorded as the most recent smear result for the individual.<br>*A subsequent adequate screening test reported by another screener will provide assurance that the individual has been followed up since the date of the identified slide.* |

[8] Screener Z is not included here because this screener only performed primary screens. They did not have a role as a checker (i.e. they did not perform second reviews of smears already screened by a primary screener)

| | | |
|---|---|---|
| 6 | **Call/Recall Status** | To include samples for individuals who remain active in the cervical screening recall system or have been ceased from recall due to age or other reason.<br><br>To exclude individuals ceased from screening as they no longer have a cervix (women who have had a total hysterectomy) as they are no longer at risk of cervical cancer.<br><br>To include individuals who have since moved out of Northern Ireland – although recognising that information to facilitate further follow up may not be available. |
| 7 | **Person** | To include individuals who are alive and have no known diagnosis of cervical cancer.<br><br>*Individuals who are deceased cannot be included in a call forward and those with known cervical cancer will not benefit from a call forward within the Review. Slides relating to women who were diagnosed with cervical cancer are reviewed as part of the invasive cancer audit. Information about this is presented in the accompanying report – "Cervical cancers in the Southern Health and Social Care Trust: A summary report"* |

A total of **117,578** women who were resident in the Southern Trust area were screened within the NICSP between 2008 and 2021 and their results analysed in the SHSCT cervical cytology laboratory.

The total number of women living in Northern Ireland initially included in the review was **17,543**. Following further data checks across a number of health information systems, 118 women were excluded. This was for the following reasons:

- A recent routine smear test result through the NICSP had been reported as normal.
- They had recently had a total hysterectomy and therefore no longer had a cervix.

As a result of these further exclusions the final number of women included in the review and reported within this document was **17,425**. A number of women within this group had a more recent smear result as part of the normal Cervical Screening Programme. The previous slides for these women were also included in the Slide Review Pathway and their outcomes are reflected in this report (where the slides were available).

There were an additional **1,540** women identified for inclusion in the review who were found to have moved outside Northern Ireland since their cervical screening test was carried out. A separate process was established to follow up these women up where possible. This is reported separately at paragraphs 6.2 and 8.4.

## 6.2 Women who had moved outside NI

**1,540** women were identified for inclusion in the review. However, because they moved outside of NI after they had their original smear/slide a separate process was established to follow these women up where possible.

*Women who had moved within the United Kingdom (n=523)*

Data sharing agreements are in place across the United Kingdom which mean that if a woman moves from NI to another UK country, patient registration data can be used to provide information on the location the woman first moves to. Where women had moved within the UK, contact was made with the other UK screening call/recall services to determine if these women had already received an up to date cervical smear from another screening programme and to inform what further actions may be required. The outcomes of this are presented at Section 8.4.

*Women who had moved outside the United Kingdom (n=1,017)*

There is no way of locating women who have moved outside the UK, and it was therefore not possible to follow these women up.

# 7.0 Stage 3: Delivering the review pathways

## 7.1 Overview of the review pathways

The aim of the CCR was to undertake a precautionary review to ensure women had been given the correct result and to minimise the risk of developing cervical cancer for anyone who may have been given an incorrect result.

At the outset of the CCR, two pathways were determined, the Slide Review Pathway and the Call Forward Pathway.

1. **Pathway 1 Slide Review** – this involved a review of the original smear test slide to determine if the original result had been reported correctly. Slide review was undertaken for women whose slide was in the cervical cytology laboratory archives and available for review.

2. **Pathway 2 Call Forward** – this involved inviting women to attend for a new smear test. These smear tests were subject to the current screening programme testing and reporting pathway i.e. all samples underwent a primary screen for HPV. Samples that were HPV positive went on to have a cytology review.

Determination of the appropriate pathway depended on the availability of smear test slides. If a slide was available in the SHSCT cervical cytology laboratory archives, and technically **suitable for review**, it was automatically progressed to the Slide Review Pathway. Women were directed onto the Call Forward pathway only when:

- their previous slide was >10 years old and had been destroyed in accordance with Retention/Disposal Guidelines[9].
- where the available slide was not technically suitable due to deterioration over time (for example, colour stains had faded, they had **dryback** or were damaged).
- the slide could not be located within laboratory archives.

Pathways 1 and 2 were dynamic, such that women within **Pathway 1 Slide Review** could move into **Pathway 2 Call Forward**. There were two main circumstances where this occurred:

1. On review the slide was found to be no longer **technically suitable** for review – in these instances a new smear result was the only way to provide the women with an assessment of their current risk.
2. If the original result changed on review - again, for these women, a new smear was required in order to provide an assessment of their current risk and to ensure appropriate follow up.

[9] Guidance on retention and disposal of slides means that slides are disposed of after a period of 10 years. This guidance is detailed in (5th edition) Guidance from The Royal College of Pathologists and the Institute of Biomedical Science April 2015.

