Written Ministerial Statement

The content of this written ministerial statement is as received at the time from the Minister. It has not been subject to the official reporting (Hansard) process.

Department of Health

NORTHERN IRELAND CERVICAL SCREENING PROGRAMME

Published at 4.00pm on Thursday 25th July 2024

Mr Nesbitt (Minister of Health): I am making this statement to provide a detailed update on a number of important issues relating to the Northern Ireland Cervical Screening Programme.

The Northern Ireland Cervical Screening Programme processes and reports between 110,000 and 120,000 cervical screening samples annually. Prior to December 2023, cervical screening involved the use of cytology as the 'first line' (primary) screening test to identify women at increased risk of developing cervical cancer, by identifying pre-cancer changes in the cells which line the cervix.

Cytology is a qualitative test undertaken in a laboratory setting by Biomedical Scientists who examine cervical 'smear' tests or 'slides' under a microscope. Cervical cytology is not a diagnostic test; it does not and cannot identify all women at risk of developing cervical cancer.

Over 99% of cervical cancers are caused by high risk types of the Human Papilloma Virus (HPV). Introducing primary HPV testing into the cervical screening pathway was recommended by the UK National Screening Committee because it is a more accurate test, and will save more lives, than using cervical cytology as the primary test.

In December 2023, the Northern Ireland Cervical Screening Programme fully implemented primary HPV testing into the cervical screening pathway locally, a key action included in the Northern Ireland Cancer Strategy (2022-32). Following full introduction of primary HPV testing into the cervical screening pathway in Northern Ireland, cytology is now used as a second line test for those women whose cervical smear test is positive for high risk types of HPV.

The Cervical Cytology Review in the Southern Health and Social Care Trust

The Royal College of Pathologists' (RCPath) Report into underperformance of the cervical cytology laboratory service in the Southern Health and Social Care Trust (SHSCT), was published by SHSCT on 9 October 2023. In its report RCPath recommended that: "*Despite the likelihood that significant numbers of women screened in this laboratory have had abnormalities missed which would have been detected elsewhere, we cannot recommend a review of previous cytology, because there is no suitable capacity in the UK to deliver this. We strongly recommended that HPV primary screening should be implemented in a quality-controlled manner, with consideration of early invitation of women considered to be most at risk."*

With the then forthcoming full implementation of primary HPV testing into the Cervical Screening Programme (achieved in December 2023), the SHSCT and the Public Health Agency (PHA) jointly determined that there would be capacity and expertise to undertake a review of the previously reported cervical cytology tests undertaken by the SHSCT as part of the NI Cervical Screening Programme. It should be noted that the SHSCT Review is a precautionary measure to check that the original cytology result as reported is/was correct.

There are two main elements to the SHSCT Cervical Cytology Review: a review of the historically held cervical cytology samples (known as the slides) and the 'call forward' of women to cervical screening (smear test) clinics, where the historical cervical cytology slides were no longer viable, or available, for review.

As of 23 July 2024, I can update members, that the total number of Cervical Cytology Reviews completed (slide review and call forward pathways) in the main phase of this Review is 17,047. This represents 97% of the total number to be reviewed (total number is expected to be 17,543). There are currently 496 cases waiting to be completed.

None of the cytology slides in the Review are being assessed by the SHSCT laboratory. Instead, these slides are being re-examined by three other HSC laboratories – in the Western, Northern and Belfast Health and Social Care Trusts. The estimated date of completion of the main component of this Review (including the call forward pathway) is early September 2024. At that point, all impacted women will have received either an outcome of their cytology slide review or the result of a more recent cervical screening test.

As previously announced by the SHSCT, an additional piece of work will be undertaken following the completion of the main Cervical Cytology Review. This will involve review of the previous cervical cytology slide of those women in the overall cohort who have had a routine cervical smear test undertaken since the SHSCT Review began. This involves about 4,000 women and will take place at the end of the main review, as women in this group have a more recent cervical smear test result (reported through the routine NI Cervical Screening Programme) indicating their current risk or otherwise of developing cervical cancer. In the context of broader changes to the delivery of the cervical screening laboratory service, it is expected that this work will carry forward into the autumn, with the end of October 2024 being the indicative date for completion.

Cervical cell changes identified by cytology are not a reliable predictor of cervical cancer, as not all cell changes will go on to develop into cancer, and many will regress by themselves without treatment. Cell changes, if found, can range from mild changes (low grade) to more moderate or severe changes (high grade). The care pathway of those with low grade changes depends on the HPV status of the sample, which determines whether the woman can be safely returned to the routine screening pathway or needs further investigation by colposcopy. High grade changes require referral to colposcopy services for a clinical examination.

