Written Ministerial Statement

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Department of Health

THE PUBLICATION OF THREE CERVICAL SCREENING RELATED REPORTS

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Mr Nesbitt (The Minister of Health): I am making this statement to coincide with the publication of three cervical screening related reports by the Southern Health and Social Care Trust and the Public Health Agency. This is a complex issue and therefore the statement is long, but this is necessary to set out the details. The three reports are:

• an independent expert opinion on the factual reports published in December 2024 on the Southern Trust's Cervical Cytology Review Outcomes report (2008-2021) and the Cervical Cancers in the Southern Trust (2009-2023) report.
• An anonymised summary of the Serious Adverse Incident (SAI) findings and learnings involving 12 patients and
• an independent review by the NHS England of the Public Health Agency (PHA) Quality Assurance arrangements for Cervical Screening in Northern Ireland.

I requested that these reports were published at the same time as they relate to the full cervical screening pathway and needed to be viewed in their entirety and in conjunction with the reports already published. The Reports already published are –

• Royal College of Pathologist Consulting report for the Southern Health and Social Care Trust published by the SHSCT on 9 October 2023;
• Southern Health and Social Care Trust Cervical Cytology Review: Activity and Outcomes Report published by the SHSCT and PHA on 11 December 2024;
• Cervical Cancers in the SHSCT area published by PHA on 11 December 2024.

I would urge Members to take the time to read and consider the contents of each report.

From receipt of the Royal College of Pathologists' report in 2023, I have given this matter my full attention and concern. I have listened intently to those that have been affected, and they remain the key focus for myself and my Department. I have met on several occasions with representatives from the Ladies with Letters group, who speak on behalf of some of the women concerned and I have also met directly with some of the families impacted by cervical cancer.

I want to thank them for their continued patience and ongoing engagement. I have listened to their concerns and understand their frustration and anger that the system let them down. One of the issues raised with me on several occasions is the feeling that women are being treated as just a number or a statistic mentioned in the pages of a report. However, I want to reassure all those involved that they are not just a statistic, I am acutely aware that behind every number is an individual woman as well as a wider family circle. I have heard first hand many of their personal stories and fully accept that for some women mistakes were made at different stages within the cervical screening pathway.

I also recognise that it has now been over two years since the publication, on 9 October 2023, by the Southern Trust of the Royal College of Pathologists' report; and over a year since my previous Written Statement to this Assembly on matters relating to the Northern Ireland Cervical Screening Programme. While I regret the time it has taken to reach this point, I believe it is important that we take the time to get this right.

It should be noted that during this period, a significant amount of work by the Public Health Agency and the Health and Social Care Trusts across the region, has been undertaken in relation to improvements to the Cervical Screening Programme. This includes:

• Implementation of all 8 recommendations contained in the RCPath report.

• Full implementation since December 2023 of primary HPV testing (human papilloma virus testing) – a better and more reliable automated test. As a consequence, cytology is now a second line test, undertaken for screening samples which test positive for the presence of HPV.

• Since November 2024 a single regional laboratory service, by the Belfast Trust, undertakes all primary HPV tests and all cytology follow-up tests for the cervical screening programme.

Cervical screening programme

A population-based cervical screening programme is a complex process. It is aimed at healthy women with no symptoms and seeks to identify pre-cancer changes in the cells which line the cervix. Evidence shows that screening programmes can help reduce the risk of developing cervical cancers. Unfortunately, no cervical screening programme can ever be 100% effective, and some women may still develop cervical cancer even if they attend all their smear tests. That risk was higher when the programme relied on the cytology-based testing pathway which is expected to detect 75% of abnormalities. As I mentioned above, since December 2023 primary HPV testing has been added to the NI cervical screening programme; and this pathway is expected to detect 90% of abnormalities.

The cervical screening programme requires many important and inter-related elements such as the invitation process, the laboratory services and the colposcopy service to work throughout the screening pathway for the programme to be most effective. The screening programme includes standards, quality controls and quality assurance which must be considered overall to assess performance.

Therefore, to help fully understand exactly what occurred in the Southern Trust over the period 2008 to 2021, several reports were commissioned. I will briefly summarise some key points in these reports.