## 7.2 Pathway 1 Slide review

### *7.2.1 Delivering the pathway*

To ensure public confidence in the CCR, a decision was taken early in the process that SHSCT cervical cytology laboratory screeners would not participate in the delivery of slide reviews. Slide reviews were therefore undertaken by the other Trust cervical cytology laboratories across Northern Ireland. This included laboratories in Belfast, Northern and Western Trusts.

For rigour, every slide suitable for review was managed in accordance with the following process (detailed in Appendix 1):

1. Each slide underwent a **detailed** screen by a primary screener.
2. If the result agreed with the original result, the slide went on to have a second shorter review by a second screener to confirm they agreed with the result.
3. If the primary screener reported a change to the original result, the slide went for review by a consultant.
4. All slides with a reported abnormality underwent a further review by a second consultant.
5. Any discrepancy in consultant opinion, the slide would then go to a **Consultant Consensus Panel**, where a number of consultants would review the slide to agree the result.

During the review, incidental findings of Endometrial Cells, Trichomonas and Herpes simplex virus were also subject to consultant level review. This was to ensure that these incidental findings could be acted on.

### *7.2.2 Reporting and follow up for Pathway 1, Slide Review*

Table 3 outlines the main results that could be reported following slide review and the action taken in response.

**Table 3: Slide Review Results and Corresponding Actions/Follow Up**

| RESULT REPORTED | ACTION/FOLLOW UP |
|---|---|
| **Slide was negative (normal) on review** | Review closed. |
| **Results previously reported as inadequate remained inadequate** | While these results were appropriately followed up at the time of the original result, records showed some women had not come forward for any further cervical smear test at that time. On that basis, these women were invited for a smear. |
| **Result changed to low-grade cell changes or inadequate** | The woman was invited to attend for a new smear at a Call Forward Clinic. |
| **Result changed from negative or inadequate to high-grade abnormalities** | The woman was referred directly to gynaecology services for colposcopy investigation/treatment. |

| | |
|---|---|
| **Result changed to borderline endo-cervical changes** | The woman was referred directly to colposcopy for investigation/treatment regardless of age. |
| **Report includes an incidental finding – endometrial cells** | If the finding of endometrial cells was not reported at the time of the original result, the woman was referred directly to gynaecology services for further investigation. |
| **Incidental finding - infection** | If an infection is found on slide review and was not reported at the time of the original result, the woman was referred to the Genitourinary Medicine Service (GUM), offered screening & treatment if required. Their GP was informed to enable them to follow up accordingly. |
| **Slide was technically unsuitable, damaged or misplaced** | The woman was invited to attend for a new smear at a Call Forward Clinic. |

## 7.3 Pathway 2 Call Forward

### *7.3.1 Designing the pathway*

It was recognised that any women in **Pathway 2** who were being called forward for a new cervical smear as part of the review may be anxious. Therefore, all possible steps were taken to design a process that was as accessible, efficient and supportive as it could be, and which would optimise attendance at the clinics. This included:

- providing clinics in evenings and at weekends;
- providing clinics at two locations (Daisy Hill Hospital and Craigavon Area Hospital);
- design of bespoke information resources for women attending the clinics;
- clinic appointments offered through **partial booking**;
- leaving the offer open - if after two reminders, a woman did not respond or did not attend a clinic, a letter was sent to both them and their GP, to advise that if at any point in the future the woman wished to arrange a smear, they could contact the Trust to arrange it;
- additional support - for any women particularly anxious about attending the Call Forward Clinic, the Liaison Team accompanied them to this appointment;
- Collecting feedback - the Trust's Liaison Team undertook a user satisfaction survey with women who attended the clinics to ensure that they were meeting the needs of the women attending.

### *7.3.1 Reporting and follow up for Pathway 2- Call Forward*

Any woman attending for a smear at a call forward clinic had their sample tested in line with the current screening pathway. Therefore, all samples were tested for primary HPV. If a sample tested positive for HPV, it went on to have a **cytology test**. Results for women attending call forward clinics were followed up in accordance with the current cervical screening pathway as set out in Table 4 below.

**Table 4: Result Categories & Follow Up for Women Attending Call Forward Clinics**

| RESULT REPORTED | ACTION/FOLLOW UP |
|---|---|
| **HPV negative/no cytology undertaken** | Returned to the Northern Ireland Cervical Screening Programme for routine recall in 3 or 5 years (dependent upon their age). |
| **HPV positive/cytology normal** | Offered a repeat cervical smear in 12 months as this result is considered low risk. |
| **HPV positive/cytology abnormal** | Referred to colposcopy for further assessment. |

# 8.0 Stage 4: Reporting CCR outcomes and closing the review

## 8.1 Activity and outcomes Pathway 1 Slide Review

**15,849** (90.9%) of the total women (17,425) in the CCR had a slide available for review. Following technical assessment, 283 slides were found to be not technically suitable for review. These women were invited to have a new cervical smear test in the **Pathway 2 Call Forward Pathway**.

**15,566** (89.3%) women had a slide review completed and the outcomes are shown in Table 5. The results are further illustrated in Figure 2.