To date, some low-grade abnormalities and a very small number (less than five) of higher-grade abnormalities have been identified as part of the SHSCT Cervical Cytology Review. It is important to reiterate that identifying abnormalities does not mean cancer has been found, but rather these women will be followed up by clinical staff with further investigation and management planned as required and appropriate to each individual.

I want to fully acknowledge the distress caused to many women by this Review and the shortcomings detailed in the Royal College of Pathologists' Report. This is deeply regrettable. All findings arising from the slide review and the call forward pathway will be assessed on an individual case basis, with the appropriate follow-up, care or treatment as required. I will await the outcome of the completed Cervical Cytology Review before considering its findings in full.

Audit of Invasive Cervical Cancers

Each year in Northern Ireland, on average around 80 women are diagnosed with cervical cancer and regrettably there are circa 21 deaths[1] annually. Data indicates that circa 50 of the 80 cases of invasive cervical cancer diagnosed each year have previously had a cervical screen (smear test) undertaken through the NI Cervical Screening Programme.

An audit of previous screening pathway(s) in patients diagnosed with invasive cervical cancer in Northern Ireland was established by the NI Cervical Screening Programme for the purpose of learning and improvement.

The process for undertaking this audit is set out in the 2014 "*NI Protocol for the audit of Invasive cervical Cancers*," guidance document. When a case of invasive cervical cancer is diagnosed the audit process commences, with the diagnosing Trust leading a review of all elements of the women's screening history, where one exists. An audit should involve a review of every element of the

[1] Northern Ireland Cancer Registry – cervical cancer cases and deaths 2016-2020 www.qub.ac.uk

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.

An appropriate audit outcome should be categorised once the respective Trust's Multidisciplinary Team has discussed and reviewed all aspects of the previous screening pathway for the case in question. Where an audit of a case of invasive cervical cancer is assigned a category 3 outcome (unsatisfactory) following discussion by the Trust's Multidisciplinary Team, a process to review and identify potential learning should be taken forward by the respective Trust under the Trust's SAI review process.

As a result of pressures experienced during the COVID-19 pandemic there have been delays in some Trusts with completion of these audits and with sharing of audit outcomes with some women. Work in this area is now being prioritised by all Trusts to ensure that these audits are completed in a comprehensive and timely manner. All women diagnosed from 2019 will be given an opportunity to receive the outcome of their audit. Women diagnosed before 2019 may request information on whether an audit of their screening history was undertaken and any associated findings.

Western Health and Social Care Trust

It is the responsibility of the diagnosing Trust's Multidisciplinary Team to determine the most appropriate outcome for each case of invasive cervical cancer that is audited. Between 2019-2023, the Western Health and Social Care Trust (WHSCT) reported an audit outcome in 12 cases as a category 3 (unsatisfactory) outcome. Review and assessment of these cases was then taken forward under the Trust's SAI procedure. This number is higher than the number of category 3 audit outcomes identified by other HSC Trusts over the similar time period.

To secure further assurance in relation to its audit of invasive cervical cancers, Public Health Wales was commissioned by the WHSCT, in conjunction with PHA, to provide a clinical opinion on the small number of cytology slides associated with these 12 cases. It is important to note that this was not a review of laboratory processes or screening pathways in the Western Trust.

On receipt of the clinical opinions from Public Health Wales, information in relation to the 12 cases (with a category 3 audit outcome and notified as SAIs) was triangulated and assessed by the WHSCT and the PHA. This assessment concluded that the number of category 3 outcomes notified by WHSCT over the years occurred as a result of the Trust applying a different threshold than others when categorising cervical cancer audits with an 'unsatisfactory' outcome. Importantly, there are no concerns by PHA that the number of category 3 outcomes reported as part of the audit process reflects underlying performance issues within the WHSCT's Cervical Screening Service.

Similar to other laboratory services provided to the NI Cervical Screening Programme, the WHSCT laboratory cytology service is subject to routine and unannounced inspections by United Kingdom Accreditation Service (UKAS), the national accreditation body. The most recent inspection by UKAS of the WHSCT cytology service was undertaken in February 2024. UKAS found the team providing the service to be dedicated and competent with a supporting quality management system that is meticulously maintained. There were no concerns identified in relation to staff competency as part of this UKAS inspection.