Royal College of Pathologists' Report

This report published in October 2023, found there was significantly poor performance over many years by individuals in the Southern Trust's cytology service, and this was not appropriately managed. It also found that the screening pathway deviated from that expected as part of the Northern Ireland Screening Programme and there was lack of progress to implement primary HPV testing across that programme. It opined that there was a "likelihood that significant numbers of women screened in this laboratory have had abnormalities missed which would have been detected elsewhere."

As I have mentioned above, the recommendations of this report have been addressed.

As a consequence of the RC Path report, consideration was given to the potential impact for two groups of women for whom laboratory services were provided by the Southern Trust –
• Those screened through the NI Cervical Screening Programme.
• Those diagnosed with cervical cancer.

Detail is provided below in respect of these reviews/reports.

Cervical Cytology Review

In respect of the screened group, a precautionary review of the cervical screening results of 17,425 women screened within the Southern Trust between 2008-2021, was undertaken. While that was a major logistical challenge undertaken by staff in laboratories then based in the Belfast, Northern and Western Trusts, I acknowledge the review caused a lot of upset and worry for the women who received letters advising them that their previous slides were being reviewed. However, this review,

undertaken following ethical considerations, was considered a necessary and important step in helping to establish the facts.

Following the completion of the precautionary review, two factual reports were published on 11 December 2024, these were the 'Cervical Cytology Review Activities and Outcomes Report (2008-2021);' and a separate companion report, the 'Cervical Cancers in the Southern Trust (2009-2023).' These reports provided factual information collated from the Cervical Cytology Review (CCR) and drew on data reported by the Northern Ireland Cancer Registry and the Audits of Invasive Cervical Cancer process.

As members will recall, the main finding of the CCR Outcomes report was that no cervical cancers were detected. 96% of the women included had no change to their original smear test result on review and required no further follow-up. The review however did identify 11 women's slides which were found to have pre-cancerous/incidental changes in the cells. These women have either completed or are undergoing a treatment pathway.
Members will note that these findings do not align with the earlier reflection in the RC Pathologists Report that there is a "likelihood that significant numbers of women screened in this [SHSCT] laboratory have had abnormalities missed which would have been detected elsewhere".

In respect of those diagnosed with cervical cancer, the Cervical Cancers in the Southern Trust report showed that there were 207 cases of cervical cancer diagnosed by the Southern Trust between 2009 and 2023. The key findings found that the epidemiology of cervical cancer in the Southern Trust area is similar to that of the other Trust areas in Northern Ireland - with no significant trends that give rise to concern. This means the report found there is no statistically significant difference - in the number of cancers diagnosed in the SHSCT between 1997 – 2021 and the stage at diagnosis of women living in the SHSCT compared with the NI average. It also found there is no statistically significant difference in the mortality rate (deaths) from cervical cancer between 2002 – 2021, in women living in the SHSCT area compared with the NI average (prior to 2002 the mortality rate in the SHSCT was lower than elsewhere).

Sixteen of the 207 cases would have met the criterial for inclusion within the Cervical Cytology Review. Each of these cases was considered – 7 are included within the multi-patient SAI which is detailed below. Of the other cases, two were subject to separate processes while the remaining 7 did not need any further action (this due to a mixture of those with either no or minor discordance only on slides reviewed at audit).

Independent Expert Opinion on findings of the Cervical Cytology Review

One of the reports published today was commissioned to assess if the intended objectives of the CCR were met; whether the CCR identified a significant difference in the number of abnormalities detected than would be expected in a routine review of cytology screening results in a typical screening laboratory, and consider the summary report of cervical cancers in the Southern Trust and opine on the profile of cancers and the effectiveness and limitations of the cervical screening programme in relation to prevention or earlier detection of these cancers.
This is an independent expert opinion by external individuals who were unconnected to the screening programme in Northern Ireland. This expert opinion was provided by Professor Allan Wilson, lead clinician for the Scottish Cervical Screening Programme and Dr Graham Brown, a consultant in Public Health Wales.
The report found, in respect of the 'Cervical Cancers in the Southern Trust (2009-2023).' that, while recognising the limitations of epidemiological analysis, the authors found the epidemiology of cervical cancer in the Southern Trust area to be similar to the other Trust areas within Northern Ireland and aligned with broader regional trends.

The opinion notes that performance measures and routine review against standards 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 within the Southern Trust (for the period aligned to the CCR) was effective at a population level.