**Table 5: The Findings of Slide Review**

| | SLIDE REVIEW RESULT* | NUMBER | PERCENTAGE % |
|---|---|---|---|
| FINDINGS DID NOT CHANGE | Negative remained Negative | 14,808 | 95.13 |
| | Inadequate changed to Negative | 75 | 0.48 |
| | Inadequate - remained Inadequate | 69 | 0.44 |
| | **SUB-TOTAL** | **14,952** | **96.06** |
| INADEQUATE SLIDE or INCIDENTAL FINDINGS | Negative to Inadequate | 243 | 1.56 |
| | Negative or Inadequate - Incidental findings reported | 19 | 0.12 |
| | *TOTAL* | *262* | *1.68* |
| FINDINGS THAT CHANGED ON REVIEW | Negative or Inadequate changed to Low Grade cervical cell changes | 322 | 2.07 |
| | Negative or Inadequate changed to Borderline Endo-Cervical cell changes | 24 | 0.15 |
| | Negative or Inadequate changed to High Grade cervical cell changes | 6 | 0.04 |
| | *TOTAL* | *352* | *2.26* |
| | **SUB-TOTAL** | **614** | **3.94** |
| | **OVERALL TOTAL** | **15,566** | **100** |

** Definitions of each of these results are detailed in Table 1, page 11.*

### 8.1.1 No change in result on slide review or result changed to Negative

**96.06%** of results (n=14,952) were negative or in agreement with the original result. Of these, **69** were originally inadequate and remained inadequate on review. While these women were followed up correctly at the time that the original result was reported, there was no record of them ever having attended for a subsequent cervical smear. These women were offered an appointment for a new cervical smear at a Call Forward clinic as part of the CCR.

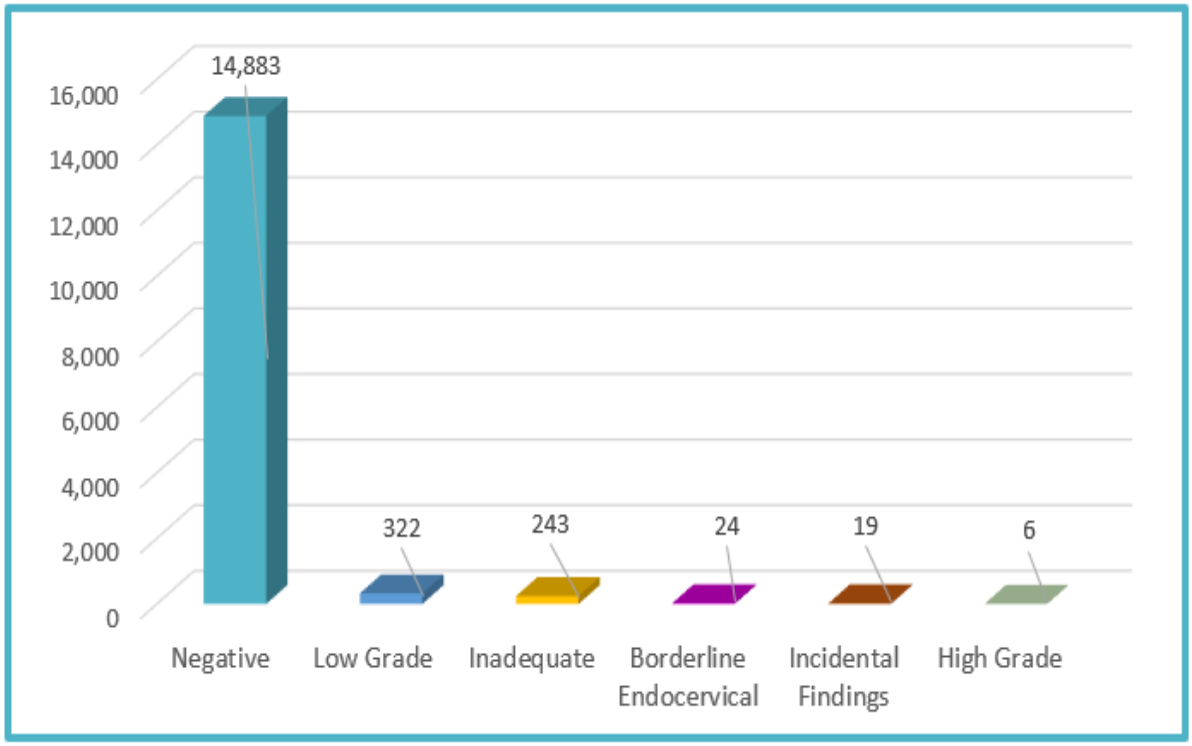
### 8.1.2 Result changed on slide review

3.94% **(n=614)** of women who completed a slide review had a change in their original result.

- 1.68% (**n=262**) had either an inadequate result or an incidental finding as follows:
  - **243** (1.56%) of women in the Slide Review Pathway had an **Inadequate** outcome result when their slide was reviewed. They were given result of 'Negative' when their slide was originally reviewed and therefore this was a change to their original result.
  - **19** (0.12%) women had a result which remained negative for cervical abnormalities, but the review indicated that there were i**ncidental findings** (for example Endometrial Cells or Trichomonas).