The PHA has recently issued updated guidance to all Trusts to support greater consistency in the categorisation of audit outcomes. It is important to note that the potential to identify such cases (where a category 3 audit outcome is assigned) can never be entirely removed. However, such cases will continue to be identified as SAIs and will continue to have the necessary review, reflective learning and education processes progressed following categorisation. This is an expected element of a population based cervical screening programme.

Routine NI Cervical Screening Programme backlog

Members will recall that during 2023 there was an unacceptable backlog in reporting of results from the routine cervical screening programme, for those women whose cervical smear test was taken prior to the full introduction of primary HPV testing in December 2023. The potential clinical risk associated with this backlog in cytology reporting was managed by testing all samples for HPV to identify those that needed to be prioritised for cytology reporting. I am now pleased to confirm that this backlog has been cleared, as of the week commencing 6 May 2024. Results for HPV negative smear tests, which constitutes the majority of cervical smear tests taken, are now being reported to a woman's GP within two weeks, in line with national programme standards.

Provision of Laboratory Services to the NI Cervical Screening Programme

As expected, with the full implementation of primary HPV testing into the NI Cervical Screening Programme in December 2023, there has been a marked decrease in demand for cytology testing. This expected decrease has meant that a single laboratory service model remained the recommendation of the primary HPV Implementation Project Board.

In line with other UK regions, where a programme of laboratory consolidation has been undertaken in conjunction with implementation of primary HPV testing into the cervical screening pathway, I can advise members that, following careful consideration and due process, the Belfast Health and Social Care Trust will provide the Regional Laboratory service for the NI Cervical Screening Programme going forward. The indicative date for commencement of this one-site laboratory service model for the NI Cervical Screening Programme is 1st November 2024.

This service model is necessary to ensure that the performance standards and minimum requirements of screeners and reporting staff are met and that public confidence in this important screening programme is maintained. Until the new service model is up and running and a full transition has occurred, the other HSC Trusts will continue to provide laboratory services for the NI Cervical Screening Programme as per the current arrangements.

HPV Vaccination Programme

It is important that members note that in addition to the NI Cervical Screening Programme, in Northern Ireland we also have a well-established HPV vaccination programme in place. A school-based vaccination programme has been in place for girls in school Year 9 since 2008 and, following new scientific evidence and advice from the Joint Committee on Vaccination and Immunisation (JCVI), this important vaccination programme was extended to include all boys in school Year 9 from September 2019. The primary aim of the HPV vaccination programme is to prevent cases of HPV-attributable cervical cancer.

I would like to highlight the significant opportunity that we have, through our joint approach of HPV vaccination and population-based cervical screening, to drastically reduce the number of cases of invasive cervical cancer which we see on an annual basis. It is imperative that uptake rates for HPV vaccination remain high. I give my commitment to do all that I can to make this ambition - a continued drive to reduce the number of cases of cervical cancer diagnosed each year - a reality for all women in Northern Ireland. To this end I would urge all those eligible for the HPV vaccine to take up the offer of vaccination when invited to do so. Everyone remains eligible to receive the HPV vaccine, either as part of our schools-based vaccination programme or on request from their GP up until they are 25 years of age if they have not previously been vaccinated.

Conclusion

While I am very mindful of the distress caused by the SHSCT's Cervical Cytology Review, it is important that we continue to reassure women that Northern Ireland's Cervical Screening Programme remains highly effective. It is essential that women keep coming forward for their cervical smear test when invited to do so. I would appeal to Members to continue underlining this message whenever and wherever possible.

I also want to acknowledge that delivery of this Cervical Cytology Review has relied upon the laboratories in three HSC Trusts across NI - the Belfast, Northern and Western HSC Trusts. Staff in these laboratories have gone above and beyond to support the work of this Review while continuing to maintain delivery of the routine NI Cervical Screening Programme throughout. They recognise the importance of giving all women impacted by this Review an outcome as soon as possible and I am grateful to these staff for the commitment they have given to date and the service that they continue to provide.

I fully recognise that this has been a difficult period for the NI Cervical Screening Programme but as outlined in this statement, a significant amount of work has been progressed particularly over the past 12 months. Most importantly, primary HPV testing has been fully implemented into the screening pathway, meaning a new era has begun in cervical screening in Northern Ireland. The programme is now using a test which is more effective at detecting those at higher risk of developing cervical cancer. Cervical screening in Northern Ireland continues to save lives.

I will provide a further update for members in the Autumn.