With respect to the 'Cervical Cytology Review Activities and Outcomes Report (2008-2021);' the authors found the process robust and logical. It noted that "in the absence of any comparable dataset

it is difficult to compare the outcomes of the CCR with other UK screening labs". Essentially, while other reviews have been completed elsewhere, there is no published comparable dataset.

The authors also found that the Cervical Cytology Review results indicated very small numbers of abnormal findings. This would suggest that the original screening results issued by the laboratory were of a high standard (i.e. sensitivity was at the high end of the expected level of cervical screening laboratories). The authors note that this "contrasts with the perception of a problem with the performance of individual screeners".

An anonymised Summary report of the Serious Adverse Incident learning review

As I have already mentioned, a screening programme can never detect all abnormalities and unfortunately there will still be some cervical cancer cases. When a case of invasive cervical cancer is diagnosed an audit process commences, with the diagnosing Trust leading a review of all elements of the women's screening history, where one exists.

An audit involves a review of every element of the screening pathway, including the invitation process, the laboratory services and the colposcopy service. A regional 'Framework for Audit of Invasive Cervical Cancers and Disclosure of Findings,' was issued to HSC Trusts by the Public Health Agency in March 2019, with advice to Trusts that all audits of invasive cervical cancer diagnosed from 1 January 2019 onwards should be managed in line with this Framework. The purpose of this framework was to standardise approaches in Northern Ireland in terms of reporting and reviewing invasive cervical cancers; categorisation of audit outcomes and informing women of audit activities and audit findings. This built on the previous 2014 Framework, which did not include a disclosure element of the results of the audit to the woman involved.

The Southern Trust today published an anonymised summary of the findings and learning of the cases of twelve women, screened by the Southern Trust, who developed cervical cancer over the period 2018-2024 and where the audit of their cases found significant issues or areas for further review or investigation.

An independent panel was established to undertake this further investigation (referred to here as a serious adverse incident learning review). Seven of these cases would have been included in the CCR; 1 was not cytology related; 3 did not meet the CCR criteria and 1 was included in the CCR but diagnosis was after December 2023 (beyond the timescale of the cancer review).

A SAI review team, with an independent external Chair and external cytology expert, examined the clinical records, laboratory records, policies and relevant guidance relating to cervical screening. The review team contacted all the women involved and a number of women agreed to meet with the team to allow them to better understand their personal histories and their experience of the disclosure process. I want to thank everyone who engaged in this difficult process.

The SAI review team considered how the Audit framework 2014 and 2019 was followed for each patient and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes. Briefly the findings concurred with the those in the Royal College of Pathologists' report that there was evidence of underperformance over many years of a small number of cytology staff and that the management of this underperformance was inadequate.

The review team found that staffing levels in the laboratory were insufficient to deal with the workload and this led to an excessive use of overtime with some screeners screening up to three times more cases than other staff. As a result, the review team found evidence that the quality of the service suffered because of these shortfalls.

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

The review team also found a poor understanding of the clinical governance systems by the laboratory staff and a lack of adequate oversight from central governance in the Trust. The Hospital Based Programme Coordinator (HBPC) was not recognised in the Trust as a key quality

assurance role and was not afforded the support required to discharge this role as envisaged by the PHA.

The review team did not find a pattern of underperformance specifically relating to the 12 women.

The review team did however note a small number of cytology staff had a disproportionate input into the false negative results for these women, resulting in a delayed cancer diagnosis and timely treatment. The review team noted that the screeners identified also screened up to 3 times more cases than other staff.

With regard to the disclosure process, which is the process of sharing the results of an audit with the woman involved, the review team were told by all the women interviewed that the disclosure process was clumsy and unhelpful. They also found that the minutes for their disclosure meetings caused offence and women interviewed stated the whole process re-traumatised them. I have heard firsthand about the very challenging circumstances some of these women experienced as part of the audit disclosure process.

I want to apologise to all the women involved and their families and I can advise members, that the process around disclosure is being urgently updated regionally as a result of their engagement, such that no women should ever go through what was experienced by some of the women. The Public Health Agency are leading this regional piece of work with input from a specialist nurse and a psychology expert, which will standardise the approach of disclosure as part of the audits of invasive cervical cancer and learnings emerging from the Serious Adverse Incident process.