- 2.26% (**n=352**) had their result changed from the original result:
  - **322** (2.07%) of women had their result changed to a **Low-Grade finding**
  - **24** (0.15%) women had their result changed to **Borderline Endo-Cervical finding**.
  - **6** (0.04%) women had their result changed to a **High-Grade** finding. Any woman who was found to have high grade changes or incidental findings on slide review was referred directly to colposcopy or gynaecology for further investigation. All other women with a change to their result were referred to **Pathway 2** to have a new cervical smear.

**Figure 3. Overview of slide review outcomes**



## 8.2 Activity and outcomes Pathway 2 Call Forward

During the review, **2,542** women were offered a new cervical smear at a Call Forward Clinic. Table 6 provides an overview of the reasons women were called forward for a new cervical smear.

**Table 6. Overview of reasons women were called forward for a new cervical smear**

| REASON FOR CALL FORWARD SMEAR | NUMBER | PERCENTAGE % |
|---|---|---|
| Result changed on slide review | 614 | 24.2 |
| No slide available for review- disposed as greater than 10 years old | 1,515 | 59.6 |
| Slide technically unsuitable for review | 283 | 11.1 |
| No slide available for review - misplaced or broken | 61 | 2.4 |
| Slide review result remained inadequate | 69 | 2.7 |
| **TOTAL** | **2,542** | **100** |

Table 7 below shows that of the **2,542** women were invited to attend for a new cervical smear. **52.9%** of women (n= 1,344) either chose to opt out when they received the invitation letter or did not respond to their cervical smear invite. A total of **1,198** (47.1%) attended for a new cervical smear.

**Table 7: Summary of Call Forward Pathway 2 activity**

| SUMMARY CALL FORWARD PATHWAY | NUMBER | PERCENTAGE % |
|---|---|---|
| Total Number who 'Did Not Respond', 'Opted Out' or who 'Did Not Attend' despite booking their appointment[10] | 1,344 | 52.8 |
| Attended for new cervical smear | 1,198 | 47.2 |
| **TOTAL NUMBER INVITED TO CALL FORWARD CERVICAL SMEAR CLINIC** | **2,542** | **100** |

Table 8 and Figure 4 detail the outcomes for those women who attended for a new cervical smear either by attending a Call Forward clinic (**Pathway 2**) or as part of the routine NI Cervical Screening Programme:

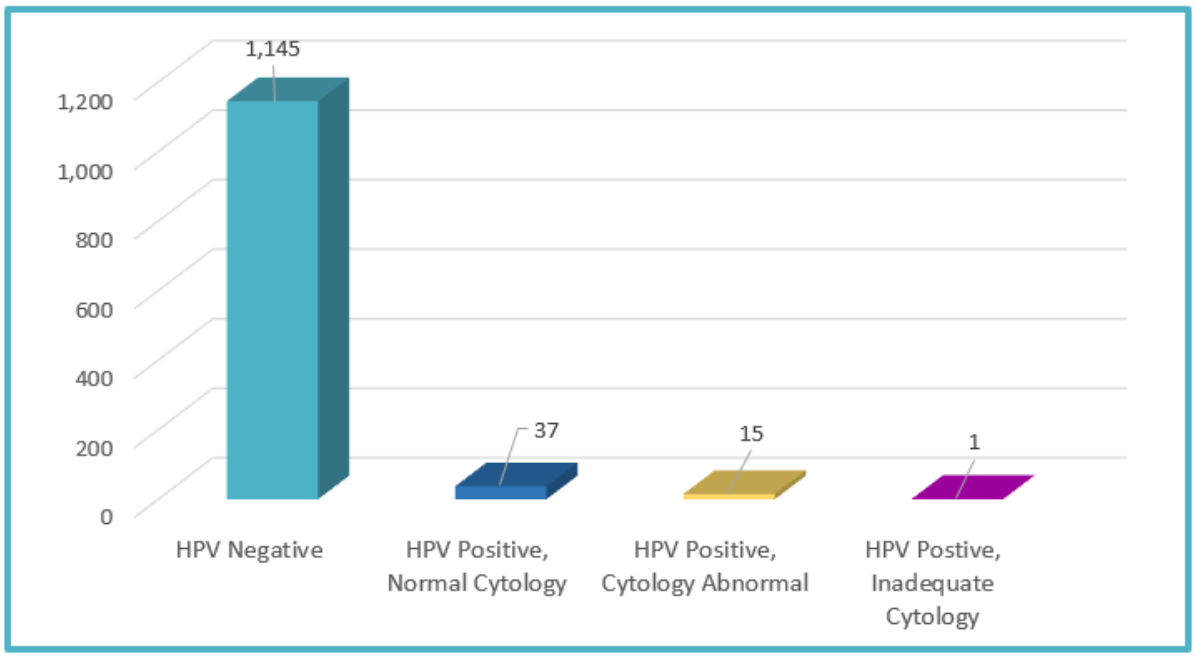
- The majority of women, **95.57%** (n=1,145) who had a new cervical smear were found to be HPV negative and required no further action by the CCR. These were returned to normal screening (i.e. to be recalled for screening in 3 to 5 years depending on the age of the woman).
- **3.09%** of women (n=37) who received a new cervical smear were HPV positive and went on to have a cytology review of their smear which was reported as normal. These women were returned to NICSP to be recalled for a smear in 1 year.
- **1.25%** of women (n=15) who received a new cervical smear were HPV positive and went on to have a cytology of their smear which was reported as abnormal. These women were referred to colposcopy for further investigation and management.

[10] *Please note, a proportion of the women opting out or not attending had already completed a slide review. Where this is the case, their slide review outcome is included in this report.*

**Table 8: Outcome of Pathway 2 Call Forward**

| SMEAR RESULT | NUMBER | PERCENTAGE % |
|---|---|---|
| HPV Negative | 1,145 | 95.57 |
| HPV Positive, Cytology Normal | 37 | 3.09 |
| HPV Positive, Cytology Abnormal | 15 | 1.25 |
| HPV Positive, Cytology Inadequate | 1 | 0.09 |
| **TOTAL** | **1,198** | **100.00** |

**Figure 4. Overview of Pathway 2 Call Forward outcomes**




## 8.3 Outcomes following colposcopy

A total of **64** women (from the Slide Review Pathway and the Call Forward Pathway) were invited to attend colposcopy or gynaecology review and were discussed at **MDM.** Of these, **56** women attended their colposcopy appointment; 8 women opted out of attending. The outcomes for the 56 women who attended for a colposcopy appointment are in 3 categories as follows:

- **37.5%** (21) had a Negative (normal) result and therefore required no treatment and were discharged.
- **42.9%** (24) had evidence of **pre-cancerous** changes to their cervix which did not require treatment. These changes usually go away on their own without treatment. However, these women have been invited for gynaecology follow up.
- **19.6%** (11) had **pre-cancerous** changes to their cervix or another significant incidental finding which required treatment. These women have either completed or are undergoing a treatment pathway.

## 8.4 Outcomes for women who had moved within the UK

**523** women were identified as having moved from Northern Ireland to England, Scotland or Wales. On follow up, it was determined that 10 of these women were no longer registered with English, Scottish or Welsh health services, including 4 registered in Isle of Man. A separate follow up process will be completed for the 4 women located in Isle of Man.

**419** of the women still registered in the UK had attended for more recent cervical screening after moving outside NI. No cervical cancers were detected.

**94** women had not attended for more recent cervical screening[11] tests after moving from NI. Of these:

- **78** had a slide suitable for review. The Slide Review confirmed the original result for all 78 women and **no further action** was needed.
- **16** women did not have a slide available in the SHSCT cervical cytology laboratory archives. Four of these women were invited by their local cervical screening programme to attend for a new smear which was reported as normal. 12 will be followed up by their local cervical screening programme.

So, in summary, **97.7%** (n=501/513) of those women who had moved within the UK were followed up with no cervical cancers reported.

[11] Or may have attended but had an inadequate sample.

## 9.0 Summary of outcomes

The total number of women included in the CCR was **17,425**. **93.8%** (n=16,346) of women completed a slide review and/or Call Forward Pathway and have a reported outcome (see Figure 1). **6.2%** (n=1,079) of women 'Opted Out', 'Did Not Respond' to a new cervical smear invitation or 'Did Not Attend' a confirmed new cervical smear appointment.

**95.2%** of women (n=15,566/16,346) had a slide review completed as part of **Pathway 1**. Of these **96%** (n= 14,951) had no change to their original result and required no further follow up. **4%** had a change to their original result.

**14.6%** of women (n=2,542) included in the review were invited for a new cervical smear through **Pathway 2**. Of these, **47.1%** (n=1,198) attended for a new cervical smear:

- **95.26%** (n=1,145) were reported as HPV Negative and were returned to the NICSP for normal recall (within 3 to 5 years depending on the age of the woman).
- **3.16%** (n=37) of women were HPV Positive and Cytology Normal which and were returned to NICSP to be recalled after 1 year.
- **1.25%** (n=15) of women were reported as HPV Positive and Cytology Abnormal and were referred to colposcopy.

A total of **64** women (from the Slide Review Pathway and the Call Forward Pathway) were invited to attend colposcopy or gynaecology review and were discussed at **MDM.** Of these, **56** women attended their colposcopy appointment; 8 women opted out of attending. The outcomes for the 56 women who attended for a colposcopy appointment are in 3 categories as follows:

- **37.5%** (21) had a Negative (normal) result and therefore required no treatment and were discharged.
- **42.9%** (24) had evidence of **pre-cancerous** changes to their cervix which did not require treatment. These changes usually go away on their own without treatment. However, these women have been invited for gynaecology follow up.
- **19.6%** (11) had **pre-cancerous** changes to their cervix or another significant incidental finding which required treatment. These women have either completed or are undergoing a treatment pathway.