NHS England Peer's Independent Review of the PHA's Quality Assurance arrangements for Cervical Screening in Northern Ireland

The final report being published today by the PHA is a peer review by NHS England of the Quality Assurance (QA) arrangements and activities relating to laboratories within the NI Cervical Screening Programme.

Since its establishment, in April 2009, the Public Health Agency has held responsibility for commissioning and quality assuring the population screening programmes in Northern Ireland, including the Cervical Screening Programme.

The core purpose of Quality Assurance is to maintain national standards and promote continuous improvement in screening programmes to ensure that all eligible people have access to a consistent high-quality service wherever they live, and in line with the Department's population screening policy.

The NHSE report recognises the limitations of looking back over seventeen years and found room for improvement in some areas, as well as things which are done well. It notes that while PHA raised concerns during quality assurance contacts with the SHSCT about performance, data collection and ways of working the documentation does not fully reflect the concerns identified. The areas for improvement include the data reviews underpinning the quality assurance role of PHA are episodic (annual) rather than year on year trend analyses and there were delays in the quality assurance process including with the issuing of reports.

The authors found that there was clear evidence of poor communication from Trusts and engagement with the PHA; as well as finding significant staffing gaps.
While the authors note there have been clear improvements over the last two years in the documentation reviewed, the report recommends that the PHA develops a Quality Assurance improvement plan, encompassing the six main recommendations findings and associated recommendations, with a focus on enhancing the QA processes going forward.

The Public Health Agency Board has fully accepted the findings and work to implement these recommendations has already begun.

Next Steps

From the outset, I have sought to understand what happened, who was responsible, why it happened and how can we prevent it happening again.
It is clear there were significant issues with the Southern Trust's laboratory including the management processes in place at a Trust level and the quality assurance of the Public Health Agency was inadequate.

As to why it was allowed to continue for so long, it is evident that the method for reviewing individual's performance within the Trust was taken in isolation and that performance trends over several years were not monitored. Cervical screening is no longer undertaken in Southern Trust and has been centralized in Belfast Trust. In the new regional screening service, screener performance trends over previous years are monitored.

The Southern Trust's laboratory added additional steps and variations into the screening pathway, which were not used elsewhere and moved outside the parameters of national standards and guidance. This impacted the ability to benchmark or assess performance in the context of national standards.

As I have consistently said the cervical screening programme is complex. Given this complexity I have asked Professor Sir Frank Atherton, previously the Chief Medical Officer in Wales, to conduct an expert review of all the published reports to date and advise if there are any gaps or areas that need to be explored further. He will report his findings directly to me, without any influence from officials in the Southern Trust, the PHA or Department. I expect his work will be completed in early 2026.

Conclusion

I acknowledge that this has been a difficult and challenging time for many people, particularly for the women who were part of the review and those impacted by cervical cancer, but I remain committed to understanding the circumstances and events which led to the precautionary review of cervical cytology in the Southern Trust. The reports published today are another important step in that process.

I can however reassure members that we are not waiting for this process to be completed to improve the system for women. Fundamentally the cervical screening programme is now different from the programme during the period in question. From December 2023 HPV has been added as the first line test in the new pathway. Since November 2024, there is one regional laboratory; this will assist in ensuring consistency of standards; quality control and quality assurance. A review is underway to standardise the approach to disclosure as part of the audits of invasive cervical cancer which should be completed by December 2025. All the recommendations made across the reports referred to above are actioned or are being actioned. I have asked for this work to be completed as a matter of priority.

While mistakes were made in parts of the Northern Ireland cervical screening programme it is important that we acknowledge that Northern Ireland has an effective cervical screening programme at a population level. The effectiveness of the programme is reflected in comparative data across the UK for the period 2017-2019, that shows that the European age standardized incidence rate of cervical cancer in Northern Ireland is similar to the UK average (Northern Ireland = 9.1 new cases per year per 100,000 females, UK average =9.9) In the Republic of Ireland there is an age standardized incidence rate of 10.43 cases per 100,000 females for the period 2018-22.

The cervical screening programme is an extremely important population-based screening programme which has been proven to save lives, and we must ensure that remains the clear message. Coverage data for 2024/25 shows a 66.9% coverage rate in age-appropriate coverage across all Trusts, which is consistent with previous years. I would urge all members to support the cervical screening programme and encourage all those eligible to take up the offer of cervical screening when invited to do so.