In addition to the 17,425 women followed up within Northern Ireland, the CCR was able to locate **513** women who had moved outside of Northern Ireland and are located within the UK. To date, **97.1%** (n=501) have been successfully followed up by their local cervical screening provider with no cervical cancers reported. The remaining **2.3%** (n=12) are still in the process of being followed up by their local cervical screening provider.

In summary, of the **17,425** women included in the CCR, there is a definitive outcome for **93.8%** (n=16,346) women (the remaining 1,079 did not attend for a new cervical smear or chose to opt out of the review). Of those who required and attended colposcopy or gynaecology appointments, **22** did not require treatment but will continue to be followed up by gynaecology services. **11** women are currently undergoing treatment or are awaiting a result of a review appointment either as a result of pre-cancerous cervical cell changes or another non-cervical gynaecological abnormality.

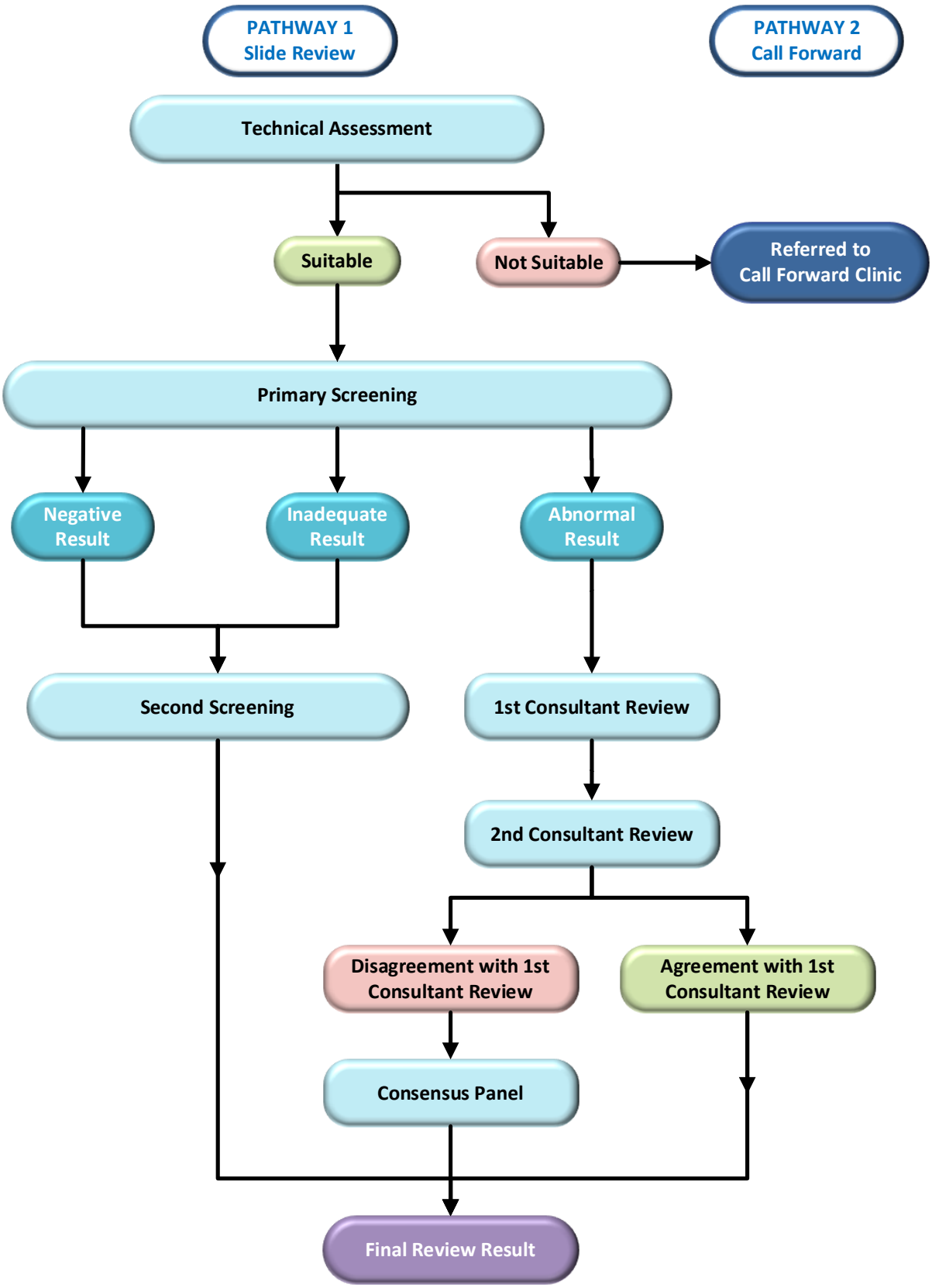
No cervical cancers were found as part of the Cervical Cytology Review for any woman during their individual slide review (Pathway 1) and/or call forward smear (Pathway 2). As noted earlier in the report, the CCR did not include women who already had a confirmed cervical cancer diagnosis. A separate companion report, *Cervical cancers in the Southern Health and Social Care Trust: A summary report (PHA & SHSCT, November 2024)*, has been produced which describes the cervical cancers reported within the Trust between 2009-2023. This aligns to screening that took place during the period covered by the CCR (2008–2021).

Since the CCR has completed a small number (less than 5)[12] of women have subsequently attended for routine cervical screening through the NICSP and have been diagnosed with cervical cancer and will be reviewed as part of the Audit of Invasive Cervical Cancer.

The CCR is based on a cervical smear test taken at a point in time and provides an assessment of risk of developing cervical cancer at that point in time. Should any woman reviewed go on to develop a cervical cancer in the future, they will be included in the ongoing Audit of Invasive Cervical Cancers. This would include a review of their cervical screening slides where a woman has attended for a smear test in the previous 10-year period.

[12] *Unable to give exact number as this could potentially identify individual patients.*

# Appendix 1. Summary of Cervical Cytology Review Pathways



# Glossary of Terms

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

**Borderline endo-cervical changes –** these are small changes in the glandular cells of the cervix that are often due to the HPV virus. These changes are usually minor and return to normal on their own. However, there is a risk that changes could progress and may require treatment.

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

**Cervical cytology screener** - a cervical cytology screener examines cells from a patient's cervix under a microscope to look for precancerous cells and cervical cell changes.

**Colposcopy** - a test where a consultant gynaecologist or advanced practice nurse takes a closer look at a woman's cervix using a type of magnifying glass. Sometimes biopsies may be taken to allow further examination of the cervical cells under a microscope. Treatment can also be provided to remove abnormal cells if required.

**Consultant Consensus Panel** – If consensus is not reached following review by consultant 1 and consultant 2, the slide is referred to a consultant in another Trust for a further review. This opinion is then be fed back to the initial reporting consultant for a final decision.

**(Cytology) Low-grade –** this means that when the cervical screener looked at the smear under the microscope, a low-grade abnormality such as borderline low-grade, mild low grade and low-grade cell changes was found. This result suggests there are some abnormalities in the cells within the cervix. Abnormal cells are not cancerous. Research suggests that at least 50% of borderline and low-grade abnormalities return to normal within 18–24 months without treatment. Before primary HPV was introduced to the NI Cervical Screening Programme, these samples underwent a further examination using HPV testing. If the test was HPV positive the woman was referred to colposcopy for further investigation. If the test was negative, they were recalled for a repeat smear after 12 months. If a woman was found to have persistent low-grade abnormalities, they were then referred for colposcopy.

**(Cytology) High-grade (moderate or severe cell changes)** – this result means that when the cervical screener looked at the smear under the microscope they saw abnormal cells in the woman's cervix. These abnormal cells are not cancerous, but they have a greater potential to develop into cancer if left untreated. Women who had moderate/severe abnormal result during the review period were referred to colposcopy for further examination and treatment.

**(Cytology) Inadequate result** – this result means that when the cervical screener looked at the smear under the microscope they were unable to report on the sample. This can happen for a number of reasons (for example, not enough cells in the sample, too much blood on the slide to view the cervical cells). In this instance, a woman is invited to attend for a further smear.

**(Cytology) Normal result** – this means that when the cervical screener looked at the smear under the microscope, no abnormal cells were detected. If the sample was reported as cytology normal or negative, women are returned to normal recall within the screening programme (i.e. they are called for another smear in 3 to 5 years depending on age and date of screen).

**Dryback –** when cytology slides are prepared a permanent mountant is used to maintain the integrity of the cells on the slide. As slides are stored, over time, the mountant tends to break down causing cracking. This gives the appearance of "dry back". When this happens, it is difficult to see the cellular material and the slide is no longer suitable for review.

**Early smear –** a women is invited to attend for a new earlier routine smear test instead to waiting for the normal recall appointment for a smear.

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

**Herpes simplex virus (HSV)** – a common viral infection that can cause painful blisters or ulcers in or around the mouth or genitals.

**HPV test** – a HPV test is a laboratory test that checks for the presence of HPV in cells which can indicate a risk of developing cervical cancer.

**Human papillomavirus (HPV)** – HPV is a common sexually transmitted infection (STI) that most people contract at some point in life. The body will usually get rid of the virus by itself, typically within a couple of years. There are different types of HPV, and if you have a high-risk type and it remains in your body for a long time, abnormal cells can begin to develop. These cells can then turn into cancer if left undetected and untreated. According to the World Health Organization Trusted Source, 95% of all cervical cancers are caused by a long lasting HPV infection. The high-risk types that tend to be responsible for cervical cancer are HPV 16 and HPV 18.

**Incidental finding** - Incidental findings are findings that are not related to the reason for the test as the cervical screening cytology test is designed to detect cell changes within the cervix only. However, the screener can sometimes identify other issues such as the presence of endometrial (womb) cells or signs of infections such as **Herpes simplex virus** (HSV) or **trichomonas**.

**Liquid based cytology testing** - this involves making a slide from the cervical smear sample. This is then looked at under a microscope to see if there are any cell abnormalities in the cervix.

**Lookback Review Guidance** - a Lookback Review Process is implemented where "…a number of people have been exposed/potentially exposed to a specific hazard in order to identify if any of those exposed have been harmed and to identify the necessary steps to ameliorate the harm (for example, repeat diagnostic test or investigation or referral to relevant clinical service, change treatment pathway, etc". Department of Health, 2021 *Policy for Implementing a Lookback Review Process* doh-pol-implem-lookback-review.pdf (health-ni.gov.uk)

**Multi-Disciplinary Meeting (MDM) -** MDMs bring together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients with pre-cancerous changes or confirmed cancer. It ensures a formal mechanism for multidisciplinary input into treatment planning and ongoing management and care of patients with gynaecological pre-cancerous changes or confirmed cancer with the aim of improving outcomes.

**NI Cancer Registry** – Is an organisation funded by the Public Health Agency to collect information about every patient diagnosed with cancer within Northern Ireland. It produces the annual Official Statistics on cancer and provides evidence to help inform decision making about cancer services. The official statistics include information on:

- Cancer incidence - how many new cases there have been that year.
- Prevalence - the proportion of the population that have the disease at any one point in time.
- Survival - The percentage of people who survive a cancer for a specific amount of time, usually up to 5 years.

**Northern Ireland Cervical Screening Programme (NICSP)** - the cervical screening programme is for women who have no symptoms of disease and is designed to detect and treat pre-cancerous changes in the cervix in order to reduce the risk of cervical cancer.
Women aged between 25 and 49 are invited to attend for screening every three years and women aged between 50 and 64 are invited every five years.

**Partial Booking –** this is a method of booking appointments which offers the woman choice. The women are sent a letter by the CCR Booking Team, inviting her to contact the CCR Booking Team to book their appointment. They are therefore able to choose the location, either Craigavon Area Hospital or Daisy Hill Hospital and a date and time to suit them from those clinics which are available.

**Pathway** – a pathway describes the review action (i.e. slide review or early smear) and follow up care provided to each review patient.

**Pre-cancerous** – may develop into cancer if left untreated.

**Precautionary review** – is a review undertaken with the aim of preventing harm. By undertaking a review of women's original slides the review would identify any woman who may have been given an incorrect negative result so that they could be given the appropriate follow up and care.

**Preventative monitoring and/or treatment** – this means undertaking monitoring and/or treatment to prevent a disease. In the case of cervical screening abnormalities, it may require a procedure to remove precancerous cells.

**Primary Human Papillomavirus (pHPV) screening** – after a woman has a smear, all samples are first tested for the presence of high-risk types of HPV. Samples which test positive for high-risk HPV then undergo cytology testing (which includes examination of the sample under a microscope) to assess which women need further follow up.

**Public Health Agency (PHA)** – an organisation within the health system which has four key functions:

- health and social wellbeing improvement;
- health protection;
- public health support to commissioning and policy development;
- HSC research and development.

The PHA provides oversight of the Northern Ireland Cervical Screening Programme to include the provision of laboratory testing.

**RCPath Consulting** – RCPath Consulting is an arm of the Royal College of Pathologists. It provides advice to organisations that need an expert, independent view on how pathology and laboratory medicine services should be organised to have the greatest impact on patient care.

**Risk assessment** - a risk assessment is a systematic process of examining a process or issue to identify hazards and evaluate any associated risks to patients.

**Screeners** – staff trained to examine cervical samples using a microscope to that they can identify abnormalities.

**Screener performance** – A cervical cytology screener's role is to examine cells from a patient's cervix under a microscope to look for precancerous cells and cervical cell changes that may, if left untreated, develop into cancer. All screeners will miss some abnormalities. A data measure (called sensitivity) is used to measure screeners' performance and ensure they are achieving a minimum standard of performance.

**Smear** – A smear test checks for abnormal cells in the cervix (neck of the womb).

**Southern Trust Senior Management Team** – the team of Directors responsible for the delivery of Trust services.

**Strategic Planning and Performance Group (SPPG)** - the Group is part of the Department of Health and is accountable to the Minister for Health. It is responsible for planning, improving and overseeing the delivery of effective, high quality, safe health and social care services for the people of Northern Ireland.

**Suitable for review -** a slide is suitable for review if the slide is intact, not faded, did not have "dryback" and was not damaged.

**Technical Assessment** – examining a smear slide to check that there are issues with the slide that would prevent screening for example damage, fading or dryback.

**Trichomonas** – a very common sexually transmitted infection that is treatable with an antibiotic.

**UK National Screening Committee** – this is an independent committee that advises the NHS and UK Ministers on population screening. It makes evidenced-based recommendations about whether to introduce, continue, change or withdraw screening programmes for a variety of conditions.